American Hospital Association™
Advancing Health in America

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September 15, 2025

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS–1834–P, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency; Proposed Rule (Vol. 90, No. 133), July 17, 2025.

Dear Administrator Oz:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations; our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers; and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system proposed rule for calendar year (CY) 2026.

The AHA supports several proposed policies set forth in the rule. For example, we support permanently extending the ability of virtual presence to satisfy direct supervision requirements for cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR) and pulmonary rehabilitation (PR) services. In addition, we support CMS' proposals to remove four measures from the Outpatient Quality Reporting program that were recently finalized for removal from the Inpatient Quality Reporting Program and the proposal to offer time extensions for data reporting for facilities experiencing an extraordinary circumstance.

However, we are deeply concerned about other proposals that would negatively impact beneficiary access to hospital-level care and new technologies, while also greatly increasing regulatory burden. Specifically, the AHA opposes CMS' proposals to:

- Reduce payment for all drug administration services furnished in excepted off-campus hospital provider-based departments (PBDs) to the "physician fee schedule (PFS)-equivalent" rate of 40% of the OPPS payment amount.
- Eliminate the inpatient-only (IPO) list over three years.
- Weaken the ASC Covered Procedures List (CPL) standard criteria and general exclusion criteria.
- Accelerate the timeline for clawing back funds resulting from the agency's unlawful policy between CYs 2018 and 2022.
- Conduct a drug acquisition cost survey of all hospitals paid under the OPPS.
- Collect market-based payment rate data for purposes of setting inpatient PPS relative weights beginning in fiscal year (FY) 2029.
- Revise the requirements for hospitals to make public their standard charges.

The AHA urges CMS not to finalize these provisions so that hospitals can continue to provide the highest quality health care to their patients and communities.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions, or feel free to have a member of your team contact Roslyne Schulman, AHA director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development

Attachment

American Hospital Association
Detailed Comments on the OPPS and ASC Payment System
Proposed Rule for CY 2026

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OPPS PAYMENT UPDATE

For CY 2026, CMS proposes a market basket update of 3.2% and a productivity adjustment of 0.8 percentage points, resulting in a net update of 2.4%. The AHA remains concerned about inaccurate and inadequate market basket updates. In recent years, the market basket forecasts utilized by CMS have consistently under-forecasted actual market basket growth. In addition, the actual market basket growth has fallen short of or has failed to exceed general inflation, despite well-documented medical inflation that surpasses that of the rest of the economy. **Especially combined with the productivity adjustment, which is inappropriate for application to the hospital field, Medicare's payment updates to hospitals have become increasingly deficient. As such, we urge CMS to eliminate the productivity cut for CY 2026, as detailed below.**

Financial Context

Hospitals and health systems continue to face serious inflationary pressures. As detailed in our comments on the FY 2026 inpatient PPS proposed rule, unprecedented levels of inflation have raised labor, drug, supply and other costs. A recent report from the AHA found that in 2024 alone, hospital expenses grew by 5.1%.[1] A large portion of this growth is attributable to increased labor costs, which make up nearly two-thirds of the inpatient PPS market basket, according to CMS. Indeed, an analysis by AHA found that hospital employee compensation grew by 45% between 2014 and 2023.[2] AHA also has found that advertised salaries for nurses have risen 26.6% in the last four years.[3] Such labor-related inflation has been driven in large part by a severe workforce shortage, which the Department of Health and Human Services (HHS) says will persist well into the future.[4]

In addition to labor costs, increasing drug and supply costs have also strained hospital finances. In fact, total non-labor expense jumped 9.1% from March 2024 to March 2025, due in part to double-digit increases in both drug and supply.[5] A recent report from HHS found that prices for nearly 2,000 drugs increased an average of 15.2% from 2017

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[1] AHA. The Cost of Caring: Challenges Facing America's Hospitals in 2025 (April 2025) (https://www.aha.org/costsofcaring).
[2] AHA. America's Hospitals and Health Systems Continue to Face Escalating Operational Costs and Economic Pressures as They Care for Patients and Communities (April 2024) (https://www.aha.org/system/files/media/file/2024/05/Americas-Hospitals-and-Health-Systems-Continue-to-Face-Escalating-Operational-Costs-and-Economic-Pressures.pdf).
[3] AHA; The Cost of Caring: Challenges Facing America's Hospitals in 2025 (April 2025) (https://www.aha.org/costsofcaring).
[4] ASPE Office of Health Policy. *Impact of the COVID-19 Pandemic on the Hospital and Outpatient Clinician Workforce*, HP-2022-13 at 1 (May 3, 2022).
[5] PWC, *The One Big Beautiful Bill Act (OBBBA): A trillion-dollar turn in US health policy* (July 10, 2025), *at* https://www.pwc.com/us/en/industries/health-industries/library/impact-of-obbba-on-us-health-system.html).

through 2023, notably faster than the rate of general inflation.[6] Further, the American Society of Health System Pharmacists has found that numerous drug shortages are impacting hospital operations,[7] as hospitals and health systems care for patients with a wide range of complex medical conditions.

In addition to direct costs of care, hospitals also have faced rising administrative costs and underpayments from Medicare Advantage plans. For example, the vast majority of MA plans require prior authorizations. As such, hospitals and health systems spend substantial amounts of time and resources navigating the prior authorization process. A 2021 study by McKinsey estimated that hospitals spent $10 billion annually dealing with insurer prior authorizations.[8] Additionally, a 2023 study by Premier found that hospitals are spending just under $20 billion annually appealing denials — more than half of which was wasted on claims that should have been paid out at the time of submission.[9] Notably, many of these denials were ultimately overturned as noted above. In fact, a study by the HHS Office of Inspector General (OIG) found that 75% of care denials that were appealed were subsequently overturned.[10] MA plans do not reimburse these costs, which instead must be absorbed by hospitals and health systems as they continue to care for a rising proportion of MA patients. Making matters worse, MA plans paid hospitals less than 90% of Medicare rates despite costing taxpayers substantially more than traditional Medicare in 2023.[11,12]

In addition, other economic headwinds are creating uncertainty. Despite ongoing efforts to build the domestic supply chain, the U.S. health care system relies significantly on international sources for many drugs, devices and other supplies needed to both care for patients and protect our health care workers. Tariffs, as well as any reaction of the

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[6] ASPE. Changes in the List Prices of Prescription Drugs, 2017-2023. (Oct. 2023). (https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs)
[7] American Society of Health-System Pharmacists. Severity and Impact of Current Drug Shortages (June 2023) (https://news.ashp.org/-/media/assets/drug-shortages/docs/ASHP-2023-Drug-Shortages-Survey-Report.pdf).
[8] McKinsey & Company. (2021). Administrative Simplification: How to Save a Quarter-Trillion Dollars in US Healthcare. https://www.mckinsey.com/~/media/mckinsey/industries/healthcare%20systems%20and%20services/our%20insights/administrative%20simplification%20how%20to%20save%20a%20quarter%20trillion%20dollars%20in%20us%20healthcare/administrative-simplification-how-to-save-a-quarter-trillion-dollars-in-us-healthcare.pdf
[9] Premier. (2024). Trend Alert: Private Payers Retain Profits by Refusing or Delaying Legitimate Medical Claims. https://premierinc.com/newsroom/blog/trend-alert-private-payers-retain-profits-by-refusing-or-delaying-legitimate-medical-claims
[10] DHHS OIG. (2023). High Rates of Prior Authorization Denials by Some Plans and Limited State Oversight Raise Concerns About Access to Care in Medicaid Managed Care. https://oig.hhs.gov/oei/reports/OEI-09-19-00350.pdf
[11] MedPAC (2021). MedPAC Report to Congress. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf#page=401
[12] Ensemble Health Partners. (2023). The Real Cost of Medicare Advantage Plan Success. https://www.ensemblehp.com/blog/the-real-cost-of-medicare-advantage-plan-success/

countries on which such tariffs are imposed, could reduce the availability of these life-saving items in the U.S. As we have detailed in our feedback regarding tariffs related to pharmaceutical and medical devices, the AHA is concerned about the potential for tariffs to raise the costs of delivering care. Indeed, a recent survey showed 82% of health care experts expect tariff-related expenses to raise hospital costs by at least 15%.[13]

These escalating costs for clinicians, personnel, drugs and other essentials have put a strain on the entire health care continuum. It also has forced hospitals and health systems to divert funds that could have been invested in patient care, new technologies and other potential efficiencies, making the inadequate market basket updates provided by CMS more concerning.

Market Basket

During this period of significant cost growth, the market basket forecasts for hospitals consistently failed to accurately predict actual market basket growth. Specifically, since the COVID-19 public health emergency, IHS Global Inc. (IGI) has routinely under-forecasted actual market basket growth, as shown in Table 1 below.

Table 1: OPPS Market Basket Updates, CY 2021 through CY 2025

Year	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	Total (Compounded)
Market Basket Update in Final Rule	2.4%	2.7%	4.1%	3.3%	3.4%	16.9%
Actual/Updated Market Basket Forecast	3.0%	5.7%	4.8%	3.6%	3.4%	22.2%
Difference in Net Market Basket Update and Actual Increase	**-0.6%**	**-3.0%**	**-0.7%**	**-0.3%**	**0.0%**	**-5.3%**

These missed forecasts have a significant and permanent impact on hospitals and health systems and the patients they care for. At current levels, this compounded underpayment of 5.3 percentage points totals approximately $6.5 billion annually. Further, future updates are based on current payment levels; therefore, absent action from CMS, these missed forecasts are permanently established in the standard payment rate for inpatient PPS and will continue to compound.

[13] Beckers (March 27, 2025). Hospital finance, supply leaders predict 15% increase in tariff-related costs. https://www.beckershospitalreview.com/supply-chain/hospital-finance-supply-leaders-predict-15-increase-in-tariff-related-costs/

Indeed, these trends have continued and exacerbated Medicare's underpayments to the hospital field. The Medicare Payment Advisory Commission (MedPAC) projects that 2025 Medicare margins *will be below negative 13%*, resulting in more than *20 straight years* of Medicare paying below costs.[14] Even among "relatively efficient hospitals," the median Medicare margin will remain about *negative* 2%. The AHA's own analysis showed that Medicare underpayments reached $100 billion in 2023.[15] **These underpayments cannot be sustained. Therefore, we urge CMS to focus on appropriately accounting for recent and future trends in inflationary pressures and cost increases in the hospital outpatient payment update, which is essential to ensure that Medicare payments for hospital outpatient services more accurately reflect the cost of providing outpatient hospital care.**

Productivity

The AHA continues to have deep concerns about the proposed productivity cut, particularly given the extreme pressures under which hospitals and health systems continue to operate. As such, we ask CMS to eliminate the productivity cut for CY 2026.

Under the Affordable Care Act, the OPPS payment update is reduced annually by a productivity factor, which is equal to the 10-year moving average of changes in the annual economy-wide, private nonfarm business total factor productivity (TFP).[16] For CY 2026, CMS proposes a productivity cut of 0.8 percentage points.

The use of the private nonfarm business TFP is meant to capture gains from new technologies, economies of scale, business acumen, managerial skills and changes in production. **This measure effectively assumes the hospital field can mirror productivity gains achieved by private nonfarm businesses; however, as we discuss in more detail below and the appendix, it is well proven by the economic literature that the hospital and health care field cannot achieve similar gains.** Moreover, by focusing only on private businesses, this measure excludes non-profit and government businesses, which account for more than 60% of hospitals and health systems. Thus, this measure is not an appropriate or reliable predictor of productivity for the hospital field.

First, measures of productivity contained in the private nonfarm business TFP are not appropriate measures of productivity for the hospital field. Outputs in the TFP are

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[14] MedPAC. (2025). https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch3_MedPAC_Report_To_Congress_SEC.pdf
[15] AHA. The Cost of Caring: Challenges Facing America's Hospitals in 2025 (April 2025) (https://www.aha.org/costsofcaring).
[16] CMS. (February 2016). Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf

measured as a function of the total quantity and prices of the goods and services produced in private nonfarm businesses. For sectors that sell tangible, physical products, measuring these outputs is relatively straightforward and often standardized. However, hospital quantity and prices do not operate in this way. For example, hospital quantity, such as volume of visits or procedures, is not necessarily an appropriate output measure; it may actually be more reflective of the disease burden of a community. More hospital volume — thus more quantity — does not equate to more productivity in the same manner as it does for private nonfarm businesses.

In addition, hospital prices per unit of service often cannot be adjusted in response to changes in demand or quality, unlike those of private nonfarm businesses. This is because much of hospitals and health systems' reimbursement is through fixed payments, such as through the OPPS. Moreover, for commercially insured patients, hospital rates are determined through negotiations, which often lock in the payment rate for several years. Thus, it makes relatively little sense to apply a TFP output function of quantity and prices that is experienced in the private sector to the hospital sector when the same output function does not apply.

Second, the TFP does not reflect specific challenges that prevent hospitals from achieving productivity improvements consistent with those in the broader economy. Specifically, the private nonfarm business sector encompasses a broad range of industries with stable and predictable production processes. In contrast, hospitals operate in a complex environment characterized by unpredictable patient volumes, rising input costs, and varying acuity levels, as well as the impact of natural disasters and pandemics. Hospitals also face heavy regulatory burdens beyond those of other industries. For example, hospitals face unique fixed costs such as requirements to keep emergency departments open 24/7 so that patients can seek care at all times. Private nonfarm businesses rarely have such onerous challenges and requirements.

Furthermore, the hospital field is different from private nonfarm businesses because the services provided by hospitals are highly labor-intensive. As discussed in more detail in the appendix, it has long been theorized in the economic literature that sustained productivity gains in service-intensive industries are difficult to achieve given their heavy reliance on labor, which cannot be scaled or automated. Hospitals are, in this way, more similar to fields like education and social assistance. These industries all experience lower total factor productivity rates. For example, the rates range from -0.4 for educational services to -0.1 for social assistance as compared to 1.9 to 4.9 for the mining, oil and gas, information, and professional services, according to the Bureau of Labor Statistics.

We appreciate that CMS itself has acknowledged that hospitals are unable to achieve the same productivity gains as the general economy over the long run. Specifically, the agency found that hospitals can only achieve a productivity gain

that is one-third of the gains seen in the private nonfarm business sector.[17] Thus, using the private nonfarm business sector TFP to adjust the market basket inappropriately exacerbates Medicare's chronic underpayments to hospitals, which we discussed in greater detail above.

Additionally, we are confused by how an indicator based on a 10-year moving average could yield a near doubling of the productivity cut in a single year. Specifically, the CY 2025 cut was 0.5%, but this year CMS proposes a cut of 0.8%. In moving from one year to the next in calculating a 10-year moving average, one only changes a single one of the 10 years; as such, this methodology should smooth fluctuations to a very large degree. **Instead, in moving from CY 2025 to CY 2026, we see the productivity cut increase by 60%.** We would appreciate CMS providing transparency into the data it used in setting this rate, as it appears that the updated 10-year moving average periods used for the CY 2026 proposed rule exclude a period of low-TFP growth in 2016. We are confused why this would be and are concerned that it has artificially and inappropriately increased the productivity adjustment.

Finally, we find it particularly troubling that the productivity adjustment is used only when it *decreases* Medicare payments. For example, in CY 2021, the 10-year moving average growth of the productivity factor forecasted by IGI was -0.1%. CMS acknowledged that subtracting a negative growth factor from the hospital market basket would have *increased* it by 0.1 percentage points. However, the agency set the productivity factor at 0, stating that it is required to reduce, not increase, the hospital market basket by changes in economy-wide productivity.[18] Thus, it appears the agency applies the productivity factor only when it cuts Medicare spending. Yet, the cumulative, compounding effect of these reductions year-over-year, and the asymmetric treatment of declines in economy-wide productivity, led to an increasing gap between payments and the cost of providing services, leaving hospitals increasingly underfunded, as discussed above.

Given all of the above, the AHA continues to have deep concerns about the proposed productivity cut, particularly given the extreme pressures in which hospitals and health systems continue to operate, which we also detailed in length in our 2023, 2024 and 2025 letters. We believe that applying the private nonfarm business TFP to the hospital field is inappropriate, and in an economy marked by great uncertainty due to tariffs and demand and supply shocks, it generates significant departures from economic reality.

[17] CMS. (February 2016). Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/ProductivityMemo2016.pdf
[18] 85 Fed. Reg. 58797 (Sept. 18, 2020).

AREA WAGE INDEX

Consistent with the FY 2026 inpatient PPS proposed rule, CMS is proposing to discontinue the low-wage index hospital policy under the OPPS for CY 2026 and subsequent years. CMS also proposes applying the 5% cap on wage index reductions to the OPPS wage index. However, the cap on reductions would be relative to the FY 2025 inpatient PPS wage index, not the 2025 OPPS wage index. Because the low-wage policy applied to the 2025 OPPS wage index, but not the FY 2025 inpatient PPS wage index, the OPPS wage index was higher than the inpatient PPS wage index for low-wage hospitals. As such, the cap could result in more than a 5% decrease in a low-wage index hospital's OPPS wage index in 2026. **The AHA urges CMS to implement the CY 2026 OPPS 5% cap relative to the CY 2025 OPPS wage index in a non-budget-neutral manner.**

PROPOSED SITE-NEUTRAL REDUCTION IN PAYMENT FOR DRUG ADMINISTRATION SERVICES IN EXCEPTED OFF-CAMPUS PBDS

Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that, except for dedicated emergency department (ED) services, services furnished in off-campus PBDs that began billing under the OPPS on or after Nov. 2, 2015 (referred to as "non-excepted" services), will no longer be paid under the OPPS. Instead, these non-excepted services are required to be paid under another applicable Part B payment system. Services furnished in off-campus PBDs that were billed under the OPPS before Nov. 2, 2015, are not subject to the site-neutral payment reductions and are referred to by CMS as "excepted." For CY 2026, the agency continues to identify the PFS as the applicable payment system for most non-excepted services and proposes to set payment at 40% of the OPPS rate for these services.

In the CY 2019 OPPS final rule, CMS described "unnecessary" increases in the volume of hospital outpatient clinic visits in hospital PBDs and, citing a provision in section 1833(t)(2)(F) of the Social Security Act (SSA), finalized its proposal to pay for clinic visits furnished in excepted off-campus PBDs at the "PFS-equivalent" rate of 40% of the OPPS rate.[19]

In this rule, CMS claims that financial incentives continue to drive service volume increases, particularly for drug administration services, leading to "unnecessary" Medicare spending and higher out-of-pocket costs for beneficiaries. Therefore, starting in CY 2026, CMS proposes to again use the statutory method described above to impose a site-neutral payment reduction. Under its proposal, it would pay the site-neutral rate of 40% of the OPPS rate for all drug administration procedures furnished in excepted off-campus PBDs. The agency also proposes to exempt drug administration

[19] "(2) SYSTEM REQUIREMENTS.— Under the payment system—… (F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services."

services furnished in excepted off-campus PBDs of rural sole community hospitals from the proposed site-neutral payment reduction. In addition, it requests comments on assessing additional services for site-neutral payment, such as on-campus clinic visits and imaging without contrast, in future rulemaking.

As it did in CY 2019, CMS proposes to implement this payment reduction in a non-budget-neutral manner. As such, it estimates that the proposal would reduce hospital payments by $280 million in CY 2026 and $10.88 billion over 10 years.

The AHA strongly opposes CMS' proposal to reduce payment for drug administration services furnished by excepted PBDs and urges the agency to withdraw it. In short, the agency:

- Lacks statutory authority to reduce payments to excepted hospital outpatient departments (HOPDs) to the level of nonexcepted HOPDs, particularly in a non-budget-neutral manner.
- Fails to consider other reasonable explanations for the increase in the volume of drug administration services in HOPDs.
- Fails to consider that OPPS payments include far more packaged costs than similar services paid under the PFS.
- Inappropriately equates drug administration services provided in HOPDs with less comprehensive and complex care provided at freestanding physician offices.
- Fails to consider that HOPDs are more likely to serve Medicare patients who are sicker, more clinically complex, and more likely to be disabled or living in poorer, rural communities than patients treated in independent physician offices.
- Ignores the harmful impact its proposal would have on rural access to care.

