Federation of American Hospitals

Charlene K. MacDonald
President and CEO

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

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1850–P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: CMS-1850-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; 91 Fed. Reg. 41,734 (July 7, 2026).

Dear Dr. Oz:

As the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States, the Federation of American Hospitals (FAH) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center Payment Systems proposed rule (Proposed Rule). FAH's detailed comments are set forth in Appendix A and Appendix B.

Executive Summary

FAH strongly supports CMS's proposed payment policy for drugs acquired under the 340B Drug Pricing Program. The proposal follows the direction Congress gave the agency, reduces beneficiary cost-sharing and directs Medicare dollars to smaller and rural hospitals, and it does so without increasing Medicare spending. FAH urges CMS to finalize it. FAH has significant concerns, however, with several other proposals in the Proposed Rule, one of which would offset much of the benefit the 340B policy is intended to deliver.

I. Finalize the Proposed Payment Policy for 340B-Acquired Drugs

FAH strongly supports CMS's proposal to pay for 340B-acquired drugs based on the acquisition cost data collected by the agency. Section 1833(t)(14)(A) of the Social Security Act requires CMS to set payment for specified covered outpatient drugs at their average acquisition cost, taking into account hospital acquisition cost survey data. CMS's survey establishes that 340B-acquired drugs are acquired at 33.4 percent below ASP, well below the statutory default rate of ASP plus 6 percent. In light of these data, FAH believes continued payment for 340B-acquired drugs at ASP plus 6 percent would be inconsistent with the statute.

The proposal also would provide substantial savings to Medicare beneficiaries, whose copayments are calculated based on the amount Medicare pays the hospital rather than the hospital's acquisition cost of the drugs. As CMS observes, in some cases a beneficiary's copayment alone exceeds the hospital's acquisition cost for the drug by hundreds of dollars. CMS estimates that its proposal would reduce beneficiary copayments by $1.15 billion in CY 2027.

Moreover, the adjustment is budget-neutral, as required by statute. CMS estimates that the reduction in payment for 340B-acquired drugs would be redistributed to all OPPS hospitals through an equivalent increase in the conversion factor for non-drug items and services, including primary and emergency care. This approach appropriately accounts for the interaction between the proposed drug payment changes and the broader OPPS payment system. Updating the adjustment annually would help ensure that payment rates remain aligned with the estimated impact of the 340B drug payment policy in each year, rather than relying on a static adjustment that could become increasingly disconnected from actual payment changes over time.

The 340B Payment Policy Provides Broad-Based Benefits to 340B and Non-340B Hospitals and Critical Support to Small, Rural Hospitals

By shifting to an acquisition-cost-based payment policy for 340B-discounted drugs, CMS would appropriately right-size OPPS payments, increasing support for emergency services, primary care, and other non-drug items and services. **FAH's analysis shows that approximately 78 percent of hospitals would see increased payments under the proposed policy, including 54 percent of 340B hospitals.** Thus, CMS's proposal would not simply shift payments among OPPS hospitals. It would increase payments for most hospitals, including more than half of 340B hospitals, while better aligning Medicare drug payments with hospitals' acquisition costs and restoring funds to the non-drug services furnished by all OPPS hospitals.

The budget neutral proposed policy would also ultimately strengthen support for rural access. Overall, the policy would direct Medicare dollars toward rural and smaller hospitals by increasing the payment rates for primary and emergency care, outpatient procedures and other non-drug services furnished by all OPPS hospitals, including 340B hospitals. Isolating the 340B payment policy and adjustment, CMS estimates payment increases of 3.5 percent for rural hospitals, with small, rural hospitals receiving a 4.8 percent payment increase. In particular, rural sole community hospitals would see an estimated 5.7 percent payment increase. **FAH's analysis, based on more recent 2025 Part B payment data, confirms these significant benefits to rural communities: 76 percent of geographically rural hospitals would see increased OPPS payments, averaging 4.66 percent, while rural referral centers and sole community hospitals would see increases of 4.78 percent and 8.17 percent, respectively.** These gains for rural hospitals that are struggling to survive and closing at an alarming rate would provide a lifeline, helping to sustain access to care in rural communities.

Further, the proposal is a Medicare OPPS payment policy and does not alter the discounts hospitals receive under the 340B Program. Critical access hospitals and rural emergency hospitals are not paid under the OPPS and therefore are unaffected, and **CMS's proposal would exempt rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals from the 340B payment policy.**

II. Rescind the OPPS Recoupment and Do Not Accelerate It

FAH strongly opposes CMS's proposal to continue and accelerate its recoupment of $7.769 billion in payments made for non-drug items and services from 2018 through 2022 by increasing the reduction to the conversion factor from 0.5 percent to 3.0 percent. Those payments were lawfully made based on CMS's then-estimates of OPPS expenditures; the policy has never been challenged, and no court has vacated it. As a prospective payment system, FAH does not believe the OPPS permits retrospective budget neutralization.

The recoupment is particularly concerning because it decreases payments to rural hospitals and sole community hospitals, which serve as critical lifelines to care in their communities but are at risk of closures and reductions in service. Accelerating the recoupment also would further advantage Medicare Advantage organizations, whose capitated rates reflect only the 0.5 percent reduction while the larger reduction would flow through to their payments to hospitals. **FAH urges CMS to rescind the recoupment and, at a minimum, not to accelerate it.**

III. Restore the Inpatient Only List and Clinical Criteria

FAH opposes CMS's proposal to remove an additional 637 services from the Inpatient Only list, following the removal of 285 services for CY 2026, without the clinical analysis that has historically supported such determinations. The IPO list reflects the invasive nature of a procedure, the need for postoperative recovery, and the condition of the patient, and most importantly, it provides coverage clarity that protects beneficiaries in both fee-for-service and Medicare Advantage.

Eliminating the IPO list would shift level-of-care determinations to expected length of stay, increase beneficiary cost-sharing, place Part A skilled nursing facility coverage at risk following post-procedure complications, and add administrative burden for physicians and hospitals. **FAH urges CMS to restore the Inpatient Only list and the clinical criteria used to update it annually.**

IV. Do Not Reduce Payment for Imaging Services at Excepted Off-Campus Departments

FAH opposes CMS's proposal to pay for 337 imaging without contrast services furnished at excepted off-campus provider-based departments at 40 percent of the OPPS rate. The data show no discernible growth in the share of these services furnished at these departments over the past five years, CMS identifies no benchmark against which to measure volume, and the proposal excludes year-to-year volume monitoring. Absent an unnecessary increase in the volume of covered outpatient department services at excepted off-campus departments, CMS lacks authority to implement a volume-control method. Moreover, the proposed change appears to function as a mere site-based payment reduction rather than a method for controlling unnecessary increases in volume under section 1833(t)(2)(F) of the Act.

The proposal further erodes the distinction Congress drew in Section 603 of the Bipartisan Budget Act of 2015. Section 603 added section 1833(t)(21) of the Act, which removed applicable items and services furnished at **new** off-campus departments from the definition of covered OPD services beginning January 1, 2017. Departments already billing on November 2, 2015, as well as on-campus departments and dedicated emergency departments remained under the OPPS. Section 16001 of the 21st Century Cures Act then added the mid-build exception. Congress had the option to reduce rates for excepted departments and chose not to do so and instead opted to preserve OPPS payments for all of these grandfathered facilities. The proposed payment cuts for statutorily excepted off-campus provider-based departments threaten to chill investment in imaging equipment and reduce access to services among Medicare beneficiaries, including those in rural communities. CMS should support, rather than penalize, hospitals that make these investments and expand beneficiary access to diagnostic imaging. **FAH urges CMS not to finalize this payment reduction, reverse the existing reductions for clinic visit and drug administration services and, at a minimum, implement any such adjustment in a budget-neutral manner.**

V. Provide Sufficient Time and Flexibility to Implement the New Provider-Based Department Requirements

FAH supports CMS's efforts to reduce burden in implementing the new statutory National Provider Identifier (NPI) and attestation requirements for off-campus provider-based departments, including a standardized attestation form, centralized electronic submission, and risk-based review. Given the significant operational work required before January 1, 2028, FAH urges CMS to issue the form and submission requirements as soon as possible, permit bulk submissions and shared documentation across departments, and confirm that timely, complete attestations preserve payment while CMS review is pending.

VI. Ensure the CY 2027 Payment Update Adequately Reflects Hospitals' Rising Costs

FAH remains concerned that the CY 2027 OPPS payment update does not keep pace with the cost of caring for Medicare beneficiaries. CMS proposes an update of 2.4 percent, which becomes 2.3 percent after application of the 0.9 productivity adjustment finalized in the FY 2027 IPPS final rule. With aggregate hospital Medicare margins remaining deeply negative, the productivity adjustment further compounds the

shortfall by assuming productivity gains that the hospital sector cannot achieve. **FAH urges CMS to recognize these significant and ongoing cost pressures in establishing adequate Medicare payment rates.**

Conclusion

FAH commends CMS for undertaking the drug acquisition cost survey and for proposing a payment policy grounded in its results and urges the agency to finalize that policy while reconsidering several other proposals described above. FAH appreciates the opportunity to comment and welcomes the opportunity to discuss these recommendations further. If you have any questions, please do not hesitate to reach out to myself or Alyssa Keefe, SVP Head of Policy at akeefe@fah.org or (202) 624-1500.

Sincerely,

/s/
Charlene K. MacDonald
President and CEO

Attachments:
Appendix A: FAH Detailed Comments on CY 2027 OPPS Proposed Rule
Appendix B: FAH September 5, 2023, Comments Regarding 340B Remedy Rulemaking

APPENDIX A
FAH Detailed Comments on CMS CY 2027 OPPS Proposed Rule (CMS 1850-P)

I. CMS Proposes CY 2027 OPPS Conversion Factor Update (Part II.B)

CMS proposes an OPPS fee schedule increase factor of 2.4 percent for CY 2027, reflecting a hospital inpatient market basket update of 3.2 percent less 0.8 percentage points for productivity, and a conversion factor of $102.004.[1] By law, CMS updates OPPS rates by the same market basket that applies under the IPPS.[2] In the FY 2027 IPPS final rule issued July 31, 2026, CMS finalized a market basket increase of 3.2 percent and a productivity adjustment of 0.9 percentage point, an update of 2.3 percent.

FAH's comments on the 340B budget neutrality adjustment and the reduced conversion factor for hospitals subject to the 340B remedy offset are set forth in section V.

FAH remains concerned that the statutory market basket update does not adequately reflect the financial pressures hospitals face in providing care to Medicare beneficiaries. MedPAC's most recent analysis found that Medicare payments for hospital inpatient and outpatient services remain well below the costs hospitals incur to provide that care, with an aggregate Medicare margin of negative 12.1 percent in 2024. MedPAC projects that hospital Medicare margins will remain deeply negative at approximately negative 10 percent in 2026.[3] These persistent and substantial shortfalls underscore the inadequacy of relying on a market basket update that is further reduced by a productivity adjustment and reinforce the need for payment updates that more accurately reflect hospitals' actual costs of delivering care.

These pressures are compounded by increasing patient volume and acuity and the unique obligation of hospitals to maintain the capacity to provide care 24 hours a day, seven days a week. Between 2019 and 2024, approximately 36 percent of hospital expense growth was attributable to treating more patients, while another 19 percent reflected the increased clinical complexity of the patients hospitals serve.[4] Hospitals cannot simply shed many of the fixed costs associated with maintaining emergency departments, specialized clinical services, facilities, equipment, and an appropriately trained workforce when Medicare payment fails to keep pace with those costs.

At the same time, approximately 56 percent of hospital costs are associated with service lines for which reimbursement falls below the cost of providing care.[5] These persistent payment shortfalls, coupled with rising costs and increasing demands on hospital resources, underscore the importance of Medicare payment updates that more accurately reflect the cost of delivering care. Against this backdrop, an OPPS update of just 2.4 percent (or 2.3 percent once the lower update in the IPPS rule is considered), particularly when Medicare hospital margins remain substantially negative, is insufficient to ensure that Medicare payments keep pace with the resources necessary to preserve beneficiaries' access to hospital care.

The Productivity Adjustment Exceeds Achievable Hospital Productivity Gains

In addition, CMS proposed reducing the proposed market basket update with a 0.8 percentage point total factor productivity adjustment that will be 0.9 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). In a memorandum dated June 2, 2022, OACT stated: "over the period 1990-2019, the average growth rate of hospital TFP [total factor productivity] 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.[6] As conveyed in prior comments, 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.

FAH understands that CMS is required by law to adjust the market basket update for total factor productivity. FAH urges CMS to consider that the adjustment for total factor productivity reduces the update below what even OACT says is reasonable for hospitals to achieve and to continue working with Congress to address this longstanding issue.

II. New Technology APCs, Including SaMS Procedures (Part III.C)

Payment Policy for Software as a Medical Service (SaMS)

FAH recognizes the growing and valuable role that software-based technologies — including artificial intelligence (AI)-enabled clinical decision support, clinical risk modeling, and computer-aided detection — play in hospital outpatient care. These tools can improve diagnostic accuracy and efficiency, support earlier detection of disease, and help address the workforce and administrative pressures confronting hospitals and health systems. FAH appreciates that CMS, after several years of study and two prior comment solicitations, is taking concrete steps toward a consistent and predictable payment approach for these services and offers the following for consideration.

Change in Terminology from "SaaS" to "SaMS"

FAH does not object to CMS's proposal to replace "Software as a Service (SaaS)" with "Software as a Medical Service (SaMS)." We agree that terminology distinguishing these clinical, medical-function services from general commercial cloud-computing offerings will reduce confusion. Because CMS has stated that the two terms are interchangeable and that existing sub-policies (such as the SaaS add-on code policy) will carry forward unchanged, we urge CMS to confirm that the change is purely terminological and will not disrupt existing coding, billing, or claims processing for these services.

Maintaining CY 2027 Payment and New Technology APC Assignments

FAH supports CMS's proposal to maintain the current New Technology APC assignments for SaMS in CY 2027, rather than re-rate these services using the universal low-volume policy or geometric-mean-cost methodology. Given the limited and still-maturing claims data for many of these services, maintaining current payment avoids disruptive swings during a transitional year and is consistent with the continued low-volume protections for New Technology APCs that FAH has supported. We view this as a reasonable bridge — but not an endpoint — as discussed below.

Payment Must Reflect the Full Cost of Furnishing SaMS

While FAH supports maintaining payment for CY 2027, we caution CMS that the payment levels being carried forward do not fully capture the cost of furnishing these services, whether they have been paid as ancillary services or through the New Technology APCs. Maintaining current payment is an appropriate floor for the transition, but the comprehensive methodology CMS ultimately adopts must be grounded in the full and adequate cost of these services, consistent with the OPPS's statutory foundation as a cost-based, prospective payment system. **As CMS develops that methodology, we urge the agency to account for the substantial costs of deploying and maintaining these tools that extend well beyond the software itself, including but not limited to:**

- **Clinical validation time**. AI-enabled and algorithmic tools augment rather than replace clinicians, who remain responsible for reviewing outputs and making final clinical decisions. Payment should reflect the clinical time required to validate and act on these analyses.

- **Ongoing maintenance and testing.** These tools require routine maintenance and post-deployment testing — often involving vendors, developers, and hospital staff — to ensure continued accuracy and integrity.

- **Cybersecurity and insurance.** The expansion of these technologies has increased cybersecurity exposure and driven up insurance premiums. Just as CMS accounts for malpractice costs in other payment systems, it should account for these rising costs here.
- **Software licensing, data storage, and infrastructure.** Acquisition and operating costs include software licenses, the large underlying data sets these tools rely on, and the servers and storage required to support them.

We further urge CMS to recognize the varied ways hospitals acquire and pay for these technologies — including subscription, license, and per-use arrangements — and ensure that any payment methodology accommodates, rather than penalizes, these legitimate acquisition models.

Any "rightsizing" of SaMS payment should not come at the expense of other outpatient services. To the extent CMS implements changes within a budget-neutral framework, FAH urges the agency to ensure that appropriate payment for these emerging services does not force offsetting reductions elsewhere in the OPPS. CMS should likewise account for geographic and infrastructure differences so that payment policy supports, rather than widens, the "digital divide" facing rural and underserved communities.

