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Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency Data; Prior Authorization; Accrediting Organization Deeming for Emergency Medical Treatment and Labor Act; and Notices of Closure of Teaching Hospitals and Opportunities to Apply for Available Slots

Dear Administrator Oz,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Calendar Year (CY) 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Payment System Proposed Rule. IDSA is a global community of 13,000-plus clinicians, scientists and public health experts working together to solve humanity's smallest and greatest challenges, from tiny microbes to major outbreaks. Infectious diseases remain among the most pressing challenges facing health care systems, frequently causing and complicating chronic disease in patients of all ages. ID physician care has been proven to improve patient outcomes, reduce hospital length of stay and reduce costs.

We are pleased to support several components of the CY 2027 OPPS and ASC Proposed Rule as well as offer suggestions to strengthen some provisions, as detailed below.

OPPS and ASC payment update

IDSA supports CMS' proposal to update CY 2027 payment rates under both the OPPS and the ASC payment system by 2.4% for hospitals and ASCs that meet applicable quality reporting requirements. We recognize that this update, grounded in the proposed hospital inpatient market basket increase of 3.2% less than the productivity adjustment of 0.8%, appropriately reflects rising input costs and helps ensure that outpatient payments keep pace with inflation and the evolving demands of providing hospital outpatient and ambulatory surgical services. We note that CMS estimates total payments to OPPS providers will reach approximately $110.9 billion in CY 2027, an increase of approximately $9.5 billion over CY 2026, while payments to ASCs will increase by approximately $520 million over CY 2026. Continued, predictable annual updates are essential for hospitals and affiliated specialized outpatient departments, including those providing complex infectious diseases management and infusion services, to maintain workforce stability, clinical infrastructure and uninterrupted patient care.

However, we flag for CMS' awareness that the hospital community continues to express concern that the proposed market basket update may not adequately capture the full extent of rising costs for hospitals, including ongoing inflationary pressures, workforce challenges and increasing supply expenses. We further caution that the 2.4% update masks significant variation across providers and services. As detailed below, many hospitals will experience the net effect of this update alongside the proposed 340B drug payment adjustment and the accelerated 340B remedy offset, and IDSA urges CMS to remain attentive to the

cumulative impact of these policies on hospitals' ability to sustain critical outpatient infectious diseases services.

OPPS drug policies

340B drug payment policy

CMS proposes to pay separately payable drugs acquired under the 340B Program at ASP –33.4%, based on the results of the OPPS Drug Acquisition Cost Survey, rather than the current payment rate of ASP +6%. CMS estimates this proposal would reduce beneficiary copayments by approximately $1.15 billion in CY 2027 and would apply the adjusted rate to separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired through the 340B Program, with limited exceptions. CMS proposes to continue paying non-340B drugs generally at ASP +6% while it continues evaluating the survey results, to provide no add-on payment for overhead and handling, and to exempt rural Sole Community Hospitals, children's hospitals and PPS-exempt cancer hospitals from the adjustment. CMS also considered an alternative methodology of ASP –28% based on Health Resources and Services Administration (HRSA) 340B ceiling price data and seeks comment on that approach. We recognize that, because this proposal is implemented in a budget-neutral manner, the reduction in 340B drug payments would be redistributed to other OPPS items and services rather than removed from the system altogether. **IDSA is concerned, however, that shifting these funds away from drug payments and tying them instead to other services would sever the direct link between 340B savings and the covered entities that generate them, undermining the ability of safety-net hospitals to sustain the under-reimbursed infectious diseases services these resources currently support.** Given the magnitude of this proposed change on safety-net hospitals and the patients they serve, IDSA urges CMS to reconsider this proposal, particularly as demand for these hospitals' services is anticipated to increase as a result of the deep cuts to the Medicaid program and the rise in health insurance costs.

IDSA appreciates CMS' statutory obligation to align OPPS drug payments with hospitals' average acquisition costs and their interest in reducing beneficiary cost-sharing. **At the same time, we are deeply concerned about the magnitude of the proposed reduction, a swing of more than 39 percentage points, from ASP +6% to ASP –33.4%, and its potential to significantly destabilize the safety-net hospitals that disproportionately care for patients with serious and complex infectious diseases who are uninsured or are covered by public programs.** The 340B Program enables covered entities to stretch scarce federal resources to reach more eligible patients and to provide essential services, including HIV and viral hepatitis care and treatment, outpatient parenteral antimicrobial therapy, management of multidrug-resistant infections and antimicrobial stewardship.

