LUGPA
Integrated Practices Comprehensive Care

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Via Electronic Submission Through regulations.gov

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1809-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule [CMS-1809-P]

Dear Administrator Brooks-LaSure,

On behalf of the Large Urology Group Practice Association (LUGPA), we appreciate the opportunity to comment on the CY 2025 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule (the "Proposed Rule").[1] LUGPA currently represents 150 urology group practices in the United States, with more than 2,100 physicians who collectively provide approximately 35% of the nation's urology services.

By way of summary, we recommend the following:

- LUGPA supports reassigning CPT code 0655T from APC 5374 to APC 5375, but CMS should revisit the issue in future years to ensure payment stability for APC 5375 is maintained.
- LUGPA supports the continuation of the PFS-equivalent rate for clinical and emergency department (ED) hospital outpatient visits because it promotes CMS's broader site-neutral policy objectives.
- LUGPA supports the adoption of invoice pricing for OPPS-payable drugs without pricing information because this methodology improves the ability to offer patients access to novel procedures and therapeutics.
- LUGPA supports (1) reducing reporting burdens on ASCs to ensure the most meaningful reporting measures apply to each facility; and (2) excluding Medicare Advantage (MA) claim volume or service data when determining the applicable case volume thresholds.
- LUGPA supports continuing to increase payment rates under the ASC payment system by using the hospital market basket methodology.
- LUGPA reiterates our belief that access to cutting-edge diagnostic tools, minimally invasive surgical techniques, and innovative therapeutic devices is essential for improving patient outcomes and quality of life.

[1] 89 Fed. Reg. 59186 (July 22, 2024) [hereinafter CY 2025 OPPS Proposed Rule].

I. Background on LUGPA

LUGPA was formed in 2008 as a way to facilitate communication between independent urology-focused (GU) groups of ten or more providers. This served the following complementary priorities: (1) the promotion of clinical and operational benchmarking to guide best practices; (2) the establishment and promulgation of quality guidelines; and (3) the utilization of resources for advocacy and communication in the legislative and regulatory arena to ensure that these providers also had an opportunity to advocate on behalf of their patients and their specialty. Since that time, LUGPA has expanded its mission to incorporate any group practice who shares the foundational principles of commitment to providing integrated and comprehensive GU services to those impacted by genitourinary diseases and conditions. LUGPA has gained membership steadily; it currently includes 150 urology group practices in the United States, representing more than 2,100 physicians who, collectively, provide approximately 35% of the nation's Medicare urology services. Furthermore, LUGPA's members provide the majority of the GU care delivered in the independent physician office setting.

As health care reform efforts in the US have evolved to direct focus towards the development and promotion of outcome driven, "best-practice" patient care delivered in the most cost-effective setting, LUGPA practices have consistently been leaders in innovative and adaptive care models. Expanding both the range of procedures and the integration of care that can be safely and effectively provided in the more convenient and cost-effective independent physician setting has resulted in demonstrable concomitant reduction in the cost of care delivery, as well as improved outcomes. In addition, LUGPA practices have been at the forefront of adopting team-based healthcare, with the inclusion of other physician specialists and a variety of advanced practice providers, maximizing both convenience and accessibility to expert treatment for a broad spectrum of GU conditions. LUGPA practices have embraced value-based care models, and the organization is among the first to create a physician-focused payment model. As such, LUGPA has served as a high-quality, cost-effective alternative to cost increases associated with the consolidation of health care services.[2,3]

LUGPA's mission has been to provide and maximize access to the resources, technology, management tools, and advocacy efforts that optimize the ability of urological surgeons and their clinical partners in the independent setting to provide integrated, comprehensive care for patients with acute and chronic illnesses affecting the GU system. During the global Public Health Emergency, LUGPA's mission was expanded to provide crucial resources to independent physician practices that enabled continuity of outpatient services even as the nation's inpatient capacity was overrun by patients stricken with COVID-19. LUGPA facilitated understanding and access to government assistance programs, coordinated sourcing of personal protective equipment, and provided crucial safety data to its members.[4] Through these and other efforts, LUGPA helped ensure that vulnerable populations were able to access crucial urological services.[5] LUGPA has expanded its role in the post COVID-19 landscape and provided critical resources to its members. LUGPA continues to navigate the challenges of rebound patient demand and inflationary pressures that are further amplified by unprecedented health care workforce shortages. Furthermore, as the movement towards implementing site neutral payment reforms as a cost-control measure gains momentum[6], LUGPA

[2] Scheffler RM, Arnold DR, Whaley CM. Consolidation trends in California's health care system: impacts on ACA premiums and
outpatient visit prices. Health Affairs. 2018 Sep 1;37(9):1409-16.