CMS Lacks the Legal Authority for this Proposal

The AHA asserts that CMS lacks the legal authority for this proposal. The proposed rule states that "section 1833(t)(2)(F) of the [Social Security] Act provides authority to implement this policy," and that the D.C. Circuit's decision in *American Hospital Association v. Azar*, 964 F.3d 1230 (D.C. Cir. 2020), supports its interpretation of that provision. But legal developments since that D.C. Circuit decision cast significant doubt on its continued viability and, more importantly, undermine the agency's reliance on Section 1833(t)(2)(F).

First, the court in *American Hospital Association v. Azar* reviewed HHS' interpretation "under *Chevron*'s two-step framework." *Id*. at 1241. But *Chevron* has since been "overruled." *See Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 412 (2024). Consequently, "courts need not and under the Administrative Procedures Act (APA) may not defer to an agency interpretation of the law simply because a statute is ambiguous." *Id*. at 413. But that is *exactly* what the D.C. Circuit impermissibly did in *American Hospital Association v. Azar*. *See* 964 F.3d at 1244 ("We thus conclude that the OPPS statute does not unambiguously foreclose HHS's adoption of a service-specific, non-budget-neutral rate cut as a 'method for controlling unnecessary increases

in' volume. The statute is at least ambiguous as to whether that sort of rate adjustment lies within the agency's (2)(F) authority.").

The agency's reading of Section 1833(t)(2)(F) must now stand on its own two feet as the best interpretation of the law. It cannot. For all the reasons that both the AHA and the district court in *American Hospital Association v. Azar*, 410 F.Supp.3d 142 (D.D.C. 2019), previously offered, the best interpretation of the law is that Section 1833(t)(2)(F) does *not* authorize HHS to "lower payments only for certain services performed by certain providers," *id*. at 160, including and especially those grandfathered under the law.[20]

Second, a separate precedential development casts particular doubt on the D.C. Circuit's decision in *American Hospital Association v. Azar*. The D.C. Circuit barely grappled with the district court's (correct) conclusion that CMS' interpretation of Section 1833(t)(2)(F) arrogates to itself vast authority to "supersede Congress' carefully crafted relative payment system" based on a single sentence in the U.S. Code. *Id*. at 158. Under HHS' view, a provision that gives the agency authority to adopt "method[s] for controlling unnecessary increases in the volume" of covered outpatient services permits it to ignore the entire OPPS system and make non-budget-neutral reductions to particular services. But that would massively "upend" the OPPS system. *Id*. at 159; *see id*. at 160 (rejecting HHS' attempt to "acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention"); *see id*. (holding that the annual OPPS "would be totally ignored and circumvented if CMS could unilaterally set OPD service-specific rates without regard to their relative position or budget neutrality"). The district court, unlike the D.C. Circuit, therefore correctly concluded that "'Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.'" *Id*. (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001)).

Since the D.C. Circuit opined on this issue in 2021, in cases like *Biden v. Nebraska* and *West Virginia v. EPA*, the Supreme Court has doubled down on this legal principle even more strongly. *E.g*., *Biden v. Nebraska*, 600 U.S. 477, 502 (2023) ("Under the Government's reading of the HEROES Act, the Secretary would enjoy virtually unlimited power to rewrite the Education Act. This would 'effec[t] a fundamental revision of the statute, changing it from [one sort of] scheme of ... regulation' into an entirely different kind, *West Virginia v. EPA*, 597 U.S. 697, 721 (2022)."). Just as in those cases, the

[20] Rather than repeating all the arguments that were made during the lengthy litigation, we incorporate our briefing in *American Hospital Association v. Azar*, as well as comments we provided to the agency during the rulemaking process. *E.g*., Letter from Thomas P. Nickels, executive vice president, Government Relations and Public Policy, to Seema Verma, administrator, Centers for Medicare & Medicaid Services, Re: *CMS–1695–P, Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model* (Sept. 24, 2018).

agency here is claiming unfettered power to depart from the OPPS based on a vague provision buried elsewhere in the statute. As the district court in *American Hospital Association v. Azar* put it, "CMS posits that in a single sentence Congress granted it parallel authority to set payment rates in its discretion that are neither relative nor budget neutral." 410 F.Supp.3d at 158. But under this recent Supreme Court caselaw, that kind of fundamental revision of the statute cannot survive the gentlest of scrutiny. HHS *must* address this recent caselaw in any final rule and explain why Congress would have given it this vast authority to "rewrite the [Medicare] Act" in the way it proposes to do here. *Biden*, 600 U.S. at 502. We respectfully submit that HHS will not be able to do so because Congress does not "use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory scheme." *West Virginia*, 597 U.S. at 723 (quoting *MCI Telecommunications Corp. v. American Telephone & Telegraph Co.*, 512 U.S. 218, 229 (1994)).

Third, the D.C. Circuit failed to properly account for Section 603 of the Bipartisan Budget Act of 2015. That provision created two categories of PBDs: (1) those established before November 2015 and (2) those established after November 2015. *See generally Am. Hosp. Ass'n*, 410 F.Supp.3d at 149. For the pre-November 2015 PBDs, Congress required CMS to continue paying off-campus PBDs (referred to in the statute as "excepted" off-campus PBDs) at the same rate as hospitals; for post-November 2015 PBDs, Congress required CMS to reimburse PBDs at the same rate as independent physicians' offices. *See* 42 U.S.C. § 13951(t)(1)(B)(v), (t)(21)(B)(ii). The following year, in the 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016), Congress reinforced this policy choice by providing that "mid-build" PBDs should be reimbursed at the same rates as existing, pre-November 2015 off-campus PBDs, *i.e.*, the same rate as hospitals. *See* 42 U.S.C. § 13951(t)(21)(B)(iv)-(v).

Section 603 forecloses HHS' authority here, as we and others have explained before. *See supra* at 13 n.20. Yet not only did HHS fail to meaningfully address the many comments discussing this provision in the 2018 OPPS rulemaking, it *still* does not account for Section 603 in the proposed rule.[21] What's more, the agency cannot simply point to the D.C. Circuit's decision in *American Hospital Association v. Azar* to avoid dealing with these legal issues because the court of appeals decision got Section 603 completely wrong.

The entire structure of the D.C. Circuit's opinion reveals how mistaken its approach to Section 603 was. In particular, the D.C. Circuit incorrectly hived off the Section 603 issue from its analysis of Section 1833(t)(2)(F). It treated Section 603 as an "alternative" argument and relegated its analysis of that provision to a separate section of its opinion from its analysis of Section 1833(t)(2)(F). But that is not how the AHA presented it to the D.C. Circuit, and it is not how HHS should consider Section 603 here.

[21] *See* Br. of Brief of Amici Curiae 33 State and Regional Hospital Associations in Support of Petitioners, *Am. Hosp. Ass'n v. Corchran*, No. 20-1113, 2021 WL 763753, at *12-*18 (2021).

Properly conducted, any analysis of Section 1833(t)(2)(F) must account for Section 603 *in relation to* Section 1833(t)(2)(F). As we have explained in previous comments and briefings, the issue of whether HHS has statutory authority under Section 1833(t)(2)(F) cannot be answered without considering whether the more specific statute — Section 603 — delimited that purported general authority. *E.g., RadLAX Gateway Hotel, LLC v. Amalgamated Bank,* 566 U.S. 639, 645 (2012) ("It is a commonplace of statutory construction that the specific governs the general. That is particularly true where... Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions."). Yet the court of appeals answered the Section 1833(t)(2)(F) question both as if it were wholly distinct from the Section 603 question and with a heavy thumb on the scale due to *Chevron* deference.

It is no answer, as the D.C. Circuit offered, that "the text of the law exempts those providers from the change mandated by section 603 itself, leaving the exempted providers subject to all the provisions of the OPPS statute, including subparagraph (2)(F)." 964 F.3d at 1246. The D.C. never responded to the argument that Section 603 is a more specific statute that relieves providers from any application of the broader Section 1833(t)(2)(F). Put another way, even though exempted providers may still be "subject to …subparagraph (2)(F)" in *some* circumstances, they *cannot* be so with respect to the issues covered by the more specific Section 603. The D.C. Circuit does not address this at all.

Nor is it an answer for the D.C. Circuit to have stated that "section 603's exemption of preexisting off-campus PBDs from the reimbursement reductions effected by that statute retains practical effect for all OPPS services except the one type of service (E & M services) addressed by the challenged rule." *Id*. That is a policy argument that barely disguises its results-driven reasoning. If Section 603's exemption applies to other services not addressed by the challenged rule, then, legally, it should also have applied to the "one type of service" at issue there, too; after all, nothing in the statute itself carved out E&M services from Section 603's coverage. And even if one were to accept the D.C. Circuit's results-driven approach to Section 603, that sentence makes clear that the decision does not apply to the instant Proposed Rule, which applies to "other services not addressed by [*that*] challenged rule." This makes the agency's total reliance on *American Hospital Association v. Azar* even more suspect.

For all these reasons, even if HHS has the authority to fundamentally rewrite the law by using Section 1833(t)(2)(F) to evade the OPPS system, it still would not have the authority to move forward with this proposal because Section 603 forecloses it. Section 603 expressly created an exception for grandfathered PBDs, but the current proposal ignores that provision altogether. Going forward, the agency cannot rely solely on *American Hospital Association v. Azar* and must instead provide a fulsome, non-conclusory legal explanation for why the text and history of Section 603 do not foreclose its authority here.

CMS Fails to Consider Other Explanations for the Increase in Volume of Drug Administration Services in PBDs

The AHA disagrees with CMS' claim that higher payments for drug administration services under the OPPS are incentivizing hospital acquisition of independent physician offices and, therefore, leading to an "unnecessary increase in the volume of services." **This assertion ignores the many factors facing physicians that have led them to abandon private practice and seek employment in PBDs.**

The fact is, when hospitals acquire independent physician practices, it often occurs because the physicians have reached a tipping point — their practices are failing due to, for example, poor payer mix, increasing regulatory and administrative burden, and declines in reimbursement. That said, it is also true that disproportionate attention has been placed on hospitals' acquisition of physician practices. However, we note that other entities, such as commercial insurers, have collectively invested billions of dollars in physician practice acquisitions. Based on an AHA analysis of Levin Associates data, private equity, physician groups and health insurers acquired the vast majority of physician practices from 2019 to 2023.[22] Comparatively, hospitals and health systems accounted for only 6% of acquisitions during this period.

Other challenges confronting physicians include rising burnout rates, escalating input costs, including the rapidly rising costs of drugs and other supplies, and a shrinking workforce. However, despite these issues, Medicare physician payments have been declining. Specifically, the Medicare PFS conversion factor declined by over 13% in real dollars from 2001 to 2024. The actual reduction when accounting for inflation was a staggering 29%.[23] Compounding this problem is that most other health care payers use Medicare reimbursement rates as an anchor for their own payments. As such, many physicians can no longer cover the costs of providing care.

This financial strain, coupled with mounting pressure to maintain productivity, has led more physicians to leave private practice. Those who do find hospital-based employment obtain greater financial stability, reduced administrative burden and access to institutional support. This trend is especially evident in rural and otherwise underserved areas, where financial margins are often thinner, patient volumes are lower, and physicians face heightened challenges in sustaining independent practices.

In turn, hospitals have become central to preserving access to care by absorbing physicians into their systems, offering more sustainable compensation models and ensuring that communities continue to have access to essential medical services despite the challenges facing independent practices.

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[22] https://www.aha.org/system/files/media/file/2023/06/Private-Equity-and-Health-Insurers-Acquire-More-Physicians-than-Hospitals-Infographic.pdf.
[23] https://www.ama-assn.org/press-center/press-releases/medicare-trustees-warn-payment-issue-s-impact-access-care

CMS Fails to Consider that OPPS Payments Include Far More Packaged Costs than Similar Services Paid Under the PFS

As part of the rationale for its site-neutral payment proposal, CMS also cites that payment rates for drug administration services in HOPDs are higher than in physician offices. **However, this fails to account for the fact that payments under the OPPS include far more packaged costs than payments under the PFS.** That is, the OPPS payment rates for individual services include the costs of many other separate "packaged" services. For instance, in the hospital outpatient setting, there is no separate payment for laboratory tests when they are billed with other services, for all drugs below the $140 per day cost threshold, for "policy packaged" drugs, for certain devices, and for many ancillary services. Instead, each OPPS APC for drug administration services packages the costs for these items and services into one APC payment rate. By comparison, under the PFS, each individual service, such as laboratory tests, drugs and other ancillary services, is paid separately, with a separate beneficiary copayment for each individual service.

Thus, comparing OPPS rates to PFS rates for individual drug administration services is comparing apples and oranges. In fact, depending on the range of services provided, the total Medicare payment for the entire encounter, as well as the total beneficiary copayment, may be higher in the physician's office. **The AHA urges CMS to more closely analyze encounter-level data and payments across settings before finalizing this or any other site-neutral policy.**

CMS' Proposal Inappropriately Equates Drug Administration Services Provided in PBDs with Less Complex Care Provided at Freestanding Physician Offices

CMS' proposal to reduce reimbursements for drug administration services in PBDs to the "physician equivalent" rate of 40% of the OPPS amount inappropriately equates care provided in hospital clinics with less complex care provided at independent physician offices and other free-standing sites of care. Hospital and health system costs are higher than physician office costs because hospitals invest significant resources to meet the stricter regulatory requirements and safety standards to which they are subject. **Therefore, such care is not equivalent, and current OPPS payment rates appropriately account for these significant differences.**

For example, unlike independent physician offices, hospitals are required to take many additional measures to ensure that medications are prepared and administered safely while also providing important care coordination services for their patients. Specifically, hospitals must take steps to ensure that a licensed pharmacist supervises drug preparation, rooms are cleaned with positive air pressure to prevent microbial contamination, and employees are protected from exposure to hazardous drugs. In addition, hospitals must remain in compliance with important safety standards such as

those required by the Food and Drug Administration, U.S. Pharmacopeia and The Joint Commission.[24]

Other differences between hospitals' and other ambulatory sites' drug administration services include that hospitals must:

- Ensure safe preparation, including conducting environmental sampling to ensure sterile conditions and complying with the Drug Supply Chain Security Act rules to prevent use of counterfeit or mishandled drugs.
- Ensure safe administration, including drug barcoding and electronic health record integration to reduce administration errors, pharmacist confirmation of safe dosing and checks for drug-drug interactions, and on-site physicians to prompt response to adverse reactions.
- Provide care coordination, including on-site pharmacies to prevent delays accessing medications and to modify dosing as necessary on the day of infusions.
- Ensure broad access to care, including providing care for the most complex patients, 24/7 access to care, and caring for uninsured and underinsured patients.[25]

Moreover, hospitals and health systems also invest significant resources to provide essential benefits and advanced levels of health care to their communities. These community benefits have value that not only accrue to Medicare beneficiaries but to all Americans. For instance, as HOPDs are extensions of the main hospital, they are held to higher regulatory and safety standards and required to serve all patients, regardless of their ability to pay, serve as a safety net for their communities, and have the standby capacity and resources to respond to local disasters and other emergencies. **However, none of these roles is specifically funded. Instead, hospitals must cover their costs through direct patient care revenue. The AHA urges CMS to consider the value that such benefits provide to beneficiaries and their communities. OPPS payment rates must be sufficient to support these higher standards of care that CMS and other regulators require to be met in hospital-based settings.**

CMS' Proposal Fails to Account for the Fact that PBDs Serve a Sicker, More Clinically Complex and More Economically Vulnerable Medicare Population

The AHA is concerned that the proposed site-neutral payment reduction, as well as the potential expansion of such cuts to other OPPS services, would force hospitals to scale back some of the critical services they are able to provide to their patients. **This is of great concern because PBDs care for a higher share of sicker, higher-need**

[24] https://www.aha.org/system/files/media/file/2023/11/aha-ashp-letter-opposing-site-neutral-legislation-11-14-2023.pdf
[25] https://news.ashp.org/-/media/assets/advocacy-issues/docs/2023/Site-Neutral-Payments-infographic-final.pdf

individuals, including those from rural and lower-income communities, making them a critical access point for essential care.

In fact, a recent study comparing beneficiaries treated in independent physician offices (IPOs) to those treated in HOPDs found that beneficiaries receiving care in HOPDs are:

- 54% more likely to be under 65 and disabled.
- 60% more likely to reside in a rural county.
- 61% more likely to be dually eligible for Medicare and Medicaid.
- 67% more likely to have multiple serious chronic conditions, including heart disease, diabetes, and cancer.
- More likely to have recently used hospital care, including:
    - 73% more likely to have prior emergency department visits.
    - 114% more likely to have prior inpatient hospitalizations.[26]

Moreover, a related study comparing beneficiaries with cancer seen in IPOs to those treated in HOPDs found even more substantial differences. Beneficiaries with cancer receiving care in HOPDs are:

- 131% more likely to be under 65 and disabled,
- 75% more likely to reside in a rural county,
- 125% more likely to be dually eligible for Medicare and Medicaid,
- 63% more likely to have multiple serious chronic conditions, and
- More likely to have recently used hospital care, including
    - 63% more likely to have prior emergency department visits
    - 113% more likely to have prior inpatient hospitalizations.[27]

These sicker beneficiaries, who are more commonly treated in HOPDs, require a greater level of care. **To the extent that these differences result in variations in the cost of care, site-neutral payments would have adverse effects on patient access to care.**

CMS' Proposal Would Harm Rural Access to Care

Hospitals and health systems play critical roles in preserving access to care for patients in rural communities. They have increasingly stepped up to fill voids in access to care by investing in access points like HOPDs. These care sites provide essential services for rural and low-income communities. Oftentimes, hospitals have been a lifeline for struggling rural physician practices by helping to keep their doors open.

[26] "Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices: Updated Findings for 2019-2024," KNG Health Consulting, LLC, September 2025
[27] "Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices among Cancer Patients Updated Findings for 2019-2024", KNG Health Consulting, LLC, September 2025

A further site-neutral payment reduction would especially jeopardize access to essential care and services for patients in rural and other underserved areas.[28] While the AHA appreciates CMS' proposal to exclude rural sole community hospitals' excepted PBDs from these cuts, this is no consideration for other rural communities whose hospitals would still face a 60% payment cut for essential drug administration services. Medicare beneficiaries in rural communities disproportionately rely on HOPDs to meet their increased health care needs. In fact, the more rural the county that a beneficiary lives in, the more likely it is that their visits will take place in an HOPD rather than a physician's office. For example, for patients from counties where 90% or more of the population lives in a rural area, 36% of physician visits are provided through an HOPD. That number drops to 25% of physician visits for the least rural counties.[29]

Requests for Information: Expanding the "Method for Controlling Unnecessary Increases in the Volume of Covered OPD Services" to Other Outpatient Department Services

In the proposed rule, CMS includes two requests for information (RFIs) seeking comments on whether it should expand its application of section 1833(t)(2)(F) to other services, referring specifically to imaging without contrast, on-campus clinic visits and other services predominately performed in the ASC or physician office setting. **For all the reasons discussed above, the AHA is strongly opposed to *any* proposals to expand site-neutral payment cuts to hospitals. To do so would fundamentally rewrite the law by using the "method" described in Section 1833(t)(2)(F) to evade the OPPS system.**

The current Medicare OPPS, as enacted by Congress, as well as its resulting payments (despite being substantially less than the cost of care), recognize that HOPDs are unique — they treat sicker, more complex patients from medically underserved populations, and they also follow more rigorous licensing, accreditation and regulatory requirements compared to other care settings.[30] Hospitals and health systems, including their HOPDs, need the financial and operational resources to provide high acuity and emergency preparedness and response services that only they can provide. This includes maintaining 24/7 capacity to respond to natural and man-made disasters, public health emergencies and other unexpected traumatic events. It also means being available to care for all individuals experiencing an emergency, regardless of their ability to pay. Further site-neutral cuts would result in hospitals closing or reducing these vital services, reducing patient access in communities nationwide, particularly in rural and underserved areas.

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[28] "Analysis: Hospitals and Health Systems Are Critical to Preserving Access to Care for Rural Communities," American Hospital Association, January 2024
[29] KNG Health Consulting calculation using 5% Outpatient and Carrier Standard Analytic Files, 2019-2021
[30] American Hospital Association (April 2025). "The Cost of Caring: Challenges Facing America's Hospitals in 2025."