Proposed Status Indicator "O1"

FAH supports the creation of a dedicated status indicator to identify SaMS and provide separate payment, and we support CMS's proposal that status indicator "O1" carry the same payment specifications as status indicator "S." We do not support the alternative CMS raises of assigning these services specifications akin to status indicator "T," which would subject SaMS to multiple-procedure payment discounting. Discounting would further erode payment that, as noted above, already does not fully reflect the cost of these services, and would be especially inappropriate where multiple distinct analyses are furnished for a single patient encounter. Program-integrity concerns, to the extent they exist, should be addressed through targeted safeguards rather than across-the-board payment reductions.

SaMS Analyses Currently Paid Under the Clinical Laboratory Fee Schedule

FAH has reviewed CMS's proposal to move certain algorithm-based laboratory analyses from the Clinical Laboratory Fee Schedule (CLFS) to New Technology APCs under the OPPS with status indicator "O1." We ask CMS to ensure that any such shift maintains payment adequacy and does not create billing or operational disruption for hospitals, and to confirm that the list of affected codes is complete and appropriate.

Quality, Efficacy, and Transparency

FAH shares CMS's interest in ensuring these tools are safe and effective. We encourage CMS to support payment for the ongoing maintenance and post-market testing necessary to sustain tool integrity, and to work with the FDA and other agencies to promote transparency into algorithmic sources and methods, given the "black box" nature of many AI systems. Consistent with patient-safety principles, these tools should support — not supplant — clinician judgment and should not be used to deny or restrict access to medically necessary care or coverage.

III. 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)(iv)(B)(12)) (Part V.B.6)

FAH has significant concerns with CMS's proposal to continue and accelerate its unlawful recoupment of $7.769 billion that was lawfully paid for non-drug items and services from 2018 through 2022. **As detailed in past comments, FAH maintains that the OPPS payments made for non-drug items and services while the prior 340B drug payment policy was in place were lawfully and properly made based on CMS's then estimates of OPPS expenditures, as required under 42 U.S.C. § 1833(t)(9)(B).** At no point has the payment policy for non-drug items and services between 2018 and 2022 been challenged, and no court has vacated the non-drug payment policy. As a prospective payment system, the OPPS does not authorize or permit adjustments to retrospectively budget neutralize its policies. These positions are more

fully set out in FAH's September 5, 2023, letter concerning the 340B remedies rulemaking, which is attached hereto as **Appendix B** and incorporated by reference. For all these reasons, FAH continues to strongly oppose any adjustment or offset to recoup $7.769 billion in Part B payments.

FAH further opposes any increase to the rate of the recoupment because a rapid increase to the recoupment will provide a windfall to Medicare Advantage organizations. For PY 2026 and PY 2027, the capitated prospective payment to Medicare Advantage organizations incorporates a 0.5 percent prospective recoupment as required under current 42 C.F.R. § 419.32(b)(1)(iv)(B)(12). Medicare Advantage plans frequently negotiate payments based on Medicare rates,[7] and are required to base out-of-network payments for covered services on Medicare rates.[8] Thus, if the proposed 3.0 percent payment cut (or any accelerated recoupment adjustment) is implemented, Medicare Advantage organizations' capitated payment will not incorporate the sixfold magnification of the payment cut in CY 2027, but at least some or perhaps most Medicare Advantage organizations will attempt to incorporate these significantly greater cuts in their outpatient payments to contracted hospitals and all will use it for non-contracted hospitals. The resulting discrepancy between the rates paid to Medicare Advantage organizations and the rates paid by Medicare Advantage organizations would create an unwarranted and inappropriate windfall for Medicare Advantage organizations and would actively harm providers while providing no benefit to Medicare beneficiaries or the Part B trust fund.

Finally, FAH continues to be concerned that the recoupment of $7.769 billion through Part B payment adjustments will effectuate a far larger recoupment from hospitals. When the prior 340B-drug payment policy was first implemented in 2018, Medicare Advantage penetration was at approximately 37%, but that number has grown to approximately 55% for 2026.[9] Because of this shift, millions fewer beneficiaries receive services through FFS Part B in 2026 than from 2018–2022 when the budget neutrality adjustment was in place. From 2018–2022, the capitated prospective payment to Medicare Advantage organizations was unimpacted by the 340B-acquired drug payment adjustment and accompanying budget neutrality adjustment. But, for PY 2026 and PY 2027, the 0.5% recoupment adjustment reduces capitated prospective payments, and if finalized, the proposed 3.0% recoupment adjustment will further reduce the capitated prospective payment for future years.[10,11] This will create significant savings for the Supplementary Medical Insurance Trust Fund, and for the most part, those savings will represent reduced Medicare Advantage payments to hospitals. Under the existing recoupment policy and the proposed accelerated recoupment policy, however, none of these significant and real savings to the Supplementary Medical Insurance Trust Fund are taken into account. Rather, the recoupment policy will result in excess savings to the Medicare program on top of the $7.769 billion CMS intends to recoup under 42 C.F.R. § 419.32(b)(1)(B)(iv)(B)(12).

IV. FAH Applauds CMS's Drug Acquisition Cost Survey and Urges the Agency to Finalize Acquisition-Cost Based Payment for 340B-Acquired Drugs (Parts V.C & V.F)

FAH strongly supports CMS's proposed budget neutral change in the payment rate for specified covered outpatient drugs (SCODs) acquired under the 340B drug discount program. Under section 1833(t)(14)(A), CMS is required to set the payment for SCODs at the average acquisition cost, which may vary by hospital group, taking into account the hospital acquisition survey data. Following CMS's extensive OPPS Drug Acquisition Cost (ODAC) Survey, it is evident that the acquisition cost for SCODs through the 340B-drug discount program is far lower than the statutory default rate of average sale price plus six percent (ASP+6%). In light of the clear survey data, CMS is required to set payment based on the average acquisition cost for 340B acquired drugs and it would be unlawful to continue using a payment rate of ASP+6% for 340B drugs.

The Proposed Payment Adjustment for 340B-Acquired Drugs Benefits Seniors and Equitably Refocuses OPPS Payments, Providing Necessary Support to Rural Hospitals (Part V.C)

FAH believes that the proposed policy is an important step to directly benefit seniors and improve the accuracy of Medicare's payment for outpatient hospital services across all hospitals treating Medicare beneficiaries. First, seniors who get their drugs at a 340B hospital will realize significant savings because the lower Medicare OPPS payment to the hospital also lowers the Medicare beneficiary's copayment obligations. Seniors generally pay a 20% copayment based on the amount Medicare reimburses

the hospital for specified SCODs, not 20% of what it costs the hospital to buy the drugs. The current payment policy—which does not account for 340B program discounts at all—negatively impacts seniors, who make disproportionately large copayments compared to 340B hospitals' costs of acquiring the drugs. In fact, as noted in the Proposed Rule, these disparities are so significant that, in some cases, the Medicare beneficiary's copayment alone exceeds the actual acquisition cost of the 340B-discounted drug by hundreds of dollars. These excessive copayments are unjustified and burden seniors undergoing chemotherapy or otherwise dependent on outpatient drugs. **Overall, CMS anticipates that the proposed policy will reduce beneficiary copayments by an estimated $1.15 billion for CY 2027, and FAH strongly supports implementing these savings for seniors.**

Second, because the policy will be accompanied by a required budget neutrality adjustment, all hospitals, including 340B hospitals, will receive a much-needed 8.44 percent 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. The inefficiencies of the current drug payment policy have tangible adverse impacts on most hospitals and the communities they serve. Because of the OPPS budget neutrality requirement, the gains realized by certain 340B hospitals with high Part B drug volume as a result of the mismatch between acquisition costs and payment rates comes at the expense of other hospitals, who receive lower non-drug OPPS payments to account for the comparatively inflated payments relative to costs for 340B-acquired SCODs. In fact, the FAH's analysis of 2025 data indicates that the right-sizing of Part B payments for 340B-acquired drugs will benefit approximately three quarters of participating hospitals.

The current OPPS payment rates increase the financial burden of providing non-drug outpatient services by paying 340B hospitals amounts well in excess of their acquisition costs for Part B drugs. As a practical matter, excess 340B drug payments require non-340B hospitals to effectively subsidize the provision of similar services to 340B hospitals serving comparable patient populations. Along those lines, an examination of cost reports as contained in the CMS Healthcare Provider Cost Reporting Information System file dated June 30, 2022, reveals that non-340B hospitals had marginally higher uncompensated care cost rates than 340B hospitals—3.7 percent of total operating costs compared to 3.5 percent. FAH member hospitals had an even higher uncompensated care cost rate of 5.7 per cent. Charity care cost rates were comparable at 340B and non-340B hospitals at 2.5 percent, and higher, 4.4 percent, at FAH hospitals.

CMS's proposed policy, including the proposed exemptions for rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals, will help level the playing field across all OPPS hospitals, reinforcing the purpose of the Medicare OPPS to incentivize efficient and equitable behavior. Overall, CMS's analysis shows that the proposed policy will increase payments to rural hospitals by 3.5 percent, with small (0 – 99 beds), rural hospitals and rural, sole community hospitals seeing the largest payment gains at 4.8 percent and 5.7 percent, respectively. FAH's internal analysis modeling drug and non-drug payments under the policy based on Part B payment data between January 1, 2025, and December 31, 2025, confirms that this policy will provide critical benefits to rural hospitals. In our analysis, 76% of all geographically rural providers would be expected to have increased OPPS payments under the budget neutralized policy, with an overall 4.66% payment increase for these hospitals. Rural referral centers and sole community hospitals would also benefit, with payments increasing by 4.78% and 8.17%, respectively. **These gains for rural hospitals that are struggling to survive and closing at an alarming rate would provide a lifeline, helping to sustain access to care in our rural communities.** More broadly, FAH's analysis shows that approximately 78% of hospitals will experience an increase in payments under the proposed policy, with roughly half (54%) of 340B hospitals receiving increased payments. **The policy foundation supporting CMS's proposed 340B-drug payment policy is clearly compelling, and FAH strongly urges CMS to finalize the proposed 340B-drug payment policy and budget neutrality adjustment.**

The Proposed Average-Acquisition-Cost Policy Appropriately Takes the ODAC Survey Into Account (Part V.C)

FAH applauds CMS's efforts in undertaking its expansive survey of outpatient drug acquisition costs, analyzing the results and proposing appropriate payment adjustments over a very short timeframe. As noted above, this focused effort has programmatic benefits and also will directly benefit

seniors, who will no longer overpay for 340B-acquired SCODs with excessive copayments. FAH supports both CMS's determination that the survey was statistically significant and believes that the compelling findings necessitate an average-acquisition-cost payment rate for 340B-acquired drugs that takes into account the survey findings.

The ODAC Survey provides hospital acquisition cost survey data under section 1833(t)(14)(D) and the Proposed Rule properly analyzes that data and takes it into account in determining the average acquisition cost for 340B-acquired drugs. CMS employed a census-based approach that sought information from all hospitals relevant to the proposed policy and ultimately obtained responses from a substantial number of hospitals, generating what FAH understands to be the largest volume of acquisition cost data for hospital outpatient drugs ever collected in connection with the Medicare program. After applying appropriate data-cleaning and validation procedures, CMS used inverse probability weighting to account for differential response rates among hospital types and evaluated the resulting estimates using established statistical techniques. Importantly, the survey produced a narrow 95 percent confidence interval for the acquisition cost of 340B-acquired drugs, with estimates ranging only from ASP minus 32.3 percent to ASP minus 34.7 percent (a range of only 2.4 percentage points). CMS calculated these confidence intervals using 10,000 bootstrap replications, a sound and established statistical technique designed to assess the precision and reliability of survey estimates. The narrowness of this confidence interval confirms that the survey data are reliable and sufficiently precise for purposes of informing CMS's determination of the average acquisition cost of 340B-acquired drugs and implementing an acquisition-cost-based payment methodology.

Moreover, CMS's approach to addressing nonrespondents likely results in a more conservative estimate of the discount associated with 340B-acquired drugs and therefore is favorable to 340B hospitals. CMS used inverse probability weighting to ensure that responding hospitals appropriately represented nonresponding hospitals in the overall population, a methodology that is widely accepted and that improved the representativeness of the final sample. To the extent that 340B hospitals with the lowest acquisition costs were less likely to respond, CMS's weighting methodology would tend to increase estimated acquisition costs for 340B-discounted drugs relative to the acquisition costs that might have been observed had all hospitals responded. Thus, if anything, the survey methodology is more likely to overstate average acquisition costs for 340B-acquired drugs than understate them. Taken together, the survey's large volume of data, rigorous weighting methodology, and narrow confidence intervals provide strong support for CMS's conclusion that the survey generated a statistically significant and reliable estimate of the average acquisition cost of 340B-acquired drugs.

Establishment of the "JG" Modifier (Part V.C.10)

In order to effectuate the proposed acquisition-cost-based payment, CMS proposes requiring the use of one of three modifiers for each Part B drug claim line: modifier "JG" would be used by non-exempted hospitals to identify separately payable drugs acquired under the 340B program, informational modifier "TB" would be used by to identify all other 340B-acquired drugs and modifier "XX" would be used by all hospitals to identify drugs that were purchased outside of the 340B program.

Although FAH supports the establishment of modifiers as needed to operationalize the proposed shift to acquisition-cost-based payment for 340B acquired drugs, we are concerned that the proposed rule imposes unnecessary reporting obligations on non-340B hospitals and on all hospitals with respect to drugs that are not separately payable (status indicators "G", "K1" and "N"). Briefly, we urge CMS to finalize: (1) the "JG" modifier for separately payable (status indicator "K"), 340B-acquired drugs furnished by non-exempt 340B hospitals; (2) the "XX" modifier for separately payable (status indicator "K") drugs acquired by 340B hospitals without the 340B discount; and (3) the "TB" modifier for separately payable, 340B-discounted drugs furnished by exempt hospitals (children's hospitals, PPS-exempt cancer hospitals, and rural sole community hospitals). **Hospitals that do not (or cannot, as is the case with tax-paying hospitals, including even those that otherwise would qualify for the program) participate in the 340B drug discount program have higher expenses for drugs and should not be further penalized with the additional burden of reporting modifiers to identify that drugs were not purchased under the 340B program. FAH urges CMS to significantly limit its current proposal to focus on gathering necessary**

information regarding separately payable drugs furnished by 340B hospitals. In addition, FAH recommends that use of these modifiers be permitted on an optional basis for non-separately payable drugs so as to further minimize the administrative burden on hospitals.

A uniform national modifier that identifies those drugs purchased by non-exempted hospitals under the 340B program (*i.e.*, the proposed "JG" modifier) appropriately focuses the modifier policy on ensuring correct payment for these drugs while minimizing unnecessary administrative burdens. Moreover, because most State Medicaid programs require hospitals to identify 340B-acquired drugs with the use of a locally defined modifier, implementing a national modifier to identify drugs purchased under the 340B program should reduce the administrative burden for 340B hospitals because it would provide a single modifier to report for Medicare and all State Medicaid programs. It is likewise appropriate to create additional modifiers to identify situations where a separately payable drug is furnished by a 340B hospital but was not acquired under the 340B program (*i.e.*, modifier "XX") and situations where a separately payable 340B discounted drug is furnished by a children's hospital, PPS-exempt cancer hospital, or a rural sole community hospital (*i.e.*, modifier "TB"). None of these modifiers should be required for non-separately payable drugs as the collection of information about non-separately payable drugs does not advance any policy interests or support operationalization of the acquisition-cost-based payment adjustment for separately payable, 340B-discounted drugs. And likewise, none of these modifiers should be used by non-340B hospitals as these hospitals are ineligible for 340B drug discounts.

Although the use of the proposed modifier(s) should only be *required* when the drug is separately payable under the OPPS, it would be burdensome if the use of the modifier for non-separately payable drugs caused the claim to be rejected by Medicare contractors. Payment status indicators for drug HCPCS codes have historically been subject to substantial change on an annual basis and are also subject to quarterly changes. In addition, drugs eligible for separate payment are packaged when reported on a claim with a procedure paid under a C-APC. If Medicare does not accept claims that include the "JG", "TB" or "XX" modifier for a drug that is packaged with a procedure paid under a C-APC or is otherwise not separately payable, hospitals would be burdened with verifying whether a particular drug is separately payable on each claim and both hospitals and Medicare contractors would incur the additional and unnecessary costs of resubmitting and processing corrected claims. Therefore, FAH urges CMS to limit the modifier requirements to separately payable drugs furnished by 340B hospitals but nonetheless instruct its contractors to accept the use of the modifier when the drug is not separately payable.