[3] Capps C, Dranove D, Ody C. The effect of hospital acquisitions of physician practices on prices and spending. Journal of health
economics. 2018 May 1;59:139-52.

[4] Kapoor DA, Latino K, Hodes G, et al. The Impact of Systematic Safety Precautions on COVID-19 Risk Exposure and Transmission Rates in Outpatient Healthcare Workers. Rev Urol. 2020;22(3):93-101.

[5] Harris RG. After COVID-19, LUGPA More Important Than Ever. Rev Urol. 2020;22(2):75-76.

[6] Kaiser Family Foundation. Five Things to Know About Medicare Site-Neutral Payment Reforms (June 14, 2024),

has led efforts[7] to broaden its practices' ability to provide outpatient alternatives for increasingly more diverse and advanced procedures. These efforts provide legislators and regulators with clinical and cost data on specialist performance to assess impacts on equity and identify actionable, reliable, and valid measures of the cost and quality of care delivered by specialist physicians. LUGPA will continue to work on behalf of its membership to ensure that the critical role of independent GU practices is recognized and optimized as we work to expand access to current and up-to-date treatment alternatives in the most cost-effective setting.

II. LUGPA supports reassigning CPT code 0655T from APC 5374 to APC 5375, but CMS should revisit the issue in future years to ensure payment stability for APC 5375 is maintained.

CMS proposes to reassign CPT code 0655T from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services).[8] CMS states 0655T shares more resource cost and clinical homogeneity with procedures in APC 5375.[9] Specifically, CMS believes CPT code 0655T shares resource and clinical homogeneity with CPT code 0714T (transperineal laser ablation of benign prostatic hyperplasia (BPH), including imaging guidance) and CPT code 52648 (laser vaporization of prostate, including control of postoperative bleeding, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, internal urethrotomy and transurethral resection of prostate are included if performed)).[10]

LUGPA supports reassigning CPT code 0655T from APC 5374 (Level 4 Urology and Related Services) to APC 5375 (Level 5 Urology and Related Services). We agree with CMS that this reassignment is appropriate because CPT code 0655T shares resource and clinical homogeneity with CPT code 0714 and CPT code 52648. However, LUGPA recommends that CMS closely monitor the impact on APC 5375 into the future. While CMS states that CPT code 0655T would not significantly impact the geometric mean cost calculations for APC 5374 and APC 5375, LUGPA recommends that CMS revisit this issue in the CY 2026 OPPS to confirm that CPT code 0655T did not adversely impact payment for APC 5375.[11]

III. LUGPA supports the continuation of the PFS-equivalent rate for clinical and emergency department (ED) hospital outpatient visits because it promotes CMS's broader site neutral policy objectives.

For CY 2025, CMS proposes to continue its current clinical and ED hospital outpatient visit payment policies.[12] Previously, CMS finalized a policy to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by non-excepted off-campus PBDs.[13] The PFS-equivalent rate for CY 2025 is 40 percent of the proposed OPPS payment.[14] CMS also proposes to continue to exempt excepted off-campus PDBs of rural Sole Community Hospitals (SCHs) from the clinical visit payment policy.[15]

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https://www.kff.org/medicare/issue-brief/five-things-to-know-about-medicare-site-neutral-payment-reforms/.
[7] LUGPA Ambulatory Surgery Center Academy https://www.lugpa.org/ambulatory-surgery-center-academy .
[8] 89 Fed. Reg. at 59282.
[9] *Id.*
[10] *Id.*
[11] *See id.*
[12] 89 Fed. Reg. at 59380.
[13] 89 Fed. Reg. at 59380.
[14] *Id.*
[15] *Id.*

LUGPA supports the continued application of a PFS-equivalent payment rate for the hospital outpatient clinic visit service when it is furnished by non-excepted off-campus PBDs. We also recognize the unique role of rural SCHs, especially in the ED setting. However, we continue to believe that CMS should continue to pursue site neutral policies in all settings, which could include ED visits in rural communities, as long as CMS implements adequate monitoring to ensure there would not be an adverse impact on patient access.

