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-1807-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies (CMS-1807-P)

Dear Administrator Brooks-LaSure,

On behalf of the Large Urology Group Practice Association (LUGPA), we appreciate the opportunity to comment on the above captioned Calendar Year (CY) 2025 Medicare Physician Fee Schedule (MPFS) 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.

Our comments underscore the significant challenges that medical practices are grappling with during this period of great transition and change. The ending of the COVID-19 Public Health Emergency (PHE) declaration may have provided a sense of relief, but regrettably, it does not mark the end of the turbulence that physicians and the U.S. healthcare infrastructure are facing. Several ongoing factors are converging to complicate the landscape for physicians and their practices, including staffing shortfalls, increased labor costs, supply chain issues, as well as the downstream effects of skyrocketing medical malpractice claims. The combination of these factors has created a complex web of challenges that impede physicians from focusing on what matters most—patient care. These pressures have cascading impacts, exemplified by the flight of health care providers at all levels, from nurse staffing crises to unprecedented levels of physician burnout and early retirement. Failure to address these challenges with consideration in mind for the perspective of the physician providers on the front lines of health care delivery has and will continue to have adverse consequences for our entire healthcare delivery system.

The most exigent challenge facing all independent practices is that of another impending cut—2.8% in 2025—despite inflation in essentially every input cost. While CMS may, correctly, insist that regulatory guidelines and the associated cuts are structural, CMS is ultimately responsible for determining their scope and impact. It is thus certainly the obligation of regulators to pursue strategies that advance the long-term goals of enhanced patient access, quality improvement, and cost reduction. Unfortunately, the ongoing degradation of the MPFS has contributed disproportionately to healthcare consolidation and associated cost increases.[2]

1 CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies Proposed Rule, 89 Fed. Reg. 61596 (July 31, 2024) ("CY 2025 MPFS Proposed Rule").

2 See Kevin B. O'Reilly, Latest proposed cut—2.8%—shows need for Medicare pay reform, American Medical Association (July 10, 2024), available at: https://www.ama-assn.org/practice-management/medicare-medicaid/latest-proposed-cut-28-shows-need-medicare-pay-reform; see also Medicare Payment Advisory Commission (MedPAC)

Our comments, discussed in greater detail in the body of this letter, are outlined below:

- CMS should make adjustments to the proposed conversion factor calculation to mitigate the effects of the payment reduction.
- CMS should reinforce the stated intent of complexity add-on code G2211 by further expanding its allowed use with coincident modifier -25.
- CMS should reconsider the proposed cuts to the CCM/PCM codes and increase the reimbursement related to these codes to incentivize greater implementation of critical care management services to chronic patients.
- CMS should finalize the proposed overpayment timeline regulations.
- CMS should develop a policy to mitigate the catastrophic impact of the clinical labor adjustment on certain GU office procedure codes, thereby preventing a precipitous rise in overall expense accompanied by a crisis in patient access.
- CMS should utilize a phased-in schedule for the Cystoscopy Supply Pack pricing update to avert catastrophic shifts in site of service.
- CMS should finalize the *Optimal Care for Patients with Urologic Conditions MVP* and, wherever reasonable, maintain and expand opportunities for specialists to participate in MIPS.
    - LUGPA supports development of the *New Optimal Care for Patients with Urologic Conditions MVP* with certain modifications.
    - Additional comments on proposals related to the Quality Payment Program (QPP) and on opportunities for specialty providers to participate in MIPS.
- CMS should codify its efforts to ensure payment parity for telehealth services.
    - It is LUGPA's opinion, however, that the current proposal to require a modifier to specify telehealth services is unnecessary and will increase coding complexity and patient confusion, therefore it should be eliminated.
- CMS should finalize its proposed telehealth flexibilities.
    - CMS should finalize its proposal to permit audio-only communication technology to meet the definition of an "interactive telecommunications system."
    - CMS should extend the definition of "direct supervision" to include audio-video communications technology for a subset of services through CY 2025, and permanently define "direct supervision" to include audio-video for a subset of "incident-to" services.
- CMS should cautiously approach implementation of transfer of care modifiers for global packages to avoid confusion and the inadvertent creation of burdensome documentation requirements on community providers.