The impact of 340B savings on outpatient HIV care illustrates precisely what is at stake. Covered entities routinely reinvest 340B savings into the full HIV care continuum, from testing and linkage to care through case management, adherence support and retention services that are essential to achieving and sustaining viral suppression. These investments produce measurable results: Ryan White HIV/AIDS Program providers, which rely heavily on 340B savings, keep approximately 89.7% of their clients virally suppressed, well above the national average of roughly 65.9% for all people living with HIV, and have used 340B savings to extend care to tens of thousands of additional patients.[1] This is not merely a matter of clinical quality. A durably suppressed, undetectable viral load renders HIV effectively untransmutable, a finding endorsed by the Centers for Disease Control and Prevention as 100% effective at preventing sexual transmission and validated by landmark clinical trials. Viral suppression therefore functions as one of our most powerful public health tools, directly reducing new HIV infections while sparing the health system the substantial downstream costs of acute care, hospitalization and lifelong treatment of newly infected individuals. Conversely, a payment change that erodes the 340B savings sustaining these programs risks a rise in patients whose virus is not suppressed, with foreseeable consequences: greater HIV transmission, higher rates of avoidable hospital admissions and materially higher costs of care. **IDSA urges CMS to weigh these public health and fiscal consequences carefully, as any short-term budgetary savings from the proposed reduction could be substantially offset by the downstream costs of undermining a demonstrably effective model of HIV care.**

IDSA is particularly concerned that the proposed rate rests on an acquisition cost survey with limited response rates. CMS reports usable data from only approximately 28.6% of 340B hospitals, yet the agency has proposed the deepest reduction within its own sensitivity range of roughly ASP –29.9% to ASP –33.4**%. We urge CMS to adopt a more conservative and better-substantiated payment rate, one that does not overstate the discounts hospitals actually**

[1] Gay, Bisexual Men Increasingly Agree: HIV 'Undetectable Equals Untransmittable.'" National Institutes of Health, U.S. Department of Health and Human Services, 1 Apr. 2025, www.nih.gov/news-events/news-releases/gay-bisexual-men-increasingly-agree-hiv-undetectable-equals-untransmittable.

realize and that fully accounts for the pharmacy overhead, handling and storage costs of acquiring and administering complex antimicrobial and biological therapies. For this reason, IDSA also urges CMS to reconsider its proposal to provide no add-on payment for overhead and handling. The statute authorizes such an adjustment, and eliminating it risks systematically underpaying hospitals relative to the true cost of furnishing these drugs.

Should CMS proceed, IDSA supports the proposed exemptions for rural Sole Community Hospitals, children's hospitals and PPS-exempt cancer hospitals, and we urge CMS to retain these exemptions and to refrain from revisiting them in future rulemaking, given the vulnerable populations these hospitals serve. We further recommend that CMS consider additional flexibilities or a transition period for safety-net and teaching hospitals that may be disproportionately affected, and that the agency closely monitor the impact of any final policy on patient access to essential infectious diseases and HIV therapies and related services. **With respect to the alternative of ASP –28% based on HRSA 340B ceiling price data, IDSA does not endorse this or any other reduction that fails to reflect hospitals' true acquisition and handling costs; we note only that, to the extent CMS remains committed to a downward adjustment, an approach grounded in objective, regularly updated ceiling price data would be less disruptive than the survey-based methodology CMS has proposed. Our overriding recommendation, however, is that CMS reconsider the magnitude of any reduction and adopt a payment rate that preserves the stability of 340B safety-net hospitals and the patients who rely on them.**

Finally, IDSA appreciates the operational rationale for the proposed billing modifiers (JG, TB and the new modifier XX) beginning Jan. 1, 2027, but we urge CMS to minimize the associated administrative burden. The requirement to append modifier XX to all separately payable non-340B drug claims, in particular, would impose new reporting obligations on every OPPS provider. We recommend that CMS provide clear guidance, adequate lead time and technical support well in advance of implementation, and that the agency confirm the modifiers will not inadvertently disrupt claims processing or patient access to time-sensitive antimicrobial and biological therapies.

340B remedy payment offset

Effective Jan. 1, 2027, CMS proposes to increase the annual reduction to the OPPS conversion factor for non-drug items and services from 0.5% to 3.0% to continue recouping the budget neutrality adjustments associated with the former 340B payment policy. CMS estimates the revised adjustment will recover the remaining $7.769 billion by the end of CY 2029. **While IDSA recognizes CMS' obligation to resolve outstanding financial matters consistent with statutory budget neutrality requirements and court orders, we are concerned about the magnitude and pace of the proposed sixfold increase in the annual offset, from 0.5% to 3.0%, and its impact on non-drug service payments, including those supporting critical infectious diseases care. This accelerated recoupment would compress a recovery originally scheduled to extend to CY 2041 into a window ending in CY 2029, concentrating a substantial reduction in non-drug payments over just a few years.** Notably, this reduction applies broadly to all affected OPPS hospitals, not only to 340B participants, even though the increased payments being recouped were distributed across all OPPS hospitals during CYs 2018 through 2022.