The following table summarizes FAH's recommendations regarding the use of modifiers to implement the proposed 340B-drug payment policy:

Hospital Type	340B Discount Status	Pass-Through Drug (SI "G")	Separately Payable Drug (SI "K")	Non-Opioid Treatment for Pain Relief Drug (SI "K1")	Packaged Drug (SI "N")
Non-Exempt 340B Hospitals	Discounted	Optional JG	JG	Optional JG	Optional JG
	Non-Discounted	Optional XX	XX	Optional XX	Optional XX
Exempt* Hospitals	Discounted	Optional TB	TB	Optional TB	Optional TB
	Non-Discounted	Optional XX	XX	Optional XX	Optional XX
Non-340B Hospitals	Non-Discounted	N/A	N/A	N/A	N/A
** Children's Hospitals, PPS-Exempt Cancer Hospitals, and Rural Sole Community Hospitals*					

FAH Supports the Proposed CY 2027 OPPS Payment Methodology for Non-340B Acquired Drugs (Part V.D.)

CMS proposes to continue paying separately payable non-340B drugs, biologicals, biosimilars, and radiopharmaceuticals using the same methodology as applied in CY 2026, which is generally at a rate of ASP plus 6 percent. As noted in the Proposed Rule, the surveyed acquisition cost of non-340B drugs was

far more variable than for 340B-acquired drugs. For non-340B drugs, the 95% confidence interval of the average acquisition cost ranged from ASP minus 3.8% to ASP plus 6.9%, a spread of 10.7 percentage points. In contrast, the 95% confidence interval for 340B-acquired drugs was far narrower, with just a 2.4 percentage-point difference between the upper and lower limits of the 95% confidence interval (*i.e.*, from ASP minus 32.3% to ASP minus 34.7%).[12] ***These results strongly counsel against changing from the current payment for non-340B acquired drugs (ASP plus 6%) because the current payment rate is within the 95% confidence interval for the acquisition cost of non-340B acquired drugs.***

In light of survey results and CMS's technical report, CMS should therefore determine that, taking into account the available hospital acquisition cost survey data, the average acquisition cost is in fact the current payment rate for non-340B drugs (ASP plus 6%). In the alternative, FAH also supports CMS's determination that hospital acquisition cost data is not currently available for non-340B drugs given the large confidence interval such that payment under section 1833(t)(14)(A)(iii)(II) (*i.e.*, ASP plus 6%) continues to be appropriate. **FAH would strongly oppose any payment at less than ASP** plus **6% for non-340B drugs because the survey data does not provide confidence that the average acquisition cost varies from this statutory default amount.**

V. An Increase to Non-Drug OPPS Payment Rates is Required as a Budget Neutral Adjustment for the Proposed Reduction in Payments for 340B-Acquired Drugs (Parts II.B.3 and V.F)

FAH strongly supports CMS's proposed budget neutral adjustment of at least 8.44 percent to offset the estimated $4.85 billion reduction in payments for 340B-acquired drugs for CY 2027 and urges CMS to revise this budget neutrality adjustment on an annual basis to ensure that each year's budget neutrality adjustment reflects the estimated reduction in drug payments for that year. CMS proposes to achieve budget neutrality through an increase to the conversion factor for OPPS non-drug items and services. This adjustment is both appropriate and required.

Prospective budget neutrality estimates are a key statutory feature of the OPPS. Pursuant to section 1833(t)(9)(B) of the Social Security Act, "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." **FAH believes that this budget neutrality requirement obligates CMS to apply all of the savings estimated to be generated in CY 2027 under this policy to offset payment increases in the OPPS. The proposed adjustment to the conversion factor for non-drug items and services would appropriately satisfy this requirement.**

FAH is concerned, however, that once a payment policy is in place, the annual budget neutrality adjustment process does not sufficiently update and account for the estimated savings under that policy in the coming year and it is therefore necessary for CMS to annually revise its estimates for purpose of budget neutrality. For example, when the prior 340B-acquired drug payment policy was in place, commenters urged an update to the budget neutrality adjustment based on more current data showing the estimated impact of the payment policy. CMS, however, declined to update the budget neutrality adjustment, emphasizing the prospective nature of budget neutrality adjustments and that the "broader budget neutrality adjustments" adopted annually adequately address changes in drug utilization and payment such that the existing budget neutrality adjustment remained appropriate as long as the 340B drug payment policy remained in place.[13] In practice, however, it appears that the higher-than-expected savings (at the time) under the 340B-acquired drug policy were not captured and reflected in annual budget neutrality adjustments, such that the budget neutrality adjustments did not continue to reflect changes in estimated expenditures under the policy in the year. Without new estimates and associated budget neutrality adjustments, payment policies risk inappropriately eroding OPPS payment rates, to the ultimate detriment of program beneficiaries.

In the context of the proposed drug payment policy, FAH is particularly concerned that the budget neutrality adjustment will be insufficient to fully neutralize the 340B drug payment policy because our internal estimates using later data indicate that savings under the program may be higher than the $4.85 billion estimated by CMS. As CMS notes, the appropriate adjustment amount may change in the final rule "as a

result of changes such as updated data, modifications to the estimate methodology, and other factors."[14] **FAH supports the use of updated data when finalizing the adjustment for CY 2027, but also urges CMS to make new estimates of savings from the acquisition-cost-based payment policy for 340B drugs in each annual OPPS rulemaking to ensure that OPPS payments are maintained.**

VI. Payment for Partial Hospitalization and Intensive Outpatient Services (Part VIII.C)

For CY 2027, CMS proposes to maintain its current methodology for setting partial hospitalization program (PHP) and intensive outpatient program (IOP) payment rates. For the four hospital-based APCs (5861, 5862, 5863 and 5864), rates are set on the geometric mean per diem cost for days with three services and for days with four or more services, using the broader OPPS data set with the same trims and exclusions applied elsewhere in the OPPS, drawn from the latest available cost reports and CY 2025 claims. For the four community mental health center (CMHC) APCs (5851, 5852, 5853 and 5854), CMS proposes to set costs at 40 percent of the corresponding hospital-based APC, applying the MPFS Relativity Adjuster finalized in the CY 2026 OPPS/ASC final rule with comment period.[15] Table 57 shows proposed geometric mean per diem costs of $326.57 for a three-service day and $434.46 for a day with four or more services at hospital-based programs, and $130.63 and $173.78 for the corresponding days at CMHCs.

Medicare has paid for PHP under the OPPS since CY 2000. The IOP benefit, established by the Consolidated Appropriations Act, 2023, took effect for items and services furnished on or after January 1, 2024, and is now in its third year. Separate rates for hospital-based programs and CMHCs have been in place since CY 2011 and reflect measured differences in resource use between the two settings. **FAH supports maintaining this methodology.**

CMS also proposes that if more recent hospital cost data become available after publication of the proposed rule, it would consider using such data to set the final CY 2027 rates. FAH does not object to CMS using the best available data. Rates built on data the public has not seen, however, cannot be replicated or checked before they take effect, and publishing that data imposes no additional analytic burden on CMS. **If CMS substitutes updated cost data in the final rule, FAH urges CMS to publish the updated data files and the recalculated geometric mean per diem costs, with the trims and exclusions applied, at the time of the final rule.** Publishing the file with the rule is consistent with CMS's existing practice of posting OPPS data and allows providers to reconcile their own experience against the rates before the rate year begins.

VII. The IPO List Should be Restored and Retained as a Critical Patient Safety Tool and to Ensure that Procedures Are Appropriately Paid and Provided Under Medicare Part A (Part IX.B)

FAH strongly opposes CMS's proposal to continue the phased elimination of the Inpatient Only (IPO) list, which designates those procedures that are not designated as hospital outpatient procedures because they are 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.

Historically, CMS has annually reviewed 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 except in very limited circumstances where the patient receives an emergent procedure on the IPO list before the patient can be admitted.[16] Ultimately, the IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing any of the 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.

For CY 2026, CMS removed 285 mostly musculoskeletal procedures from the IPO list, leaving 1,438 services remaining on the list. CMS now proposes to remove 637 services from the IPO list, which would leave approximately 810 services on the IPO list for CY 2027 (Addendum E). FAH opposes the proposed continued phase-out of the IPO list. Instead, FAH supports reinstating the IPO list—which consists of procedures that are currently performed appropriately and safely only in the inpatient setting—as well as CMS's prior process for removing procedures based on clinical criteria. The five criteria previously 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 determined that one or more of these criteria was met for a given procedure under consideration for removal from the IPO list, CMS could remove it.

By annually applying these clinical and patient safety-oriented criteria on a case-by-case basis, CMS appropriately responded to the evolution of medical technology and practices that allowed services to migrate to ambulatory settings when evidence indicated they could be performed safely in those settings, while also maintaining the staunch patient safety protections afforded by the IPO list. Following the CY 2026 Final Rule, however, these clinical considerations no longer come into play and Part A coverage would turn largely on the physician's expectations concerning the length of stay under 42 C.F.R. § 412.3(d)(1).[17]

FAH maintains that the 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—cited by CMS as justification for eliminating the IPO list did not and do not warrant the 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 health care system.** ***FAH continues to oppose the 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 IPO List Reduces Administrative Burdens Without Eroding Professional Judgment.

As a general matter, FAH agrees that the appropriate site of service for a particular procedure should typically be determined by physicians 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 providers should only remove entire organs—e.g., the lung (CPT code 32440), kidney (CPT code 50220), bladder (CPT code 51570), stomach (CPT code 43620) or spleen (CPT code 38102)—from Medicare beneficiaries on an inpatient basis and that these procedures should be paid only under the IPPS simply reflects the invasive nature of the procedures and their indisputable and inherent risks. By categorically restricting coverage to the inpatient setting for these organ removals based on the clinical evidence, CMS has appropriately advanced patient safety without meaningfully limiting any physician's clinical judgment. Moreover, in doing so, CMS has fulfilled its statutory obligation to designate services as "hospital outpatient services" under section 1833(t)(1)(B)(i) of the Social Security Act. In short, these are not hospital outpatient services, CMS has properly not previously designated them as such, and CMS should not now designate them as hospital outpatient services.

Meanwhile, the continued elimination of the IPO list will inappropriately result in level-of-care determinations based largely on the patient's 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.[18] 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. Although CMS has, with FAH's strong support, rightly foreclosed medical review activities for services and procedures removed from the inpatient only list on or after January 1, 2021, unless and until the Secretary determines that the services or procedure is more commonly performed in the outpatient setting than the inpatient setting, this rule does not provide the same coverage clarity that the full IPO list previously offered.

CMS's prior IPO list policy ensured 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 not being appropriate for removal under CMS's prior criteria.

Despite argument to the contrary, the continued elimination of the IPO list effectively eliminates Part A coverage for these invasive 1-day procedures except in circumstances where the physician exercises his or her clinical judgment under 42 C.F.R. § 412.3(d)(3) and orders 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. Establishing that an inpatient one-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 one-day procedures to the outpatient setting simply out of reluctance to use the case-by-case exception. Acknowledging that final sentence of 42 C.F.R. § 412.3(d)(2) appropriately shields these cases from medical review**, FAH nonetheless believes that CMS should reinstate the IPO list and the clear coverage it provides in these cases.** 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 CY 2026 OPPS rulemaking and the current Proposed Rule do not address the provider burdens or patient risks inherent in eliminating clear inpatient coverage under Medicare Part A and Part C for 1-day procedures currently on the IPO list.

Rather than reinstating a long-standing policy 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. 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-oriented tactics cannot and do not do. Rather than relying on adverse consequences for unsafe care, FAH urges CMS to continue to facilitate patient safety by itself adhering to patient safety criteria when defining "hospital outpatient services" under section 1833(t)(1)(B)(i) of the Social Security Act.

The elimination of the IPO list also risks 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 receiving observation care is considered for purposes of the two-midnight rule, it is not considered for purposes of the three-day qualifying hospital stay. Without the IPO list, some inpatient admissions will likely be newly delayed by one or more midnights, and as a result, some Medicare beneficiaries will not qualify for Part A SNF coverage due to time spent receiving observation care. 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.

Elimination of the IPO List Erodes the Part A Benefit and May Increase the Financial Burden on Beneficiaries.

The continued elimination of the IPO list also creates financial burdens for Medicare beneficiaries because, in certain circumstances, 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. CMS is proposing to assign the vast majority (566) of procedures to be removed from the IPO list for CY 2027 to a comprehensive APC (C-APC) upon removal, limiting beneficiaries to a single, capped coinsurance obligation for the C-APC. 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 continued 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's supporting files include proposed APC assignments for 598 of the procedures proposed to be removed from the IPO list, 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.[19] But the assignments proposed in the file titled "Proposed Procedures for Removal from the IPO List for CY 2027" are not supported by any analysis or rationale. Without a sufficient explanation of the methodology for proposing APC assignments for these procedures, stakeholders cannot meaningfully comment on the proposed assignments.

Adverse Impact for Medicare Part C Beneficiaries.

The continued elimination of the IPO list also risks adverse impacts for Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, but the CY 2026 OPPS rulemaking and the Proposed Rule fail 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,"[20] 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. The IPO list therefore serves as a clear and easily administrable Medicare coverage standard for procedures that warrant inpatient treatment. 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, Medicare beneficiaries that elect Part C coverage are more likely to experience increased denials of inpatient coverage for invasive procedures that require intensive postoperative monitoring and care. 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 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, but that significant problems remain with respect to application of the two-midnight benchmark and case-by-case exception. In fact, even after recent amendments to 42 C.F.R. § 422.101, data indicates that 3-day inpatient stays are approximately 6 times as likely to be fully denied by MA plans (14.4% denial rate) as compared to 3-day inpatient stays for Medicare Part A beneficiaries (2.4% denial rate).[21] Elimination of the IPO list risks reversing the coverage gains that have been made, 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 in the Outpatient Setting

CMS's proposal to continue the phased elimination of 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, however, proposes to complete its elimination of the IPO list and price all services under the OPPS by CY 2028, and this will unnecessarily require the agency to 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, including the various organ removals proposed for removal in CY 2027.

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 prior removal policy allows such procedures to be brought to their attention and removed from the IPO list and for CMS to carefully consider how to price such procedures on an outpatient basis. This approach was consistent with CMS's statutory responsibility for designating "hospital outpatient services" under section 1833(t)(1)(B)(i) of the Social Security Act, whereas the current elimination policy will improperly designate *every* procedure as a hospital outpatient service.

Alternative Proposal

Although FAH supports the full reinstatement of the IPO list, if CMS continues the phased elimination of the IPO list, FAH strongly urges CMS to shift to 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 reinstate 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.

Finally, FAH urges CMS to undertake meaningful education of the physician community as part of any continued elimination of the IPO list. To date, CMS has not communicated to physicians that procedures removed from the IPO list may still be appropriately performed on an inpatient basis. Without clear guidance, physicians may misinterpret removal as a signal that these services should be furnished only in the outpatient setting, leading to inappropriate care decisions and coverage disputes. FAH recommends that CMS develop and disseminate provider-facing educational materials clarifying that removal from the IPO list does not preclude inpatient performance when clinically indicated.

VIII. Imaging Without Contrast 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 (Part X.A.)

The Proposed Rule would cut the payment rate for the 337 different imaging without contrast services that are currently assigned to Ambulatory Payment Classification (APC) codes 5521, 5522, 5523, 5524, 8004, 8005, and 8007 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.[22]

CMS has asserted that it has the authority to implement this significant payment adjustment in a non-budget neutral manner under section 1833(t)(2)(F) of the Social Security Act, which requires CMS to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department (OPD)] services." **FAH continues to strongly oppose this proposed payment reduction, as well as the continuation of the current payment reduction for clinic visit and drug administration services in excepted, off-campus PBDs. The policy 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 fails to provide appropriate deference to physicians' judgment regarding the clinical necessity of care in the hospital outpatient setting.** For these reasons, FAH strongly urges CMS not to finalize the payment reduction for imaging without contrast services and to eliminate the payment reduction for clinic visit and drug administration services. Furthermore, FAH maintains that these existing and proposed 60 percent payment cuts constitute "adjustments" that are subject to the budget neutrality requirements set forth in section 1833(t)(9)(B), and we urge CMS to return the OPPS to the budget neutral payment system required by Congress.

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.

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." 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. Ultimately, Congress "retains for itself the authority" to make these kinds of complicated payment decisions, and CMS cannot ignore and circumvent the multi-factored, complicated annual process required by statute by unilaterally setting service-specific rates without regard to their relative position or budget neutrality.