Possible Errors in CMS' Calculation of the Estimated Effect of the Proposed Drug Administration Policy

The AHA believes that CMS may have made an error in the savings shown in Table 111 on page 33,839 of the proposed rule (copied below). This table relates to its estimate of the annual and 10-year impacts of the proposed drug administration services policy. In particular, we are unable to understand or duplicate the substantial savings that accrue to the Part B Trust Fund for 2027 and future years. We have analyzed this in many ways and have concluded that the savings shown in the table must contain an error.

In the AHA's analysis, we came relatively close to replicating CMS' 2026 savings amount of $280 million using the CY 2024 outpatient claims data, which CMS states that it also used. This figure implies that total excepted off-campus drug administration spending, absent the policy reduction, would be approximately $467 million.[31] This also implies that spending on drug administration services by excepted off-campus providers after the reduction would be approximately $187 million ($467 million minus $280 million). However, for 2027, Table 111 shows savings of $780 million, which is greater than the *total* 2026 drug administration spending by more than $300 million. This implies, holding other factors such as payment rates constant, that drug administration spending in excepted off-campus providers would nearly triple from 2026 to 2027. We simply cannot envision any scenario where such a significant increase in spending would apply in just one year. Indeed, the Table 111 savings in later years do not show as large an increase from one year to the next and are more in line with the Congressional Budget Office's (CBO's) growth in outpatient spending shown in their June 2024 Medicare baseline.

Therefore, the AHA requests that CMS clarify how it arrived at the amounts in Table 111, whose title indicates that the savings are only for "proposed changes to drug administration services when furnished at excepted off-campus providers," or whether there was an error in the calculations.

[31] AHA calculated this as $280 million divided by 0.6 to reflect the 60% reduction in payment, given CMS' PFS relativity adjuster of 40% that it applies to the OPPS rate.

TABLE 111: ESTIMATED EFFECT OF PROPOSED CHANGES TO DRUG ADMINISTRATION SERVICES WHEN FURNISHED AT EXCEPTED OFF-CAMPUS PROVIDERS (IN $ MILLIONS)

CY	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2026 - 2035
Part B Trust Fund benefits	(280)	(780)	(860)	(950)	(1,050)	(1,150)	(1,250)	(1,390)	(1,520)	(1,650)	(10,880)
Premium offset	70	200	210	240	270	290	310	350	380	410	2,730
Net Part B Trust Fund impact	(210)	(580)	(650)	(710)	(780)	(860)	(940)	(1,040)	(1,140)	(1,240)	(8,150)
Beneficiary cost-sharing	(70)	(200)	(210)	(240)	(270)	(290)	(320)	(360)	(390)	(420)	(2,770)

PROPOSAL TO ACCELERATE THE TIMELINE OF HHS' UNLAWFUL CLAWBACK OF FUNDS

The AHA strongly opposes HHS' proposal to accelerate the claw back of funds under 42 § 419.32(b)(1)(iv)(B)(*12*). We have explained many times why *any* clawback is unlawful and never should have been finalized.[32] We need not repeat those lengthy arguments here. Instead, we incorporate our previous submissions, urge the agency to reconsider its legal position, and emphasize in the strongest possible terms that the acceleration of an illegal rule only compounds its illegality. **If HHS is going to revisit this claw back in its final rule, it should rescind subsection 419.32(b)(1)(iv)(B)(*12*) altogether because the agency lacks the statutory authority for *any* such claw back on *any* timeline**.

If HHS chooses to persist with this unlawful clawback, it should *not* accelerate the existing timeline. When it codified a 16-year timeline in the Final Remedy Rule, HHS stated that it sought to "comply with the statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities."[33] In suddenly changing course, the agency now asserts that it "insufficiently accounted for" what it calls the "main premise

[32] *E.g.*, Letter from Melinda Reid Hatton, general counsel and secretary, American Hospital Association to Chiquita Brooks-LaSure, administrator, CMS re: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (RIN 0938-AV18) (Aug. 7, 2023), *at* https://www.aha.org/lettercomment/2023-08-07-aha-letter-cms-remedy-340b-acquired-drug-payment-policy-calendar-years-2018-2022; letter from Melinda Reid Hatton, general counsel and secretary, American Hospital Association to Samuel Bagenstos, general counsel, HHS (Feb. 1, 2023), at https://www.aha.org/system/files/media/file/2023/02/aha-requestsmeeting-with-hhs-to-discuss-340b-remedial-payment-outlines-principles-to-accelerate-processletter-2-1-23.pdf; letter from Stacey Hughes, executive vice president, American Hospital Association to Chiquita Brooks-LaSure, administrator, CMS, Re: CMS–1772–P (Sept. 13, 2022), at https://www.aha.org/lettercomment/2022-09-13-aha-commentsopps-and-asc-payment-system-proposed-rule-cy-2023.

[33] *Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022*, 88 Fed. Reg. 77,150, 77, 179 (Nov. 8, 2023) (hereinafter "Final Remedy Rule").

of the Final Remedy rule": the need to return 340B hospitals to the financial position they would have been if HHS had never implemented its illegal policy in the first place. According to the proposed rule, a 6-year time frame "better balances that goal and [its] budget neutrality obligations against hospital burden and reliance interests."

This analysis is wrong for many reasons. *First*, the agency misapprehends the need to "restore[] affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018." This reasoning fails on its own terms because what should have been the "main goal" of any remedy rule has already been accomplished. Under the 2023 Final *Remedy* Rule, 340B hospitals in need of a *remedy* for HHS' illegal actions have already been remediated. As the proposed rule itself recognizes, those "affected 340B covered entity hospitals" received "one-time lump sum payments" in early 2024. The only thing that is at issue now is the timeline for when money is taken away from OPPS hospitals — some of which are 340B hospitals, some of which are not — to offset those legally-required remedial payments.

Second, it may be that the proposed rule's language is clumsy, and HHS' actual "main goal" is simply to return *all* hospitals as quickly as possible to the net financial position that would have existed had it not acted illegally from 2018 to 2022.[34] The agency's desire to bring the claw-back period "closer to the timeframe the 340B Payment Policy was in place" supports this understanding of the agency's true goal here. But that is just another way of saying that the Final Remedy Rule did not value achieving budget neutrality highly enough and therefore got the balancing wrong. If that is what is really going on here, HHS' new balancing dramatically misapprehends and undervalues the "hospital burden and reliance interests" side of the equation.

Starting with reliance interests, the proposed rule states: "Because we are proposing this policy in advance of CY 2026 and before any rate reductions go into effect for OPPS and Medicare Fee for Service payments, any reliance interests hospitals have in a policy that has not been implemented yet for these payment systems would be minimal." This reasoning reflects a fundamental misunderstanding of how hospitals operate in the real world. Hospitals plan their budgets years in advance. They must make decisions about opening new facilities, buying new medical equipment, hiring

[34] The proposed rule speaks only of restoring the financial position of "affected 340B covered entity hospitals." Astonishingly, it does not appear to recognize that the clawback will impact *all* hospitals subject to OPPS payments — including those that are not part of the 340B program and those that were exempted from the unlawful 2018-2022 payment policies (*e.g.*, rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals). In fact, those hospitals received no lump-sum payment from the government in 2024, but will be subject to a clawback, simply because the government acted illegally from 2018 to 2022. These hospitals had no choice but to receive additional funding during those years a result of the government's illegal actions, yet they are now being forced to repay money that they spent years ago, including during the COVID-19 pandemic. The proposed rule's exclusive reference to "affected 340B covered entity hospitals," without ever acknowledging the clawback's impact on these other providers, demonstrates how poorly conceived an accelerated timeframe is and suggests that the agency did not accurately consider the Proposed Rule's likely effects.

employees and expanding service lines based on what they expect to occur years into the future. HHS seemed to have recognized this reality in the Final Remedy Rule when it delayed the start of these clawbacks to 2026 so that hospitals could "assess and prepare for the new payment rates that will be calculated using a reduced conversion factor."[35] The agency has not identified any changes in relevant facts and circumstances since it made that assessment in the Final Remedy Rule.[36]

Hospitals have been preparing for nearly two years. All the hospitals subject to this unlawful clawback have been planning for a 0.5% recoupment since the Final Remedy Rule was promulgated in November 2023. **It therefore makes no difference that the rate reductions have not yet gone into effect; hospitals have relied on the previously announced timeline when planning their budgets for 2026 and beyond.** If the agency finalizes this unexpected quadruple annual increase from 0.5% to 2.0% just two months before 2026, the budgets that hospitals produced based on that 0.5% figure will be thrown out of whack, upsetting settled expectations with little time to readjust and creating serious cash flow problems. That is the paradigmatic reliance interest, and the agency is wrong to state that those interests are "minimal." Any final rule here must better account for the hospital field's reasonable, good-faith reliance on the timeline the agency itself announced only two years ago.

HHS also must better account for the burdens that the proposed accelerated timeline will inflict on hospitals. The Final Remedy Rule rightly recognized that its clawback "will affect hospitals' medium-term revenue," and so it "moderated that effect by spreading out our recovery of unwarranted payments over a period of many years."[37] With its near-exclusive focus on recalibrating the budget neutrality side of the balancing, the proposed rule does not seem to consider the real burdens that will be imposed on hospitals. It certainly does not seek to "moderate" the effect of those impacts when accelerating the clawbacks by a decade.

But increasing the annual clawback amount from 0.5% to 2.0% will impose significant financial costs on hospitals and health systems. On average, this will be a 300% annual increase in recoupment per hospital. The actual cost could be millions of dollars each year for some hospitals.[38] This is money that hospitals can no longer spend on care for patients and communities. And this is money that hospitals cannot afford.

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[35] Final Remedy Rule, 88 Fed. Reg. at 77,180.

[36] *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1111 (D.C. Cir. 2019) ("An agency cannot ignore its prior factual findings that contradict its new policy.").

[37] *Id*. at 77,176; *see id*. at 77,172 (stating that it chose a 0.5% annual clawback to avoid "imposing too significant of a reduction on hospitals *in any particular year*" (emphasis added)).

[38] According to AHA analysis of Medicare OPPS claims data, on average, each hospital will need to repay over $300,000 in just CY 2026 under a 2% annual clawback. Moreover, nearly 200 hospitals will have repayments over $1 million in CY 2026. OPPS hospitals have an average Medicare payment to cost ratio — a measure of how much Medicare underpays a hospital relative to its costs — of approximately *negative* 7% according to 2023 AHA Annual Survey Data. Further, for hospitals with projected recoupments of $5 million or more, their average Medicare payment to cost ratios are approximately *negative* 23%.

The proposed sudden, accelerated clawback comes at a precarious moment for hospitals. According to independent data from Strata Decision Technology, LLC, hospitals' operating margins narrowed during the first quarter of 2025, dropping below 1% for the first time in 15 months.[39] But more important than this snapshot-in-time data are the long-term trends that contribute to these razor-thin margins. Those trends will continue to unfold during any accelerated clawback period, and they will continue to place downward pressure on hospital finances. In particular, hospitals will face a range of headwinds during the proposed clawback period: persistent cost growth, inadequate reimbursement, and shifting care patterns driven by both recent policy changes and an older, sicker population with more complex, chronic conditions.[40]

As for costs, the same Strata Decision Technology, LLC report explained: "Hospitals across the country continued to see expenses rise across most measures, with non-labor expenses seeing the biggest [year-over-year] increases. As mentioned earlier, total non-labor expense jumped 9.1% from March 2024 to March 2025, due in part to double-digit increases in both drug and supply expenses."[41] This is consistent with recent historical patterns. In 2024, total hospital expenses grew 5.1%, significantly outpacing the overall inflation rate of 2.9%.[42]

Costs are growing in several major categories. Take pharmaceuticals: average drug expenses per patient increased nearly 20% between 2019 and 2022.[43] In addition, a government report found that drug companies increased prices faster than inflation for approximately 2,000 drugs between January 2022 and January 2023, with an average price increase of 15.2%.[44] Compounding this problem are decisions made by drug

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[39] *Strata Performance Trends Report Market Insights from Q1 2025* at 6, *at* https://www.stratadecision.com/resources/report/quarterly-healthcare-performance-trends-report.
[40] *See also* Kaufman Hall, *The more things change: Navigating the next healthcare crisis under the One Big Beautiful Bill* (July 17, 2025), *at* https://www.kaufmanhall.com/insights/article/more-things-change-navigating-next-healthcare-crisis-under-one-big-beautiful-bill ("[M]any macro factors have shifted, and legacy playbooks will not provide the answers for an evolving healthcare environment. Today's landscape includes fragile post-pandemic financial stabilization, payers grappling with new margin pressures, employer premiums outpacing inflation, costs required to provide care that have surged nearly 50% since 2010 and unprecedented workforce challenges including shortages of primary care physicians, behavioral health professionals, nurses, direct care workers and others that accelerated during the pandemic."); PWC, *The One Big Beautiful Bill Act (OBBBA): A trillion-dollar turn in US health policy* (July 10, 2025), *at* https://www.pwc.com/us/en/industries/health-industries/library/impact-of-obbba-on-us-health-system.html) ("Hospitals and health systems, particularly those in rural and underserved areas, continue to operate under considerable financial pressure. Persistent inflation in wages, medical supplies, and services has tightened margins across the board.").
[41] *Id*.
[42] Am. Hosp. Ass'n, *The Cost of Caring: Challenges Facing America's Hospitals in 2025* at 4 (April 2025) (hereinafter "2025 Cost of Caring Report"), *available at* https://www.aha.org/system/files/media/file/2025/04/The-Cost-of-Caring-April-2025.pdf.
[43] *Id*.
[44] Office of the Assistant Secretary for Planning and Evaluation, Changes in the List Prices of Prescription Drugs, 2017-2023 (Oct. 6, 2023), *at* https://aspe.hhs.gov/reports/changes-list-prices-prescription-drugs.

companies to price new drugs coming onto the market at record-high levels, with the median price of a new drug in 2023 costing $300,000 and increasing to $370,000 in 2024.[45,46]

Also consider medical supplies and equipment: between 2019 and 2022, laboratory expenses per patient increased by 27.1%. During that same period, expenses for emergency service equipment — including ventilators, respirators and other life-saving supplies — increased by nearly 31.9%.[47] Overall, supply expenses per patient increased 18.5% between 2019 and 2022, nearly matching the increases in labor and drug costs.[48]

Another telling indicator is the "average age of plant" — a measure of the age of hospital infrastructure — which has risen by more than 10% over the last two years. This trend suggests that hospitals are increasingly unable to reinvest in critical physical assets, such as facility upgrades, which are important to ensure high-quality patient care. An accelerated clawback period will make these overdue investments even more difficult, and they will make it even harder for hospitals to keep up with these trends in rising non-labor expenses. The proposed rule does not consider, much less analyze, any of these cost trends.

Yet despite these escalating expenses, Medicare reimbursement continues to lag behind inflation — covering just 83 cents for every dollar spent by hospitals in 2023, resulting in over $100 billion in underpayments.[49] In December 2024, the Medicare Payment Advisory Commission noted in a preliminary presentation to commissioners that hospital Medicare margins had sunk to an all-time low of negative 12.6%, and were projected to remain at that level in 2025.[50] Again, this is part of a long-term downward trend. From 2022 to 2024, general inflation rose by 14.1%, while Medicare net inpatient payment rates increased by only 5.1% — amounting to an effective payment *cut* over the past three years.[51] When you add Medicaid underpayments to the mix, hospitals absorbed $130 billion in combined Medicare and Medicaid underpayments in 2023 alone.[52] And these shortfalls are worsening — growing on average 14% annually

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[45] Deena Beasley, *Prices for new US drugs rose 35% in 2023, more than the previous year*, Reuters (Feb. 23, 2024), *at* https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/.
[46] Deena Beasley, *Prices for new US drugs doubled in 4 years as focus on rare disease grows,* Reuters (May 22, 2025), at https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-doubled-4-years-focus-rare-disease-grows-2025-05-22.
[47] *Id*. at 4.
[48] *Id*.
[49] *Id*. at 1.
[50] Alison Binkowski et al., Medicare Payment Advisory Commission, *Assessing payment adequacy and updating payments: Hospital inpatient and outpatient services* at 13 (Dec. 12, 2024), *available https://www.medpac.gov/wp-content/uploads/2023/10/Tab-D-Hospital-payment-adequacy-and-REH-mandate-December-2024_SEC-1.pdf*.
[51] 2025 Cost of Caring Report at 1.
[52] *Id*. at 2.

between 2019 and 2023.[53] The proposal to hasten the clawback will only exacerbate this growing revenue-shortfall problem.

Many other factors will also squeeze hospital margins in the coming years, including changing patterns of care and the growing impact of MA on hospital finances as previously discussed.[54] The proposed rule nowhere considers these increasing burdens in its proposal to accelerate the clawback timeline. Nor does it account for the recent passage of the One Big Beautiful Bill Act (OBBBA), which will have direct, adverse impacts on hospital finances. Critically, the impacts of that new law will be exacerbated by HHS' proposed accelerated clawback timeline because they will adversely impact hospitals' finances *at exactly the same time*. As the independent firm Kaufman Hall put it: "The CBO projects that over the ten-year period ending FY 2034, the OBBBA will reduce cumulative federal health spending by approximately $1 trillion. This impact ramps up over time, with 59% of the maximum annual spending reductions expected to impact providers in FY 2029. **In general, meaningful increases in uncompensated care could begin in 2026 and accelerate in 2027, increasing in subsequent years.** The next 18 months will be a critical period for hospitals and health systems, who must assess the likely impacts of the law on their local population and launch a coordinated plan to navigate new challenges."[55]

Although individual hospitals across the country are still assessing exactly how the OBBBA will affect their own finances, as "[a]ll providers will be affected," and "[f]or some, the magnitude of change could threaten their ability to sustainably serve their local population."[56] Just one part of that law, the provisions related to state-directed

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[53] *Id*.
[54] *Id.* at 2-4.
[55] Kaufman Hall, *The more things change: Navigating the next healthcare crisis under the One Big Beautiful Bill* (July 17, 2025), *at* https://www.kaufmanhall.com/insights/article/more-things-change-navigating-next-healthcare-crisis-under-one-big-beautiful-bill.
[56] *Id*.; *see also* PWC, *The One Big Beautiful Bill Act (OBBBA): A trillion-dollar turn in US health policy* (July 10, 2025), *at* https://www.pwc.com/us/en/industries/health-industries/library/impact-of-obbba-on-us-health-system.html)("Hospitals, especially rural providers, will face growing financial pressure. With more uninsured patients and fewer Medicaid dollars, providers may see increases in uncompensated care, with rural hospitals being particularly vulnerable despite a $50 billion funding provision."); *id.* ("Healthcare providers, especially hospitals and health systems, may experience significant pressures as federal Medicaid funding shrinks, and the number of uninsured patients grows."); Gabriella Cruz Martinez, What to Know About New Medicaid Cuts: Is Your Local Hospital Closing Soon?, *at* https://www.kiplinger.com/taxes/medicaid-cuts-and-your-local-hospital ("Some experts predict that cuts to Medicaid will impact nearly every state, with most expected to see more than 25% of their hospitals shut down. In 11 states, the risk is even higher, with 50% or more of hospitals at risk."); Laura Dydra, *One Big Beautiful Bill Act fallout: Health system CEOs brace for change*, Becker's Hospital Review (July 7, 2025), *at* https://www.beckershospitalreview.com/hospital-management-administration/one-big-beautiful-bill-act-fallout-health-system-ceos-brace-for-change/ (describing the consequences of the OBBBA on hospital financial stability); Travis Jackson, et. al, *One Big Beautiful Bill Act Has Many Impacts for Nonprofit Health Systems* (May 29, 2025), *at* https://www.mwe.com/insights/one-big-beautiful-bill-act-has-many-impacts-for-nonprofit-health-systems/ ("[T]he the Act would threaten already thin operating margins at nonprofit hospitals and health systems.… Any increase in operating expenses or decrease in reimbursement that

payments and provider taxes, is estimated to cut Medicaid spending by $340 billion. This will indisputably result in direct decreases in payments to many hospitals.[57] And increases in the number of uninsured Americans resulting from the OBBBA will only accelerate the trend towards increasing bad debt and charity deductions.[58]

Put simply, by adding to the anticipated adverse financial consequences of the OBBBA, an accelerated clawback timeline is a bridge too far for America's hospitals. If the agency is truly trying to balance its purported budget neutrality obligations against "hospital burden and reliance interests," it cannot ignore the effects of the OBBBA. And when it includes the OBBBA in its analysis, as it must, the burden of a clawback (on top of the burdens of the OBBBA) surely tips the balance *against* accelerating the timeline.[59]

All in all, the proposed rule errs by conducting a new balancing that completely fails to account for the full scope of burdens that it will impose on hospitals. Although the proposal does not sufficiently explain *how* HHS conducted its balance, it appears as if the agency simply kept the burdens constant from the Final Remedy Rule (despite the evident change in circumstances) and readjusted the value of the perceived need to achieve budget neutrality (despite the absence of any change in circumstances).[60] The proposal is doubly flawed because it fails to recognize how the burdens on hospitals

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results from the Act may push many nonprofit hospitals across the thin line that separates profitability from financial distress.").