LUGPA's longstanding position is that site neutrality should be one of CMS's primary guiding principles in determining payment policy under the OPPS. Site neutrality promotes beneficiary access to items and services in a more convenient and cost-effective setting of care, and it generally empowers patients to take a more active role in their care as they also have a wider selection of outpatient-based providers from which to seek care. CMS should maintain site neutrality as a primary guiding principle in setting OPPS/ASC payment policy and it should continue promoting site neutral payment under the OPPS/ASC PPS.

IV. LUGPA supports the adoption of invoice pricing for OPPS-payable drugs without pricing information because this methodology improves the ability to offer patients access to novel procedures and therapeutics.

CMS proposes to adopt an invoice pricing policy beginning in CY 2026 for drugs administered in the hospital outpatient department and ASC settings without available pricing information.[16] For CY 2025, the affected drugs and biologicals would continue to be assigned a non-payable status indicator until CMS implements an invoice pricing policy, if adopted.[17] Further, CMS proposes that it would not begin using invoice pricing for drugs, biologicals, and radiopharmaceuticals without pricing information until CY 2026 because it would need to make technical updates to outpatient hospital claims to allow the hospitals to report drug invoice pricing.[18]

With respect to separately payable drugs or biologicals for which CMS does not provide a payment rate, CMS proposes that the Medicare Administrative Contractors (MACs) would calculate the payment based on provider invoices.[19] Specifically, the drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions.[20] 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.[21] If both conditions are met, CMS proposes 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.[22]

LUGPA supports the CMS proposal to adopt an invoice pricing policy for OPPS-payable drugs without pricing information because this methodology improves our ability to offer patients access to novel procedures and therapeutics. Currently, when a drug is listed in the OPPS Addenda with an E2 status, indicating the absence of pricing data, we face the potential non-reimbursement for the drug. Although CMS often updates payment rates for these drugs via transmittals once the pricing becomes available, this does not mitigate the immediate financial uncertainties we encounter when administering these drugs. Establishing the ability for providers to seek reimbursement for these products based on their invoice cost helps alleviate this financial barrier, thereby enhancing the availability of these treatments for their patients.

[16] 89 Fed. Reg. at 59369.
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*

V. LUGPA supports reducing reporting burdens on ASCs to ensure the most meaningful reporting measures apply to each facility and excluding MA claim volume or service data when determining the applicable case volume thresholds.

CMS proposes to require reporting for all non-claims-based specialty-specific measures for which case counts reach a specified case threshold minimum.[23] Under this proposal, mandatory data reporting for non-claims-based specialty-specific measures will occur only if an ASC meets established case threshold minimums.[24] Currently, the ASCQR Program's measure set captures clinical quality across all ASCs, including specialty clinical procedures performed only by a subset of ASCs.[25] Under this framework, ASCs are required to attest if they do not have cases for a given measure, which thereby increases the reporting burden.[26]

The current ASCQR Program measure set has seven generally applicable measures for which reporting in this framework would be required for all ASCs: (1) four patient safety measures (Patient Burn; Patient Fall; Wrong Site, Wrong Patient, Wrong Procedure, Wrong Implant; All-Cause Hospital Transfer Admission); (2) one general surgery measure (Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers); (3) one vaccination measure (COVID-19 Vaccination Coverage Among Health Care Personnel); and (4) one patient experience of care survey measure (OAS CAHPS).[27]

Further, the following are specialty-specific measures addressed by the current ASCQR Program measure set: (1) unplanned anterior vitrectomy; (2) cataracts visual function; (3) normothermia outcome; (4) risk-standardized patient-reported outcome-based performance measure (PRO–PM) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) in the ASC setting (THA/TKA PRO–PM); (5) hospital visits after orthopedic ASC procedures; (6) endoscopy/polyp surveillance: appropriate follow-up interval for normal colonoscopy in average risk patients; (7) facility 7-Day risk-standardized hospital visit rate after outpatient colonoscopy; and (8) hospital visits after urology ambulatory surgical center procedures.

Four of these specialty-specific measures are not claims-based and, under CMS's proposed framework, would not be applicable or required for all ASCs to report, but would rather be available for selection upon meeting a specified case threshold minimum: (1) unplanned anterior vitrectomy; (2) cataracts visual function (previously referred to as cataracts: improvement in patient's visual function within 90 days following cataract surgery) (voluntary); (3) normothermia outcome; and (4) risk-standardized patient-reported outcome-based performance measure (PRO– PM) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) in the ASC setting (THA/TKA PRO–PM).[28]

LUGPA supports reducing reporting burdens on ASCs to ensure the most meaningful reporting measures apply to each facility. Requiring an ASC to report on measures minimally relevant to their patient population unnecessarily increases reporting burdens and diverts valuable resources that could instead be applied to patient care.