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 its 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. 369 (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 "is the best one."[23] In doing so, the Proposed Rule cites the D.C. Circuit decision without noting the court's 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, drug administration services, or imaging without contrast services at excepted, off-campus provider-based departments. CMS should therefore decline to adopt the proposed new payment cut and reverse the existing payment cuts or, at a minimum, budget neutralize their application consistent with statute.

The Proposed Adjustment is Not a Permissible "Method for Controlling Unnecessary Increases in the Volume of Covered OPD Services."

CMS's proposal to reduce the payment rate for 337 different imaging 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 significant growth in the proportion of ambulatory imaging without contrast services furnished in excepted off-campus PBDs over the past five years. Our analysis[24] shows that the share of imaging-without-contrast utilization furnished in excepted off-campus PBDs remained essentially flat from 2021 to 2025, increasing by only 0.2 percentage points (from 3.3 percent in 2021 to 3.5 percent in 2025). Over the same period, the inpatient share declined by 2.7 percentage points and the physician-office share increased by 0.3 percentage points (from 30.8 percent in 2021 to 31.1 percent in 2025), indicating a broader redistribution of imaging across settings rather than disproportionate growth in excepted off-campus PBDs.

Setting	Share of Reported Units (2021)	Share of Reported Units (2025)
Inpatient	18.0%	15.3%
Outpatient, On-Campus	27.2%	28.5%
Outpatient, Excepted, Off-Campus ("PO")	3.3%	3.5%
Non-Excepted, Off-Campus ("PN")	0.4%	0.9%
Physician Office	30.8%	31.1%
All Other	20.3%	20.6%

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,"[25] the Proposed Rule would cut payment rates for some imaging services that physicians do not typically furnish in their offices. In fact, there was negligible to no reporting of some of the HCPCS codes on physician office claims. For example, transesophageal echocardiography (TEE) is rarely performed in a physician office. Our analysis shows zero or fewer than 11 physician-office units annually from 2021 through 2025 for HCPCS codes 93313 (probe placement only), 93315 (complete TEE for congenital cardiac abnormalities), and 93318 (TEE for monitoring). In addition, physician offices accounted for less than 1 percent of reported utilization for HCPCS code 93312, which describes a complete diagnostic TEE examination. These utilization patterns contradict the premise that these services are ordinarily available in physician offices and that excepted, off-campus PBD utilization is a product of financial incentives. Overall, our analysis identified 58 HCPCS codes for which there was no physician office utilization in 2025, 30 codes with no physician office utilization over the past five years, and 78 codes with only negligible utilization (fewer than 11 reported units per year) for each of the past five years. 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, it potentially represents unnecessary utilization of the OPD setting."[26] 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. The proposal, therefore, does not satisfy the statutory requirements of section 1833(t)(2)(F) of the Act, which requires CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services."

The inclusion of services with no or negligible utilization in excepted off-campus PBDs in the proposal further demonstrates that the payment cut is not tailored to control an unnecessary increase in volume. The proposed payment reduction would apply to some services that are not currently furnished in excepted, off-campus PBDs. Much of the analysis in the Proposed Rule focused on the small subset (70 codes) of imaging without contrast codes that account for most utilization in excepted, off-campus PBDs, but this approach omits the 267 imaging without contrast codes (nearly 80 percent) that are rarely furnished in excepted, off-campus PBDs and for which the Proposed Rule does not suggest any unnecessary increase in utilization. In fact, the proposed policy would apply to the 60 imaging without contrast codes that were not reported by any off-campus, excepted PBD in 2025, including HCPCS code 0349T (radiostereometric analysis, upper extremity exam), HCPCS code 70390 (X-ray exam of salivary duct), HCPCS code 93315 (echocardiography transesophageal), and HCPCS code 93893 (transcranial Doppler study of the intracranial arteries; venous-arterial shunt detection with intravenous microbubble injection), and 22 dental radiography codes. Overall, approximately one-third of the imaging without contrast codes (111 codes) that would be subject to this policy each had fewer than 50 reported units in excepted, off-campus PBDs in 2025. And 42 of these codes have not been reported on a single hospital claim for an excepted, off-campus PBD between 2021 and 2025 (*e.g.*, HCPCS codes 93313 (echocardiogram transesophageal), 70557 (MRI brain without dye), 0558T (CT scan for biomechanical CT analysis) and 70320 (full mouth x-ray of teeth).) A reduction in payment for a service with no or negligible utilization cannot control an increase in that service's utilization. At most, it establishes a reduced payment rate in anticipation of hypothetical future utilization, which is not the volume-control problem CMS claims to be addressing.

Moreover, to the extent that utilization of imaging without contrast is growing more rapidly in hospital outpatient department settings than in physician offices, this likely reflects hospitals' investment in communities where physicians lack the capital, scale, or operational capacity to independently offer these services. The largest driver of a change in utilization of imaging without contrast services at any provider or supplier location would be the acquisition of new and improved imaging equipment that is capable of providing imaging services that were not previously available or of providing more accurate and higher resolution imaging results. Thus, the most reasonable interpretation of data showing that utilization of imaging without contrast services is increasing more rapidly at excepted, off-campus provider-based departments as compared to physician offices is that it is hospitals that are investing in the equipment necessary to furnish those services at the quality demanded by referring physicians. Medicare beneficiaries disproportionately reside in rural areas where services, including imaging services, may be less accessible, and these communities stand to suffer diminished access if CMS implements payment cuts for imaging without contrast services at off-campus provider-based departments that render these services unsustainable. CMS should support, rather than penalize, hospitals that make these investments and expand beneficiary access to diagnostic imaging.

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.[27] 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 began operation and would result in an additional $90 million in estimated outlays.[28] 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.[29]

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 statutorily addressed growth. Rather, the data analysis should appropriately focus on more recent growth, which is also the only data 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, largely relies on 2016 as a baseline year for hospital outpatient department utilization comparisons.

Focusing on the 70 codes that are the focus of analysis in the proposed rule, declining inpatient utilization appears to be a significant factor in utilization changes in ambulatory settings. For example, inpatient utilization of HCPCS code 93970 (extremity study) declined by more than 16 percent between 2021 and 2025, but had a modest utilization increase of 2.3 percent in off-campus, excepted PBDs and a far greater utilization increase of 9.4 percent in physician offices, indicating shifts in care settings without any excess growth in excepted, off-campus PBDs. Along similar lines, a significant number of these codes have higher growth rates in the physician office setting compared to the excepted, off-campus PBD setting. For example, utilization of HCPCS code 77091 (DXA bone density/peripheral) has grown by over 170 percent in the physician office settings, far outpacing the nearly 53 percent growth in excepted, off-campus PBDs. Likewise utilization of HCPCS codes 75571 (CT heart without dye with coronary calcium test), 73200 (CT upper extremity without dye), 72110 (x-ray exam, spine, lumbosacral, minimum of four views), 73564 (X-ray exam, knee, 4 or more views), 93978 (vascular study), 72082 (X-ray exam entire spine, 2 or 3 views), 72146 (MRI chest spine without dye), 73221 (MRI joint upper extremity without dye), 73110 (X-ray exam of wrist), 72148 (MRI lumbar spine without dye) grew faster in physician offices, outpacing any excepted,

outpatient department utilization growth by more than 10 percentage points between 2021 and 2025. Although utilization of these services is growing at a significantly slower pace in the excepted, off-campus PBD setting as compared to physician offices or in some cases is actually declining (*e.g.*, HCPCS code 72110 and 93978), these codes would nonetheless be subject to a payment reduction under the Proposed Rule. The Proposed Rule, however, provides no explanation as to why slower growth services can or should be subject to a volume-control measure under subsection (t)(2)(F).

Overall, the Proposed Rule does not present evidence of unnecessary growth in the volume of imaging without contrast services 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 imaging without contrast services in excepted, off-campus PBDs is not designed to control unnecessary volume increases, and therefore cannot be implemented under section 1833(t)(2)(F) of the Act. CMS has not identified a rate by which the volume of imaging without contrast services should necessarily increase 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, 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.

Along these lines, data on utilization trends and non-excepted, off-campus PBDs confirms that the proposed payment cut is unlikely to control unnecessary increases in the volume of covered OPD services. Across all imaging without contrast services, utilization in non-excepted, off-campus PBDs that are paid at the same 40 percent of OPPS rate proposed to be applied to excepted, off-campus PBDs grew by nearly 166 percent from 2021 to 2025. In fact, between 2024 and 2025, utilization of these services increased by nearly 33 percent in non-excepted, off-campus PBDs, reflecting significant and sustained growth notwithstanding reduced payments. 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.

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

FAH also maintains that the proposed payment cut is flawed as a matter of policy. Much of the Proposed Rule discussion of the proposed payment reduction is premised 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 with respect to imaging without contrast services, 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 the imaging services 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.[30] With respect to imaging without contrast services more specifically, a physician may refer a patient to the hospital for a particular imaging study because the hospital is the only provider in the community that has invested in the imaging equipment and undertaken the significant maintenance and personnel costs necessary to provide high-quality and reliable imaging. Hospitals are subject to specific conditions of participation for diagnostic radiologic services under 42 C.F.R. § 482.26, and by referring a patient to the hospital, a physician can be assured that his or her patient will only receive imaging services under the supervision of a radiologist. As a result, hospital outpatient departments typically care for higher-acuity patients and can provide more complex care and imaging studies 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 imaging without contrast 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 imaging without contrast 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 imaging without contrast services, which are the subject of this proposal, because physicians actually order each imaging without contrast and outpatient departments are limited in their ability to control the volume of imaging services furnished.

The proposed payment cut for imaging without contrast 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 acutely by rural providers,[31] 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 beneficiaries' access to imaging without contrast and other services. If imaging without contrast 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 for imaging services. 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. **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.**

FAH also 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 imaging without contrast services, for example, hospitals incur the costs of complying with specific conditions of participation under 42 C.F.R. § 482.26, enabling the hospital to safely maintain and operate radiologic equipment. These costs are not captured by the PFS relativity adjuster. At a minimum, it is inappropriate to use the PFS relativity adjuster to pay hospitals less than physicians would receive under the PFS for any imaging without contrast services, and a PFS-based payment floor is necessary to avoid such an absurd result.

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' consideration of MedPAC's recommendation to eliminate the difference in payment between HOPDs and physician 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 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 337 imaging without contrast 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.

Regardless of Whether This Proposal is a "Method to Control Volume" Within the Meaning of Section 1833(t)(2)(F), it is an "Adjustment" That Is Subject to the Statute's Budget Neutrality Requirement.

FAH believes that, in addition to being deeply flawed and unlawful, the proposed payment cut for imaging without contrast services and billed with the "PO" modifier is an adjustment under section 1833(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, 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, section 1833(t)(9)(B) of the Act 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 (section 1833(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 from section 1833(t)(9)(B), which requires that "adjustments" under subsection (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 section 1833(t)(9)(A) expressly include "other adjustments described in paragraph (2)." Notably, the referenced adjustments are not restricted to adjustments under section 1833(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 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 337 imaging without contrast 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 section 1833(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 misses 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, FAH strongly urges CMS not to finalize the proposed rate cut for imaging without contrast services 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 and drug administration services in excepted off-campus departments, or, at a minimum, implement them in a budget neutral manner.

IX. Hospital Outpatient Quality Reporting Program (OQR) (Parts XIV–XV)

Removal of Appropriate Follow-Up Interval for Normal Colonoscopy Measure (Part XIV)

CMS proposes to remove the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure from both programs, beginning with the CY 2027 reporting period/CY 2029 payment determination.

FAH supports removal of this measure from OQR and ASC Quality Reporting Programs. We do not believe that the benefit of this measure outweighs the burden of data collection. We also encourage CMS to review the case minimums required for the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure, which will continue to be reported in these programs. During the last endorsement review, the minimum reliability of the measure was below 0.3 with at least 30 patients in the denominator. While this outcome may be more meaningful and relevant to patients, the reliability must be improved to ensure that it provides the most useful information to these facilities.

Advance Care Planning eCQM RFI (XV.C.)

CMS seeks feedback on potential inclusion of an Advance Care Planning electronic clinical quality measure (eCQM) and other quality measure concepts related to advance care planning for the Hospital Outpatient Quality Reporting Program.

FAH supports patient-centered care and recognizes that advance care planning is an important component of high-quality care across the continuum. However, we believe that this measure should undergo additional testing to determine whether it is feasible and appropriate for use in hospital outpatient departments (HOPDs), including whether it should be tailored to specific procedures and conditions. For example, we do not believe that discussing advance care planning prior to every cataract procedure is warranted or necessarily meaningful to the patient's care.

More robust testing beyond what was conducted in the inpatient setting is also needed to ensure that the data are collected in a reliable and valid manner. Specifically, data element validity was only evaluated in one electronic health record system (EHR), and feasibility was assessed in two EHRs. Based on hospitals' experiences with the data elements required for the Hybrid Hospital-Wide All-Cause Readmission measure, we know that this testing is insufficient to demonstrate that the required data can be consistently captured across different EHR platforms and incorporated into existing workflows without significant burden or unintended consequences.

CMS must also provide HOPDs sufficient implementation time for hospitals and their EHR vendors to develop, test, validate, and refine the technology and workflows necessary to accurately capture and report the required data. Hospitals frequently depend on EHR vendors to develop functionality needed to implement new eCQMs. When implementation timelines are too short, vendors may be forced to prioritize interim patches, manual workarounds, or other "band-aid" solutions designed primarily to meet a reporting deadline rather than developing sustainable functionality that integrates appropriately into hospital workflows. Such approaches can increase administrative burden, introduce opportunities for error, and ultimately undermine the reliability of the data CMS seeks to collect.

Adequate implementation time is essential not only to reduce burden, but also to protect the integrity and validity of the measure itself**.** Hospitals need sufficient time to work with vendors to configure systems, complete mapping, test data capture, educate clinicians and other staff, assess whether the measure is functioning as intended, and correct problems identified during implementation. CMS should recognize that developing a durable eCQM solution that works across different EHR platforms and hospital environments requires an iterative process and cannot reasonably be accomplished through compressed implementation timelines.

Assuming that an Advance Care Planning eCQM for HOPDs would be designed like the one proposed for the Hospital Inpatient Quality Reporting Program, the numerator requirements are complex, and implementation will need to comply with any individual state requirements. Any eCQM on advance care planning should also ensure that an individual's religious and/or cultural beliefs can be honored; specifically, the measure should include an exception or guidance allowing the documentation of a discussion to account for those individuals for whom the conversation would be forbidden.

FAH therefore urges CMS to ensure that any Advance Care Planning eCQM addresses these important patient-centered concerns and undergoes robust testing across multiple EHR vendors and HOPDs of varying size, geographic location, ownership, and technological capabilities before it is finalized for use in any quality reporting program. This testing should demonstrate not only that the measure can be technically implemented, but also that the required data can be reliably captured through sustainable workflows without requiring excessive manual intervention or temporary vendor workarounds.

Finally, CMS should provide HOPDs at least two years following publication of final technical specifications to prepare for reporting, followed by a minimum of two years of voluntary reporting before considering mandatory adoption. This phased approach would provide hospitals and EHR vendors sufficient time to develop durable technical solutions, identify and resolve implementation challenges, evaluate data quality, and ensure that the measure is producing valid and meaningful information before hospitals are held accountable for reporting performance.

Validation Overhaul (Part XV.D.)

CMS proposes several changes to the Hospital OQR Program validation process, including incorporating (eCQMs) into the existing validation process for chart-abstracted measures. Beginning with the CY 2030 payment determination, CMS would select up to 400 hospitals for validation, with up to 200 selected randomly and up to 200 selected based on established targeting criteria. Hospitals selected for validation would submit both chart-abstracted and eligible eCQM data. CMS also proposes to validate up to 32 cases per measure, align the submission periods and processes for chart-abstracted measures and eCQMs, and move to a three-year validation cycle. In addition, CMS would apply the existing 75 percent validation threshold to eCQMs and extend the educational review process to eCQM validation. These changes would generally align the Hospital OQR validation process with the approach used in the Hospital Inpatient Quality Reporting (IQR) Program.

FAH supports CMS's proposed changes to the Hospital OQR Program validation process. We appreciate CMS's efforts to align eCQM and chart-abstracted measure validation and, where possible, use processes that are consistent with those already established under the Hospital IQR Program. Hospitals are familiar with these approaches, and greater consistency across the inpatient and outpatient quality reporting programs should make validation requirements easier to understand and administer. We also support reducing the overall number of hospitals selected for validation while placing greater emphasis on hospitals that meet established targeting criteria.