I. Background on LUGPA.

LUGPA was formed in 2008 to facilitate communication between independent urology-focused (GU) groups of ten or more providers. This served the complementary priorities of: (1) the promotion of clinical and operational benchmarking to guide best practices; (2) the establishment and promulgation of quality guidelines; and (3) collaborative utilization of resources for advocacy and communication in the legislative and regulatory arena. LUGPA was thereby able to facilitate provider and practice advocacy on behalf of GU patients and the specialty at a national level. Since that time, LUGPA has expanded its mission to incorporate any non-hospital-based 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 over 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.[3] Furthermore, LUGPA's members provide the majority of GU care delivered in the independent physician office setting.

[3] CMS, Utilization numbers based on cross-referencing LUGPA membership data with 2020 Medicare Physician &

As healthcare reform efforts in the U.S. have evolved to redirect focus toward the development and promotion of outcome-driven, "best-practice" patient care, 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 independent physician setting has improved access, reduced care delivery costs, and showed equivalent as well as improved outcomes. In addition, LUGPA practices have been at the forefront of adopting team-based healthcare, with broad incorporation of other physician specialists and a variety of advanced practice providers, maximizing both convenience and accessibility to expert treatment for the full spectrum of GU conditions. As such, LUGPA has continued to be a leader in the development of high-quality, cost-effective alternatives for care delivery as a counterbalance to the cost increases associated with the trend toward consolidation of health care services.

During the COVID-19 pandemic, 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. Whether facilitating understanding and access to government assistance programs, coordinating sourcing of personal protective equipment, or providing crucial safety data to its members, LUGPA helped ensure that vulnerable populations continued to be able to access crucial urological services.[4,5]

In the post-COVID-19 landscape, LUGPA again expanded its role to provide critical resources to members who have been assailed by a multitude of challenges, rebound patient demand, double-digit inflationary pressures, and unprecedented healthcare workforce shortages. Furthermore, as the movement toward some degree of site neutrality as a cost-control measure gains momentum,[6] LUGPA has led efforts to broaden our practices' ability provide outpatient alternatives for increasingly more diverse and advanced procedures. LUGPA members have been actively engaged in initiatives that provide clinical and cost data for legislators and regulators to pursue CMMI mandates around enhanced data and profiling tools to provide data on specialist performance to assess impacts on equity and to 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 integral 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. CMS Should Exercise its Section 402 Demonstration Authority to Make Adjustments to the Proposed Conversion Factor Calculation to Mitigate the Effects of the Payment Reduction.

The Consolidated Appropriations Act (CAA), 2023 applied a payment increase of 1.25% to services furnished from January 1, 2024 through March 8, 2024. The CAA, 2024 increased this amount to 2.93%, applicable to services furnished from March 9, 2024 through December 31, 2024. For CY 2025, CMS proposes to calculate the estimated CY 2025 MPFS conversion factor by removing the payment increase percentages, then multiplying by the statutorily required budget-neutrality adjustment. Therefore, CMS calculates the proposed

Other Practitioners Public Use Files. Accessed at: https://data.cms.gov/provider-summary-by-type-of-service/medicarephysician- other-practitioners, September 1, 2020.

[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] *See* Dave Muoio, *Site-neutral payments draw blanket, bipartisan support at House Budget hearing*, Fierce Healthcare (May 23, 2024), available at: https://www.fiercehealthcare.com/providers/site-neutral-payments-draw-blanket-bipartisan-support-house-budget-hearing.

CY 2025 MPFS conversion factor as 32.3562, or $32.36, which is a decrease of $0.93 (approximately 2.80%) from the CY 2024 conversion factor of $33.29.

LUGPA strongly opposes this proposed conversion factor, which will result in payment cuts for providers, compounding prior year reductions as well as other payment cuts that CMS proposes across the physician fee schedule. CMS's downward pressure on physician payments is unsustainable and is contributing to the increasing erosion of independent community practices, accelerating provider consolidation, and exacerbating early retirement and workforce shortages. As independent physicians, we are deeply troubled by this fallout as patients lose access to choice, and, almost uniformly, lower-cost settings of care in their local communities.

While the physician fee schedule is certainly not the only headwind we face, the impact of these compounding cuts is devastating, particularly for practices and specialties that care for a large number of Medicare patients—in some cases, accounting for half or more of insurance billing. Furthermore, Medicare cuts depress payments from private payors.[7] These shortfalls, in which Medicare fails to sufficiently compensate physicians for the services rendered to Medicare patients, has an erosive effect, which when severe and/or chronic can push practices to the edge of financial ruin, particularly when market conditions are volatile.