[57] Congressional Budget Office, *Estimated Budgetary Effects of Public Law 119-21, to Provide for Reconciliation Pursuant to Title II of H. Con. Res. 14, Relative to CBO's January 2025 Baseline* at Title VII tab, (July 21, 2025), *at* https://www.cbo.gov/publication/61570.

[58] The same Strata Decision Technology, LLC report discussed above explains that hospitals "across the country already experienced significant increases in bad debt and charity deductions in recent years." *Id*. at 5; *see id*. ("The median charity deduction for health systems nationwide increased 5.4% from Q1 2024 to Q1 2025, and jumped 21.4% versus the first quarter of 2023. Bad debt deductions also rose over the same periods. The median health system bad debt deduction increased 9.2% from Q1 2024 to Q1 2025 and 16.9% versus Q1 2023."). Increases in unreimbursed care obviously impact the revenues that hospitals receive, tightening hospital margins even further. And the trend towards greater bad debt and charity care deductions will increase in the coming years following any coverage losses resulting from the One Big Beautiful Bill Act. *See id*. ("Disruptions in health insurance coverage can drive increases in bad debt and charity care deductions for U.S. hospitals and health systems."); Kaufman Hall, *The more things change: Navigating the next healthcare crisis under the One Big Beautiful Bill* (July 17, 2025), *at* https://www.kaufmanhall.com/insights/article/more-things-change-navigating-next-healthcare-crisis-under-one-big-beautiful-bill ("[T]he OBBB is projected to decrease healthcare coverage and increase bad debt for hospitals and health systems.… Although the challenge of caring for an underinsured population is familiar, the landscape is now different, with little margin for error.").

[59] HHS also must consider how accelerated timeline would interact with *other* policies it finalizes that will adversely, impact hospital finances. To take just one example, the agency's proposal regarding a "Method To Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off- Campus Provider-Based Departments (PBDs)" also will reduce hospital revenues. As the agency conducts its balancing here, it cannot ignore the *cumulative* burdens that result from its regulatory decisions.

[60] *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 223 (2016) ("But when it came to explaining the good reasons for the new policy, the Department said almost nothing.… Whatever potential reasons the Department might have given, the agency in fact gave almost no reasons at all." (cleaned up)).

have worsened since 2023 — and how an accelerated clawback timeline will worsen those burdens further. Circumstances have changed since 2023. Reliance interests have changed. And so have the burdens on hospitals, including the OBBBA. The final rule *must* account for and discuss these changes on the reliance/burden side of the balance. The AHA respectfully submits that the balance has not shifted in favor of a faster clawback and would actually counsel in favor of no recoupment (or, at the very least, a longer recoupment period) given the increased financial pressures on hospitals in the coming 16 years.

Unsurprisingly, then, the proposed rule also does not consider a sufficient number of alternatives. It states that the agency considered an even faster clawback period (three years). But the agency nowhere explains why it arbitrarily chose that alternative when other "significant and viable and obvious alternatives" exist.[61] Why didn't the agency consider nine years? Or 12 years? Or 20 years? And why does the balancing cash out favorably, in its view, at six years but not *those* time periods?[62] These are a "manageable number of alternatives to present a reasonable spectrum of policy choices that meet the goals of the action," and so the agency is duty-bound to consider them and explain why six years achieves the needed balancing better than these other timeframes.[63] Even though the AHA ultimately believes the 16-year time frame should go undisturbed or even lengthened (only if, of course, an unlawful clawback is preserved at all), the number of considered alternatives is manifestly deficient.

Ultimately, the AHA urges HHS to abandon this unlawful, unwise proposal. Because any clawback is illegal, it should rescind subsection 419.32(b)(1)(iv)(B)(*12*) altogether. If HHS continues to disagree with that legal analysis, it should maintain or extend the existing clawback timeline. In so doing, we would urge HHS to remember what it wrote in the Final Remedy Rule: "We take full responsibility for the legal error ultimately found by the Supreme Court."[64] In other words, HHS has acknowledged that hospitals are not to blame for this situation, has not changed that position and has articulated no basis for doing so. Hospitals that received additional payments as a result of HHS' illegal policy could not have declined those payments, even if they wanted to. Thus, *full* acceptance of responsibility would involve HHS recognizing that hospitals should not be punished for HHS's mistakes, many years after HHS made those mistakes, by having to return funds that they have long since spent. *Full* acceptance of responsibility definitely would *not* involve (much less require) taking *more* money from hospitals each year — especially when those hospitals relied on HHS' previously-announced timeline to plan their future budgets and investments,

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[61] *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013).
[62] At best, the Proposed Rule justifies its 6-year proposal by stating that the "6 years we expect that the revised policy would be in effect, by contrast, is closer to the timeframe the 340B Payment Policy was in place." But that was also true two years ago when the agency chose 16 years. The agency fails to explain why a "closer-to-the-timeframe" approach is necessary now but was not necessary then — especially when circumstances have changed for the worse since 2023.
[63] *Oceana, Inc. v. Evans*, 384 F. Supp. 2d 203, 241 (D.D.C. 2005).
[64] Final Remedy Rule, 88 Fed. Reg. at 77,176.

and especially when hospital finances will face increasing downward pressures in the coming years.

MEDICARE OPPS DRUGS ACQUISITION COST SURVEY

HHS also should abandon its proposal to conduct a drug acquisition cost survey of all hospitals paid under the OPPS. This administration is rightly focused on a deregulatory agenda. As HHS Secretary Robert F. Kennedy Jr. has explained: "To Make America Healthy Again, we must free our doctors and caregivers to do what they do best—prevent and treat chronic disease. We cannot allow their time and talent to be wasted on bureaucratic red tape and paperwork."[65] Unfortunately, a cost acquisition survey is exactly the kind of wasteful government paperwork that diverts hospitals' attention away from patient care. It inflicts unnecessary costs on hospitals and their employees, all with the apparent (and ill-advised) goal of cutting Medicare payments to certain groups of hospitals beginning in CY2027. A cost acquisition survey is flawed in both design and intent, and it should not be conducted at this time.

Cost acquisition surveys are, in a word, costly. The Proposed Rule estimates that each hospital will require 73.5 hours to complete the survey at an approximate cost of $4,000. But this grossly underestimates both the cost and time required to complete any survey. **Our members have informed us that it will take exponentially more hours and dollars to complete a survey of the acquisition costs "for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs."[66]**

In its 2006 report to Congress about the lessons learned when conducting hospital acquisition cost surveys, the Government Accountability Office (GAO) stated that the surveys "created a considerable burden for hospitals," which "signal[ed] the difficulties that CMS would face in implementing similar surveys in the future."[67] Hospitals told the GAO that "to submit the required price data, they had to divert staff from their normal duties, thereby incurring additional costs."[68] What's more, such surveys imposed significant costs and burdens on CMS itself, something the government cannot afford at

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[65] *HHS, FDA Issue RFI on Deregulatory Plan to Lower Costs and Empower Providers* (May 13, 2025), at https://www.hhs.gov/press-room/fda-10-to-1-deregulatory-plan-to-lower-costs-empower-patients.html.
[66] Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency, Proposed Rule, 90 Fed. Reg.135 at 33,653.
[67] Government Accountability Office, *Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS* at 5 (Apr. 2006), at https://www.gao.gov/assets/250/249967.pdf.
[68] *Id*. at 12; *see id*. ("The burden was more taxing for some hospitals than for others.… A number of hospitals … either collected the data manually, provided us with copies of paper invoices, or had automated information systems that were not designed to retrieve the detailed price data needed and required additional data processing effort. Hospitals' data collection difficulties were particularly pronounced regarding information on manufacturers' rebates, which affect a drug's net acquisition cost.").

this time. For all the reasons stated above with respect to the accelerated clawback timeline, *see supra* at 25-28, CMS should ask itself whether now is the time to impose these additional burdens on hospitals. For the AHA's financially struggling members, surely it is not.

Ultimately, however, the main reason to abandon this proposed cost acquisition survey is that its eventual goal should never be pursued. CMS appears to be conducting this survey in the service of reducing Medicare reimbursements in CY 2027 and beyond. But as noted above (at 26-27), Medicare payments *already* lag far behind the costs hospitals incur for providing care to Medicare beneficiaries. And for all the reasons stated above, *see id*., hospitals cannot afford further revenue reductions in CY 2027, just as the impacts of the OBBBA will begin to negatively affect their finances. Put simply, an additional Medicare cut would be unsustainable. Hospitals may be forced to stop purchasing certain high-cost drugs, putting access to those drugs at risk for Medicare beneficiaries. And for the most financially challenged hospitals, particularly in rural and other underserved areas, these Medicare cuts could force closures, jeopardizing access to care for the patients and communities those hospitals serve. **If the goal of this survey is to cut Medicare payments, the survey should not be conducted at all**.

The agency also must keep in mind that any survey results are of limited value. CMS does not appear to appreciate the constantly fluctuating nature of drug prices. Any survey will only yield a point-in-time estimate of a drug's acquisition cost, which can change wildly quarter to quarter. For example, if a hospital reports a drug's acquisition cost as $100 in the survey, that same drug's acquisition cost a few months later could be $200. As a result, if CMS were to set prospective payment rates based on prior year drug acquisition cost survey data, the agency could be grossly underpaying for drugs for which acquisition costs have risen sharply. Similarly, the point-in-time survey will not account for new, expensive drugs that enter the market after the survey is completed; this will result in lower payments over time, making it more difficult for Medicare beneficiaries to access new, potentially curative drug therapies. **For this reason alone, the AHA urges the agency to abandon its drug acquisition cost survey proposal.**

The specific questions that HHS asks in the proposed rule underscore the inherent limitations of any cost acquisition survey. *First*, CMS asks whether it "should make responding to the survey a mandatory requirement of all hospitals paid under OPPS," but it identifies no statutory authority for such a mandatory requirement. Section 1833(t)(14)(D)(iii) — the only provision cited in that discussion — certainly does not provide the agency with the authority to mandate hospitals' responses. All it does is set forth the requirements for *the agency* to conduct a survey. If Congress wanted to require *hospital* participation in a drug acquisition cost survey or allow the secretary to take enforcement action for a non-response, it would have done so, as it has in other

contexts, including in adjacent sections of the same law.[69] As the Supreme Court has made clear, "[w]hen Congress includes particular language in one section of a statute but omits it from a neighbor, we normally understand that difference in language to convey a difference in meaning (*expression unius est exclusion alterius*)."[70] **Thus, absent such statutory authority and absent any way to enforce a response requirement, the agency lacks the authority to compel participation in a drug acquisition cost survey. Accordingly, it must explicitly acknowledge in the final rule that participation in any cost acquisition survey is *purely voluntary*.**

Second, perhaps recognizing that it has no legal authority to require a survey response, the agency "welcome[s] comment on how we might propose to interpret non-responses to the survey." The proposed rule includes four options that the agency could use to interpret a hospital's non-response to its survey. But *none of these options* would satisfy the statutory requirement that a survey "…have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."[71]

There are many reasons why a hospital might not respond to the survey. As noted, surveys are costly and burdensome. Or perhaps the hospital's contract with a wholesaler contains a strict non-disclosure provision to protect against anti-competitive pricing behavior. Whatever the reason, CMS cannot supply an explanation for a non-response when the hospital has not given one. The agency cannot contrive responses where there are none and then claim that there is a large enough sample size. What's more, the agency's made-up interpretations of non-responses would yield inaccurate data that is in no way "statistically significant." Put simply, the Medicare statute does not

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[69] For example, under SSA § 1833(t)(17), CMS explicitly requires each hospital to "submit data on [quality] measures…to the Secretary in a form and manner, and at a time, specified by the Secretary." That section of the statute also expressly imposes the financial penalty of a reduction of "2.0 percentage points" on the "[outpatient department] fee schedule increase factor" for hospitals that fail to report data. SSA § 1833(t)(17)(A)(i). *See also* SSA § 1150A(a) (certain plans and pharmacy benefit managers "shall provide the information …to the Secretary…at such times, and in such form and manner, as the Secretary shall specify"); SSA § 1150A(d) (imposing civil penalties for "fail[ure] to provide information required under subsection (a) on a timely basis or…knowingly provid[ing] false information"); 42 U.S.C. § 1834(l)(17)(C) ("For each year, a provider or supplier of ground ambulance services identified by the Secretary under subparagraph (B)(i)(II) as being required to submit information under the data collection system with respect to a period for the year shall submit to the Secretary information specified under the system. Such information shall be submitted in a form and manner, and at a time, specified by the Secretary for purposes of this subparagraph."). There is proposed legislation to amend the Medicaid statute to mandate pharmacy participation in the National Average Drug Acquisition Cost survey, authorized under SSA § 1927(f) and *not* containing mandatory reporting or enforcement provisions; this demonstrates Congress's recognition of the need to include such express language to mandate reporting. *See* S. 927, 119th Cong. (2025).

[70] *Bittner v. United States*, 598 U.S. 85, 94 (2023); *see Russello v. United States*, 464 U.S. 16, 23 (1983) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972))).

[71] 42 U.S.C. § 1833(t)(14)(D)(iii).

authorize CMS to make generalized and unfounded assumptions about the costs of non-responding hospitals. **So, if the agency is truly concerned about the lack of responses from hospitals, it should not issue a survey in the first place.**

ELIMINATING THE IPO LIST OVER THREE YEARS

The AHA opposes CMS' proposal to eliminate the IPO list over three years. Instead, the AHA recommends that CMS continue with its standard process for removing procedures from the IPO list. If the agency is looking to speed removal of procedures on the list, we suggest it examine its general criteria for removal by incorporating, for examples, analysis of average length of stay, peer-reviewed evidence, patient factors including age, co-morbidities and social support, and other factors relevant to positive patient outcomes.

We are concerned that, given the depth and breadth of the 1,731 procedures on the IPO list, it would be reckless to eliminate them all. The IPO list was put into place to protect beneficiaries. Many of its services are surgical procedures that are high risk, complicated and invasive, with the potential for multiple days in the hospital and an arduous rehabilitation and recovery period. These services also require the care and coordinated services of the inpatient setting of a hospital. The fact is that more than one-third of all Medicare beneficiaries live with four or more chronic conditions, and more than one-quarter have one or more limitations in activities of daily living that limit their ability to function independently, which could make these procedures even more complicated and risky if furnished in outpatient settings.[72]

The appropriate setting for a procedure should be determined with a careful focus on patient safety and peer-reviewed evidence. **As such, we are concerned that CMS is proposing a blanket policy to essentially remove all procedures without an examination of any safety or other implications.** For instance, there are some services on the IPO list that may never be appropriate to furnish in an outpatient setting and certainly should not be removed from the list within the next three years. These include, for example:

- CPT code 33935 Transplantation heart/lung.
- CPT 32853 Lung transplant double.
- CPT code 19306 Mastectomy, radical, including pectoral muscles, axillary and internal mammary lymph nodes (Urban type operation).
- CPT code 33523 Coronary artery bypass, using venous graft(s) and arterial graft(s), six or more.

These services, as well as many others among the 1,731 services on the IPO list, could not be performed safely in hospital outpatient or other ambulatory settings because of their complex and high-risk nature, and the fact that they require far more than 24 hours

[72]https://www.kff.org/medicare/health-policy-101-medicare/?entry=table-of-contents-what-is-medicare

of postoperative recovery and monitoring time before the patient could be safely discharged.

We also are concerned that, among the 285 primarily musculoskeletal procedures proposed for removal in 2026, there are procedures without adequate data to support the appropriateness of their performance in the outpatient setting, particularly in an ASC setting. These high-risk procedures require more than 24 hours of recovery or monitoring time, such as:

- CPT 20808 Replantation, hand (includes hand through metacarpophalangeal joints) complete amputation.[73]
- CPT 21630 Radical resection of sternum.
- CPT 27590 Amputation, through femur, any level.
- CPT 37617 Ligation, major artery (e.g., post-traumatic, rupture), abdomen.

Eliminating these procedures from the IPO list, all of which are also proposed to be covered in an ASC in 2026, would pose serious risks and have negative quality of care implications for vulnerable Medicare patients.

In addition, while CMS has proposed APC assignments for those musculoskeletal and other procedures proposed for removal from the IPO list in 2026, we are concerned that the agency does not have the claims, cost or other needed data to appropriately determine the APCs in which they should be incorporated. The agency also does not have adequate data for creating new APCs to capture the remaining IPO list procedures. With over 1,400 more IPO services proposed to be removed by Jan. 1, 2029, grouping procedures into APCs and creating new APCs where necessary will be a huge undertaking. Three years is clearly not enough time to do so. **Services should not be removed from the IPO list until there are adequate data available to create new or revised APCs and these APCs are established.**

Moreover, we are concerned about the financial and administrative burden of the IPO list elimination over such a short period of time. For example:

- When a procedure is taken off the IPO list, it tends to be generally healthier Medicare beneficiaries, with shorter lengths of stay, whose care migrates to the outpatient setting, leaving the sicker and more complex patients as inpatients. Eliminating the entire IPO list over three years would magnify this impact on hospital costs, which would come without a commensurate increase in reimbursement.
- CMS' proposed policy would also increase the complexity of billing and claims processing because determining the appropriate billing codes for 1,731

[73] According to AAPC at https://www.aapc.com/codes/cpt-codes/20808 "The replantation of a hand after complete amputation is a major, or open, invasive medical procedure to reattach the amputated body part at the relevant body area."

procedures previously on the IPO list over a three-year period would not only require greater scrutiny but would also be an overwhelming effort, likely leading to large numbers of payment denials or delays if not managed correctly.

- This policy also would result in downstream issues regarding Medicare coverage and reimbursement of post-acute care. For example, without a three-day inpatient hospital stay, Medicare beneficiaries who would have previously qualified for Medicare-covered skilled-nursing facility care would no longer qualify. AHA's health system members that own SNFs have indicated that the musculoskeletal procedures proposed for elimination in CY 2026 would have a substantial impact on beneficiary access to post-acute care. Specifically, between 25% and 50% of beneficiaries who would have previously qualified for Medicare-covered skilled-nursing facility care would no longer be able to access this care.
- There also would be increased administrative effort involved in ensuring appropriate clinical decision-making and potentially navigating disputes with payers regarding the chosen site of service.

If, despite AHA's concerns, CMS finalizes this proposal, we recommend that additional steps be taken to minimize the patient safety and financial impact of this policy. First, currently, the Medicare IPO list policy provides crucial protection to hospitals and physicians, such as making listed IPO procedures exempt from the 2-midnight rule and not subject to prior authorization. We recommend that, if the IPO list is eliminated, CMS provide clear guidance to physicians to help them determine which surgeries and procedures should be performed in an outpatient setting versus those that still qualify for inpatient, even if the case does not cross the two-midnight threshold. It is also important that Medicare continues to exempt these services from potential prior authorization.