FAH also supports CMS's proposal to validate eCQMs once a full year of mandatory reporting data is available and to use the same electronic medical record submission process that hospitals already use for chart-abstracted measures. Applying a common process to both types of measures provides a clear and consistent approach to validation. Similarly, we support CMS's proposal to align the data submission periods for chart-abstracted measures and eCQMs and transition to a three-year validation cycle. This alignment should make it easier for hospitals to track their validation activities and allow CMS sufficient time to complete the validation and review process.

Finally, FAH supports expanding the educational review process to eCQMs and allowing educational review results from all four quarters of chart-abstracted measure validation to be incorporated into the final validation score. Hospitals should have a meaningful opportunity to identify and resolve questions or errors in their validation results before those results affect payment. The additional time available under the three-year validation cycle appropriately allows CMS to complete these reviews and incorporate corrected scores into the final validation determination. Extending the same opportunity to eCQMs also provides hospitals with a consistent process for understanding and addressing potential discrepancies across measure types.

Validation Updates and Payment Reduction / Reporting Ratio (Parts XV.E–F)

CMS proposes to remove the requirement that hospitals resubmit medical records and other materials that were previously submitted to CMS when requesting reconsideration of a Hospital OQR validation determination. Under the proposal, hospitals would only need to submit evidence supporting their

reconsideration request, unless CMS specifically requests previously submitted materials. Hospitals would retain the ability to submit a revised medical record when necessary. This change would begin with CY 2026 reporting period data affecting the CY 2028 payment determination and would align the Hospital OQR Program with the approach already adopted for the Hospital IQR Program.

FAH supports CMS's proposal to remove the requirement that hospitals resubmit medical records and other materials that CMS already has as part of the validation reconsideration process. Requiring hospitals to resubmit the same documentation creates unnecessary administrative work without providing CMS with additional information needed to evaluate the reconsideration request. The proposed change appropriately streamlines the process while preserving hospitals' ability to provide new or revised information, when necessary. We appreciate CMS's efforts to reduce unnecessary reporting burden and we encourage CMS to finalize this proposal.

X. Expansion of Botulinum Toxin Injection Codes for Hospital Outpatient Department Prior Authorization (Part XIX)

CMS proposes to expand the botulinum toxin injection prior authorization category at proposed revised 42 CFR 419.83(a)(2) to include eight additional codes, effective for service dates on or after July 1, 2027. Seven are procedure codes: 64611, 64616, 64617, 64642, 64644, 64646 and 64647. The eighth is a drug code, J0589. CMS also proposes to remove the effective-date language from the regulatory text and to renumber the paragraphs of 419.83(a). CMS established prior authorization for HOPD services under Section 1833(t)(2)(F) of the Social Security Act, which directs the Secretary to develop a method for controlling unnecessary increases in the volume of covered outpatient services. Botulinum toxin injections were among the five categories in the CY 2020 OPPS/ASC final rule with comment period that require prior authorization.[32] CMS added two categories in the CY 2021 OPPS/ASC final rule[33] and an eighth category in the CY 2023 OPPS/ASC final rule.[34] The governing regulations are at 42 CFR 419.80 through 419.89. **Given the gaps in the evidence and rationale CMS presents in support of its proposed expansion of prior authorization, FAH urges CMS to delay this proposed expansion to a future rulemaking cycle until the agency can more fully justify its proposed expansion.**

CMS bases the proposal on relative growth. Claim volume for the eight codes rose from approximately 43,500 in 2017 to approximately 62,103 in 2024, an increase of 42.8 percent and an average annualized rate of 4.6 percent. Over the same period, overall OPD claim volume fell 8.3 percent. The eight codes account for approximately $102 million in annual Medicare payments. CMS states that it reviewed potential explanations, including changes in clinical need and coding changes, and did not identify sufficient evidence to account for the magnitude of the increase. CMS acknowledges that new FDA approvals may have contributed but concludes they do not explain the magnitude, without presenting the supporting analysis. FAH shares CMS's responsibility to protect the Medicare Trust Funds and does not dispute that utilization of these services has grown. However, the record does not yet support the conclusion CMS draws from that growth, and the proposed remedy carries patient-access consequences that CMS itself has asked commenters to address.

Therapeutic Indications With No Cosmetic Use

The seven procedure codes describe therapeutic chemodenervation for specific neurological conditions. Code 64611 treats the salivary glands for sialorrhea, the severe drooling associated with conditions including amyotrophic lateral sclerosis and Parkinson disease. Code 64616 treats the neck muscles for cervical dystonia. Code 64617 treats the larynx for spasmodic dysphonia. Codes 64642 and 64644 treat the muscles of an extremity, and codes 64646 and 64647 treat the trunk muscles, for spasticity. None of the seven has a cosmetic application. That distinguishes them from the botulinum toxin codes CMS added in CY 2020, where an alternative cosmetic use gave CMS a concrete basis to be concerned that non-covered services were billed to Medicare. The rule identifies no comparable basis for these seven codes.

Clinical Context: Adoption of an Established Therapy

The growth in these codes does not stem from a wave of new indications. With one exception, the therapeutic uses these codes describe are long established. Botulinum toxin has been a standard treatment for cervical dystonia for roughly two decades, and for adult spasticity and spasmodic dysphonia for many years. The one genuinely new adult indication in the 2017 to 2024 window is chronic sialorrhea (code 64611), for which FDA approved the first products in 2018 and 2019, and it is the fastest-growing code in the set, which is the expected result of making an effective treatment available on label. The remaining growth reflects the ordinary adoption of an established, minimally invasive therapy with substantial functional and quality-of-life benefits. Rising use of a safe and effective treatment is not, by itself, the unnecessary increase in volume that Section 1833(t)(2)(F) addresses, and CMS has offered a growth rate in place of any data showing that the added volume is unnecessary. FAH made a parallel point in its comments on the CY 2020 OPPS/ASC proposed rule, that growth in botulinum toxin use reflected expanding, medically necessary, non-cosmetic indications rather than misuse.[35]

Growth is not Specific to the Hospital Outpatient Setting

CMS benchmarks the growth in these codes against the 8.3 percent decline in overall OPD claim volume. That decline is not an independent measure of appropriate utilization. It reflects, in part, CMS policies that moved services out of the hospital outpatient department during the same period, including the site-neutral payment policy for clinic visits at excepted off-campus provider-based departments that began in CY 2019 and successive expansions of the ASC covered surgical procedures list. The direct test is not growth against a shrinking denominator, but growth in the hospital outpatient setting compared with growth in the physician office setting for the same codes, and CMS's own public data allows that comparison.

In CMS's Medicare Physician and Other Practitioners data, the physician office setting accounted for approximately 76 percent of the professional claims for these seven codes in 2024, and facility settings for approximately 24 percent, a split that was essentially unchanged from 2017.[36] The facility category is predominantly hospital outpatient, but it also includes ambulatory surgical centers and other facility settings. Prior authorization applies only to hospital outpatient department services as a condition of payment, under 42 CFR 419.80, and the identical injection furnished in a physician office is not subject to it, so the share of these services actually reached by the requirement is at most about one quarter. Over the same 2017 to 2024 period, office volume for these codes grew at approximately the same rate as facility volume, roughly 26 percent and 29 percent respectively. Growth that appears in both settings at a similar rate reflects broader clinical demand and the diffusion of these therapies, not a pattern specific to hospital outpatient departments. This data measures professional claims by place of service, and is a companion to, not a substitute for, the facility claims CMS analyzed, but it captures the cross-setting comparison the proposed rule does not present.

This raises two concerns. First, a requirement that reaches at most a quarter of these services cannot address their utilization across the program, and it creates an incentive to furnish the injection in the office setting, where prior authorization does not apply, even where an HOPD may be clinically appropriate based on a beneficiary's medical complexity and clinical needs, the nature of the procedure or the resources necessary to furnish the service safely. Second, the single growth rate CMS cites combines codes with very different trends. In the same data, growth over the period ranges from essentially flat for some codes to more than 50 percent for salivary gland chemodenervation (code 64611), the one code tied to a new therapeutic indication in the window. One of the eight codes, the drug J0589, also entered the market only in 2022, so its growth is measured from a base of zero. A blended growth rate cannot show whether the increase is broad or concentrated in a few codes. **FAH urges CMS to publish code-level utilization for each of the seven procedure codes, together with a comparison of hospital outpatient volume to physician office volume for the same codes and period, and to confirm the cross-setting pattern in its complete claims data before finalizing prior authorization for these codes.**

Administrative Cost Relative to the Spending at Issue

CMS's own estimates show the administrative cost of the proposal is large relative to the spending at issue. In Table 94, CMS estimates annual private sector costs of $1,957,592 across 41,555 burden hours. In Table 95, CMS estimates its own annual administrative cost at $7,632,439. Together, that is approximately $9.6 million a year to administer prior authorization for approximately $102 million in annual payments, or about 9 percent of the spending at issue. Table 94 also assumes 58,998 initial prior authorization requests a year against approximately 62,103 annual claims, which means nearly every claim would require a request. It further assumes 19,360 resubmissions, an implied resubmission rate of approximately 33 percent. A process in which roughly one request in three is submitted a second time adds workload and burden for providers and for CMS without a demonstrated improvement in program integrity. That assumption is difficult to reconcile with CMS's description of the process as operating without adding onerous new documentation requirements. **FAH urges CMS to explain the basis for the assumed resubmission rate and to identify the steps it will take to reduce that rate before expanding the category.**

Continuity of Care and the Existing Exemption Authority

The conditions these codes treat are chronic. Because the effect of botulinum toxin is temporary, sustained control generally requires repeat injections, and the FDA labeling for the on-label indications sets a minimum re-treatment interval, no more often than every 12 weeks for cervical dystonia and spasticity and every 16 weeks for sialorrhea.[37] For a patient established on such a regimen, an authorization that lapses does not delay an elective procedure. It interrupts an ongoing course of treatment. The proposed rule requests comment on the potential for unintended clinical consequences that may result from the addition, and interruption of established treatment is one such consequence.

CMS's regulations already provide a mechanism to relieve compliant providers of the prior authorization requirement. Under 42 CFR 419.83(c), CMS may exempt a provider from the prior authorization process when the provider demonstrates compliance with Medicare coverage, coding, and payment rules through that process.[38] Hospitals have furnished botulinum toxin injections under the existing prior authorization category since 2020, and many have an established record of provisional affirmations on those claims. **FAH urges CMS to apply the provider exemption under 42 CFR 419.83(c) to the added codes, to count a hospital's demonstrated compliance on the existing botulinum toxin category toward exemption for the newly added codes rather than requiring a separate record to accrue after July 1, 2027, and to apply the exemption on published, transparent criteria so that compliant hospitals can rely on it.** An exemption applied this way would also reduce the resubmission volume CMS projects in Table 94.

Operational Readiness

The proposed effective date is July 1, 2027. Hospitals have operated under the existing botulinum toxin prior authorization requirement since 2020, and their experience with turnaround times and non-affirmation rates under that process is the best available predictor of how an expansion would perform. **FAH urges CMS to publish current Medicare Administrative Contractor turnaround performance for the existing botulinum toxin category and to confirm contractor capacity to absorb the projected additional request volume before the July 1, 2027 effective date.**

XI. Codification of Section 6225 of the CAA, 2026 (Provider-Based Attestation and NPI Requirements) (Parts XX)

Section 6225 of the Consolidated Appropriations Act, 2026 (CAA) conditions Medicare payment to off-campus provider-based departments (PBDs) on two new requirements: each department must obtain its own National Provider Identifier (NPI), and the hospital must attest to the department's compliance with the provider-based requirements of 42 CFR § 413.65, with an initial attestation due during the two-year window before January 1, 2028. In this rule, CMS proposes to codify these requirements at new 42 CFR § 419.23, with conforming changes to § 413.65, including a standardized attestation form, a centralized electronic

submission system, and Medicare Administrative Contractor (MAC) review serving as CMS's initial determinations.

FAH members support accurate and transparent provider-based enrollment. Currently, hospitals' off-campus departments are subject to, and must comply with, the provider-based requirements of § 413.65. As MACs seek to verify hospital compliance with these requirements, this process should be designed to avoid unnecessary disruption to patient care, undue administrative burden on providers and MACs, and payment risk for hospitals arising from circumstances beyond their control. FAH commends CMS's efforts to implement Section 6225 of the CAA in a practical and operationally feasible manner, as well as the agency's continued engagement with FAH and its members to implement a successful program. FAH's comments below address each element of the proposed framework.

Proposed OPPS and §413.65 Modifications, Including Separate NPI and Off-Campus Definition (Part XX.C.)

FAH supports the proposed CMS-standardized attestation form and centralized electronic submission system, which are proposed to replace MAC-specific templates and address the inconsistency across MAC jurisdictions. To improve the transition process, **FAH urges CMS to finalize and release the standardized form and system as early as possible in 2027 and to provide a testing and familiarization period before submissions are required through the new system. FAH also requests that CMS confirm that attestations submitted under existing 42 CFR § 413.65(b)(3) at any point during the statutory window remain valid without resubmission once the new system is live.**

In addition, FAH also recommends that the submission portal accept batch submissions. A standardized template listing the attestation elements as fields, with one row per department, would allow a system attesting for dozens of departments to file once rather than location by location. It would also help multi-department systems answer the attestation elements consistently, which CMS has indicated it will compare across a provider's attestations.

Documentation Requirements for Provider-Based Attestations (Part XX.D)

FAH strongly supports CMS's proposal that a provider that submits its initial attestation within the two-year period before January 1, 2028, will have met the requirements of Section 6225 even if CMS has not issued a provider-based determination by that date. The statute conditions payment on the provider's submission, not on the government's processing speed, and CMS's proposal correctly places the payment consequence on what the hospital controls. **FAH requests that CMS clarify this policy expressly in the regulation text at 42 CFR § 419.23, not only in preamble, and confirm in the final rule that claims from a department with a timely, complete attestation pending review are payable without interruption.**

For all off-campus outpatient departments providing services on or before January 1, 2028, CMS proposes initial attestations must be submitted between January 1, 2026, and December 31, 2027, and off-campus outpatient departments that begin providing services after January 1, 2028, must submit an attestation within the 2 years prior to when the billed services are delivered. As the timing of the initial certification is linked to the 2-year period prior to when the services are delivered, FAH requests that CMS confirm that "initial" means "one-time" in both circumstances (e.g., once for a provider already providing services on January 1, 2028, and once in the 2-year period before beginning to furnish services for a provider that begins providing services on or after January 1, 2028).