Given ongoing resource constraints and mounting pressures on outpatient care infrastructure, particularly for hospitals serving high-risk, complex or underserved patient populations, such an abrupt increase in the offset may jeopardize operational stability, staffing and patient access to essential infectious diseases services. We urge CMS to weigh carefully the trade-offs of a faster recoupment period and to consider a more gradual approach, such as the 2.0% annual reduction on which CMS also seeks comment, or retention of the existing 0.5% reduction, that would better preserve the integrity of care delivery while still achieving the agency's mandated financial objectives. **Should CMS proceed with the 3.0% reduction, we recommend robust monitoring for unintended consequences and consideration of targeted flexibilities for safety-net and teaching hospitals that may be disproportionately affected.** It is imperative that efforts to restore payment equilibrium do not inadvertently undermine care for vulnerable beneficiaries with complex infectious diseases.

IPPS payment

Request for information on separate IPPS payment for domestic procurement of personal protective equipment and essential medicines

CMS seeks comment on potential approaches to provide separate Inpatient Prospective Payment System (IPPS) payments for the additional resource costs hospitals incur when procuring domestically manufactured personal protective equipment (PPE) and essential medicines. This request builds on CMS' existing voluntary payment policies for

domestic NIOSH-approved surgical N95 respirators and for buffer stocks of essential medicines maintained by small, independent hospitals, and contemplates expanding eligibility to additional forms of domestic PPE, including gloves and gowns, and to certain FDA-approved essential medicines with domestic finished dosage form production.

IDSA strongly supports CMS' continued attention to strengthening the domestic supply of PPE and essential medicines, which are foundational to emergency public health preparedness and to the day-to-day practice of infectious diseases. The supply chain disruptions of early 2020 demonstrated how shortages of respirators, gloves, gowns and critical medicines directly compromise infection prevention, clinician safety and patient care. Infectious diseases physicians rely on a stable supply of PPE to protect health care personnel and patients during the care of individuals with transmissible infections, and on an uninterrupted supply of generic antibiotics and sterile injectables, many of which have experienced recurrent shortages over the past decade, to treat serious infections effectively.

IDSA is especially supportive of CMS' proposal to prioritize non-substitutable sterile injectables and generic antibiotics in developing the potential list of eligible essential medicines, as these products are both clinically indispensable and particularly vulnerable to shortage. We encourage CMS to align any eligible-medicines list closely with the priorities identified by the Administration for Strategic Preparedness and Response, and to update the list regularly as shortage risks evolve. As CMS designs a payment methodology, we urge the agency to keep the reporting and administrative requirements as simple as possible; the low uptake of the existing surgical N95 payment adjustment, with fewer than 100 hospitals reporting the necessary information in FY 2024, underscores the risk that a well-intentioned incentive will go unused if the associated burden is too high. A claims-based approach that automatically calculates the payment adjustment, where feasible, is likely to achieve broader participation than a cost-report-based mechanism.

IDSA also encourages CMS to ensure that any definition of "domestic" and any verification process are clear and workable and do not create inadvertent barriers to access or exacerbate existing shortages. To the extent that a public file of attested eligible products is established, it should be easy for hospitals and their supply chain staff to use and should be maintained on a timely basis. We would welcome the opportunity to work with CMS as it develops these policies to ensure that efforts to bolster domestic manufacturing capacity strengthen the availability of the PPE and essential medicines on which infectious diseases care depends.

Conclusion

IDSA appreciates the opportunity to provide feedback on the CY 2027 Hospital OPPS and ASC Proposed Rule. We urge CMS to implement payment and policy reforms that sustain access to high-quality infectious diseases care and support the unique needs of both patients and providers. As the health care landscape continues to evolve, it is essential that regulatory updates promote care equity, protect vulnerable populations and advance public health goals. IDSA looks forward to continued collaboration with CMS to achieve these shared priorities. If you have any questions or if we may be of any assistance to you, please do not hesitate to contact Yasmin Rafiq, IDSA's regulatory and reimbursement policy manager, at yrafiq@idsociety.org.

Sincerely,

Ronald G. Nahass, MD, MHCM, FIDSA
President
Infectious Diseases Society of America