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September 15, 2025

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

Re: 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 (RIN 0938-AV51) (July 17, 2025)

Dear Administrator Oz:

On behalf of the Suburban Hospital Alliance of New York State, which represents hospitals and health systems on Long Island and in the Hudson Valley, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) hospital outpatient prospective payment system and ambulatory surgical center payment system (OPPS) proposed rule for calendar year (CY) 2026.

We offer comment on the proposal to accelerate recoupment of 340B funds, conduct a drug cost acquisition survey, extend site-neutral payment policy for drug administration services at grandfathered hospital outpatient departments (HOPDs), phase out the inpatient-only (IPO) list, collect market-based payment rate information on the Medicare Cost Report and require hospitals to make public their standard charges.

Taken together, these proposals combined with another inadequate payment update will significantly worsen the financial condition of hospitals by widening the gap between Medicare reimbursement and the cost of providing care and creating new administrative burdens. Hospital and health system finances continue to be stressed by inflationary pressures that sharply exceed those in the economy generally. This is most evident in the healthcare labor market, which continues to face acute shortages that are expected to persist for the next decade or longer. In a statewide survey conducted last fall, New York hospitals reported that between 2019 and 2024, contract labor expenses doubled, and total labor expenses grew 36.4 percent. This exceeds general inflation by more than 13 points.

The increases in other goods and services are disproportionately impacting hospitals as well. In that same survey, hospitals across the state reported that pharmaceutical prices had increased 83 percent, supplies 36 percent and energy costs by 25 percent. The general rate of inflation for this period was only 23 percent. Proposed tariffs on medical devices and pharmaceuticals or active pharmaceutical ingredients will worsen these stresses. Hospitals

will only fall farther behind relative to inflation in 2026 given the proposed marketbasket update.

PROPOSAL TO ACCELERATE THE TIMELINE OF CLAWBACK OF 340B FUNDS

The Suburban Hospital Alliance strongly opposes CMS's proposal to accelerate the clawback of funds under $42 \ 8 \ 419.32(b)(1)(iv)(B)(12)$. The American Hospital Association has explained many times why any clawback is unlawful and therefore never should have been finalized. We need not repeat those lengthy arguments here. Instead, we endorse the AHA's legal analysis and urge the agency to reconsider its position. Consequently, CMS should rescind subsection 419.32(b)(1)(iv)(B)(12) altogether because the agency lacks statutory authority for any such clawback on any timeline.

If CMS persists with this unlawful clawback, it should not accelerate the existing timeline. When it codified a 16-year timeline in the Final Remedy Rule, CMS 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." In suddenly changing course, CMS now asserts that it "insufficiently accounted for" what it calls the "main premise of the Final Remedy rule" — the need to return 340B hospitals to their financial position had CMS never implemented its illegal policy in the first place. According to the proposed rule, a six-year time frame "better balances that goal and [its] budget neutrality obligations against hospital burden and reliance interests."

This analysis gets the balancing completely wrong because it does not adequately account for changes on the burden/reliance interest side of the equation. First, 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 that 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.

Like all hospitals and health systems, New York's suburban hospitals make planning decisions about budgets based on what they expect to occur in future years. They therefore began planning for this clawback as soon as CMS announced it in 2023. As we have previously commented, the final Medicare inpatient and outpatient marketbasket updates in recent years have been woefully inadequate. When payment updates fail to keep up with the inflationary pressures that providers face, even the previously finalized 0.5 percent clawback is significant to hospitals' financial planning. Relative to inflation, Medicare reimbursements are already declining year over year.

It therefore makes no difference that those rate reductions have not yet gone into effect. If the agency finalizes this unexpected increase from 0.5 percent to 2.0 percent just two months before 2026, the budgets our member hospitals have produced based on that 0.5 percent figure will be undermined, 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."

Second, CMS also must better account for the burden that the proposed accelerated timeline will inflict on hospitals and health systems. An annual increase from 0.5 percent to 2.0 percent

will meaningfully impact their margins. Last year New York hospitals reported a median statewide operating margin of 0.0 percent. Any negative adjustments send operating margins into the red. Relatedly, the agency's balancing fails to account for adverse financial trends since 2023. As stated above, hospital costs have increased and are continuing to trend in the wrong direction.

In addition, the proposed rule fails to consider the recent passage of Public Law No. 119-21, referred to as the One Big Beautiful Bill Act (OBBBA), which will have direct, adverse impacts on our member hospitals' finances. When fully implemented, we anticipate an \$8 billion annual loss to New York hospitals. Accordingly, 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 or these other financial trends.

All in all, the proposed rule errs by conducting a new balancing that completely fails to account for the burdens that it will impose on hospitals. Although the proposal does not sufficiently explain how CMS conducted its balance, it appears as if the agency simply kept the burdens constant from the Final Remedy Rule and readjusted the value of the perceived need to achieve budget neutrality. The final rule must discuss and account for these changes on the reliance interest/burden side of the balance. When it does, the balancing will tip sharply against accelerating the timeline.