Therefore, the AHA urges CMS to work with stakeholders, including physician specialty societies, to develop guidelines for the circumstances under which procedures removed from the IPO list may safely and appropriately be performed in outpatient settings versus inpatient settings. For example, CMS should work with stakeholders to identify peer-reviewed evidence to help physicians make such site-of-service determinations. One important resource we suggest CMS utilize is the American Society of Anesthesiologists' (ASA) Physical Status Classification System.[74] This is a fundamental tool in perioperative medicine, providing health care professionals with a standardized method to assess and categorize patients' physiological status before surgery. The value of this system lies in its ability to help predict operative risk and guide clinical decision-making, although its application requires careful consideration of various patient factors and comorbidities.[75]

[74] Statement on ASA Physical Status Classification System
[75] https://www.ncbi.nlm.nih.gov/books/NBK441940/

Second, because the IPO list is both a financial and a beneficiary safety policy, we strongly recommend that CMS ensure that any policies related to removing procedures from the IPO list under traditional Medicare also be applied to MA plans. AHA's hospital and health system members tell us that often, when CMS removes procedures from the IPO list, MA plans adopt the policy as well, but Medicare's "option" for the outpatient setting becomes the MA plan's justification for making it the default location. **Therefore, the AHA recommends that when a service is removed from the IPO list, not only should CMS maintain its coverage as an inpatient service under traditional Medicare, but it also should require that MA plans continue to consider it as a covered inpatient service.**

Third, although CMS proposes to continue applying its existing policy of indefinitely exempting procedures removed from the IPO list from certain medical review activities related to the 2-midnight policy, we believe that this medical review policy should go further. **That is, if a service is removed from the IPO list, CMS should require that this prohibition on medical review activities also apply to MA plans for an appropriate period during which the plan could not deny them as an inpatient service.**

Fourth, as noted above, CMS does not provide any explanation of how the procedures proposed for removal from the IPO list in 2026 were assigned to APCs. **To be more transparent, we suggest an alternate approach that may be more pragmatic for hospitals and their clinical staff. That is, CMS could create a system edit for when an IPO list procedure is performed in the HOPD that suspends the claim and directs the claims processing system to allow the Medicare Administrative Contractor (MAC) to determine OPPS pricing.** The MAC could assign the procedure to a new technology APC or clinical APC based on hospital cost information provided to the MAC as part of the manual pricing process. Once there is sufficient information on hospital costs, CMS could then assign such a procedure to a clinical APC using its normal processes. This process would be parallel to what CMS does currently with new technologies that have insufficient claims to be assigned to a clinical APC and are assigned to a new technology APC based on approximate cost data derived from other sources until sufficient claims data is available to assign the procedure to a clinical APC. As utilization grows for a given procedure being performed on an outpatient basis, this process would no longer be needed, as CMS' conventional processes using hospital costs could be used to assign a procedure to an APC. CMS could further minimize the potential number of claims that would require manual pricing by examining 2021 outpatient utilization during the one year that many musculoskeletal procedures were priced under the OPPS. Costs could be examined for any of these procedures with sufficient utilization to make an APC assignment.

Errors in CMS Tables 69 and 81. Tables 69 and 81 in the rule, excerpted below, contain discrepancies in either the CPT code or the narrative descriptor of the code as compared to the American Medical Association's (AMA's) CPT® 2025 professional edition, as published by the AMA Press.

Table 69: Proposed Procedures for Removal from the IPO List for CY 2026

20802	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)
20805	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)

Table 81: IPO List Removals Proposed for Addition to the List of ASC Covered Procedures for CY 2026

20802	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)
20805	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)

The correct CPT narrative descriptors for codes 20802 and 20805, as described in the AMA's CPT® 2025 professional edition, are listed below. **The AHA recommends that CMS correct this in the final rule. We also recommend that CMS review the other codes and narrative descriptors in these tables for accuracy.**

- CPT code 20802, Replantation, arm (includes surgical neck of humerus through elbow joint), complete amputation.
- CPT code 20805, Replantation, forearm (includes radius and ulna to radial carpal joint), complete amputation.

CONTINUATION OF PAYMENT POLICY FOR RADIATION THERAPY SERVICES FURNISHED AT NONEXCEPTED OFF-CAMPUS PBDS

In September 2024, the CPT Editorial Panel approved the revision of CPT codes 77402, 77407 and 77412 to establish a technique-agnostic family of codes and bundle imaging into the three CPT codes, and the deletion of CPT codes 77385, 77386 and 77014. CMS has used these CPT codes for payment under the OPPS since 2015.

Historically, CMS has not used these specific CPT codes for payment under the PFS. Instead, under the PFS, 17 G-codes were established that mirrored the pre-2015 CPT codes. For CY 2026, CMS proposes to delete the 17 G-codes and CPT codes 77385

and 77386 and recognize the newly revised CPT codes for payment under the PFS as well as the OPPS.

The AHA has concerns about these newly revised CPT codes, specifically, CMS' proposals regarding its APC assignments in the OPPS proposed rule. These policies are also important for valuing these services in the PFS, as CMS proposes to link PFS reimbursement for these services to the OPPS reimbursement. In particular, we believe that CPT codes 77407 (Radiation treatment delivery, >=1 MeV; intermediate) and 77412 (Radiation Treatment Delivery, >1 MeV; complex) are proposed for assignment into inappropriately low-valued APCs in the OPPS proposed rule. To preserve appropriate reimbursement for Intensity-Modulated Radiation Therapy (IMRT), we make the following recommendations:

- **CPT code 77407 should be assigned to APC 5623 (Level 3 Radiation Therapy), which has a proposed payment of $600.14, rather than the proposed assignment into APC 5622 (Level 2 Radiation Therapy) with a proposed payment of $275.34.**
- **CPT code 77412 should be assigned to APC 5624 (Level 4 Radiation Therapy) with a proposed payment of $715.83, rather than the proposed assignment into APC 5622 (Level 2 Radiation Therapy) with a proposed payment of $275.34.**

There are both clinical and cost rationales for including CPT codes 77407 and 77412 in the higher level APCs. As a threshold matter, we note that the current IMRT codes – namely, CPT codes 77385 (Ntsty modul rad tx dlvr smpl) and 77386 (Ntsty modul rad tx dlvr cplx) are assigned to APC 5623 (Level 3 Radiation Therapy). Assigning the newly revised IMRT CPT codes 77407 and 77412 to lower APCs would be inconsistent with how CMS has valued these codes for the previous decade. At a minimum, we recommend that CPT codes 77407 and 77412 should be assigned to the higher level APC 5623 (Level 3 Radiation Therapy), consistent with longstanding CMS policy. However, since the CPT code description for CPT code 77412 is intended to account for the highest-complexity therapy, including image guidance and motion management, we strongly believe that it would be most appropriately assigned to APC 5624.

OUTPATIENT QUALITY REPORTING PROGRAM

Proposed Measure Removals. With a stated purpose of reducing regulatory burden to hospitals, CMS proposes to remove the following four measures from the Outpatient Quality Reporting Program (OQR) that were recently finalized for removal from the Inpatient Quality Reporting Program:

- COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) (proposed for removal effective with the CY 2024 reporting period/CY 2026 payment determination).

- Hospital Commitment to Health Equity (proposed for removal beginning with the CY 2025 reporting period).
- Screening for Social Drivers of Health (proposed for removal beginning with the CY 2025 reporting period).
- Screen Positive Rate for Social Drivers of Health (proposed for removal beginning with the CY 2025 reporting period).

The AHA greatly appreciates CMS' recognition of the importance of striking an appropriate balance of burden and value in quality measurement programs and supports the removal of these four measures from the OQR and other CMS programs. The AHA has long advocated that all federal quality reporting and value programs use "measures that matter" — that is, measures that are focused on the highest priority areas for quality improvement, are feasible to collect and report, and whose value outweighs their burden. Streamlining the number of measures in federal quality reporting programs can help hospitals focus their resources on high-priority topics of national importance while freeing up resources to help hospitals address the quality issues that matter most to their organizations.

The AHA especially applauds CMS' proposal to sunset the COVID-19 vaccination coverage among HCP measure. While hospitals continue to support efforts to vaccinate health care workers for COVID-19 in a manner consistent with federal guidelines, the COVID-19 public health emergency (PHE) concluded in May 2023. Since then, the level of administrative effort and resources needed to collect and report the HCP COVID-19 vaccination measure has become impractical and untenable. In 2023, the Centers for Disease Control and Prevention (CDC) and CMS shifted the measure definition to measure the proportion of HCP who are "up to date" on COVID-19 vaccinations. The measure collection protocol uses a reference period for determining up-to-date vaccination status that changes every quarter. Practically speaking, this means that an HCP who counted as "up to date" during one quarter may no longer be up to date in the next quarter. Hospitals are also asked to take into consideration any recent positive COVID-19 tests, which would affect the timing of when an HCP should receive a vaccine. To collect and report the measure, hospitals must conduct near-continuous tracking of each employee's vaccination status, including obtaining documentation of either the vaccination, a recent COVID-19 test or an exemption.

Furthermore, the CDC's current vaccination guidance suggests that some individuals with certain risk factors should consider receiving an additional booster dose. Yet, hospitals usually do not have routine access to data to know which of their HCP may need an additional booster. In short, the resource intensiveness of collecting data under the CDC's current definitions may outweigh its value, especially given that the COVID-19 pandemic has concluded. We believe removing this measure from CMS programs will allow hospitals to focus data collection resources on other important opportunities to improve care; also, the measure has already been removed from the Inpatient Quality Reporting Program (IQR) and thus removing it from the Outpatient Quality Reporting Program (OQR) would keep the two programs in alignment.

In addition, while hospitals continually work to improve the health outcomes of all patients and communities they serve, none of the three CMS social drivers of health measures were endorsed by a consensus-based entity (CBE) before being put into the OQR. The AHA has generally urged that measures in federal programs be endorsed by a CBE to help ensure they are accurate, reliable, feasible and based on a strong foundation of validated evidence. Furthermore, hospitals and health systems have raised concerns about the soundness of the scoring methodologies, the redundancy of measure data reporting between inpatient and outpatient settings, and the clarity of measure implementation guidance. For these reasons, we believe it is appropriate to remove these measures at this time.

Proposed Adoption of Emergency Care Access and Timeliness eCQM. CMS proposes to adopt this measure related to ED throughput into the OQR beginning with voluntary reporting in CY 2027 and mandatory reporting in CY 2028 and beyond. An eCQM, the measure is informed by data extracted electronically from the hospital's EHR. The measure calculates the proportion of all ED encounters during a 12-month period where the patient experiences any one of the following:

1. Waited more than one hour after arrival in the ED to be placed in a treatment room/area for evaluation.
2. Left the ED without being evaluated.
3. Boarded in the ED for longer than four hours, as defined by the time between the Decision to Admit order and ED Departure for admitted patients, excluding encounters with ED observation stays.
4. Had an ED length of stay longer than eight hours, as defined by the time from ED arrival to ED physical departure, excluding encounters with ED observation stays.

Raw measure scores are standardized by ED case volume using z-scores; this process provides a comparison to the average for EDs with similar volumes (in strata of 20,000 ED visits). For CMS Certification Numbers with more than one ED, the adjusted scores are combined as a weighted average. Results are stratified into four groups based on age (18 years and older, under 18 years) and whether the patient received a principal diagnosis of mental illness (not including substance use disorder diagnoses).

The AHA agrees that tracking information related to wait times and length of stay in the ED is important for hospital and health system planning purposes. We also agree that ED boarding is a significant issue that affects patients' experience of care and that can make it more challenging to deliver the best outcomes for patients. At the same time, ED wait times, throughput and boarding are also broader systemic issues whose drivers are often well beyond the control of hospitals and health systems. By adopting this measure, we are concerned that CMS would be asking hospitals to shoulder the accountability for addressing this issue alone, but with often limited ability to make improvements in measure performance. Furthermore, we are concerned by several

other technical and conceptual shortcomings of this measure and believe further work is necessary for the measure to be ready for use in any national measurement program. **For these reasons, the AHA does not support the adoption of this measure into the OQR.**

Conceptually, the measure's specifications do not sufficiently capture the complexity of ED operations and those of the hospital care continuum. The measure relies upon time windows without a clear base in evidence to determine appropriate access, assumes that ED throughput is solely a factor of ED and hospital operations, and inadequately accounts for differences in patient case mix and volumes. The field currently lacks evidence-based guidelines on how to improve performance on the measure. However, we believe that a more proactive approach to addressing these issues would involve CMS working with the AHA, its members, policymakers and other stakeholders to investigate and implement effective solutions rather than using a generalized accountability measure.

The measure concept focuses on ED operations; the idea of "throughput" relies on the conclusion that other parts of the hospital can accommodate any ED volume at any time, and thus, inadequate ED operations are the lone driver of delays. This is erroneous. The reasons for variations in wait times in the ED are many, and several, if not most, of these drivers are outside of the control of the ED and the hospital as a whole. Admission times rely partly on the availability of staffed inpatient beds; patient turnover decisions elsewhere in the hospital, such as in the ICU, are made based on patient clinical needs. While initial triage in the ED is based on medical priority, delays in admission can occur after the initial evaluation as providers wait for insurance authorization.

As has been well documented by providers as well as by HHS OIG and congressional investigations, the prior authorization process used by MA and large commercial health plans places a significant administrative burden on hospitals and other providers. Perhaps more importantly, it is directly harmful to Medicare beneficiaries — at best delaying their care and at worst outright denying medically necessary treatment. Despite important steps taken by CMS in recent years to strengthen the oversight of MA plans' use of prior authorizations, providers have seen little meaningful change in MA plan behavior and no increased access for beneficiaries. Additionally, post-acute care providers still face challenges with MA plans listing them within their networks.

For these reasons, we are concerned that those hospitals that care for larger proportions of MA patients could perform worse on this measure because of decisions by an insurer to delay needed care and narrow their networks, and not because of the quality of care hospitals deliver. This situation could be especially problematic given that there remains variation in MA participation nationally. While it is true that in 2024, MA covered approximately 50% of Medicare beneficiaries, 21 states and the District of Columbia had MA rates under 50%, and 14 states had enrollment rates under 40%. For public reporting programs like the OQR to work in a fair manner, hospitals must be

assured that their measure performance is truly their own and not disproportionately influenced by factors beyond their control.

The proposed measure also does not account for other factors that are not solely within hospitals' control but could greatly impact ED throughput and boarding, and therefore, measure performance. Certain diagnoses may require specialist consultations, which can be difficult to garner in health professional shortage areas. A severe shortage of primary care in many communities means that conditions that could have been caught before they became emergent become serious and lead to larger volumes of emergency department visits. In addition, for medical issues that require prompt but not emergent attention, long wait times for primary care mean that patients have few choices other than an emergency department to receive care. In addition, our nation continues to face critical shortages of behavioral health care professionals, inpatient psychiatric beds and other supportive care for those who need behavioral health services. These issues impact the ability of hospital EDs to move patients to the next level of care and, therefore, how long a patient may spend in the ED. By assessing ED operations in a vacuum, the measure would not provide insight into the predominant drivers of long ED waits that are influenced by hospitals. Instead, it could simply be measuring the variation.

We are also concerned that the measure assesses performance based on timing, which is not well supported by evidence as having an impact on patient outcomes. The measure calculates the proportion of all ED encounters during a 12-month period where the patient experiences a wait or stay in the ED longer than a specified length of time (e.g., one hour after arrival to be placed in a treatment room for evaluation). However, it is unclear whether there exists evidence that these particular time windows — one hour, four hours, etc. — have any marginal influence on patient outcomes. Studies cited in the measure's documentation demonstrate that longer wait times are sometimes associated with poorer outcomes, but the various studies use definitions of ED length of stay ranging from two to 24 hours. We are unsure that it would be accurate to determine that a hospital that averaged 61 minutes to place a patient in a room for evaluation is "worse" than a hospital that averaged 59 minutes to do the same thing.

We appreciate that the measure has been updated since its assessment in the Pre-Rulemaking Measure Review process to stratify rates by age and mental health diagnosis. However, we are concerned that the latter stratification approach does not include patients with primary diagnoses of substance use disorder (SUD). Clinical and federal guidelines generally include SUD alongside mental illness in the category of behavioral health due to their frequently overlapping patient presentation. In other words, separating ED throughput rates acknowledges the unique considerations for treating patients with diagnoses of mental illness; patients with SUD diagnoses require those same considerations.

Finally, the field has yet to coalesce around best practices to improve performance on this measure. Several of the examples of changes in care for improvement provided in

the measure's supporting documentation are related to transformations of the care environment outside of the ED, such as the use of "hospital home" care models. Others are suggestions that would require significant investments, clinical research, and policy change, such as "changes to diagnostic testing/imaging processes" or "Triage interventions, including predictive models, use of clinicians, and others." Quality measures serve the dual purposes of informing patient decision-making and informing quality improvement efforts; due to the lack of targeted interventions demonstrated to influence measure performance, this measure is unlikely to fulfill those purposes.

Proposed Removal of Median Time from ED Arrival to ED Departure for Discharged ED Patients and Left Without Being Seen Measures. CMS proposes to remove these two measures beginning with the CY 2028 reporting period because their numerators overlap with those included in the proposed Emergency Care Access & Timeliness measure, and because they are both informed by burdensome chart abstraction.

The AHA supports the removal of these measures, regardless of the adoption of the Emergency Care Access & Timeliness measure. Like other measures recently finalized for removal from the OQR by CMS, these two measures have also lost endorsement by a CBE; the Median Time measure was actually recommended for removal from the OQR during the CBE Measure Set Review process, irrespective of the proposed adoption of the new ED Timeliness measure. Both measures lack evidence linking their use to improved patient outcomes. These measures do not offer valuable insight into hospital care and thus should be removed from the program even if they are not replaced by an alternative measure.

Proposed Modification of Excess Radiation Dose eCQM. CMS proposes extending the voluntary reporting period for this measure indefinitely. The measure was originally adopted in the CY 2024 OPPS/ASC final rule, beginning with voluntary reporting in CY 2025 and mandatory reporting beginning in CY 2027. As we noted in our comments on the FY 2024 inpatient PPS and CY 2024 OPPS proposed rules in which CMS originally proposed to adopt this measure into the IQR and OQR, we have questions and concerns about the feasibility of reporting the measure. In this rule, CMS acknowledges that they have indeed heard from the field regarding the financial burden and operational infeasibility of translating CT radiology data into standardized eCQM-consumable data for purposes of measure calculation. **For this reason, we support CMS' proposal to indefinitely extend the voluntary reporting period for this measure.**

Proposed Extraordinary Circumstances Exception (ECE) Policy Updates. For approximately a decade, CMS has had an ECE policy across its hospital quality reporting and value programs that enables the agency to grant reporting exceptions in the event of natural disasters, systemic problems with data collection systems and other extenuating circumstances that either affect hospitals' ability to submit data or significantly distort measure performance for reasons beyond hospitals' control. CMS

proposes several changes to the ECE policy. In this rule, CMS proposes to update regulations to specify that the agency can provide an extension of time to comply with data reporting requirements as part of an ECE. In addition, CMS proposes to shorten the time frame for requesting an ECE from 90 days to 30 days.

The AHA supports CMS' proposal to allow the agency to grant exceptions to one or more hospitals even if those hospitals have not requested an exception. The AHA also supports CMS' proposal to offer time extensions for data reporting for facilities experiencing an extraordinary circumstance and appreciates CMS' recognition of varying needs for different facilities and different circumstances. However, we are concerned that the agency may replace reporting exemptions with time extensions, regardless of the circumstances necessitating an ECE. The AHA understands and shares CMS' commitment to transparency on the quality of care delivered in hospitals. At the same time, we urge CMS to continue to grant complete reporting exemptions in the case of an extraordinary circumstance, and to use time extensions sparingly.

The AHA does not, however, support CMS' proposal to shorten the time frame for requesting an ECE. In the proposed rule, CMS states that shortening the time frame to request an exception would better align the hospital ECE policy with other CMS systems implementation requirements across all quality reporting programs. While this might be true for some — but certainly not all — quality reporting programs, we believe a 90-day window to request an ECE is necessary given the increasing frequency of, and devastation caused by, storms, cyberattacks and other emergencies. In the early days and weeks following these types of extraordinary events, hospitals and other health care settings often struggle just to stay operational and care for their patients and communities. Requiring hospitals to prioritize paperwork over patients just to get a one-time exception to reporting seems counter to the intended goals of the CMS quality reporting and value programs. We fear such a change to the process of requesting an ECE would divert critical staff at a time when they are needed most. Indeed, CMS did not finalize a similar proposal in the FY 2026 inpatient PPS final rule, instead allowing for 60 days to request an ECE. For these reasons, we urge CMS to retain its current policy and allow hospitals to request an ECE for up to 90 days following a disaster or other extraordinary event.