Increasingly, we have seen the consequences when groups are forced to "insulate" themselves because of rising costs coupled with little or inverted cost cushion: near extinction of the smallest and most rural practices of 1-4 providers and the consolidation, often into a large hospital or health system, of smaller practices of 4-10. Recently, we have even seen the collapse of a moderate-to-larger-size practice of 15-20 providers in a major metropolitan area. Buffeted by a variety of factors, and amplified by spiraling post-COVID inflation, this GU specialty practice was forced into receivership and dissolution. A large hospital system eagerly hired a plurality of the providers, highlighting the economic incentives that continue to drive consolidation and favor hospital site of service for care, which often results in decreased patient access and higher healthcare costs for the local population.

We recognize that CMS has previously stated that it lacks statutory authority to halt a reduction in the conversion factor. However, we challenge the legal basis of the Agency's futility. Based on our observations, CMS has frequently utilized its statutory authority expansively to protect access to services, even in the face of access threats posed by legislative measures. A prime illustration of CMS's proactive measures is the recent implementation of the "Part D Premium Stabilization Memo" to safeguard Part D participants from premium increases due to the Inflation Reduction Act's (IRA's) modifications. In a Health Plan Management System (HPMS) memo dated July 29, 2024,[8] CMS outlined the initiative as a "voluntary" demonstration model under § 402 of the Social Security Act (the Act) that is:

> *designed to test whether additional policy changes stabilize year-over-year changes in premiums for participating standalone [prescription drug plans], leading to more predictable options for beneficiaries during the initial implementation of the Inflation Reduction Act of 2022's (IRA's) benefit improvements, creating more gradual enrollment changes, and allowing participating Part D sponsors to accumulate the experience necessary for bidding in future years, consistent with prior demonstrations CMS has conducted to test policies that might address transitional issues associated with the implementation of major changes to the Medicare program.*[9]

[7] Todd Shryock, *Physician Payment Outlook*, Medical Economics Journal (Jan. 31, 2023), available at: https://www.medicaleconomics.com/view/physician-payment-outlook.

[8] "Voluntary Part D Premium Stabilization Demonstration for Standalone Prescription Drug Plans, Release of the *De Minimis* Amount, and Operational Guidance" (July 29, 2024).

[9] *Id.*

CMS asserts that the model is consistent with its authority under § 402(a)(1)(A) of the Social Security Act Amendments of 1967, which "authorizes the Secretary to carry out demonstration projects to determine whether changes in methods of payment or reimbursement under Medicare would have the effect of increasing the efficiency and economy of health services covered under Medicare through the creation of additional incentives to these ends."[10]

In a similar vein, the continuity of patient access to essential physician services is jeopardized by a substantial drop in reimbursement rates following the cessation of Congressional relief measures that previously mitigated such instability in healthcare, particularly during and in the aftermath of the COVID-19 pandemic. It is perplexing why CMS would not invoke the same § 402(a)(1)(A) authority in this context to maintain stability in the conversion factor for CY 2025. This would allow for an evaluation of whether "changes in methods of payment or reimbursement under Medicare would have the effect of increasing the efficiency and economy of health services covered under Medicare through the creation of additional incentives to these ends."[11]

LUGPA recommends that CMS exercise its § 402 demonstration authority to prevent a decline in the conversion factor. Doing so would grant physician practices an extended period to adjust to the simultaneous influx of various changes in reimbursement policies, which helps protect Medicare beneficiary access to vital physician services.

III. LUGPA Respectfully Requests that CMS Enhance the Stated Intent of Complexity Add-on Code G2211 by Further Expanding its Allowed Use with Coincident Modifier -25.

CMS in the CY 2024 MPFS Final Rule finalized a separate payment for the office/outpatient (O/O) evaluation and management (E/M) visit complexity add-on code G2211. According to CMS, this code captures the "inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship."[12] Additionally, in the 2024 Final Rule, CMS finalized its proposal to not permit the use of G2211 when reported with CPT modifier -25, which denotes a significant, separately identifiable O/O E/M visit by the same physician on the same day as a procedure.