Finally, the proposed rule fails to consider a sufficient number of alternatives. It states that the agency considered an even faster clawback period (3 years). But the agency nowhere explains why it arbitrarily chose that alternative when others exist. The agency easily could have considered timelines between 6 and 16 years. It could have—and should have—considered periods longer than the existing 16-year timeframe to better account for post-OBBBA realities. The agency must consider these reasonable alternatives and explain why, in its view, six years achieves the needed balancing better than these other timeframes.

Ultimately, the Suburban Hospital Alliance urges CMS to abandon this unlawful, unwise proposal. Because any clawback is illegal, it should rescind subsection 419.32(b)(1)(iv)(B)(12) altogether. If CMS continues to disagree with that legal analysis, it should maintain or extend the existing clawback timeline.

MEDICARE OPPS DRUG ACQUISITION COST SURVEY

CMS also should abandon its proposal to conduct a drug acquisition cost survey of all hospitals paid under the OPPS. The survey will inflict 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 CY 2027.

Cost acquisition surveys consume considerable financial and personnel resources. The proposed rule estimates that each hospital will require 73.5 hours to complete the survey at an approximate cost of \$4,000. In its 2006 report to Congress about the lessons learned when conducting hospital acquisition cost surveys, the Government Accountability Office stated that the surveys "created a considerable burden for hospitals." Based on our members' experience with surveys of this kind, this is true. And based on that same experience, we assure you that the proposed rule grossly underestimates both the cost and time required to complete any survey.

Ultimately, however, the main reason for abandoning 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 Medicare payments already lag far behind the costs hospitals incur for providing care to Medicare beneficiaries -- covering just 83 cents for every dollar spent by hospitals in 2023, resulting in more than \$100 billion in underpayments. As Medicare inpatient rates continue to lag general inflation, hospitals are subject to an effective payment cut. An additional Medicare cut resulting from this proposed survey would be unsustainable. Thus, if the goal of this survey is to cut Medicare payments, the survey should not be conducted at all.

The agency also must consider that any survey results are of limited value, and the specific questions that CMS asks only highlight those limitations.

First, CMS asks whether it "should make responding to the survey a mandatory requirement of all hospitals paid under OPPS," but CMS identifies no statutory authority for such a mandatory requirement. Section 1833(t)(14)(D)(iii), the only statute cited in that discussion, certainly does not provide the agency with the authority to mandate hospital responses. All it does is set forth the requirements for a survey. If Congress wanted to require hospital participation in a drug acquisition cost survey or allow the Department of Health and Human Services Secretary to take enforcement action for a non-response, it would have done so, as it has in other contexts. Absent such statutory authority, and absent any way to enforce a manufactured response-requirement, the agency must explicitly acknowledge in the final rule that responding to 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. However, 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." Put simply, 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 manufactured interpretations of non-responses would yield inaccurate data that is in no way "statistically significant." If the agency is truly concerned about the lack of responses from hospitals, it should not issue a survey in the first place.

PROPOSAL TO IMPLEMENT THE "PFS-EQUIVALENT" PAYMENT RATE FOR DRUG ADMINISTRATION SERVICES IN EXCEPTED OFF-CAMPUS HOPDS

Suburban Hospital Alliance opposes CMS' proposal to reduce the payment for drug administration services furnished in excepted off-campus HOPDs to the "PFS-equivalent" rate of 40 percent of the OPPS rate. We also oppose the option the agency raises of possibly expanding such site-neutral cuts to other services furnished in HOPDs. We urge the agency to withdraw these proposals from consideration.

CMS lacks statutory authority to reduce payments to excepted HOPDs to the level of nonexcepted HOPDs, particularly in a non-budget-neutral manner. The 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. However, legal developments since that decision cast significant doubt on its continued viability and, more importantly, undermine the agency's reliance on Section 1833(t)(2)(F). Specifically, the proposed rule fails to grapple with three critical legal deficiencies in relying on *American Hospital Association v. Azar*. These are: (1) with the Supreme Court's overturning of the *Chevron* framework, the agency's interpretation of Section 1833(t)(2)(F) is not entitled to deference and does not provide the Department of Health and Human Services (HHS) with statutory authority to implement this policy; (2) more recent Supreme Court decisions like *Biden v. Nebraska* and *West Virginia v. EPA* have strongly emphasized that agencies cannot fundamentally rewrite statutes, but HHS is doing precisely that in using Section 1833(t)(2)(F) to completely evade the OPPS system; and (3) the proposed rule does not address Section 603 of the Bipartisan Budget Act of 2015, which does not cover HOPDs established before November 2015.

