IDSA
Infectious Diseases Society of America

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The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: CY 2025 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Payment System Proposed Rule

Dear Administrator Brooks-LaSure,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to comment on the calendar year (CY) 2025 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) Payment System Proposed Rule. On behalf of IDSA, which represents more than 13,000 physicians, scientists, public health practitioners and other clinicians specializing in infectious diseases (ID) prevention, care, research and education, thank you for your focus on reforming physician payment. Our members care for patients with a wide variety of serious infectious diseases, including COVID-19, antimicrobial-resistant infections, HIV, viral hepatitis and infections associated with cancer care, solid organ transplantation and injection drug use. Our members also lead hospital programs charged with antimicrobial stewardship, infection prevention and control, and emergency preparedness and response. We are pleased to support several components of the CY 2025 OPPS and ASC Proposed Rule as well as offer suggestions to strengthen some provisions, as detailed below.

OPPS Conversion Factor Update

The Centers for Medicare and Medicaid Services (CMS) proposes the CY 2025 OPPS conversion factor to be $89.379. This generates a general overall increase of 2.6%. The overall increase (before budget neutrality adjustments) is based on the proposed hospital inpatient market basket increase of 3.0% minus a productivity adjustment of 0.4%. According to CMS, this generates a proposed increase of $5.2 billion in CY 2025. CMS proposes that if more recent data become available, it will use the updated data to alter the conversion factor in the OPPS final rule with a comment period. **IDSA supports the budgetary increase to generate more funding for hospitals and ultimately improve patient care.**

OPPS Payment Provisions

Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients

In the CY 2025 physician fee schedule (PFS) proposed rule, CMS proposes to revise the definition of direct supervision at § 410.32(b)(3)(ii) to extend the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS through Dec. 31, 2025. CMS discusses how it seeks uniformity under the PFS and OPPS in how regulations are applied to similarly situated providers and how it has concerns about beneficiary access if it reverts to a pre-public health emergency (PHE) definition of direct supervision. CMS therefore proposes to revise § 410.27(a)(1)(iv)(B)(1) and § 410.28(e)(2)(iii) to allow for the direct supervision of CR, ICR, PR services and diagnostic services via audio/video real-time communications technology (excluding audio-only) through Dec. 31, 2025. **IDSA encourages an expansion of direct supervision of patient care services through audio/video real-time communications technology. ID physicians regularly perform outpatient parenteral antimicrobial therapy (OPAT) duties through the use of virtual direct supervision to provide a safe, cost-effective alternative to prolonged hospitalization for the management of patients requiring intravenous antimicrobials. Virtual home OPAT visits (tele-OPAT), using an interactive audio-visual communication system, may eliminate travel costs for patients, improve outcomes, reduce clinic no-show rates, reduce costs and improve patient satisfaction. Such telehealth solutions are especially desirable in low-income regions, where distance and transportation are common barriers to care.**

Request for Comment on Payment Adjustments under the IPPS and OPPS for Domestic Personal Protective Equipment

In the CY 2023 OPPS/ASC final rule, CMS implemented payment adjustments under the OPPS and IPPS to offset the marginal costs that hospitals face in procuring domestically made National Institute for Occupational Safety and Health-approved and Food and Drug Administration-certified surgical N95 respirators. CMS notes that, although the payment adjustments for the respirators under the OPPS and IPPS have applied to cost reporting periods beginning on or after Jan. 1, 2023, use of the payment adjustments has been limited. Furthermore, market data suggest that a majority of surgical N95 respirators purchased by hospitals are not wholly domestically made.

CMS is interested in feedback and comments on potential modifications to the payment adjustment to reduce reporting burden and achieve the policy goal to maintain a baseline domestic production capacity of personal protective equipment (PPE) to ensure that quality PPE is readily available to health care personnel when needed. Specifically, CMS seeks input in the following areas:

- Payment adjustment methodology
- Payment adjustment eligibility
- Types of N95 respirators

IDSA supports payment adjustments that offset marginal costs of hospitals purchasing domestic N95 respirators to ensure that quality PPE is available to all health care personnel when needed.

Payment for HIV Pre-Exposure Prophylaxis in Hospital Outpatient Departments

In advance of the final national coverage determination (NCD), CMS proposes to pay for HIV pre-exposure prophylaxis (PrEP) drugs and related services as preventive services under the OPPS if covered in the final NCD. CMS proposes to pay for these services when furnished in hospital outpatient departments similar to if they were furnished in a physician office. CMS also includes the following proposals:

- Administration: CMS proposes to assign G0012 (Injection of pre-exposure prophylaxis [prep] drug for HIV prevention, under skin or into muscle) to APC 5692 (Level 2 Drug Administration).
- Counseling: CMS proposes to add G0013 (Individual counseling for pre-exposure prophylaxis [prep] by clinical staff to prevent human immunodeficiency virus [HIV], includes: HIV risk assessment [initial or continued assessment of risk], HIV risk reduction and medication adherence) to a clinical APC (according to Addendum B, APC 5822 (Level 2 Health and Behavior Services); but CMS does not propose to pay under the OPPS for counseling performed by physicians because that is a "physician-only" service.
- Drug Costs: CMS proposes an OPPS payment rate for HIV PrEP drugs using the ASP methodology when ASP data is available. If ASP data is not available, CMS proposes to rely on alternative pricing sources as outlined in the Medicare PFS. In addition, CMS proposes to assign the drug products covered as additional preventive services a status indicator of "K" (Non-Pass-Through Drugs and Non-Implantable Biologicals, Including Therapeutic Radiopharmaceuticals; Paid Under OPPS; separate APC payment).
- Pharmacy Supplies: If the NCD is finalized as an additional preventive service and in line with past policy for pharmacy supply or dispensing fees, CMS proposes to assign all HCPCS codes describing pharmacy supply fees for HIV PrEP a status indicator of "B" (codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill (12x and 13x); not paid under OPPS.

PrEP is a critical part of the strategy to dramatically reduce new HIV infections and end HIV as an epidemic. **Because only one-third of people who could benefit from PrEP have access to it, with significant disparities among the people most heavily impacted by HIV, it is imperative that access is expanded through the Medicare program.**

Conclusion

IDSA thanks you for your attention to these important issues impacting our hospitals' approaches to preventing, tracking and reporting on infectious diseases. We hope that our comments are useful as you work to finalize the CY 2025 OPPS and ASC rule. If you have any questions or if we may be of any assistance to you, please do not hesitate to contact Amanda Jezek, IDSA senior vice president for public policy and government relations, at ajezek@idosciety.org.

Sincerely,

Steven K. Schmitt, MD, FIDSA, FACP
IDSA President