In our comments for the CY 2024 MPFS Proposed Rule, LUGPA expressed concern about modifier -25 exclusion, as this arises frequently in urologic care, where we often manage multiple chronic conditions simultaneously, and it is very common for certain diagnostic procedures to be performed as part of the ongoing management of a patient with one or more chronic genitourinary conditions. In our comments, LUGPA recommended that CMS consider permitting the use of modifier -25 in situations where a surgical code is associated with a 0-day global period and where the usual site of service is an O/O setting, as this would permit the use of diagnostic testing needed for management of patients with chronic conditions, as well as those with multiple conditions managed at the same visit. As an alternative, LUGPA suggested that CMS exempt CPT codes 52000 and 51741 (determination of cystoscopy and urinary flow rate, respectively) from the modifier -25 exclusion so urologists can continue to perform these tests and be appropriately reimbursed for the simultaneous provision of longitudinal care.

In the CY 2025 MPFS Proposed Rule, CMS proposes to modify its policy to allow payment of G2211 when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit, vaccine, or any Medicare Part B preventive service furnished in the office or outpatient setting. If finalized, this complex code modifier would therefore be permitted for the routine intervention (IM injection) for a vaccine while prohibited for the identical service (IM injection) in the context of treatment for terminal metastatic cancer. Furthermore, LUGPA reiterates its prior suggestion that the proposed modifier allowance

[10] *Id.* (internal quotations omitted).

[11] *Id.*

[12] CY 2025 MPFS Proposed Rule, at 61696-97.

coincident with G2211 billing be broadened to include all situations where a procedure code is associated with the criteria previously outlined, thereby allowing its use when caring for complex urologic (and other) conditions routinely coincident with in-office procedures.

LUGPA appreciates CMS's efforts to pay for unaccounted resources inherent in the complexity of longitudinal care delivery. However, we oppose CMS's proposal to permit expanded billing of G2211 under only these specific scenarios; applying this code to the most routine of health interventions does not align with CMS's previous characterization for application to recognize the additional cognitive effort required to manage chronic conditions. We respectfully request that CMS reconsider our previous recommendation that CMS lift the restriction on utilization of G2211 with modifier -25.

IV. CMS Should Reconsider the Proposed Cuts to the CCM/PCM Codes and Increase the Reimbursement Related to These Codes to Incentivize Greater Implementation of Critical Care Management Services to Chronic Patients.

As demonstrated in the table below, CMS in the CY 2025 MPFS Proposed Rule is proposing a significant reduction to non-complex and complex chronic care management (CCM) codes and principal care management (PCM) codes:

Table 1: CCM / PCM 2025 Proposed Rule Reimbursement Impact

CPT	CPT Description	CPT Classification	Overall % Difference
99426	PRIN CARE MGMT STAFF 1ST 30	Eval Mgmt	-0.19%
99427	PRIN CARE MGMT STAFF EA ADDL	Eval Mgmt	6.78%
99439	CHRNC CARE MGMT STAF EA ADDL	Eval Mgmt	-4.15%
99487	CPLX CHRNC CARE 1ST 60 MIN	Eval Mgmt	-1.59%
99489	CPLX CHRNC CARE EA ADDL 30	Eval Mgmt	-2.35%
99490	CHRNC CARE MGMT STAFF 1ST 20	Eval Mgmt	-3.31%
99495	TRANSJ CARE MGMT MOD F2F 14D	Eval Mgmt	-2.48%
99496	TRANSJ CARE MGMT HIGH F2F 7D	Eval Mgmt	-2.10%
99497	ADVNCD CARE PLAN 30 MIN	Eval Mgmt	-2.80%
99498	ADVNCD CARE PLAN ADDL 30 MIN	Eval Mgmt	-2.80%

Since 2015, Medicare has been paying for CCM services separately under the MPFS. In its *Chronic Care Management Toolkit*, CMS refers to CCM as a "critical component of primary care that contributes to better health and care for patients," and notes that "[t]wo thirds of people on Medicare have two or more chronic conditions," therefore CCM services can help providers furnish "coordinated care to … patients to improve their health and increase satisfaction with their care."[13] In response to the perceived value of the program, as well as in response to provider and patient input, CMS expanded eligibility to these types of services by establishing Principal Care Management (PCM) codes in 2020, which outlined similar care delivery for patients with a single chronic condition or multiple chronic conditions when the provider focuses on only one condition.