In addition, CMS fails to consider other explanations for the increase in drug administration. Indeed, we disagree that higher payments for these services are incentivizing hospital acquisition of independent physician offices and leading to an "unnecessary increase in the volume of services." This assertion ignores many factors that have led physicians to abandon private practice and seek employment in HOPDs, including inadequate payments from both Medicare and private payers, as well as excessive administrative burdens.^{1,2}

Next, CMS' proposal equates care provided in hospital clinics with less complex care provided at independent physician offices and other free-standing sites. However, such care is not equivalent, and current OPPS payment rates account for these significant differences. As an example, unlike independent physician offices, hospitals are required to take many additional measures to make certain 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.³

Finally, the proposal does not account for the fact that HOPDs serve a sicker, more clinically complex and more economically vulnerable Medicare population.^{4,5} A study conducted for the American Hospital Association by KNG Health Consulting found that beneficiaries receiving care in HOPDs are more likely to be under 65 and disabled, dual eligible, from lower-income areas, have multiple chronic conditions and have already needed emergency and inpatient care.

¹ <u>https://www.aha.org/system/files/media/file/2023/06/fact-sheet-examining-the-real-factors-driving-physician-practice-acquisition.pdf</u>

² https://www.ama-assn.org/press-center/press-releases/medicare-trustees-warn-payment-issue-s-impact-access-care

³ https://www.aha.org/system/files/media/file/2023/11/aha-ashp-letter-opposing-site-neutral-legislation-11-14-2023.pdf

 ^{4 &}quot;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
5 "Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices: Updated Findings for 2019-2024", KNG Health Consulting, LLC, September 2025

PROPOSAL TO ELIMINATE THE IPO LIST OVER THREE YEARS

We also strongly oppose CMS' proposal to eliminate the IPO list over three years. The IPO list was created to protect beneficiaries. Many of its services are complicated and invasive surgeries that may involve multiple days in the hospital, special protections against infections, and significant rehabilitation and recovery periods, requiring the care and coordinated services of the inpatient setting of a hospital.

Instead, Suburban Hospital Alliance recommends that CMS continue its standard process for removing procedures from the IPO list. The agency should consider setting general removal criteria based upon, for example, average length of stay, peer-reviewed evidence or patient factors such as age.

PROPOSAL TO COLLECT MARKET-BASED PAYMENT RATE INFORMATION BY MS-DRG ON THE MEDICARE COST REPORT FOR COST REPORTING PERIODS ENDING ON OR AFTER JAN. 1, 2026

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 prior to the submission of their cost report to report the median payer-specific negotiated charge that they negotiated with their Medicare Advantage (MA) organizations. The agency proposes to then use the submitted information to set inpatient PPS relative weights beginning in FY 2029.

This proposal contains serious policy and legal deficiencies. Because of this, we strongly urge its withdrawal. Specifically, this proposal would impose a significant new regulatory burden with no rational basis and ignores critical issues associated with the use of MA negotiated rates to set Medicare fee-for-service MS-DRG relative weights.

Furthermore, CMS has not and cannot analyze the impacts of its proposed policy because the underlying data are not currently maintained in the format CMS would require. Blindly using MA data to overhaul the inpatient PPS relative weights is improper, and we are very concerned about the substantial negative impacts for our hospital and the communities we serve. Given these shortcomings, if finalized, the proposal would be arbitrary and capricious because CMS cannot sufficiently explain the dramatic potential shift in the regulatory framework.

Finally, the proposal is likely not authorized by the cited statutory authority; in fact, it is precluded by other existing statutory requirements.

PROPOSAL TO REVISE THE REQUIREMENTS FOR HOSPITALS TO MAKE PUBLIC THEIR STANDARD CHARGES AND CMS' ENFORCEMENT OF HOSPITAL PRICE TRANSPARENCY REGULATIONS

Our member hospitals are committed to advancing price transparency and share the Administration's goal of giving patients clearer, more actionable cost information. While certain refinements to the transparency rule are useful, CMS should focus on policies that directly help patients rather than increasing administrative burden without improving understanding of costs.

Attestation Concerns

CMS proposes updating the machine-readable file attestation language, requiring hospitals to affirm they have provided "all necessary information" for the public to derive service prices. We believe that this proposed update to the affirmation statement is unnecessary and problematic. Most importantly, 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. We urge CMS to retain the current "good faith effort" attestation, which reflects what hospitals can realistically provide.

In addition, CMS proposes to require CEOs or other senior executives to sign the attestation. This would be unnecessarily burdensome. We ask that the agency not add to the burdens of hospital leaders; instead, 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. **Therefore, we encourage the agency not to finalize this proposal.**

Allowed Amount Data Elements

In 2026, CMS would require hospitals to publish median, 10th percentile and 90th percentile allowed amounts, plus a count of the claims used for the calculations. We have several concerns regarding the methodology, and we point you to the comments from the American Hospital Association regarding issues related to patient privacy, the lookback period for data, and the methodology for calculating medians and percentiles.

In addition, we strongly request that CMS allow hospitals at least one year to adopt the new data elements. At a time when hospital resources are stretched thin, we are concerned about the additional burden the new requirements would place on their staff, especially given the short timeline for implementation.

Thank you again for the opportunity to comment. If you have any questions, please do not hesitate to contact me.

Sincerely,

1s/ Wendy D. Darwell

Wendy D. Darwell President and CEO