RFI: Measure Concepts Under Consideration for Future Years: Well-being and Nutrition. CMS seeks comments on tools and measures that assess overall health, happiness and satisfaction in life, and optimal nutrition and preventive care. The agency intends to use this input to inform future measure development efforts.

The AHA appreciates CMS' focus on whole-person care and on improving the health of all Americans. At the same, it is important to note that hospitals alone cannot address the broader challenges of nutrition and well-being. Indeed, making progress requires collaboration and resources from public and private sector partners. Hospitals and health systems often play a key convening role for these partners who have

implemented innovative strategies ranging from school-based mental health clinics to food pantries and other health-promoting activities. In some communities, public and private sector partners are willing, able and have the resources to bring to bear to address these challenges, but this is not the case everywhere. Yet, quality measurement programs like the OQR are inherently designed to assess the performance of hospitals and health systems alone. As CMS continues to explore measures of well-being and nutrition, we caution the agency against adopting measures that are scoped so broadly that they end up reflecting differences in the availability of community resources rather than true hospital performance.

ASCQR PROPOSALS

Proposed Adoption of the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery Patient Patient-Reported Outcome-Based Performance Measure (PRO-PM). CMS proposes to adopt this patient-reported outcome measure with voluntary reporting in CY 2027 and CY 2028 and mandatory reporting beginning in CY 2029. The measure was adopted for the OQR in the CY 2025 OPPS/ASC Final Rule.

The AHA does not support the adoption of this measure; if CMS moves forward with its proposals, we encourage the agency to maintain voluntary reporting indefinitely and to extend voluntary reporting of the measure in the OQR as well. Considering the recent addition of the patient-reported outcomes following elective primary total hip and/or total knee arthroplasty (THA/TKA) as well as additional Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey questions recently adopted in the FY 2025 inpatient PPS final rule and the recently mandatory (as of Jan. 1, 2024) Outpatient and Ambulatory Surgery (OAS) CAHPS survey, the AHA is concerned about the increasing burden on patients of the ever-growing list of provider survey questions they are being asked to answer. To be sure, hospitals and health systems deeply value the patient perspective on their care and use data from patient experience and PRO-PM measures across their efforts to make care safer, higher quality and more equitable. PRO-PMs are a newer measure type that carries important potential to capture whether patients are regaining function and activities that matter in their daily lives.

At the same time, such measures also require patients to provide a significant amount of information — often the same information multiple times. With the recent already adopted inpatient and outpatient surveys, not to mention individual CAHPS surveys from individual clinicians who were involved in an outpatient procedure, we worry that reliance upon patients for data production could affect survey response rates across the board. It also could lead to confusion among patients about what aspect of their care they are being asked to assess. This is especially true of this PRO-PM, which could potentially overlap with the PRO-PM for THA/TKA.

CMS argues in its proposal that the administration timeline of PRO-PM proposed in this rule "mitigates overlap" with OAS CAHPS and PRO-PM for THA/TKA — the Patient Understanding of Key Information PRO-PM survey would be administered between two and seven days post-procedure, whereas the OAS CAHPS is administered on the first day post-procedure with follow-up of non-respondents at 14 days, and the survey for PRO-PM for THA/TKA is administered up to 90 days before the procedure and 300-425 days following. While it is true that the surveys would not be administered on the exact same day, we do not believe this "mitigates" overlap, as the same patient could still receive survey after survey after survey in the span of three days of a surgical procedure.

In addition to the logistical challenges presented, this particular measure suffers from conceptual disadvantages. The name of the measure, Patient Understanding of Key Information, and the purpose of the measure, to evaluate the clarity of clinical information, are inconsistent. A patient's understanding of information presented to them certainly relies partly upon the completeness and articulation of the information; however, there are other factors, including general literacy and health literacy, not to mention the literacy of any proxy or caregiver who may complete the survey on the patient's behalf, that would influence the patient's evaluation. In other words, this measure does not evaluate the quality of information provided to the patient, but rather the patient's ability to comprehend it; PRO-PMs are inherently subjective, but this particular topic is assessed objectively elsewhere. Indeed, the study that CMS cites in the background of its proposal that identifies disparities in end-of-visit summaries between those provided in the inpatient and outpatient settings bases its conclusions on *documentation review* rather than patient responses. Similarly, the Transfer of Health Information to the Patient measure used in post-acute care quality reporting programs assesses the *content and timeliness* of medication profiles provided to the patient, family and/or caregiver at discharge.

The subjective nature of the response categories (Very, somewhat, and not) may pose challenges for providers to interpret as well. The survey does not provide details as to how the information could be clarified or what information was missing. Hospitals already work closely with their Patient and Family Advisory Councils to meaningfully improve their patient communications, and this measure is unlikely to provide additional insight into that process, especially as the survey informing the measure in question is to be administered anonymously (thus limiting opportunities for follow-up). Further, we have heard from our members that CMS' estimates on the costs to implement this measure, approximately $10,000 per ASC and $29,500 per HOPD, are low. **In summary, the AHA does not believe the burden of administering yet another patient survey is worth the shallow information gleaned from it.**

RURAL EMERGENCY HOSPITAL QUALITY REPORTING PROGRAM PROPOSALS

Proposed Adoption of Emergency Care Access & Timeliness eCQM. CMS proposes to adopt this measure related to ED throughput into the Rural Emergency

Hospital Quality Reporting Program (REHQR) beginning with optional reporting in CY 2027. The same measure is being proposed for adoption in the OQR and is described above. **The AHA does not support the adoption of this measure into the REHQR for the same reasons we do not support its adoption into the OQR.** Indeed, this measure is even less suitable for the REHQR, considering the unique nature of these rural facilities. Conceptually, there are many factors, such as weather or local transport modalities, that may lead REHs to appropriately hold patients in the ED. Logistically, the low volumes treated by these facilities likely would be incompatible with the measure's calculation methodology. In the OQR, CMS proposes to standardize scores on the measure by ED case volume in strata of 20,000 ED visits; according to MedPAC, in 2022, REHs averaged about 720 Medicare FFS ED visits (or about two per day). Not only would these low numbers make the measure's output statistically unreliable, but they would also likely not glean much useful information.

OVERALL STAR RATINGS METHODOLOGY PROPOSAL

To calculate a hospital's Overall Star Rating, CMS uses hospital performance on measures in five categories: Safety, Mortality, Readmissions, Patient Experience, and Timely & Effective Care. To have a score calculated for each category (or "group"), a hospital must report at least three measures in that category; in addition, to have an Overall Star Rating, a hospital must report at least three measures in either the Safety or Mortality group.

Based on analysis of the July 2024 calculation of Overall Star Ratings, CMS found that there was generally a strong relationship between hospital performance on measures in the Safety group and the hospital's Overall Star Rating (i.e., hospitals that had good scores on measures related to patient safety tended to also have higher star ratings and vice versa). However, the agency found that a small number of hospitals (14, or 0.5%, of all rated hospitals) had scores in the bottom quartile of performance on Safety measures and still received the highest Overall Star Rating of five stars. CMS therefore concludes that a hospital can be rated highly while delivering unsafe patient care and thus believes that a methodological change to increase the importance of the Safety measure group is appropriate.

To address this issue, CMS proposes making methodological updates to the Star Ratings in two phases. First, in 2026, CMS would limit hospitals in the lowest quartile of scores in the Safety group that were eligible to receive a score for that group (that is, hospitals that reported at least three measures in that group) to a maximum of four stars. Using this cap on stars as a transition to a permanent change, CMS would implement a blanket reduction in score of one star for hospitals in the lowest quartile of scores in the Safety group that were eligible to receive a score beginning in 2027. The minimum possible Overall Hospital Star Rating would remain one star.

The AHA does not support these methodological changes for several reasons. Patient safety has been and will remain a top priority for hospitals and health

systems, but making piecemeal updates to the Star Ratings calculations due to scores for 0.5% of hospitals is unlikely to better inform patients about their care choices. The AHA agrees that it is important to consider the safety of care provided at a hospital when choosing where to receive services. However, the changes proposed by CMS would likely further undermine the already challenging task of applying a single score to represent the quality of hospital care. As CMS has acknowledged in past work, the Overall Star Rating is not itself a comprehensive reflection of quality, but rather a reflection of hospital performance on the measures that the agency has chosen to include in the program. Further, the Overall Star Rating is not solely focused on Safety — indeed, the rating is informed by dozens of measures addressing other topics and issues that vary in importance to individual patients and providers. Because of these characteristics, the Overall Star Rating is not universally helpful or applicable to all patients in all circumstances. That is why CMS' own Care Compare website recommends that people searching for care "consider a variety of factors when choosing a hospital, like physician guidance about your care plan." In other words, the Overall Star Rating alone does not determine the optimal hospital, so changing the math so that the rating is more informed by the Safety measure group alone does not make certain higher-scoring hospitals safer.

We also have several logistical concerns with these proposals. In short, the existing methodological disadvantages of the Overall Star Rating program would be exacerbated by modifying just the Safety group. The measures included in the Safety group change over time as CMS adopts and removes measures from the IQR and OQR programs; in addition, performance in the Safety group does not reflect the same measures for each hospital. For example, Hospital A's Safety score may be based on its performance on measures related to central line-associated bloodstream infections, catheter-associated urinary tract infections and C. diff, while Hospital B's Safety score may be based on performance on measures related to TKA complications and surgical site infections regarding colon surgery or hysterectomy. Thus, increasing the weight of the Safety group to address this unique outcome exacerbates the lack of comparability between these hospitals and decreases the usefulness of the ratings in informing a patient seeking a hospital for colon surgery.

This result would be particularly concerning for facilities whose volumes and patient mix allow them to be scored on more measures in the Safety group. Such facilities could have a higher "exposure risk" stemming not from differences in quality of care, but instead from simply being scored on more measures. Comparing their performance directly to the facilities scored on fewer measures in the Safety group could result in inequitable comparisons because those other hospitals simply do not have sufficient volumes to calculate a statistically reliable score on some or all of the health care-associated infections measures. In other words, hospitals that can be scored on more safety measures could be at greater risk of losing a star compared to hospitals that do not have enough data to even calculate performance in the Safety category.

Finally, the AHA believes a major overhaul to the Overall Star Rating methodology to address an issue involving less than 1% of hospitals eligible to receive a rating is unnecessary at this time. Further, the change to the methodology would more likely affect hospitals receiving two and three stars than those receiving four and five stars, as there are more hospitals in the middle of the distribution of scores; if the existing methodology is functioning as intended, the performance of those hospitals should already be reflected in their star rating and thus modifying the methodology could artificially shift distribution.

The AHA appreciates that CMS is contemplating ways to improve the Overall Star Ratings methodology, and we are supportive of several of the changes the agency has incorporated over the past few years to make the ratings easier to understand. We would be interested in any further analysis CMS has on its modifications under consideration and their potential effects of the changes on different types of hospitals (e.g., large, freestanding, academic medical centers, etc.) or reporting groups. However, we do not support the approaches to emphasize the measures in the Safety of Care group as outlined in this proposed rule.

PROPOSED ASC PAYMENT SYSTEM UPDATE

For CYs 2019 through 2025, CMS adopted a policy to update the ASC payment system using the hospital market basket update. The agency proposes extending this policy through CY 2026. Therefore, for CY 2025, CMS would increase ASC payment rates by 2.6% for ASCs that meet the quality reporting requirements under the ASCQR Program.

The AHA remains opposed to this policy and CMS' proposal to extend it through CY 2026. Medicare payment should reflect providers' underlying costs and patients served. Hospitals and ASCs obviously have different costs and serve different patients. As such, it is inappropriate to use the hospital market basket to update payments for ASCs. **We instead recommend that CMS work expeditiously with ASC stakeholders to develop and implement a minimally burdensome way to collect ASC costs that could then be used to calculate an appropriate update mechanism**.

We are not alone in our continued concern in this area. Indeed, MedPAC has, since 2010, recommended that CMS collect ASC costs. In its March 2025 report, it states, "[h]owever, CMS has never required ASCs to submit cost data, and information about the quality of care has been of limited value. The Commission recommended that CMS require ASCs to submit cost data; in the absence of that data, the Commission has opted not to make an update recommendation since 2022. Instead, we provide a status report on ASCs."[76] MedPAC has suggested several streamlined cost-collection

[76] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch10_MedPAC_Report_To_Congress_SEC.pdf

processes that could be used to determine an appropriate input price index for ASCs, which CMS should consider.

PROPOSED CHANGES TO ASC COVERED PROCEDURES LIST

CMS proposes substantial revisions to its regulatory criteria used to evaluate potential additions to the ASC covered procedures list (CPL). This would include modifying its general standard criteria used to evaluate potential additions to the ASC CPL by retaining only the criteria that a procedure must be separately paid under the OPPS to be on the CPL. The remaining two general standard criteria that are proposed to be removed and placed into a new section of "nonbinding physician considerations for patient safety" are that the procedure is:

- Not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC.
- Such that standard medical practice dictates the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

CMS also proposes to eliminate five regulatory ASC CPL general exclusion criteria and move them to the new nonbinding physician considerations section. These are covered surgical procedures that do not include those surgical procedures that:

- Generally result in extensive blood loss.
- Require major or prolonged invasion of body cavities.
- Directly involve major blood vessels.
- Are generally emergent or life-threatening in nature.
- Commonly require systemic thrombolytic therapy.

The agency would thus retain regulatory authority to exclude only those surgical procedures that:

- Are designated as requiring inpatient care under the IPO list.
- Can only be reported using a CPT unlisted surgical procedure code.
- Are otherwise excluded from coverage.

As a result of these proposed changes, CMS proposes to add 276 surgery or surgery-like codes to the CPL that are not on the CY 2025 IPO list and add 271 surgery or surgery-like codes to the CPL that are proposed for removal from the IPO list in CY 2026.

The AHA opposes the proposal to modify the agency's process and criteria for adding and excluding surgical procedures to the ASC CPL. We are concerned

that these proposed changes to the ASC criteria substantially weaken the agency's oversight in determining whether surgical procedures may be safely performed in an ASC. Finalizing them would result in far more and higher-risk surgical procedures being covered in ASCs in a manner that could negatively impact Medicare beneficiary safety and quality of care. The current regulatory general inclusion and exclusion criteria serve two critical purposes. First, they are important patient safety guardrails intended to exclude from coverage those procedures that would pose a high risk of complications that ASCs are not equipped to handle. In addition, they allow appropriate surgical procedures to be added to the ASC CPL. We do not support CMS eliminating such meaningful patient safety guardrails. For example, the agency should not eliminate a criterion that prevents a provider who does not have emergency capabilities from conducting surgeries that are emergency or life-threatening in nature. **Therefore, the AHA recommends that CMS preserve the five general exclusion criteria in its regulations.**

Furthermore, although the AHA opposes CMS' proposal to eliminate the IPO list, as stated above, if the agency were to nevertheless finalize this policy, we also urge CMS not to add the 271 surgery or surgery-like codes that were on the IPO list as of Dec. 31, 2025, to the ASC CPL. In general, procedures that would be removed from the IPO list during the proposed three-year phase-out have not been evaluated for clinical appropriateness in an HOPD, let alone in an ASC. Several examples of these surgical procedures were discussed above in the AHA's comments on the elimination of the IPO list.

In addition, the AHA also opposes CMS' proposal to add 276 surgery or surgery-like codes to the ASC CPL that are not on the CY 2025 IPO list. CMS proposes these additions with only the most minimal of rationales. Notably, it justifies its proposal with generic statements regarding "the progress in medical practice and ASC capabilities" and that "*many* ASCs often undergo accreditation as a condition of state licensure and share *some* similar licensure and compliance requirements with hospitals" (emphasis added).[77] CMS not only fails to appropriately justify these additions, but in proposing the elimination of its current standard inclusion and exclusion criteria, it is putting Medicare beneficiaries at risk. For example, CMS did not provide any evidence that these procedures are not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, or that a beneficiary would not typically expect to require active medical monitoring and care at midnight following the procedure. In fact, CMS acknowledged that "several of the identified procedures may typically require hospital care that lasts beyond midnight," but notes patient selection could address that concern. For instance, consider: CPT code 20808 – Replantation, hand, (includes hand through metacarpophalangeal joints), complete amputation, CPT code 21184 – Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (e.g., fibrous dysplasia), with

[77] https://www.govinfo.gov/content/pkg/FR-2025-07-17/pdf/2025-13360.pdf, at page 33,717.

multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm and CPT code 27076 – Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum. For each of these services, the AMA's Relative Value Update Committee assigned a total service time of 11 hours or more, which includes the physician time specific to intra-service, immediate post-service and other hospital time.[78] **As such, not only would these procedures pose a significant safety risk to the beneficiary if done in an ASC, but also, given their duration, they would likely require active medical monitoring and care at midnight following the procedure.** These are just a few of the many procedures included among the 276 CMS proposed for ASCs that should not be performed in that setting for the safety of Medicare's beneficiaries.

Furthermore, although the AHA strongly opposes the proposed changes to the ASC CPL process and criteria, if the agency were to nevertheless finalize it, we urge it to work with clinical experts and other stakeholders to make commensurate changes to the ASC Conditions for Coverage (CfC) that account for the fact that these higher-risk services would be covered in the ASC setting. There are complications associated with any major surgery, such as anesthesia-related risks, allergic and other medication reactions, and those related to comorbid medical conditions. ASCs often are not equipped to handle such life-threatening events, and we anticipate that if CMS finalizes its proposal, many patients would be sent emergently from ASCs to the nearby hospital ED when such complications arise.

More specifically, in the 2019 Medicare and Medicaid burden reduction final rule, CMS weakened the CfC requirements that required a plan to be in place in the event such emergencies arise.[79] That is, it eliminated the requirement that ASCs have a written transfer agreement with a nearby hospital or ensure that its physicians have admitting privileges at a hospital. Instead, the agency now only requires ASCs to have a procedure for transferring to a hospital and to periodically provide the local hospital with written notice of their operation and patient population served. As a result, if a patient has a medical emergency that cannot be addressed within the capabilities of the ASC, it only needs to call an ambulance and send the crashing patient to the nearest hospital ED, without any further responsibility for the beneficiary's condition**. In light of the proposal to add so many complex, invasive surgical procedures to the ASC CPL, CMS should restore the CfC requirements regarding written hospital transfer agreements or physician admitting privileges at a hospital.**

Furthermore, with a broad expansion in the number and kinds of procedures that are proposed for addition to the ASC CPL, including procedures that may have never been furnished in this setting, even greater oversight is necessary to

[78] American Medical Association. (2025). *CPT® 2025 professional edition*. American Medical Association Press.

[79] https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-20736.pdf

protect Medicare beneficiaries. CMS should consider coordinating with clinical experts on enhancements to the anesthesia, emergency equipment and discharge planning standards for the ASC CfCs. We suggest several possible changes that may be worth pursuing for CY 2026, including:

- Making risk evaluations more prescriptive and including an attestation that an individual patient can safely undergo the procedure in an ASC.
- Requiring that an adequate number of nurses be on duty in the ASC.
- Requiring that staff certified to provide Advanced Cardiac Life Support be present in the ASC in the event of life-threatening emergencies.
- Adding specific CfC requirements that ASCs would need to meet for particular patient conditions or more complex and invasive surgical procedures.

Finally, in addition to the inherent risks associated with more complex services being performed in the ASC setting, beneficiaries may also unexpectedly face higher out-of-pocket costs for surgeries performed in an ASC than in an HOPD. This is because the beneficiary copayment for services provided in an HOPD is capped at the inpatient deductible amount, while the same is not true for services provided in an ASC. This is especially a concern because physician owners of ASCs are not subject to the Stark self-referral regulations and so may have a personal financial interest in performing surgery at an ASC instead of a hospital. **To ensure that beneficiaries are aware of this potentially increased financial liability, the AHA recommends that the ASC CfC patient rights section be revised to include a condition requiring that ASCs inform patients in writing, prior to their procedure, of their copayment obligation. This should include information that, by virtue of the services being performed in an ASC rather than an HOPD, they may incur higher out-of-pocket costs, and the difference in amount.**

PRICE TRANSPARENCY

CMS proposes significant changes to the hospital price transparency rule, particularly regarding further standardization of the hospital machine-readable files. **Hospitals and health systems are dedicated to improving price transparency and look forward to working with the administration on this important goal.** In addition to our specific comments on the changes proposed, we share some additional context and ideas for consideration.