Departments with Existing Provider-Based Determinations

CMS seeks comment on the initial attestation for departments that received a provider-based determination before January 1, 2026, and remain in compliance, and describes a streamlined affirmation (a letter from the authorized official with the CMS determination attached). Many FAH member departments have already demonstrated compliance through the existing attestation and determination process, in some cases recently. Requiring these departments to restart the full process would generate increased and

unnecessary workload and burden without demonstrated improvements in program integrity**. For a department that received a provider-based determination before January 1, 2026, and remains compliant, FAH recommends that CMS allow the main provider to satisfy the initial attestation by attesting that the department continues to meet the requirements of 42 CFR 413.65, without resubmitting or attaching the prior determination CMS already holds in its records.** Members also report instances in which an attestation was submitted under the current process, but no determination or acknowledgment was returned. **Where CMS or its contractor holds a hospital's previously submitted attestation, that submission should satisfy the initial requirement. The hospital's dated submission records should be accepted as evidence of filing.**

Submission Timing and MAC Capacity

Under the proposal, every existing off-campus department in the country must file within the same January 2026 through December 2027 window. Past experience with current provider-based reviews suggests MAC processing times will be strained by the volume. The predictable result is a surge of filings against the statutory deadline. **FAH recommends that CMS publish MAC processing-time expectations, and monitor MAC turnaround performance with intervention when timeliness thresholds are missed. FAH further recommends that CMS designate representatives within the agency to assist multi-state health systems in coordinating attestation submissions across multiple MAC jurisdictions, providing a single point of contact for systems filing large volumes of attestations.**

Subsequent Attestations

CMS proposes a maximum five-year interval for subsequent attestations, with the details deferred to the 2028 rulemaking cycle. FAH notes that Section 1833(t)(23)(A)(iii) of the Social Security Act requires "a subsequent attestation" within the timeframe the Secretary specifies. CMS's proposed regulation text follows the statute. Proposed § 413.65(b)(6) requires an initial attestation "and a subsequent attestation within a period not to exceed 5 years thereafter," and proposed § 419.23(a)(3) likewise conditions payment on "a subsequent attestation."[39] The preamble, however, refers to "subsequent attestation(s)" submitted "at an interval."[40] **FAH recommends that CMS conform the final rule to the statute and to its own regulation text. The subsequent attestation should be a single attestation at the full five-year interval, structured as the streamlined affirmation of continued compliance described above rather than a full resubmission.**

Documentation Requirements and Risk-Based Review

FAH supports CMS's proposal to require submission of a completed attestation form while allowing hospitals to retain supporting documentation and produce it only upon request through a targeted, risk-based review process. This approach appropriately balances program integrity with administrative efficiency for both hospitals and CMS. In addition, **FAH urges CMS to consider the following modifications:**

- The final rule should state clearly that the documentation categories in section XX.D are retention-and-production standards, not submission requirements, and that a complete attestation form is sufficient for CMS to process the attestation unless the review identifies a specific concern.
- CMS anticipates giving providers a period "generally not to exceed 60 days" to furnish requested documentation. FAH recommends that the final rule guarantee a minimum of 60 days, with extensions for good cause, since document production across a large system's departments routinely requires coordination among enrollment, compliance, and revenue cycle functions.
- Sampling from each main provider's universe of departments to gauge system-wide compliance is a reasonable screening device, but findings from a sampled department should only trigger department-specific review, not extrapolated determinations across a provider's universe.
- The location element should rely on the system's automated distance verification wherever possible, reserving supporting documentation for the exceptional cases CMS identifies.
- Hospitals identify a department as part of the main provider through a combination of patient-facing communications, consistent with 42 CFR 413.65(d)(4). CMS should confirm that a hospital may

demonstrate this element through any reasonable combination of those communications and that no single element, including any particular form of signage, is required or dispositive, and that MACs will apply a consistent standard for this element across jurisdictions.

CMS Verification and Oversight Activities (Part XX.E)

CMS proposes that an attestation that fails to demonstrate compliance, or a failure to furnish requested information, would result in a denial with applicable appeal rights. CMS also proposes at § 413.65(k) that failure to produce documentation on a timely basis may result in a determination of noncompliance and recovery of payments. FAH is concerned that under this proposal a compliant hospital that attests in good-faith and is later found deficient on a technical or documentation point may face payment recovery, potentially years after the fact. **FAH recommends that the final rule provide an opportunity to correct a deficiency in these circumstances: where a provider has attested in good-faith and a deficiency is identified on review, the provider should receive notice and a reasonable corrective action period before any payment consequence attaches, and payment recovery should be prospective from a final determination of noncompliance rather than retroactive to the attestation date, absent evidence of fraud or material misrepresentation.** FAH urges CMS to describe the appeal process and standards in the final rule, including the timeline for appeal determinations, so that hospitals understand their procedural rights before the payment condition takes effect. Likewise, site visits, remote audits, and program integrity referrals should remain targeted at genuine risk indicators rather than routine features of the process.

NPI Transition, Systems Readiness, and Billing Guidance

The proposed department-level NPI requirement raises important operational issues that CMS must address in the final rule, as hospitals cannot complete the necessary systems changes without this guidance. The first question the final rule should resolve is how the statutory requirement that services be "billed under" a department-level NPI will be reported on the institutional claim. The proposed rule does not address this. Under longstanding billing practice, all outpatient services furnished to a beneficiary on a single date of service are reported on one claim under the main provider. The OPPS payment methodology depends on that structure:

- Comprehensive APC packaging applies to the services reported on the claim;[41]
- Conditionally packaged services are paid separately or packaged depending on what else appears on the claim;
- The multiple imaging composite policy pays a single rate when a claim contains more than one procedure from the same imaging family;[42] and
- The geometric mean costs used to set comprehensive APC relative weights are calculated from complete claims.

Splitting claims by department would disrupt each of these mechanisms. Some services would be paid separately that CMS intends to package, and some packaged services would go unpaid. The claims data used for rate setting would also degrade with each year of split billing. Splitting would serve no payment purpose: Medicare's site-specific payment policies operate through the PO, PN, and ER modifiers, which function independently of the billing NPI.

FAH recommends that CMS confirm in the final rule that the department NPI requirement does not change outpatient claim architecture. A single claim per beneficiary per date of service under the main provider should remain the standard, with department-level NPIs reported within that claim. The service facility location fields already accommodate the NPI of one off-campus department. For dates of service involving more than one off-campus department, the additional provider identifier fields on the institutional claim (Form Locator 57 and its electronic counterpart) can carry the additional department NPIs. This approach meets the statute's transparency purpose with fields that exist today. Approaches that depend on modifying the HIPAA transaction standard could not realistically be completed before January 1, 2028.

The enrollment systems require the same advance work. PECOS does not currently provide a way to obtain an NPI for an off-campus department linked to a main provider, and no provider taxonomy code exists for a provider-based department of a hospital. Without a dedicated code, departments would default to taxonomy codes that misdescribe them, either as free-standing entities or as distinct-part units whose services are reported on separate claims. **FAH recommends that CMS establish a taxonomy code specific to provider-based departments of a main provider and update PECOS to accept department NPI applications linked to the main provider, including batch applications for systems with many departments**.

In addition, FAH urges CMS issue billing and enrollment guidance well in advance of the January 1, 2028, implementation date. At a minimum, the guidance should address:

- How existing enrolled departments will transition to department-level NPIs across PECOS, CMS-855A enrollment records, and Medicare claims processing systems;
- Whether the PO, PN, and ER modifiers will remain necessary once department-level NPIs provide the same information on the claim, or whether CMS intends to retire those modifiers to eliminate duplicative reporting; and
- Confirmation that assigning a department-level NPI does not alter a department's provider-based status or affect the hospital's ownership, governance, centralized billing arrangements, or financial integration.

Hospitals need sufficient time to coordinate new NPIs with commercial payers and health plans. The agency's implementation timeline and enforcement approach should provide adequate time for these operational changes to occur before payment consequences apply.

Definitional Changes

FAH supports the proposed conforming changes to 42 CFR § 413.65, including the new definition of an off-campus outpatient department of a provider consistent with Section 1833(t)(23)(C) of the Social Security Act and the exclusion of departments within 250 yards of a remote location of a hospital from the off-campus requirements of § 413.65(e). These changes align the regulation with the statutory definitions Congress has used since section 603 of the Bipartisan Budget Act of 2015.

XII. Consideration of Potential Approaches for Separate IPPS Payment for Domestic Procurement of PPE and Essential Medicines (Part XXII)

FAH supports the shared goal of a resilient health care supply chain and reliable access to essential medicines and personal protective equipment (PPE), and we appreciate CMS's continued engagement on this issue following the Advance Notice of Proposed Rulemaking (ANPRM). As we explained in our comments on the ANPRM, however, the challenges CMS seeks to address originate upstream, and the most effective and durable solutions must be directed there.

Supply-chain resilience must be addressed upstream, not through hospital procurement

Extensive analysis from federal agencies, academic experts, and health system stakeholders, including the National Academies, finds that shortages of pharmaceuticals and medical supplies are driven overwhelmingly by supply-side factors: manufacturing disruptions, quality failures, shortages of raw materials, limited manufacturing redundancy, and economic decisions by manufacturers about which products to produce.[43] These structural vulnerabilities occur upstream and are largely outside the control of hospitals. Recent shortages of sterile injectable oncology drugs (such as cisplatin and carboplatin), sterile saline, and IV fluids, all arose from manufacturing disruptions at a small number of facilities, not from hospital purchasing decisions.[44]

Hospitals, moreover, generally procure pharmaceuticals and supplies through distributors, wholesalers, and group purchasing organizations that negotiate contracts across large networks of providers. Individual hospitals typically cannot independently determine, much less verify, where a product or its components

are manufactured,[45] and cannot alter national supply-chain dynamics through their own procurement. Policies that place procurement mandates, reporting requirements, or hospital-directed payment at the center of this effort will therefore do little to address the root causes of shortages, while adding operational and administrative burden to hospitals that already devote substantial resources to managing shortages when they occur.[46]

Accordingly, FAH urges CMS to focus first on supply-side manufacturing incentives, improved transparency into production disruptions, and strengthened national preparedness — directing incentives to the manufacturers and upstream stakeholders who control production decisions. The experience with the existing surgical N95 filtering facepiece respirator (FFR) payment adjustment underscores the point: despite being available since CY 2023, fewer than 100 hospitals claimed it on their FY 2024 cost reports. As FAH has previously noted, that limited uptake reflects not only administrative burden but a more fundamental constraint — domestic manufacturers have at times lacked the capacity to meet hospital demand at scale. Expanding a hospital-facing payment before that capacity exists is unlikely to change these outcomes.

Essential Principles for Any Hospital Payment Methodology

If CMS moves forward with a separate payment adjustment for domestically manufactured PPE and essential medicines, FAH offers the following principles to guide the development of that policy. Because CMS has not yet proposed a specific payment methodology, these comments are intended to identify the characteristics of an effective approach rather than endorse any particular model. FAH looks forward to reviewing and commenting on the agency's specific proposal once it is developed.

Any payment adjustment should be adequate to support the policy objective, voluntary for hospitals, broad enough to encompass the full range of qualifying products, administratively simple, and designed to avoid the implementation challenges associated with the current surgical N95 FFR payment policy. Consistent with these principles, **FAH generally supports the following:**

- **Voluntary participation, tied to actual domestic purchases.** FAH encourages CMS to adopt a voluntary participation approach, with payment attached to the domestic products a hospital actually purchases and no minimum-purchase threshold or designation imposed as a condition. Under such a design, a hospital that cannot obtain domestic product during a disruption would simply not receive the adjustment for those items in that period, rather than face any penalty.

- **Non-budget-neutral funding, under both the IPPS and the OPPS.** FAH believes that any adjustment should be funded on a non-budget-neutral basis; redistributing dollars within an already-underfunded system would not shift purchasing and would come at the expense of other services and patients. Because these products are used across settings, FAH encourages CMS to apply any payment consistently under both the IPPS and the OPPS, and to seek whatever authority is necessary to pay the full marginal cost rather than only the Medicare inpatient fee-for-service (FFS) share.

- **Recognizing costs across all patients, not FFS alone.** Because hospitals do not purchase differently by payer — a contract for domestic gloves covers every patient, FAH encourages CMS to consider recognizing these added costs across all patients, or at a minimum all Medicare patients, including Medicare Advantage, rather than tying payment to FFS days alone, an approach that grows weaker as MA enrollment rises.

- **A cost-report approach rather than claims-based billing.** As between the two payment mechanics CMS describes, FAH would favor a cost-report approach (Approach 2) over claims-based billing (Approach 1). Appending domestic NDCs, units, and unit-cost calculations to individual claims would be materially more complex and burdensome, particularly for PPE, where tracking use at the individual patient level is not feasible. A cost-report approach aligns with how the existing surgical N95 FFR and essential-medicine buffer-stock payments already operate.

- **A standardized national cost differential, with minimal new reporting.** FAH supports the use of a standardized, nationally applicable cost differential that is updated annually, eliminating the need for individual hospitals to calculate or substantiate their own price differentials. CMS should rely on existing transparent data sources whenever possible and limit any new reporting to the minimum necessary. Any cost differential should reflect hospitals' actual incremental acquisition costs. As CMS recognized, domestically manufactured nitrile gloves cost approximately 1.5 to 3 times more than imported gloves, while domestically manufactured active pharmaceutical ingredients cost approximately 12 times more than their non-domestic counterparts.

- **A broad eligible-product scope.** FAH encourages CMS to adopt a broader list of qualifying products than the respirators, gloves, gowns, and limited set of sterile injectables and antibiotics currently identified. For example, CMS should consider including other high-volume PPE and medical supplies, such as surgical masks, face shields, isolation gowns, syringes, needles, catheters, and wound care dressings, as well as additional essential medicines. As domestic manufacturing capacity expands, CMS should phase in coverage of additional qualifying products.

- **Manufacturer-Based Verification.** FAH supports a verification process that places responsibility on manufacturers rather than hospitals. Because hospitals cannot independently verify a product's country of origin, CMS should adopt a voluntary manufacturer attestation process and maintain a publicly available HHS list of eligible products identified by NDC or UDI. This approach would allow hospitals to identify qualifying products without assuming responsibility for verifying country of origin.

- **A definition of "domestic" that references that published list.** FAH would favor treating a product as domestic and payment-eligible if it appears on the HHS-maintained list of attested eligible products (by NDC or UDI) described above, with hospitals entitled to rely on that list rather than independently applying the underlying legal definitions (for example, the Make PPE In America Act for PPE, or "substantial transformation" of the finished dosage form and exclusion of active pharmaceutical ingredients from foreign-adversary countries for essential medicines). Manufacturers alone have the information to document product origin, and that burden should rest with them.

- **No spending cap with clawback.** FAH would be strongly concerned by a prospective annual cap allocated across hospitals with any excess reconciled at cost-report settlement as still bundled into the MS-DRG. Such an approach would reintroduce the retrospective-recoupment uncertainty FAH has consistently opposed, deter participation, and penalize good-faith domestic purchasing. If any aggregate limit is used, it should not expose participating hospitals to clawback of payments for products they actually purchased.

- **No Hospital IQR structural measure.** FAH would continue to strongly oppose incorporating domestic-procurement requirements into the Hospital Inpatient Quality Reporting Program. Procurement is an operational supply-chain matter, not a measure of clinical quality or patient outcomes; domestic and imported products alike must meet the same FDA requirements, and there is no evidence linking country of origin to outcomes. A yes/no structural measure would add compliance cost, quickly become topped out, and is inconsistent with both the IQR Program's purpose and CMS's burden-reduction goals.

- **No Payment Conditioned on a Designation or Procurement Threshold.** FAH does not support conditioning payment on a Secure American Medical Supplies designation or on phased procurement thresholds, such as 25, 50, or 75 percent. If CMS adopts such a framework, any procurement threshold should be tied to demonstrated domestic manufacturing capacity and should never exceed what hospitals can reasonably source. CMS also should establish an extraordinary circumstances exception, similar to those used in its quality and value based purchasing programs, to ensure hospitals do not lose a designation or payment eligibility because of product shortages, natural disasters, supply chain disruptions, or other circumstances beyond their control.

FAH appreciates CMS's commitment to strengthening the nation's medical supply chain and looks forward to continuing to work with the agency and its federal partners. The most effective approach is to advance

domestic manufacturing through supply side incentives and greater transparency. If CMS moves forward with a hospital payment adjustment, it should be adequate, non budget neutral, broad in scope, administratively simple, voluntary, and designed to support hospitals' efforts to strengthen domestic supply chains without creating unnecessary financial risk. FAH looks forward to reviewing and commenting on any specific proposal CMS develops.

XIII. Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data (Part XXIII)

FAH strongly supports price transparency initiatives that provide patients with clear, accurate, and actionable information. However, the current approach of publishing vast amounts of hospital reimbursement data does not provide patients with the meaningful and actionable pricing information they need to make more informed choices for their medical care. 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 complex data on payer-specific negotiated rates, gross charges, and discounted cash prices, and then standardizing and further expanding publicly posted data to include a wide variety of data elements. During this timeframe, hospitals have worked diligently to comply with these detailed and technical display requirements, with hospitals affiliated with health systems leading the way.

In the face of CMS's detailed requirements for hospital disclosure in large machine-readable files (MRFs), amounting to the availability of terabytes of data to the public, the few consumers that access these data often struggle to understand its contents. A large reason for this struggle is that spreadsheets full of raw hospital financing data do not add value to individuals who seek meaningful, actionable information. Rather, patients rarely use hospital shoppable service pricing information in any form, preferring to rely on provider referrals for decision-making about hospital services or prioritizing quality of provider care over prices.[47] However, as explained in greater detail below, when patients seek individualized pricing information from hospitals, it is best achieved through the use of hospital or payer online price estimator tools. Hospitals have invested significant resources in developing these tools, and a recent survey confirms a strong public preference for interactive web tools over static spreadsheets.[48] In addition, hospitals make available to consumers direct contact with specialized hospital billing personnel and financial navigators who can further assist consumers, when needed. In this process, billing specialists can, in real time, verify a consumer's insurance benefits, confirm in-network status, and map them to the exact medical codes ordered by their physician.