CMS's proposed reimbursement cuts, highlighted in the table above, are particularly discouraging to practices that have made significant investments in the infrastructure, staffing, and software required to provide these services and to document the specific, and often unique, required measurement metrics.

[13] CMS, *Chronic Care Management Toolkit*, 4, available at: https://www.cms.gov/files/document/chronic-care-management-toolkit.pdf.

V. CMS Should Finalize the Proposed Overpayment Timeline Regulations.

In response to comments for the 2022 Medicare Parts A and B Overpayment Proposed Rule (87 Fed. Reg. 79452, December 27, 2022), CMS is proposing to revise existing regulations at 42 C.F.R. § 401.305(b) regarding the deadline for reporting and returning overpayments. CMS proposes several technical modifications to the regulations. Additionally, CMS is proposing to add § 401.305(b)(3) to specify the circumstances under which the deadline for reporting/returning overpayments would be suspended "to allow time for providers to investigate and calculate overpayments."

Under newly proposed § 401.305(b)(3)(i), the deadline would be suspended if (1) an overpayment has been identified, but a good-faith investigation to determine the existence of related overpayments that may arise from the same or similar cause or reason has not been completed; and (2) the person conducts a timely, good-faith investigation. If these above conditions are met, then pursuant to newly proposed § 401.305(b)(3)(ii), the deadline for reporting and returning the additional identified overpayments would be suspended until the earlier of either (1) the date the additional related overpayments are identified, and the aggregate amount of initial and additional overpayments is calculated; or (2) 180 days after the date the initial overpayment was identified.

LUGPA supports CMS's proposed modifications to 42 C.F.R. § 401.305(b). The proposed changes would give healthcare providers the necessary time to conduct a thorough and good-faith investigation into the overpayments. This is crucial because overpayment issues can be complex and involve intricate billing systems and numerous transactions. A rushed investigation might lead to inaccurate repayment amounts, either over or under the actual overpayment, which could further complicate matters.

VI. CMS Should Develop a Policy to Mitigate the Catastrophic Impact of the Clinical Labor Adjustment on Certain GU Office Procedure Codes, Thereby Preventing a Precipitous Rise in Overall Expense Accompanied by a Crisis in Patient Access.

In the CY 2022 MPFS rulemaking, CMS proposed and finalized a clinical labor pricing update that stakeholders, including LUGPA, broadly denounced for its adverse impact on payment for physician services that were comprised of significant direct practice expenses under the RVU methodology. It was our assessment at the time that the clinical labor update would create substantial unintended consequences, such as delayed or reduced patient access to services; reduction or elimination of treatments appropriately furnished in office settings with reallocation to facility settings; disincentives for developing innovative medical procedures that enable efficiencies in the office; and increased overall costs to Medicare due to impediments to patient access to less-costly, in-office sites of service.

In response to stakeholder comments, CMS decided to phase-in its proposed update over a 4-year period, starting with CY 2022 and ending with final updated prices in CY 2025. In our comments for the CY 2023 MPFS Proposed Rule, LUGPA urged CMS to pause further implementation of the clinical labor update because we observed that it was having significant payment repercussions for our independent physician practices. Now, in the CY 2025 MPFS Proposed Rule, we are again confronted with the adverse effects of CMS's poorly timed clinical labor adjustment on the viability of performing certain procedures in lower-cost settings, such as ASCs and physician offices.

As illustrated in Table 2, the clinical labor adjustments, in combination with the proposed cystoscopy supply pack revaluation, have resulted in an average 18% payment reduction for the professional service component of cystoscopy procedures. This reduction compounds the payment declines experienced last year, also driven by the clinical labor adjustments imposed by CMS on physician payment rates.

Table 2: Proposed 2025 v. (October) 2024 Payment Information for Cystoscopy Procedures

Code	2025 Work RVU (2024)	2025 PE RVU (2024)	2025 Malpractice RVU (2024)	2025 Total RVU (2024)	2025 NF Rate (2024)	Percentage Change
52000	1.53 (1.53)	4.11 (5.47)	0.18 (0.11)	5.82 (7.19)	$ 188.34 ($239.34)	-21.30%
52001	5.44 (5.44)	5.39 (7.04)	0.65 (0.67)	11.48 (13.15)	$371.50 ($437.73)	-15.13%
52005	2.37 (2.37)	4.71 (6.44)	0.28 (0.29)	7.36 (9.10)	$238.17 ($302.92)	-21.38%
52007	3.02 (3.02)	8.25 (10.06)	0.39 (0.39)	11.66 (13.47)	$377.32 ($448.38)	-15.85%
52010	3.02 (3.02)	6.31 (8.06)	0.37 (0.37)	9.70 (11.45)	$313.90 ($381.14)	-17.64%
						Average Decline $-18.26%

