AACU
American Association of
Clinical Urologists, Inc.

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Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1809-P
P.O. Box 8010
Baltimore, MD 21244-8010

September 9, 2024

Re: CMS-1809-P

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

By Electronic Mail: (*OPPS-ASC-Rulemaking@cms.hhs.gov*)

Dear Administrator Brooks-LaSure,

On behalf of our physician and medical student members, the American Association of Clinical Urologists (AACU) respectfully submits these comments to the Centers for Medicare & Medicaid Services (CMS) on the Hospital Outpatient Prospective Payment System (OPPS) published in the Federal Register on July 22, 2024.

Founded in 1968 by urologists concerned by the government's increasing role in the practice of medicine, the AACU is a professional organization representing the interests of more than 3,700+ member urologists, and urologic societies engaged as advocacy affiliates across the United States. We are dedicated to developing and advancing health policy education as it affects urologic practice in order to preserve and promote the professional autonomy of our members and support the highest quality of care for patients.

We appreciate the opportunity to respectfully provide comments on the following provisions of the proposed rule.

Below is the relevant portion of the proposal that the AACU would like to focus on, which involves invoice pricing.

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D. Invoice Drug Pricing Proposal for CY 2026

We have observed that in recent years there has been an increasing number of drug and biological HCPCS codes for which ASP, WAC, AWP, and mean unit cost information is not available. These are often HCPCS codes for new drugs or biologicals that have been approved for marketing, but for which the manufacturer does not have sales data, and WAC, AWP, and mean unit cost information is not available. As a result, we are unable to assign a payable status indicator to these drugs or biologicals due to of a lack of payment data. The numbers of drug and biological HCPCS codes without payment rates from Addendum B for the CY 2022 through CY 2024 OPPS/ASC final rules with comment period are listed in Table 66.

In order to provide appropriate payment rates for these drugs and biologicals without pricing data, we propose to adopt an invoice pricing policy beginning in CY 2026. Because this policy necessitates significant operational changes to implement, we propose to implement it beginning in CY 2026, rather than CY 2025. For CY 2025, the affected drugs and biologicals would continue to be assigned a non-payable status indicator until we implement our invoice pricing policy, if adopted. We believe invoice pricing is appropriate for use under the OPPS because it provides temporary drug or biological cost information to generate a representative payment rate for a drug or biological and supports the utilization of new drug or biological HCPCS codes. Otherwise, the new drug and biological HCPCS codes would not receive payment under the OPPS, which would discourage their use by providers. Currently, the Physician Fee Schedule utilizes invoice pricing for drugs and biologicals when other types of pricing information are not available.

We propose that, for separately payable drugs or biologicals for which CMS does not provide a payment rate in Addendum B, which would indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, we propose that MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. We generally would expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under 1847A of the Act. For drug products that are not required to

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report ASP under 1847A of the Act (i.e., diagnostic pharmaceuticals), invoice pricing may be used longer term until a MUC can be calculated. We propose that we would not begin using invoice pricing for drugs, biologicals, and radiopharmaceuticals without pricing information until CY 2026 because we would need to make technical updates to outpatient hospital claims to allow the hospitals to report drug invoice pricing. We intend to work with the National Uniform Billing Committee (NUBC) in order to create a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals for purposes of this policy."

AACU Comments on Invoice Pricing

The AACU would like to comment that we agree with the adoption of invoice pricing as this methodology allows us to both provide and deliver state of the art care to our valued patients.

The AACU is grateful to CMS for allowing us the opportunity to provide these comments on the Hospital Outpatient Prospective Payment System (OPPS) proposed rule. We look forward to future opportunities to provide comments to provide our viewpoints in order to work with CMS to make urology policy stronger. We stand by to readily serve as a resource to you.

Please reach out to Ron Lanton, AACU Director of Government Affairs at rlanton@aacuweb.org with any questions or concerns.

Sincerely,

Harbhajan S. Ajrawat, MD, FACS

Harbhajan S. Ajrawat, MD, FACS
President
American Association of Clinical Urologists, Inc.

Terrence Regan, MD

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