We also reemphasize 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 remains largely intact from its original form and CMS has not made public any data about enforcement activity and industry compliance. **Therefore, FAH recommends that CMS take advantage of this opportunity to promote meaningful price transparency in all settings by enforcing the Transparency in Coverage regulations, as CMS has enforced the Hospital Price Transparency regulations.**

Period of Stability Is Needed for Improved Implementation of Multiple Iterations of Transparency Requirements

FAH continues to have strong concerns about the frequency and extent of changes in the rules for making public standard charges which have imposed significant costs and burdens on hospitals. In spite of this, hospitals continue to demonstrate their good-faith efforts to meet these expectations, even as CMS has continued to require the display of an ever-increasing number of data elements (some of which go well beyond those necessary for display of "standard charges") and has made midstream revisions to guidance that sometimes reverses prior guidance or program instructions with short timelines for compliance. For example, the most recent changes to the Hospital Price Transparency rule (*e.g.*, inclusion of the median, 10th and 90th percentile allowed amounts and other revisions made in the 2026 OPPS/ASC

final rule (90 FR 53448)) only took effect on January 1 of this year with a delay in enforcement to April 1 and subsequent guidance released on June 26. Hospitals have not yet undergone a full update cycle under the new requirements. These new rules replaced rules that CMS had established less than one year prior which required hospitals to display "estimated allowed amounts." [49]

One unintended consequence of these continual new requirements is the outsized negative impact on smaller and less resourced hospitals which are most vulnerable to CMS enforcement actions as a result of these frequent and costly changes. As evidenced by CMS's issuance of civil monetary penalty notices in 2025 and 2026, the bed count of penalized hospitals ranged from "less than 30" (the smallest increment calculated by CMS) to 140 with a median of only 33 beds.[50] We believe that the dramatic increase in highly prescriptive formatting and data element requirements have contributed to this problem for small and rural hospitals who may not have ready access to technical personnel and lack resources for hiring specialists. Additionally, highly prescriptive technical requirements are more likely to lead to inadvertent and minor inconsistencies and errors in the files of all hospitals, not just small hospitals. For example, in the wake of the updated regulations earlier this year, CMS reviewed and issued over 519 warning letters and corrective action requests to hospitals, many of which were for minor technical or formatting errors that were rectified within days.[51] Such deficiencies do not reflect intentional noncompliance by hospitals, rather, they are an inadvertent byproduct of CMS's increasingly frequent and detailed requirements.

As we stated in our recent response to CMS's hospital price transparency 2025 request for information (RFI) and again in response to the 2026 OPPS/ASC proposed rule (90 FR 33476), against this backdrop, 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 may be further improved. Rather than revising recently implemented requirements yet again so soon, CMS could instead continue to focus on improving training and compliance program tailored for small and rural hospitals that are struggling to comply with the already technically complex requirements.[52] Better still, CMS could focus on examining the lessons learned to date from disclosure of these data and consider revisiting its earlier, potentially faulty assumptions regarding hospital pricing data, and in particular, the way that payers establish payment rates with hospitals. In doing so, CMS could work with hospitals to establish a more reasonable and streamlined approach for disclosing information that is most valuable for consumers – that is, information that is comparable and actionable – and lowers burden in accordance with Executive Order 14192 in which federal agencies are charged by the President to alleviate unnecessary regulatory burdens introduced by the prior administration. ***Therefore, FAH recommends that CMS prioritize regulatory stability and preserve flexibility to minimize technical compliance risk while also working with hospitals to achieve its goal of providing consumers with meaningful and actionable information while also seeking ways to reduce hospital burden.***

Consumer-Friendly Display Request for Public Comment

In the 2020 OPPS/ASC final rule (84 FR 65524), CMS established requirements for hospitals to display 300 items and services, 70 of which CMS specified, in a consumer-friendly display (at 45 CFR 180.60). CMS provided limited specifications related to data requirements for display of this information, allowing hospitals flexibility in the format which must be either in a shoppable services file or an online price estimator tool. In this proposed rule, CMS summarizes feedback and concerns the agency received from a series of listening sessions held last summer related to the required consumer-friendly display. CMS expresses a desire to strengthen the comparability of the data included in the consumer-friendly display to enhance consumers' ability to shop for care and obtain pricing information in advance of scheduled services.

While consumer-friendly, comparable pricing data was unavailable when CMS established its hospital price transparency rules in 2019, the regulatory landscape has since transformed. Under the No Surprises Act (NSA) and Transparency in Coverage (TiC) rules, group health plans and insurance issuers have been required since January 1, 2023, to provide members with an internet-based price comparison tool. This tool offers real-time estimates of cost-sharing liabilities, in-network rates, accumulated deductibles, out-of-network allowed amounts, and prior authorization requirements for bundled shoppable services. ***Because payer tools successfully fulfill CMS's goal of enabling consumers to shop for care and obtain***

advance pricing, FAH reiterates its recommendation that CMS align its policies and reduce hospital administrative burden—in accordance with Executive Order 14192.

As discussed above, hospitals offer personalized, real-time price estimator tools which offer significantly greater consumer utility than static MRFs or spreadsheets. As demonstrated by existing MRF disclosures, the average consumer cannot easily decipher sprawling spreadsheets filled with obscure medical codes and complex payer information. Research has shown that, compared to spreadsheets of shoppable services information, patients universally prefer the more user-friendly price estimator tools offered by hospitals.[53] Crucially, static files can only capture generic, population-level data; they lack the dynamic capability to account for an individual consumer's real-time deductible accumulation, co-insurance liabilities, unique copays, or insurer-specific plan structures – all of which can be provided by payers. In short, the further the method diverges from having up-to-date information, including payer information regarding a consumer's out-of-pocket costs, the more depersonalized and lower utility the billing data becomes to the consumer. Of the two choices CMS presents in its RFI, dynamic online price estimator tools are far superior than static data-filled flat files for achieving CMS's goal of providing consumers with personalized prices in advance of having a health care service. ***Therefore, we support CMS's current policy of permitting hospitals flexibility to choose to offer either a flat file or a price estimator tool.*** This flexibility strikes an appropriate balance for hospitals that are unable to support and maintain the more sophisticated web-based tools that provide consumers with real-time, personalized pricing information.

In response to CMS' inquiry regarding the number and type of shoppable services made available, we note that some hospitals do not regularly bill for some of the 70 CMS-specified shoppable services. For example, hospitals report that while they offer all the services on the CMS list of 70 shoppable services, they may not have billed for a significant proportion of them in the past twelve-month period or rather bill for them using an inpatient DRG code rather than outpatient CPT code. While we appreciate that CMS has held several listening sessions with health care consumers, we believe that additional regulatory requirements under consideration and related to display of shoppable services should be informed from structured input from hospitals (perhaps through a technical expert panel (TEP)) before CMS proceeds to implement more detailed requirements related to display of pricing information for shoppable services. We note that CMS previously engaged stakeholders in a TEP before implementing the MRF template format which served to test and evaluate formatting options before making them a requirement. This thoughtful and collaborative approach resulted in a much better product with more buy-in than if CMS had moved forward without such input. ***Therefore, FAH recommends that CMS work with hospitals prior to rulemaking to test out different approaches for displaying shoppable services information.***

Additionally, our member hospitals continue to express serious concerns regarding the application of the shoppable services requirements under §180.60 to specialized care settings, for example, Inpatient Rehabilitation Facilities (IRFs) and behavioral health facilities. By definition under §180.20, a shoppable service is a service that a consumer can schedule in advance on a non-urgent basis. Because admissions to IRFs and behavioral health hospitals occur urgently following acute crises or acute-care discharges, patients have zero opportunity for advance planning or consumer comparison. Since these specialized services cannot be scheduled in advance, they inherently fail to meet the statutory definition of a 'shoppable service.' ***FAH therefore strongly urges CMS to clarify that services provided by IRFs and behavioral health hospitals are not 'shoppable' and thus would not be expected to display any data under 45 CFR § 180.60.***

Regarding CMS's questions about achieving comparability of the price of services, we question the premise, given all the different variables that must be taken into consideration, including that each hospital serves a unique patient population, pricing can vary according to time and place of service and the specific payer involved. Health care services cannot be likened to mass-produced widgets that are sold in grocery stores, rather, hospital services are bespoke, taking into account individual needs and differences, and adjusting care as needed in real-time. That being said, online price estimator tools and payer comparison tools can achieve this goal. Depending on the complexity of the service, such personalized prices would be as comparable as the personalized estimates one might obtain from other service professionals, such as estimates provided by an accountant, mechanic, interior designer, or financial planner.

Against this backdrop, we appreciate CMS's inquiry regarding variance between hospital MRFs and consumer-facing online tools. These tools serve fundamentally different purposes, and it is critical to distinguish between their methodologies. For example, a discounted cash price is a term that is defined as a rate that is available to all patients regardless of insurance status and if available, it is provided in the MRF. Hospital MRFs reflect static, historical, population-level "standard charge" data bound to a specific reporting period.

Alternatively, real-time web-based tools can generate personalized patient estimates by dynamically synthesizing current payer data and transaction-specific details using a more personalized estimate based on various pricing inputs including consideration of individual circumstances. Accordingly, the two may display different prices because they rely on different reference points. Differences between MRFs and price estimator tools may become even more pronounced in the future, given CMS's recent revision of its rules to eliminate the "estimated allowed amount" (which permitted use of the best data available to hospitals) with the "median, 10th, and 90th percentile allowed amounts" (which may only be derived from remittance advice). In other words, the fundamental differences in data sources, timing, and purpose of the data can result in differences between the MRF and price estimator tool displays.

Machine-Readable File Request for Information

In the 2027 OPPS/ASC proposed rule, CMS also seeks feedback on enhancements to the format and content of the MRFs that the agency is considering in light of concerns raised by users of the files. First, CMS notes that file users are encountering problems understanding hospital contracting provisions. Users of MRFs believe that these contracting provisions can be standardized, and that the standardization will help users better understand when a standard charge applies to payer-specific negotiated charges at the item/service level, and in what circumstances such charges would not apply. In general, CMS seeks to better understand when contracting provisions generally apply broadly across items and services and when they do not.

While FAH appreciates the opportunity to respond to CMS's questions, it is important to acknowledge that the payment methodologies described in payer contracts are for purposes of hospital payment for services furnished to individuals that are covered by insurance products. When a claim is submitted to a payer, the payer adjudicates the claim and determines whether and what payment is owed to the hospital. Thus, the best source of the detailed proprietary algorithmic and methodologic information used to process the claim lies with the payor, not the hospital.

In prior rulemaking, CMS agreed with commenters who pointed out that hospital contracting approaches are varied and challenging for the public to understand, and that it is not practical for all contracting methodologies to be encoded, stating, "they can be difficult for a hospital to encode in its MRF and even more difficult [for] those who seek to use hospital pricing data to assess or estimate individual costs or to compare across hospitals for particular items or services."[54] We agree, and hospitals are currently working to include such information to the extent practical in free text fields as directed by CMS in guidance released as recently as June 26.

Even if MRFs were able to contain enough of the detailed methodological information that CMS and other interested parties seek, we do not believe there to be any simple, standardized approach that could be applied to display these algorithms and methodologies in an MRF. For a given hospital's contract, there may be some high-level or overarching methodological concepts (such as stop-loss provisions, carve-outs, outlier payments, etc.) that apply across certain (but not all) hospital items and services, but there also may be unique applications for the items and services provided in certain settings in the hospital, or for certain individual items or services, or for patients with certain health care diagnoses. Therefore, within a hospital, certain methodological terms could apply at any number of levels, or at different combinations of levels at different points in time or in different departments or settings. This is why a hospital can submit the exact same set of codes to two different insurance companies and receive entirely different automated payout amounts or claim denials. Additionally, across hospitals, the methodologies or algorithms that a payer uses for determining payment for one hospital may not be comparable to the methodologies or algorithms that a different payer (or even sometimes the same payer) may use for determining payment for another hospital,

even if similar descriptive terms are used. To summarize, a format that works for the algorithms in one contract is unlikely to work for all, hence the need for formatting flexibility. Moreover, the recently issued technical guidance has already set a standard by which hospitals must approach including contractual algorithms in MRFs, and hospitals are currently in the process significantly modifying their MRFs to comply. ***Therefore, FAH strongly urges CMS to pause to evaluate the impact of the technical guidance before making additional modification or encoding the current guidance in regulation.*** We further recommend that, as part of this evaluation, CMS hold a TEP on this complex issue, similar to the TEP held by MITRE prior to implementation of the initial MRF format, before implementing any additional changes to its guidance or regulation.

Aside from these practical operational considerations, from a policy standpoint, we question the need for the additional file complexity that would occur, should CMS require additional data elements related to payer-specific negotiated charge algorithms and methodologies. In particular, we note that CMS previously established a requirement for hospitals to "include an estimated allowed amount in order to bring context to a payer-specific negotiated charge when such a charge can only be expressed as a percentage or algorithm, rather than a standard dollar amount".[55] CMS now requires hospitals to display, instead, the median, 10th, and 90th percentile allowed amounts for each item or service to which an algorithm applies. The displayed dollar amounts for the median, 10th, and 90th percentile allowed amounts are calculated by hospitals from remittances received from third-party payers *after* the hospital claims have been adjudicated by the payer, that is, after the payer has applied its methodology or algorithm. Thus, the dollar amounts displayed in the MRFs by hospitals currently reflect the allowed amounts reported to hospitals through remittances following the payer's adjudication of claims, without regard to whether the payer's adjudication accurately reflects the parties' contractual terms. As such, we would suggest that the displayed dollar amounts are far more user-friendly and standardized than the complexity that may result from an attempt to describe contracting details in the MRF which may not be complete and may not perfectly replicate the payer's adjudication software.

For both of these policy and operational reasons, we have strong concerns that the expectations of CMS and file users that underpin CMS's RFI can never be satisfied with any representation displayed by hospitals in the MRFs, regardless of what formatting or standardization CMS ultimately requires. As noted above, we continue to have strong concerns about the frequency and extent of changes in the rules for making public standard charges which have imposed significant costs and burdens on hospitals. ***FAH therefore recommends that CMS instead prioritize meaningful and actionable consumer information vis-a-vis price estimator tools and minimize regulatory instability that would be generated with increasing the complexity of MRF data displays. CMS should also prioritize payer tools that provide patients with real-time, individualized out-of-pocket cost information, as payers—not hospitals—have access to the patient-specific benefit design, deductible status, and other cost-sharing information necessary to generate meaningful estimates.***

Second, CMS seeks comments on a number of questions related to standardization of MRFs that would enhance their utility. In particular, CMS notes that users of files are encountering variations in the names of payers and plans across hospitals' MRFs. Users of MRFs believe that if the names of payers and plans are standardized (or include publication of a unique identifier for each payer or plan), then the standard charges for items and services would be comparable across hospitals. In response to CMS's questions related to standardization of the names of payers and plans, we note that CMS has previously received input[56] from hospitals that payer contracts generally do not include such detailed information, and those challenges remain today. For example, in many instances, for purposes of efficiency a hospital will contract with a payer for coverage across multiple plans. In this situation, hospitals would not know with any precision what plans that particular payer offers or may develop in the coming contract year. Additionally, hospitals only know the name of the plans to the extent the payer includes them in the contract. Finally, we are unaware of any source of payer/plan identifiers that could be accessed by hospitals and uniformly applied to hospital MRFs.

In response to CMS's question regarding additional considerations for enhancing the utility and comparability of MRF data, as noted in our introductory comments, we believe that flexibility for disclosure of standard charges remains a necessity, given that each hospital serves a unique patient population and

has unique services and financing structures. Additionally, as noted above, we are concerned that the more prescriptive CMS's requirements become, the greater the likelihood that hospitals will be penalized for minor technical errors.

[1]The proposed CY 2027 conversion factor reflects the increase factor and the proposed wage index budget neutrality, wage index cap and transitional exception, cost-of-living, cancer hospital, 340B budget neutrality, and pass-through adjustments applied to the CY 2026 conversion factor of $91.415.

[2]Section 1833(t)(3)(C)(iv) of the Social Security Act; see also section 1833(t)(3)(F)(i) (applying the productivity adjustment described in section 1886(b)(3)(B)(xi)(II)).