While CMS has acknowledged that the update rebalances payment rates in favor of specialties with higher clinical labor costs, it has inadequately considered the adverse impact on specialties with substantial equipment expenses. Performing cystoscopy in an office setting requires significant expense outlays and ongoing expenses associated with purchasing, maintaining, and sterilizing cystoscopes and the instruments used in conjunction, in addition to the costs for cameras and video equipment. The expectation that urologists can simply "adapt" to costs higher than reimbursement over the transition period is unrealistic and effectively translates to the elimination of physician office site of service where this becomes the case.

The current reimbursement rates are unsustainable for physician offices, prompting a likely shift of procedures such as cystoscopies to higher-cost settings such as Hospital Outpatient Departments (HOPDs). This transition will inevitably lead to increased expenditures for Medicare and higher out-of-pocket costs for beneficiaries. Table 3 provides an estimate of the additional costs Medicare would incur due to such shifts in service settings *for every single case* that is reallocated. Table 3 does not take into account the increased differential and cost to Medicare that will take place once the market basket increases for OPPS go into effect in 2025, nor the potential impact of the decreased reimbursement in 2025 for the MPFS based on the Proposed Rule.

Table 3: Current 2024 Site of Service Estimated Total Cost of Care Differential between Office and HOPD for Cystoscopy (CPT 52000)

HCPCS Code	Short Descriptor	Relative Weight	Office Based Global Payment	HOPD Payment Rate	Part B Physician Professional Fee	Facility Total Cost*	Cost: HOPD vs. Office Global Payment
52000	Cystoscopy	7.4484	$239.34	$650.86	$79.22	$730.08	**$490.74**

**Assumes no anesthesia professional fee.*

In 2023, LUGPA practices that participated LUGPA's benchmarking program performed 327,176 cystoscopies, of which 76% were performed in the office setting and 24% were performed in the facility setting. The financial reality of the proposed cut will result in practices shifting cystoscopies to different settings, as they will no longer be financially sustainable in the office-based setting. Ignoring the proposed market basket increases to the ASC and OPPS settings, if the impacted practices were to shift as few as 25% of the cystoscopies from the office-based setting to the ASC, any projected savings to CMS from decreasing the office-based reimbursement would be completely eliminated. If only half of the procedures were shifted to the HOPD, CMS's costs would double. LUGPA endorses CMS's overarching goal for policies that promote innovation and care delivery in the lowest-cost equivalent site of service when possible. Reducing reimbursement in the office-based setting directly contravenes that ambition.

Given these substantial concerns, LUGPA urgently calls on CMS to universally pause implementation of the clinical labor adjustment increase or, alternatively, to temporarily set aside implementation, at least for the specific set of cystoscopy codes (52xxx), as a cut of this magnitude will inevitably change behavior. Patients who formerly had access to relatively "routine" cancer screening cystoscopies in the office setting will be shifted to more expensive, and more importantly, often logistically far more complicated, sites of care. This can lead to additional challenges with patient compliance and delayed detection of cancer recurrence. Patients who present with acute urinary retention (AUR), now often treated in an office setting with cystoscopy and dilation, may well be directed to an emergency department (ED), where the urologist will not be responsible for providing the scope, disposable supplies, or any subsequent sterilization or repair of instruments, likely delaying care and precipitously increasing costs to the patient and the system. Proceeding with the current adjustment plan will result in a massive and devastating reduction in patient access to essential procedures in the office setting and a significant shift toward more expensive sites of care, thereby contravening CMS's goals for cost-effective and accessible healthcare delivery.

VII. CMS Should Utilize a Phased-in Schedule for the Cystoscopy Supply Pack Pricing Update to Avert Catastrophic Shifts in Site of Service.