The guiding principle of price transparency policies should be to provide patients with clear and accurate information to help plan for care. We are concerned that the emphasis on the machine-readable files, rather than the consumer-friendly shoppable service information, diverts attention away from the price transparency efforts that are most meaningful to patients.[80] A recent Morning Consult survey, conducted on behalf of

[80] https://www.aha.org/toolkitsmethodology/fact-sheet-price-estimator-tools

the AHA to assess consumer experiences with hospital pricing information, found that patients prefer price estimator tools to shoppable services spreadsheets when estimating potential medical costs, and a strong majority find them helpful in knowing where to seek medical care.[81] Recent focus groups conducted by NORC at the University of Chicago in partnership with the AHA found similar results. During the focus groups, which included 41 commercially insured adults with varying backgrounds and experiences, participants were shown demonstrations of both hospital cost-estimator tools and shoppable services files.[82] Compared to the spreadsheet of shoppable services files, focus group participants universally preferred the more user-friendly price estimator tools. Participants found the shoppable services files confusing and difficult to navigate. In addition, participants felt that price estimator tools more effectively provided the information they sought. **We encourage CMS to focus future efforts on the information that will best help patients understand and compare their expected costs prior to care.**

Given that some patient estimates may vary significantly from a patient's final bill, CMS has, to date, focused more heavily on the machine-readable file data. However, as discussed in our response to the recent CMS RFI, the machine-readable file data is no more "real" than the information provided by a price estimator tool and, in fact, it can be less accurate and even misleading in comparison.[83] Cost estimator tools are able to take into account how insurers commonly group services for purposes of payment and apply the patient's specific cost-sharing obligations, something that cannot be achieved by using the machine-readable files alone. The outsized focus on machine-readable file data can distract patients from the more intuitive tools that provide individualized, and therefore more accurate, estimates based on patients' cost-sharing requirements, their progress toward meeting their deductible, and other pertinent information such as patient demographics.

CMS should not discount the value of price estimates but instead consider taking steps to ensure that pre-service estimates are as accurate as possible. One way to do this would be to change benefit design requirements to reduce or eliminate cost-sharing that is calculated after the course of care is complete and instead rely solely on flat co-payments. That way, even if the total price varies, the patient portion remains the same and can be accurately estimated prior to care. Another alternative could be to remove providers from the cost-sharing collection process altogether and instead require insurers to be responsible for cost-sharing estimates and collections. This would incentivize more predictable, affordable and transparent health plan benefit design as insurers would likely adopt simpler cost-sharing requirements if they were at risk for patient non-payment as providers are today.

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[81] Ibid.
[82] Ibid.
[83] https://www.aha.org/lettercomment/2025-07-22-aha-comments-cms-rfi-hospital-price-transparency-accuracy-and-completeness

Finally, price transparency efforts would benefit from a comprehensive review of the numerous and sometimes conflicting requirements at both the state and federal levels.

We urge CMS to focus future efforts to reform price transparency on streamlining policies to reduce the risk of conflicting information, improving accuracy and alleviating costly administrative burden for both providers and insurers. The current landscape of pricing information is challenging for patients and employers to navigate and use effectively, and it adds excessive costs, confusion and workforce burden to the health care system.[84,85,86] Addressing the hospital's machine-readable files in isolation is misguided and only serves to add to the confusion and burden. For example, while CMS argues that the changes proposed here are intended to ensure better alignment of the hospital and insurer machine-readable files, the proposal will not align the hospital files with the current insurer files; nor has CMS proposed changes to the insurer files that would result in better alignment. Without concurrent policy changes to the insurer price transparency rule, these changes only serve to add additional burden to hospitals without achieving CMS' goal of greater alignment across hospital and insurer files.

Our specific comments on the agency's proposals follow.

New Allowed Amount Data Elements. CMS proposes requiring several new machine-readable file data elements, beginning Jan. 1, 2026, in instances when payer-specific negotiated charges are based on a percentage or algorithm. The new data elements include the median allowed amount, the 10th percentile allowed amount, the 90th percentile allowed amount and a count of all allowed amounts. CMS proposes requiring a specific methodology to calculate these values, including a set lookback period and data source, to hopefully create more consistency across calculations and better alignment with the insurer data. These data elements would replace the "estimated allowed amount" in the machine-readable files, which was added in the final CY 2024 OPPS/ASC rule and went into effect Jan. 1, 2025. CMS argues these changes are necessary to address ongoing confusion around the "estimated allowed amount," citing recent audits and public feedback received since the value went into effect.

At a time when hospital resources are stretched thin, we are concerned about the additional burden the new requirements would place on hospital staff, especially given the short timeline for implementation. We appreciate the administration's focus on freeing the health care system from burdensome administrative requirements. Unfortunately, the hospital machine-readable file requirements are already excessively burdensome, and CMS' proposed changes would significantly increase the level of administrative burden without corresponding benefits. Under the current standard

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[84] https://www.aha.org/fact-sheets/2023-02-24-fact-sheet-hospital-price-transparency
[85] https://www.aha.org/system/files/media/file/2023/09/aha-comments-on-cms-outpatient-and-ambulatory-surgery-prospective-payment-system-proposed-rule-for-cy-2024-letter-9-8-23.pdf
[86] https://www.aha.org/system/files/media/file/2021/03/aha-comments-on-no-surprises-act-price-transparency-provisions-letter-3-16-21.pdf

format, hospitals typically need at least three months to update their machine-readable files each year. Given the complexity of the files, most hospitals contract with vendors to help create their updated files, which can cost between $10,000-30,000 per hospital. Hospitals that develop their annual files without vendor support report needing 5-30 full-time equivalents, depending on the number of hospital sites and insurer contracts, to pull together the updated data from disparate sources, perform necessary calculations, comply with file formatting requirements, perform quality assurance and validate the files using the CMS validator tool. Because most hospitals update their files on an annual basis at the start of the year, they will already be in the process of pulling together their files when CMS releases the final OPPS CY 2026 rule, and it will not be possible to implement the new data elements before Jan. 1, 2026.

In addition, given the added complexity of the new data elements, many hospitals that have previously been able to update their files independently anticipate needing to hire vendors going forward should CMS finalize this proposal. Hospitals expect additional vendor fees of $20,000-$30,000 just to meet these new requirements on such a tight time frame. CMS understood the need for sufficient implementation time when finalizing the “estimated allowed amount” data element in the OPPS CY 2024 final rule, allowing hospitals more than one year to implement the change. **We strongly request that CMS allow hospitals at least one year to adopt the new data elements. In addition, CMS should provide funding or the equivalent technical support to hospitals that are unable to afford vendors, given that the requirements are becoming too complex to comply with for many hospitals, particularly those that are small and/or rural.**

In addition, we have several concerns with the methodology proposed by CMS. First, CMS requires hospitals to report the count of all allowed amounts used for the new calculations. While we understand that this provides the user with important information about the robustness of the analyses, we are concerned that small-value claims could conflict with the Health Insurance Portability and Accountability Act (HIPAA) de-identification standards and longstanding CMS data suppression policies. Typically, federal agencies require data masking or data suppression for datasets with counts below 12. Not only can outliers significantly impact analyses done with such a small dataset, but individuals looking at the data could access HIPAA-protected information in instances when the count is too small. This is particularly problematic in small, rural settings and for low-volume items and services that are unlikely to have significant claim counts during the CMS proposed look-back period. **We recommend CMS return to the previous guidance, allowing hospitals not to include values derived from 11 or fewer data points.** If CMS does not return to previous guidance, hospitals should be exempt from including an exact count of allowed amounts in instances with 11 or fewer data points and instead be allowed to encode “<12” as the “count of allowed amounts” value.

CMS also proposes a 12-month lookback period for the allowed amount data from the time the machine-readable file is posted, assuming the contract terms do not change over the course of that period. In instances when the contract terms change, the

lookback period would be even shorter, from the date of the contract change to the date the file is posted. While we appreciate CMS' attempt to standardize the calculation, we are concerned that this limited lookback period will not provide sufficient data for most calculations. As discussed previously, hospitals generally need to pull data three months before they post it. Additionally, hospitals typically experience claims adjudication lags of several weeks, which would render data in the weeks leading up to the data pull unusable as well. Effectively, this would result in hospitals only being able to use approximately 6-8 months of the allowed amounts, if not less. In many instances, this will result in incredibly small counts of allowed amounts, which will not provide meaningful data due to the issues discussed previously. **To ensure hospitals have enough claims data for these analyses, we recommend that CMS finalize a lookback period of at least 18 months.**

Finally, CMS proposes non-standard calculations for the median and percentile values, defining those as the higher of two observed values in the case of an even count of allowed amounts, rather than the average of the two. Not only is the standard methodology of taking the average of the two statistically valid, but this deviation from the standard calculation will require hospitals to implement custom formulas for these calculations rather than the out-of-the-box formulas. This will add an additional and unnecessary administrative burden to hospitals as they create their files. **Should CMS finalize this proposal, we recommend that CMS allow hospitals to calculate these new values using the standard methodology.**

New Attestation Language. CMS proposes an update to the required attestation language, replacing the current affirmation statement declaring that a hospital has made a good faith effort to ensure that the machine-readable file data is true, accurate and complete. For the reasons that follow, we believe that this proposal is misguided and ultimately misses the mark. First, it fails to account for the reality of hospital billing, which depends, in significant part, on insurer behavior and calculations, which in turn depend on a host of factors that cannot be easily calculated by a third party. Second, the attestation in its current form risks exposing hospitals to undue risk or liability, and current assurances that this requirement falls outside the scope of the False Claims Act are insufficient to allay hospital and health system concerns.

Although, as the proposal contemplates, different hospitals and health systems negotiate different agreements with different payors, publicizing those negotiated rates and frameworks or even the full text of every single one of their contracts (which would raise serious anticompetitive legal risks) would not be sufficient to enable a patient to calculate their final bill. Critically, that bill is dependent not only on the negotiated rate for the service, but on a host of other factors, including insurers' own proprietary algorithms, whether the service was provided in conjunction with other services, the applicability of any volume discounts or stop-loss amounts, as well as other unique features of a patient's insurance plan. It is therefore impossible for hospitals to *unilaterally* provide sufficient information to enable patients to undertake these calculations on their own. That impossibility dooms this proposal. After all, the

imposition of an impossible requirement is, by definition, arbitrary and capricious. *See Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991) ("Impossible requirements imposed by an agency are perforce unreasonable."); *Messina v. U.S. Citizenship & Immigr. Servs.*, No. CIV.A. 05CV73409DT, 2006 WL 374564, at *6 (E.D. Mich. Feb. 16, 2006) ("It is arbitrary and capricious to require compliance with a regulation when compliance is impossible."). At the very least, CMS' failure to consider the operability of this requirement is arbitrary and capricious as well. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("[A]n agency rule would be arbitrary and capricious if the agency … entirely failed to consider an important aspect of the problem.")

Moreover, the proposed modification to the machine-readable file affirmation statement — and in particular the affirmation that the hospital "*has provided all necessary information available to the hospital for the public to be able to derive the dollar amount"* — risks ensnaring hospitals and health systems in a trap. In the first instance, there will always be some additional piece of information that an individual could use to more accurately calculate a particular charge. Particularly given the variation among insurers, among plans in a single insurer, and even among beneficiaries of a single plan, hospitals can never be entirely certain that they have provided "*all* necessary information . . . for the public to be able to derive the dollar amount." Second, as explained above, "all necessary information available to the hospital" simply may not be sufficient to calculate the dollar amount. Given insurers' penchant for proprietary systems and calculations, there may be nuances that are not readily available to or shareable by hospitals. Though CMS contends that "strengthening this attestation... would better assure [CMS] and machine-readable file users that the data encoded is accurate and complete," changing the attestation does not change the reality on the ground. Instead, this proposal creates a classic "trap for the unwary." We propose retaining the existing "good faith effort" attestation as it better aligns with the information hospitals can be expected to provide, without raising the risk of liability for the failure to identify every single piece of information ("all") that may exist. At the very least, the agency must account for this problem by clarifying the reasonable scope of "all necessary information."

Finally, CMS states that these new affirmation requirements will not "alter our view that the False Claims Act is outside the scope of this proposed rule just as we expressed at 88 FR 82086 that it was outside the scope of that final rule with comment period." But this is cold comfort to hospitals. Although we appreciate CMS' perspective that noncompliance with this new requirement would not implicate the False Claims Act (FCA), there is no evidence that the Department of Justice (DOJ), regulators or judges would agree. To ensure that these new attestation requirements do not generate FCA challenges, CMS must articulate *why* the rule would not give rise to FCA liability. Perhaps the DOJ could co-issue a policy stating that it would move to dismiss all FCA cases based on this attestation requirement. *See* 31 U.S.C. § 3730(c)(2)(A). Short of that, however, no signatory can be confident that an attestation will not be used against him or his institution by an aggressive prosecutor or whistleblower.

CMS also proposes to add a new general data element to the machine-readable file, *attester name*, which would be defined as the hospital CEO, president or alternative senior official designated to oversee the creation of the machine-readable file and attest to its accuracy and completeness. The agency offers no support for requiring "hospitals to encode the name of the chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data in the machine-readable file." At best, it states that this requirement "will provide the necessary reassurance that hospitals have provided in their machine-readable files meaningful, accurate information to users of the machine-readable files about their standard charges for health care items and services." But as noted, this is a significant imposition of time on senior-level executives. The agency nowhere considers these burdens, nor does it provide any support for why other employees within a hospital would not provide "meaningful, accurate information." This conclusory reasoning cannot withstand scrutiny. Absent actual support for this assertion, the agency must not add to the burdens of hospital leaders and instead replace this requirement with a requirement to share hospital contact information that is actively monitored by hospital employees. CMS should trust the good faith of others within the hospital who are far closer to the information and can verify its accuracy far more easily than someone higher on the organizational chart with broader responsibility.

Enforcement. To expedite civil monetary penalty payments, CMS proposes to reduce the penalty amount in certain instances when a hospital admits to a price transparency violation and waives its right to an administrative law judge (ALJ) hearing. CMS argues that this change is necessary as most of the 27 hospitals that have received monetary penalties to date have opted for an ALJ hearing. While we appreciate the options for lower penalty amounts and administrative simplification, it is important to recognize that the vast majority of enforcement actions are closed before reaching the penalty stage, and efforts to improve the earlier enforcement processes would yield greater results.

Between Jan. 7, 2021, and March 31, 2025, CMS engaged in over 6,000 audits and enforcement actions related to hospital price transparency compliance as part of over 3,000 unique cases.[87] Of these more than 3,000 cases, almost 1,000 were found to comply at the time of the audit, and another nearly 2,000 came into compliance following CMS action. Most of the roughly 300 remaining cases were opened in 2025, and the hospitals in question are now actively working to come into compliance.

As a result of a steep learning curve, many of the initial issues CMS identified required weeks, or sometimes months, for hospitals to resolve. The issues identified now are typically minor, and AHA has heard from hospitals that cases are often opened and closed within hours. We understand that the relationship between CMS and hospitals

[87] https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/hospital-price-transparency-enforcement-activities-and-outcomes

throughout this process has been positive and collaborative, and we appreciate CMS' willingness to work with hospitals to achieve compliance.

There are steps that CMS could take, however, that would help streamline the auditing and compliance process. **To begin, we recommend that CMS notify hospitals following a positive audit to let them know that they are in compliance with the requirements.** It appears that CMS tracks this based on the publicly available enforcement data, but hospitals are not currently receiving this information directly from CMS.

In addition, we have heard from many hospitals that more clarity in CMS' initial warning notices would be helpful. In many instances, delays in responding to compliance concerns are due to confusion around what issue CMS is identifying. **We encourage CMS to provide more detail about what specific issues were found during the audits, so that hospitals can more promptly address them.**

Finally, we encourage CMS to direct additional auditing and enforcement resources to the Transparency in Coverage requirements. The insurer data holds great potential to advance CMS' price transparency objectives and allow for better streamlining, but these benefits will not be realized until the data is more usable and reliable.

MARKET-BASED MS-DRG RELATIVE WEIGHT DATA COLLECTION AND METHODOLOGY CHANGE

CMS proposes to collect market-based payment rate data on the Medicare cost report for cost reporting periods ending on or after Jan. 1, 2026. Hospitals would use the payer-specific negotiated charges from their most recent machine-readable file published before the submission of their cost report to identify the median payer-specific negotiated charge that they negotiated with their MA organizations. The agency proposes to then use the submitted information to set inpatient PPS relative weights beginning in FY 2029. **This proposal raises serious policy and legal concerns. Because of this, we strongly urge its withdrawal.**

As explained below, this proposal ignores critical issues that arise with the use of MA negotiated rates. For example, using them to set Medicare FFS Medicare Severity-Diagnosis-Related Groups (MS-DRG) relative weights would be circular, because MA rates often are based on Medicare FFS weights. In addition, although the agency states that these rates are market-based, most MA markets scarcely resemble competitive marketplaces. This is evidenced by the substantial challenges hospitals have in being adequately compensated by MA plans, including because of utilization management practices, like prior authorization, which are not widely used in the Traditional Medicare program. Such challenges would not exist in a truly competitive marketplace. Further, CMS has not analyzed, and cannot analyze, the impacts of its proposed policy because the underlying data are not currently maintained in the format CMS would require and

have not been collected or reported historically. Blindly using newly generated data to overhaul the MS-DRG relative weights is unwise, given the substantial negative impacts it could have for hospitals and the communities they serve. Beyond these policy concerns, as detailed in the following sections, this proposal is not authorized by the cited statutory authority and, in fact, conflicts with other statutory provisions. And because this proposal would impose a significant new regulatory burden with no rational basis, it is arbitrary and capricious, even independent of the statutory legal infirmities.

Additionally, CMS has set forth specific changes to the Medicare cost report that would effectuate its proposal to collect median payer-specific negotiated charges that hospitals negotiated with their MA organizations. Given that the proposed policy raises serious policy and legal red flags, we also urge CMS to withdraw its changes to the cost report.

Policy Basis for Proposal. CMS has offered no sound justification for the imposition of a significant new regulatory burden. In fact, the agency cannot know either the impact of the new burden or even what the data will show because the data it has requested is not already being collected in this format. The proposal presumes without justification that the burden of the collection effort is minimal and fails to appreciate the complex processes required to collect and process new forms of information. In the proposed rule, CMS asserts that this proposal will "result in less administrative burden overall because hospitals would already be required to calculate and disclose these data in compliance with the hospital price transparency requirements." (90 FR 33476, 33805). But CMS cannot know whether this estimate is reasonable because these data are not currently maintained in the format CMS would require and have not been collected or reported historically. In addition, and as discussed elsewhere, the proposed price transparency data elements that would be carried over for this proposal would be excessively challenging for hospitals to generate. Utilizing the data for this additional purpose does not reduce our concerns about the significant administrative burden of the price transparency changes included in this proposed rule.

In addition, when CMS first proposed this policy in the FY 2021 inpatient PPS proposed rule, MedPAC cautioned that using MA-negotiated rates to set Medicare FFS MS-DRG relative weights would be circular for the same reason mentioned above: because MA rates are often based on Medicare FFS weights. MedPAC also noted that market-based prices embed plan-specific contracting dynamics (e.g., network leverage, utilization management, quality bonuses and risk-sharing) and data limitations that do not reliably reflect the statutory standard of relative hospital resources used.[88] These concerns are as valid today as they were when MedPAC first raised them.