[3] Medicare Payment Advisory Commission (MedPAC). (2026). *Report to the Congress: Medicare Payment Policy* (Chapter 3, Hospital Inpatient and Outpatient Services). Washington, DC: MedPAC, March 2026.

[4] American Hospital Association. (2026). *Costs of caring: Challenges facing America's hospitals as they care for patients in 2026*. American Hospital Association. https://www.aha.org/costsofcaring

[5] Ibid

[6] Ibid

[7] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems, 90 Fed. Reg. 33,476, 33,806 (proposed July 17, 2025) (CY 2026 OPPS/ASC proposed rule).

[8] 42 C.F.R. § 422.214.

[9] KFF. (2026, June 5). *Medicare Advantage in 2026: Enrollment update and key trends*. https://www.kff.org/medicare/medicare-advantage-in-2026-enrollment-update-and-key-trends/

[10] Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* (Apr. 7, 2025), https://www.cms.gov/files/document/2027-announcement.pdf

[11] Centers for Medicare & Medicaid Services, *Announcement of Calendar Year (CY) 2027 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* (Apr. 6, 2026), https://www.cms.gov/files/document/2027-announcement.pdf

[12] Centers for Medicare & Medicaid Services. (2026, July). *Technical report: 2026 Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey (ODACS)*. https://www.cms.gov/files/document/opps-drug-acquisition-cost-survey-technical-report.pdf

[13] 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021).

[14] 91 Fed. Reg. at 41,764.

[15] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems, 90 Fed. Reg. 53,448, 53,775-53,776 (Nov. 25, 2025) (CY 2026 OPPS/ASC final rule with comment period).

[16] Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,443 (Apr. 7, 2000).

[17] 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.

[18] 78 Fed. Reg. 50,496, 50,947 (Aug. 19, 2013).

[19] 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).

[20] 78 Fed. Reg. 75055 (Dec. 10, 2013).

[21] Hyve Health Vitality Payor Score Card data, As of June 30, 2026, Sample size 1200 hospitals. Accessed on 08/13/2026.

[22] 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 33,687 (CY 2026 OPPS/ASC proposed rule).

[23] 91 Fed. Reg. at 41,908.

[24] FAH's analysis uses the 100 percent outpatient claims file for hospital outpatient utilization and the 5 percent Carrier sample, extrapolated to the Medicare fee-for-service universe, for other settings. The 2025 Carrier data are based on quarterly data and were annualized.

[25] 91 Fed. Reg. at 41,910.
[26] 91 Fed. Reg. at 41,910.
[27] 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.
[28] Congressional Budget Office. (2016, November 28). *Direct spending and revenue effects for H.R. 34, the 21st Century Cures Act* (p. 3). https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr34.pdf
[29] 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.
[30] 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).

[32] 84 Fed. Reg. 61,142, 61,446-61,456 (Nov. 12, 2019) (CY 2020 OPPS/ASC final rule with comment period).
[33] 85 Fed. Reg. 85,866, 86,236-86,248 (Dec. 29, 2020) (CY 2021 OPPS/ASC final rule with comment period).
[34] 87 Fed. Reg. 71,748, 72,224-72,233 (Nov. 23, 2022) (CY 2023 OPPS/ASC final rule with comment period).
[35] Federation of American Hospitals. (2019, September 27). *Comments on the CY 2020 OPPS/ASC proposed rule* (CMS-1717-P) FAH_CY2020_OPPS_Comment_Letter_FINAL-2.pdf .
[36] Centers for Medicare & Medicaid Services, *Medicare Physician & Other Practitioners – by Geography and Service* (national files, calendar years 2017 and 2024), https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-geography-and-service (last accessed Aug. 14, 2026). FAH analysis of Medicare Part B professional claims by place of service (facility versus office).
[37] See FDA-approved prescribing information for the referenced botulinum toxin products, including onabotulinumtoxinA (Botox), abobotulinumtoxinA (Dysport), incobotulinumtoxinA (Xeomin), and rimabotulinumtoxinB (Myobloc).
[38] 42 C.F.R. § 419.83(c).
[39] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems, 91 Fed. Reg. 41,734 (proposed July 7, 2026) (proposed 42 C.F.R. §§ 413.65(b)(6), 419.23(a)(3)).
[40] 91 Fed. Reg. at 41,982.
[41] 91 Fed. Reg. at 41,744.
[42] 91 Fed. Reg. at 41,752; see also 73 Fed. Reg. 68,559 through 68,569 (adopting the multiple imaging composite policy).
[43] U.S. Food and Drug Administration. (2020). *Drug shortages: Root causes and potential solutions* (Rev. ed.; original work published 2019). https://www.fda.gov/drugs/drug-shortages/report-drug-shortages-root-causes-and-potential-solutions; National Academies of Sciences, Engineering, and Medicine. (2022). *Building resilience into the nation's medical product supply chains*. The National Academies Press. https://doi.org/10.17226/26420
[44] Cavazzoni, P. (2023, June 22). *The state of pharmaceutical quality* [Remarks to the IPA 8th Global Pharmaceutical Quality Summit]. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. https://www.fda.gov/media/170765/download; Meyer, P. A., & McAllister, R. K. (2024, November 15). The sterile intravenous (IV) fluid shortage crisis update. *APSF Newsletter*. Anesthesia Patient Safety Foundation. https://www.apsf.org/article/the-sterile-intravenous-iv-fluid-shortage-crisis-update/
[45] National Academies of Sciences, Engineering, and Medicine. (2022). *Building resilience into the nation's medical product supply chains*, ch. 4. The National Academies Press. https://doi.org/10.17226/26420
[46] Vizient. (2025, June 17). *New Vizient survey finds drug shortages cost hospitals nearly $900M annually in labor expenses* [Press release]. https://www.vizient.com/newsroom/news-releases/new-vizient-survey-finds-drug-shortages-cost-hospitals-nearly-900m-annually-in-labor-expenses
[47] Physician agency, consumerism, and the consumption of lower-limb MRI scans, Journal of Health Economic, March 2021, accessed on August 13 at https://www.sciencedirect.com/science/article/pii/S0167629621000126

[48] A Morning Consult survey was conducted on behalf of the American Hospital Association and can be accessed here: price-estimator-tools-fact-sheet.pdf

[49] We also note that CMS issued guidance on June 26, 2026, "Hospital Price Transparency: Guidance on Encoding Outlier Contracting Clauses in a Hospital's Machine-Readable File," on how hospitals should encode outlier contracting provisions in their MRFs and hospitals are currenting implementing this guidance. Yet, the RFI in this Proposed Rule seeks information on outlier provisions and other contract terms addressed by the guidance. We urge CMS not to again change the rules after issuing guidance on these provisions just over 60 days ago.

[50] Nearly half of hospitals penalized by CMS in 2025 and July 2026 had less than 30 beds. Centers for Medicare & Medicaid Services. *Enforcement actions.* U.S. Department of Health and Human Services. https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/enforcement-actions

[51] Cass, A. (2026). Hospitals cite technical issues for price transparency notices. Becker's Hospital Review. https://www.beckershospitalreview.com/finance/hospitals-cite-technical-issues-for-price-transparency-notices/ and Centers for Medicare & Medicaid Services. Hospital price transparency enforcement activities and outcomes data dictionary (current) [Data set]. U.S. Department of Health and Human Services. https://data.cms.gov/resources/hospital-price-transparency-enforcement-activities-and-outcomes-data-dictionary-current

[52] Office of Inspector General, U.S. Department of Health and Human Services. (2024). *Not all selected hospitals complied with the Hospital Price Transparency Rule* (Report No. A-07-22-06108). https://oig.hhs.gov/reports/all/2024/not-all-selected-hospitals-complied-with-the-hospital-price-transparency-rule/

[53] Focus group study by American Hospital Association and NORC at University of Chicago, October 2024. American Hospital Association. (2024). Fact sheet: Price estimator tools. https://www.aha.org/toolkitsmethodology/fact-sheet-price-estimator-tools

[54] CY 2024 OPPS/ASC final rule (88 FR 82090).

[55] Id.

[56] CY 2024 OPPS/ASC final rule (88 FR 82093).

APPENDIX B

Charles N. Kahn III
President and CEO

September 5, 2023

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

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

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

Dear Administrator Brooks-LaSure:

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

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

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

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

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

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

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

Effective for calendar year 2018, CMS decreased the Medicare reimbursement rate for drugs purchased by hospitals under the 340B program, reasoning that the decrease was justified because 340B hospitals acquire drugs at significantly reduced prices.[1] *See* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017). The agency

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

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

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

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

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

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

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

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

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

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

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

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

The Medicare statute does not allow CMS to recoup or reallocate actual payments under the OPPS such that unanticipated expenditures in one area are offset by retroactive claw backs elsewhere. That absence of authority makes sense: The fundamental premise of the OPPS is that the payment system is *prospective*. To that point, the relevant subsection is entitled "*Prospective* payment system for hospital outpatient department services". It begins by requiring that "the amount of payment . . . shall be determined under a *prospective* payment system," and it (unsurprisingly) addresses the factors CMS must consider when determining the OPPS rates for the *following* calendar year. 42 U.S.C. § 1395*l*(t) (emphasis added). By its clear terms, the Medicare Act requires that CMS *prospectively* adjust payment rates within the OPPS in a budget neutral manner to account for the decreased payments for 340B drugs *in advance of* the commencement of each OPPS fiscal year. *See* 42 U.S.C. § 1395*l*(t)(9)(B). Importantly, while Congress very clearly intended that budget neutrality be reached within this *prospective* payment system, Congress permits that the Secretary make adjustments only to achieve a *prospective estimate* of budget neutrality. To conceive of budget neutrality as a retrospective requirement would be inconsistent with the text and structure of the statute and wreak havoc on Medicare's payment systems and the reliance interest of stakeholders throughout the health care system.

The text of the Medicare Act plainly conveys the prospective-only nature of the budget neutrality requirement:

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

42 U.S.C. § 1395*l*(t)(9)(B) (emphases added).[4] Paragraph (9) is entitled "Periodic review and adjustments components of prospective payment system," and subparagraph (A), which triggers

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

the budget neutrality provision, requires the Secretary to review and revise "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)" not less than annually to take into account various factors and information. 42 U.S.C. § 1395*l*(t)(9)(A). These statutory provisions describe the OPPS prospective rulemakings that CMS undertakes with respect to each calendar year prior to the start of that calendar year. The budget neutrality provision cited above addresses only *estimated* costs for the *coming* calendar year, and it provides no basis for addressing expenditures in *prior* years or for reconciling adjustments with the *actual* amount of expenditures. The estimates are just one of the inputs into the OPPS formula subject to the agency's notice-and-comment rulemaking each year—and, critically, after a rule is finalized for a particular year, the estimates do not change as a result of unanticipated increases or decreases in spending, and the budget neutrality provision, by its plain terms, has no further application. CMS itself has long-recognized the prospective nature of this budget neutrality requirement. *See, e.g.,* CY 2003 Final Rule, 67 Fed. Reg. 66,718, 66,754 (Nov. 1, 2002) ("With respect to budget neutrality, section 1833(t)(9)(B) of the Act [42 U.S.C.§ 1395*l*(t)(9)(B)] makes clear that any adjustments to the OPPS made by the Secretary may not cause *estimated* expenditures to increase or decrease.") (emphasis added). While budget neutrality remains a rate-setting requirement guiding adjustments *prospectively,* the law does not permit the proposed *post-hoc* recoupment to achieve budget neutrality *after* actual payments are made to providers.

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

Critically, the Medicare Act ***does not permit after-the-fact reconciliation*** to achieve *actual* budget neutrality in a given payment year under any prospective payment system (except in very narrow circumstances explicitly prescribed by Congress). Thus, where, for *any* reason, a prospective payment system ultimately produces payments beyond those anticipated, such payments may not be recouped absent specific statutory authorization. By way of example, the provisions of the Medicare Act establishing the inpatient prospective payment system (IPPS) and those establishing the OPPS each contain language authorizing the Secretary to adopt prospective adjustments to the IPPS or OPPS payment amounts to eliminate estimated *future* (but not past) changes in aggregate payments that are due to changes in the coding or classification of inpatient discharges or covered outpatient department services that do not reflect real changes in case mix or service mix. 42 U.S.C. §§ 1395ww(d)(3)(A)(vi), 1395*l*(t)(3)(C)(iii).[5]

[5] In relevant part, the statutory language provides as follows: "Insofar as the Secretary determines that [certain IPPS or OPPS] adjustments . . . for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the . . . year that are a result of changes in the coding or classification of [discharges or covered outpatient department services] that do not reflect real changes in [case mix or service mix], the Secretary

Although the Medicare Act permits CMS to implement *prospective* adjustments to eliminate anticipated excess payments in future years (42 U.S.C. § 1395ww(d)(3)(A)(vi)), the statute includes no general authority for CMS to impose adjustments designed to recoup prior-year payments later assessed to have increased aggregate expenditures. This would undermine the fundamental statutory scheme inherent in a prospective payment system. A narrow exception proves this general rule: In 2007, Congress passed the TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–87 (2007) (TMA), to specifically authorize additional adjustments during specified fiscal years to recoup certain FY 2008 and FY 2009 payments that CMS attributed to changes in coding or classification rather than case mix. And in 2013, Congress amended the TMA to authorize additional adjustments during specified fiscal years to recoup a related $11 billion in purported excess payments between FY 2008 through 2013. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) (ATRA). Tellingly, Congressional action was required to specifically authorize such after-the-fact reconciliation. *See, e.g.,* Hospital IPPS and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any FYs 2010 through 2012 "overpayments could not be recovered by CMS [prior to the passage of ATRA] as section 7(b)(1)(B) of Public Law 110–90 [TMA] limited recoupments to overpayments made in FY 2008 and FY 2009"). No comparable specific statutory authorization for recoupment of amounts properly paid at the prospectively set CYs 2018-2022 OPPS rates exists here.

Bolstering this plain understanding of the statute, as CMS routinely has opined and various courts have agreed, the idea that payment will be made at a predetermined, specified rate serves as the foundation of the Medicare prospective payment systems, of which the OPPS is one. *See, e.g., Methodist Hosp. of Sacramento v. Shalala,* 38 F.3d 1225, 1232 (D.C. Cir. 1994); *Anna Jacques Hosp. v. Burwell,* 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala,* 80 F.3d 379, 386 (9th Cir. 1996). The D.C. Circuit has recognized these core principles of predictability and finality, finding that "the Secretary's emphasis on finality protects Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates" and permits hospitals to rely on the predetermined rates and resulting payments made thereunder. *Methodist Hosp.,* 38 F.3d at 1232. ***Any attempt at after-the-fact rebalancing would be contrary to such principles and therefore fundamentally at odds with Congress's intent that rates be established*** **prospectively** ***under the OPPS.*** And the Supreme Court's recent analysis in *Biden v. Nebraska* (*see* n.3, above) provides further support for rejecting CMS's attempt to distort the fundamental nature of prospective budget neutrality adjustments by characterizing recoupment of prior-year budget neutrality adjustment payments as (another) budget neutrality "adjustment."

Moreover, it cannot seriously be disputed that CMS has authority to correct underpayments in a non-budget neutral manner: CMS *itself* has long retroactively corrected underpayments in a non-budget neutral fashion under Section 1395*l*(t) voluntarily, without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr. v. Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018). For example, in 2006, CMS made a "retroactive payment adjustment" under § (t)(2)(E) that applied to a group of rural hospitals the agency said it had mistakenly excluded from that year's prospective adjustment. Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment

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may adjust [the average standardized amounts or the conversion factor] computed under this [paragraph or subparagraph] for subsequent fiscal years so as to eliminate the effect of such coding or classification changes."

Rates, 71 Fed. Reg. 67,960, 68,010 (Nov. 24, 2006). The agency did not offset the cost of doing so by retroactively recouping payments it had already made to other providers. *H. Lee Moffitt Cancer Ctr.,* 324 F. Supp. 3d at 15. The government recognized in *H. Lee Moffitt Cancer Center* that "retroactively recalculating payments under the OPPS" could "adversely impact[] the reliance interests of hospitals operating under the OPPS." Gov't MSJ (ECF No. 17), *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1 (D.D.C. No. 1:16-cv-02337-CKK). The same fundamental fairness concern exists here. In line with the finality and predictability principles underlying the OPPS, FAH member hospitals relied on, received reimbursement under, and have long-since used or obligated funds from amounts paid at the prospectively-set payment rates for 2018 through 2022 to deliver services to Medicare patients.[6]

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,