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[23] 89 Fed. Reg. at 59473.
[24] *Id.*
[25] 89 Fed. Reg. at 59471.
[26] *Id.*
[27] *Id.*
[28] 89 Fed. Reg. at 59472.

Further, LUGPA supports excluding Medicare Advantage (MA) claim volume or service data when determining the applicable case volume thresholds. ASCs offer a diverse range of services, and the patient population can vary significantly from one center to another. Including MA claim volume in the threshold determination could lead to a misrepresentation of the services most commonly provided by an ASC. Moreover, as noted above, the administrative burden associated with reporting is a significant concern for ASCs. Including MA claim volume in the threshold calculation could potentially increase the number of measures an ASC is required to report on, many of which may be irrelevant to the facility's primary services. By excluding MA claim volume, ASCs can focus their efforts on reporting measures that are meaningful and reflective of their clinical practice, thereby optimizing the use of resources.

VI. LUGPA supports continuing to increase payment rates under the ASC PPS using the hospital market basket methodology.

Using the hospital market basket methodology, CMS proposes to increase payment rates under the ASC payment system by 2.6 percent for ASCs that meet the quality reporting requirements under the ASCQR Program.[29] This proposed increase is based on a proposed hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.4 percentage points.[30] CMS estimates that total payments to ASCs for CY 2025 under this proposed update will be approximately $7.4 billion, an increase of approximately $202 million compared to estimated CY 2024 Medicare payments.[31] Stated differently, CMS estimates the impact of applying the proposed inpatient hospital market basket update to ASC payment rates will increase payments by $202 million under the ASC payment system in CY 2025.[32]

LUGPA supports continuing to increase payment rates under the ASC payment system using the hospital market basket methodology. Our endorsement of the hospital market basket as the update mechanism for the ASC Payment System is rooted in the belief that it offers a more precise representation of the operational and material costs that ASCs incur. Since ASCs provide outpatient services that are often similar to those offered by hospital outpatient departments, it is logical to align their payment updates with the cost trends of the hospital sector. The proposed increase for CY 2025 not only ensures that ASCs are compensated in line with cost trends but also supports the sustainability and quality of outpatient surgical care. The continuation of this update methodology by CMS is a step towards maintaining a viable financial environment for ASCs, which ultimately benefits patients by preserving access to high-quality, cost-effective surgical services.

VII. LUGPA supports policies that ensure equitable access to urological technological advancements.

LUGPA remains steadfast in its commitment to ensuring that patients receive the highest standard of urological care. Central to this commitment is our unwavering support for comprehensive access to the full spectrum of technological advancements in urological procedures. We believe that every patient deserves the opportunity to benefit from the latest innovations, whether it be cutting-edge diagnostic tools, minimally invasive surgical techniques, or novel therapeutic devices. Our advocacy for technology access is driven by the profound understanding that these advancements can significantly improve patient outcomes, reduce recovery times, and enhance the quality of life for those we serve.

LUGPA's position is that access to technology should not be a privilege but a fundamental aspect of modern healthcare. By supporting the integration of diverse technologies into urology practices, we aim to empower

[29] 89 Fed. Reg. at 59190.
[30] *Id.*
[31] *Id.*
[32] *Id.*

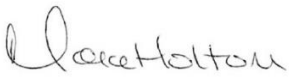
physicians to tailor treatments to individual patient needs, thereby optimizing personalized care. We are dedicated to working collaboratively with healthcare providers, policymakers, and industry partners to overcome barriers to technology access.

In light of this, we urge CMS to adopt and maintain policies that actively protect and promote access to these innovative technologies. Reimbursement frameworks and regulatory requirements should be designed to support the integration of new technologies into urological practice. Such policies should recognize the value of technological advancements and facilitate their adoption, ensuring that all patients, regardless of their socioeconomic status, can benefit from the best available care. While this is a broad concern, particularly in light of the heterogeneity of clinical presentation and treatment goals for patients with BPH, LUGPA uniformly supports measures which protect patient access and choice to elect for treatments which have been approved. We are particularly concerned with reimbursement changes that discourage innovation or preclude utilization of procedures or therapies in one or another outpatient setting (office or ASC).

VIII. Conclusion

On behalf of LUGPA, we would like to thank CMS for giving us this opportunity to comment on the Proposed Rule. Please contact Dr. Mara Holton at (410)504-4004 or mholton@aaurology.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Thank you,



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