Indeed, CMS' focus on median MA negotiated rates embodying market-based prices further overlooks the fact that most MA markets scarcely resemble competitive marketplaces. According to a recent KFF analysis, virtually every county was either

[88] https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/07072020_fy2021_ipps_medpac_comment_v2_sec.pdf.

highly concentrated (79%) or very highly concentrated (18%) in 2024, and 90% of Medicare beneficiaries lived in a county where just one or two insurers controlled at least half of MA enrollment.[89] In markets where a dominant payer faces limited competition, negotiated rates may reflect the enhanced bargaining power of the payer facing limited competition rather than the efficient delivery of care in a truly competitive market. Anchoring FFS weights to MA prices would entrench a feedback loop between MA and FFS payments and risk mispricing services unrelated to resource costs.

Remarkably, CMS notes in the proposed rule that "[w]e continue to believe that payer-specific charges negotiated between hospitals and MAOs and Medicare inpatient PPS payment rates are generally well-correlated" (pg. 33807). If that is in fact the case, it invites the question of why imposing a new burden on providers by replacing the longstanding existing process with this new process and reporting system is necessary or advances any policy goals at all. Moreover, as detailed above, the circularity of this new approach — looking to negotiated rates, which are often based on MS-DRG calculations, as a new and independent source of truth for MS-DRG calculations — is deeply problematic from an operational standpoint as well. These policy failings are bad enough, but the agency's failure to properly consider them violates the APA as well. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("[A]n agency rule would be arbitrary and capricious if the agency … entirely failed to consider an important aspect of the problem.").

Proposal's Impact on Hospitals and Communities. CMS has not analyzed, and cannot analyze, the impacts of its proposed policy because, as noted above, the underlying data are not maintained in the format CMS would require and have not been collected or reported historically. **Blindly using the proposed data to overhaul the inpatient PPS relative weights in FY 2029 is especially ill-advised, given the substantial negative impacts it could have for hospitals and the communities they serve.** While seeking to use any not-yet-existent data to make such a significant change to one of Medicare's largest payment systems is concerning, proposing to use data that is so likely to be unreliable for the purpose it is meant to serve is particularly alarming. CMS also fails even to acknowledge the potential risks of this model — detailed further below — that it noted in 2021 when it first proposed this mechanism for calculating MS-DRG weights. Specifically, as detailed in the price transparency section of this letter, the AHA is greatly concerned about the quality of the new price transparency data elements due to CMS' proposed methodology. The methodology proposed likely will lead to insufficient sample sizes for most calculations, leading to overweighting of outliers and imprecise results.

When the agency last overhauled the inpatient PPS relative weights for FY 2007, it extensively analyzed the impacts of its proposal. Specifically, it included a lengthy

[89] https://www.kff.org/medicare/issue-brief/most-medicare-advantage-markets-are-dominated-by-one-or-two-insurers/.

section entitled “Impact of Refinement of DRG System on Payments” that included impacts organized by:

- Medical DRGs versus surgical DRGs.
- Selected high-volume DRGs.
- Heart, orthopedic or surgical specialty of hospitals.
- Indirect Medical Education/Disproportionate Share Hospital (DSH) status.
- Urban or rural location of hospital.
- Region of hospital.
- Bed size of hospital.
- Teaching status of hospital.
- Medicare payor mix of hospital.[90]

Some of these impacts were substantial. For example, rural hospitals were estimated to see a decrease in payment of 3.1%. Hospitals with fewer than 50 beds and hospitals with 50 to 100 beds were expected to experience decreases in payment of 5.2% and 2.8%, respectively.

The fact that CMS’ proposal to again overhaul the relative weights could potentially result in negative impacts of this magnitude is concerning on its own, but is particularly concerning given that MedPAC projects that 2025 Medicare margins will be *less than negative 13%, resulting in more than 20 straight years of Medicare paying below costs*.[91] Even among relatively efficient hospitals, the median Medicare margin will remain about negative 2%. Indeed, margins for these hospitals have been negative for the past seven years.[92] The AHA’s own analysis showed that Medicare underpayments reached $100 billion in 2023.[93]

These underpayments cannot be sustained, let alone made worse. Yet it is not outside the realm of possibility that CMS’ relative weight proposal would cut inpatient payments to certain hospitals by another 3%, 4% or 5% as the previous proposal did. **Potentially implementing cuts of this magnitude, especially blindly, without analysis or discussion, and on top of hospitals’ already substantially and persistently negative Medicare margins, is completely inappropriate and would greatly hurt their abilities to provide critical medical care to help ensure the well-being and stability of their communities.**

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[90] 71 FR 24020.
[91] MedPAC. (2025). https://www.medpac.gov/wpcontent/uploads/2025/03/Mar25_Ch3_MedPAC_Report_To_Congress_SEC.pdf
[92] Excluding COVID relief funds.
[93] AHA. The Cost of Caring: Challenges Facing America’s Hospitals in 2025 (April 2025). https://www.aha.org/costsofcaring.

Finally, as noted above, CMS notes that it believes that "payer-specific charges negotiated between hospitals and MAOs and Medicare IPPS payment rates are generally well-correlated" (pg. 33807). As evidence, the agency cites research that "hospital payments by MAOs are much more similar to Medicare FFS levels than they are to commercial payment levels." We note, however, that MAO payments being more similar to FFS rates than to commercial rates is not the same as MAO payments being "well-correlated" with FFS rates. This again underscores that examining the data in reality, rather than in theory, is critical. Nevertheless, even if CMS' assertion of the rates being well correlated did happen to be true, and therefore the impacts of its proposal are potentially minimal, as noted above, it raises the question of why this proposal is necessary or how it advances any policy goals at all. Indeed, it seems to be a solution in search of a problem, again making it inappropriate for implementation.

Statutory Authority for Proposal. In addition to these significant policy concerns, this proposal also raises substantial legal questions. Specifically, it is likely unauthorized by the cited statutory authority and precluded by other existing statutory requirements. Moreover, CMS' proposal fails to sufficiently explain this dramatic shift in the regulatory framework, rendering this effort arbitrary and capricious.

CMS cites two statutes as providing the requisite authority to require hospitals to report their MA-negotiated rates on Medicare cost reports:

- Sec. 1815(a) **[**42 U.S.C. 1395g**]**, which provides in relevant part: "[N]o such payments shall be made to any provider **unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider** under this part for the period with respect to which the amounts are being paid or any prior period."
- Sec. 1833(e) **[**42 U.S.C. 1395l**]**, which provides: "No payment shall be made to any provider of services or other person under this part **unless there has been furnished such information as may be necessary in order to determine the amounts due such provider** or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Yet, as the statutory language makes clear, the data requested must be necessary "to determine the amounts due such provider" for the provision of services. Accordingly, these provisions are commonly understood to authorize data collection specifically pertinent to determining the payment owed to providers for items or services rendered. *See, e.g.,* Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS), 85 FR 70358-01 ("Section 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under Medicare Part B unless there has been furnished such information as may be necessary to determine the amounts due such provider or other person under that part. To process claims and determine payment for items and services under Medicare, we need a way to appropriately identify the items and services billed.")

To be sure, these provisions give HHS broad discretion to collect information. But broad discretion is not unlimited discretion. Even a broad authority is limited by the terms of the law. The statutory language at issue here makes clear that this broad authority is confined to the types of information necessary *to determine payment to providers for services provided*. Absent congressional authorization, this authority cannot be extended to require providers to submit market data about rates negotiated with MAOs (which, as explained above, are often themselves based on IPPS rates rather than an independent set of factors) and that provide no information about the types of care provided by a hospital or the costs of providing that care. Under the plain language of the statute, there must be some nexus between the information demanded and the determination of amounts due to a provider for services rendered; here, the purported link is too attenuated to authorize the proposed requirement. And to the extent that CMS may try to lean on statutory ambiguity to permit its expansive interpretation, that effort will be all the more difficult post *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 412 (2024), especially because the agency has previously indicated the need for a relationship between the information requested and a particular payment. *See* Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS), 85 FR 70358-01 ("Section 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under Medicare Part B unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under that part. In order to process claims and determine payment for items and services under Medicare, we need a way to appropriately identify the items and services billed.").

Conflicts with Other Statutory Requirements. This proposal to use MAO market-based data to calculate MS-DRGs conflicts with the existing statutory requirement to use a resource-based weight to calculate MS-DRGs, underscoring that this request is entirely outside the scope of the cited authority. Specifically, Sec. 1886(d)(4)(B) [42 U.S.C. § 1395ww] provides: "For each such diagnosis-related group the Secretary **shall assign an appropriate weighting factor which reflects the relative hospital resources** used with respect to discharges classified within that group compared to discharges classified within other groups." The following subsection, Sec. 1886(d)(4)(C)(i) further provides: "The Secretary shall adjust the classifications and weighting factors established under subparagraphs (A) and (B) … to reflect changes in treatment patterns, technology …, **and other factors which may change the relative use of hospital resources**."

CMS repeatedly refers in the proposed rule to "MS-DRG relative weights" and cites to Sec. 1886(d)(4)(B) in its discussion of this proposal, and yet seems to altogether ignore the fact that the "relative weights" it seeks to determine concern the relative weight of hospital resources required for the treatment of different conditions. Congress expressly required that these MS-DRG calculations be based on the relative use of hospital resources in treating different conditions — not payment rates negotiated with MAOs or

any other market-based factors that offer no indication of the relative hospital resources used to treat different conditions. CMS acknowledged this very point when it implemented the current DRG system in 2007. *See* Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, 71 FR 23996, 24004 ("Congress recognized that it would be necessary to recalculate the DRG relative weights periodically to account for changes in resource consumption. Accordingly, section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually . . . to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.").

Arbitrary and Capricious Standard. Independent of the statutory frailties, this unacknowledged and unjustified pivot in regulatory approach is arbitrary and capricious. The current MS DRG process — the reasons for which CMS carefully articulated in its 2007 rulemaking — has worked well for nearly 20 years and understandably has engendered substantial reliance interests in that time. The reliance by MAOs on the existing system to inform their reimbursement rates is further evidence of that. Moreover, CMS has been reimbursing hospitals for care for 40 years without requiring this kind of negotiated rate information. Although the Supreme Court has clarified that an agency need not show that a new policy is better than an old one, "**[s]ometimes it must — when, for example, its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account."** *FCC v. Fox Television Stations, Inc.,* 556 U.S. 502, 516 (2009). CMS has violated this principle by failing to sufficiently explain the reason for this dramatic change.

The history here is instructive. For FY 2007, CMS shifted its approach to MS-DRG rate-setting calculations in response to recommendations made by MedPAC, as described in that rulemaking. 71 FR 23996, 24004. Specifically, the FY 2007 proposed rule explains at length the MedPAC recommendations for specific changes to the calculations to improve accuracy and the steps CMS took to assess and analyze the proposals in support of potential implementation. See 71 FR 23996, 24004 et seq:

- "We also indicated that we planned to further consider all of MedPAC's recommendations and thoroughly analyze options and their impacts on the various types of hospitals in the FY 2007 IPPS proposed rule. Following the publication of the FY 2006 IPPS final rule, we contracted with 3M Health Information Systems to assist us in performing this analysis."
- "In performing this portion of the analysis, we studied hospital cost report data, departmental cost-to-charge ratios (CCRs), MedPAR claims data, and HSRV weighting methodology. Our intention in undertaking this portion of the analysis was to find an administratively feasible approach to improving the accuracy of the DRG weights."
- "As we present below, we believe that the recommendations made by MedPAC, or some variants of them, have significant promise to improve the accuracy of the

payment rates in the IPPS. For instance, the percent of DRGs with payment-to-cost ratios between 0.95 and 1.05 will increase substantially from adoption of these recommendations."

- "In the following sections II.C.2. through C.6. of this proposed rule, we present our analysis and discuss a number of issues related to the MedPAC recommendations. We also present the estimated impacts of implementing the recommendations and conclude with a specific proposal for FY 2007 and some proposed intended actions for implementation for FY 2008. We also are soliciting comments on other possible proposals or actions in FY 2007, FY 2008, or a combination of both."

In stark contrast, the current proposed rule offers little reasoning to support such a dramatic shift in policy. Though CMS repeatedly declares that it wants to reduce reliance on the hospital chargemaster for setting DRG weights because of concerns about inflated prices on the chargemaster, it has failed to demonstrate how this untested proposal, utilizing heretofore uncollected and unanalyzed data, will accomplish that goal. Moreover, the calculations address *relative* weights, rather than absolute numbers, so even if chargemaster numbers were in fact inflated across the board — a notion that AHA contests — the calculation should not be undermined by that. But CMS merely asserts without basis that to reduce reliance on the hospital chargemaster, it has determined that using the payer-specific negotiated charges for MAOs would be best. *See, e.g.*, 90 FR 33476, 33807 ("we believe it would be appropriate to propose the use of hospitals' median payer-specific negotiated charges for MAOs, to be collected on the Medicare cost report."), 90 FR 33476, 33808 ("the collection of this market-based data on the Medicare cost report would allow for the adoption of a market-based strategy to determine the appropriate weighting factors to reflect the relative hospital resources used with respect to hospital discharges"). This conclusory explanation is insufficient.

VIRTUAL SUPERVISION OF CARDIAC REHABILITATION, INTENSIVE CARDIAC REHABILITATION, PULMONARY REHABILITATION SERVICES AND DIAGNOSTIC SERVICES FURNISHED TO HOSPITAL OUTPATIENTS

In CY 2025, CMS extended virtual supervision flexibilities for CR, ICR services and PR services and diagnostic services. Specifically, it allowed direct supervision to be furnished via two-way, audio/visual communication technology (excluding audio only) for these services. In this rule, CMS proposes to extend these virtual supervision flexibilities for OPPS *permanently*.

The AHA strongly supports the proposed permanent extension of virtual presence to satisfy direct supervision requirements by interactive telecommunications technology. This critical flexibility has supported improved access to care for patients in underserved areas.

COMMENT SOLICITATION ON PAYMENT POLICY FOR SOFTWARE AS A SERVICE

The AHA recognizes the pivotal role that health technology plays in care delivery today and its potential to transform the patient and provider experience in the future. From artificial intelligence (AI) to mobile apps, software as a service (SaaS) technology can support reduced administrative burden and improved efficiency for patients, caregivers and providers. Moreover, we believe that this technology has the potential to address some of the prevalent challenges confronting the health care ecosystem today, including supporting provider burnout and staffing shortages driven by administrative burdens.

The use cases and approved SaaS applications continue to expand over time. The FDA has approved over 1,200 AI-enabled medical devices, including over 140 in 2025 alone.[94] Recognizing the benefits of certain AI tools to improve patient experience and drive efficiencies, hospitals and their outpatient departments have adopted tools in new and innovative ways. For example, AI is augmenting the accuracy and efficiency of X-ray and MRI reviews in hospital outpatient settings. AI can detect and alert clinicians to subtle changes in tissue images, which is crucial for early disease detection.

We applaud CMS for acknowledging the continued evolution of new software-based technologies, like AI applied in outpatient settings, and the desire to consider updated methodologies to appropriately reimburse for these services.

Factors to Consider When Setting Payment Rates. Implementing new technologies and standards often requires significant financial investment and workflow changes for health care providers. Ensuring appropriate reimbursement for services can support wider adoption of these tools and ultimately support improved access to services. **While we have appreciated the efforts to update reimbursement for new technologies, historical OPPS payment for SaaS has not fully accounted for the costs of these services.** This includes payment as an ancillary service as well as the New Technology APCs.

In general, updates to Medicare outpatient hospital payment have been inadequate as many hospitals — especially those in rural and underserved communities — operate under challenging financial pressures. Furthermore, the budget-neutral aspect of payment increases has meant that increases in certain services have resulted in cuts in others. While we support “rightsizing” of payment for SaaS, this should not come at the expense of other services. Also, geographic differences must be accounted for, as certain areas (like rural areas) may have additional infrastructure barriers to implementing SaaS services. Updates to payment should not further exacerbate the

[94] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

"digital divide," where rural and other underserved areas have less access to digital services.

As such, there are a variety of factors that CMS should consider when setting payment rates for these services, since the costs associated with developing, deploying and maintaining SaaS tools like AI extend beyond the software. Examples of cost factors that should be considered include:

- **Clinical time for validation.** AI-enabled tools are used to augment — not replace — human capacity. In fact, these tools still require a significant amount of human direction, such as when developing treatment plans and supervising outcomes. For example, while an AI-enabled tool may recommend a particular course of treatment, ultimately, a clinician is still making the final decision in consultation with patients and their caregivers. Reimbursement should account for the time required to validate AI outputs.
- **Maintenance.** SaaS tools require stakeholders to engage in routine maintenance and post-deployment testing to ensure the ongoing integrity of tools. Maintenance may include technology vendors, developers and providers.
- **Cybersecurity insurance.** While the expansion of SaaS offerings holds tremendous promise, there are also potential risks from a cybersecurity perspective. According to U.S. government reporting, the most significant cyber threats targeting U.S. critical infrastructure, including health care, originate from noncooperative foreign jurisdictions.[95,96,97,98] Cross-border hacking incidents, which result in the theft of protected health information (PHI) and ransomware attacks targeting health care, have increased dramatically, rising nearly tenfold since 2020. Most PHI data breaches reported to Office for Civil Rights (OCR) were the result of hacking incidents targeting non-hospital health care providers, including third-party service and software providers. The rise in frequency and severity of cyberattacks accompanying the expansion of SaaS tools has driven increased cybersecurity premiums. Reimbursement models should account for this. Just as CMS factors malpractice into payment (e.g., malpractice RVUs in the Physician Fee Schedule), we encourage the agency to consider rising cybersecurity insurance costs.
- **Software and storage fees.** These costs also include software licenses, as well as costs for data storage. SaaS offerings generally rely on large data sets, which also require servers. We encourage CMS to consider the costs for maintaining this underlying data infrastructure.

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[95] https://www.dni.gov/files/ODNI/documents/assessments/ATA-2025-Unclassified-Report.pdf
[96] https://www.ic3.gov/AnnualReport/Reports/2024_IC3Report.pdf
[97] https://usun.usmission.gov/remarks-at-a-un-security-council-briefing-on-ransomware-attacks-against-hospitals-and-other-healthcare-facilities-and-services/
[98] https://www.cisa.gov/topics/cyber-threats-and-advisories/nation-state-cyber-actors

Quality and Efficacy of SaaS. Patient safety is a hospital's top priority, and hospitals and health systems are committed to ensuring quality and efficacy for tools impacting patient care. The AHA has several recommendations regarding evaluation of quality and efficacy of SaaS tools.

First, the AHA encourages payment for maintenance of SaaS tools to support the time required for ongoing evaluation of efficacy. We recognize the importance of ongoing testing to ensure the integrity of such services. As mentioned above, that is why we encourage CMS to account for maintenance when calculating reimbursement rates for SaaS, which can support execution of post-market testing.

To support ongoing maintenance, we also encourage the agency to work with other agencies (like the FDA, Assistant Secretary for Technology Policy and OCR) to develop policies to promote data transparency sources and weights. The closed source (or "black box") nature of many AI systems makes it hard for hospitals and health systems to identify flaws in the models that might produce incorrect analyses and recommendations.

Second, we encourage appropriate payment for clinical validation to account for clinical time needed to review AI recommendations. AI-enabled tools should not make final decisions that would deny or otherwise restrict access to care or coverage. The clinical time required to validate AI outputs should be accounted for.

Finally, we encourage the agency to work with other agencies like the FDA to streamline the evaluation of the quality and safety of Software as a Medical Device (SaMD). The FDA's SaMD regulations require testing of the safety and efficacy of AI-enabled medical devices through a pre-market submission program. As the administration considers approaches to streamlining this evaluation, we encourage the agency to consider end-user burden and take steps to minimize it.

INDIAN HEALTH SERVICE AND TRIBAL HOSPITALS

Currently, the Indian Health Service (IHS) and tribal outpatient departments are excluded from the Medicare OPPS and are paid the Medicare outpatient hospital all-inclusive rate (AIR). The IHS determines the AIR from cost reports and updates the rate annually. However, IHS and tribal hospitals have increasingly provided higher-cost drugs along with more complex and expensive services, such as cancer-related services. Therefore, beginning on Jan. 1, 2025, CMS began separately paying IHS and tribal hospitals for high-cost drugs furnished in HOPDs through an add-on payment in addition to the AIR. CMS proposes to continue this policy in CY 2026. **We support this proposal.**