In the CY 2025 MPFS Proposed Rule, CMS proposes to implement supply pack pricing updates and associated revisions, as recommended by the American Medical Association (AMA) Relative Value Scale Update Committee's (RUC's) workgroup in 2024. The RUC workgroup assessed discrepancies in pricing for certain supply packs. If the RUC workgroup's recommendations are finalized for CY 2025, CMS's proposed supply-pack pricing update would have a significant redistributive effect on the family of cystoscopy services, as two cystoscopy supply packs would decrease in value, one of which (pack, urology cystoscopy visit) would experience a 67% decrease, from $113.70 to $37.63.[14] CMS has previously recognized that cuts of this magnitude require a phased-in schedule to mitigate the effects and allow for adjustment; LUGPA therefore suggests that CMS deploy a similar strategy to implement this over-50% reduction over a 7- to 10-year period.

VIII. CMS Should Finalize the *Optimal Care for Patients with Urologic Conditions MVP*, and, Wherever Reasonable, Maintain and Expand Opportunities for Specialists to Participate in MIPS.

Fundamentally, LUGPA has concerns about the MIPS program and framework, particularly for specialty and sub-specialty provider participation. Requiring physicians to report multiple measures to CMS is burdensome. Physicians and administrators are estimated to spend over 200 hours per physician per year on MIPS-related activities, and the cost of compliance is estimated to exceed $12,811 per physician per year.[15] There is little

[14] CY 2025 MPFS Proposed Rule, at 61691-92 (*Table 16, CY 2025 Invoices Received for Existing Direct PE Inputs*).

[15] Khullar D, Bond AM, O'Donnell EM, et.al. Time and Financial Costs for Physician Practices to Participate in the Medicare Merit-based Incentive Payment System: A Qualitative Study. *JAMA Health Forum*. 2021;2(5):e210527.

upside to these investments, as the MIPS program compensates high-performing physicians from a zero-sum pool that can only be funded by poorer-performance providers. It is increasingly apparent that the MIPS program has not meaningfully improved care quality, nor rewarded high-performing providers.[16]

In prior comments, LUGPA expressed disappointment in the few opportunities for specialty-level and sub-specialty-level participation in APMs and other value-based payment frameworks and expressed our intent to continue engaging with CMS as it considers expanding opportunities specific to urology-related specialties. We commend CMS for its ongoing efforts to improve providers' ability to participate in APMs through a robust MIPS Value Pathway (MVP) framework. LUGPA applauds CMS's proposal to expand these opportunities to permit specialty-level and sub-specialty-level participation, and we thank CMS for expanding participation opportunities specific to urology-related specialties and for proposing measures that advance the MVP's clinical concepts.

A. LUGPA Supports Development of the *New Optimal Care for Patients with Urologic Conditions MVP* with Certain Modifications.

For the CY 2025 performance year/CY 2027 payment year, CMS is proposing a new *Optimal Care for Patients with Urologic Conditions MVP*. According to CMS, this MVP "focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence, bladder cancer, and prostate cancer."[17] CMS anticipates this MVP would be "most applicable to clinicians who treat patients within the practice [of] urology including general urologists, urology oncologists, and sub-specialists focused on urology care for women, including nonphysician practitioners (NPPs) such as nurse practitioners and physician assistants."[18]

While enthusiastic about the MVP overall, LUGPA urges CMS to remove (1) the *Medicare Spending Per Beneficiary (MSPB)* cost measure, and (2) the *COVID-19 Vaccine Achievement for Practice Staff Improvement Activity (IA)* from the MVP. LUGPA is concerned about attribution of COVID-19 cases to the consultant urologist, who has little to no control over the cost of a hospital episode. Several finalized MVPs include specialty-specific cost measure options only, therefore there is precedent for excluding an overall population-level cost measure, such as the MSPB. Further, we do not support adding the *COVID-19 Vaccine Achievement for Practice Staff IA* to this MVP, as we believe focusing on this activity might shift focus from IAs that are more clinically relevant to urology and more closely aligned with the quality measures in the MVP.

B. Additional Comments on Proposals Related to the Quality Payment Program (QPP) and on Opportunities for Specialty Providers to Participate in MIPS.

LUGPA supports expansion of already-developed MVPs to include measures and activities pertinent to subspecialties, as we believe CMS's earlier desire for an arbitrarily short list of measures and activities conflicts with subspecialists' needs. However, LUGPA asks that CMS avoid including specialty-relevant measures across a large number of MVPs, as this could complicate the MVP selection process and add complexity and burden to the program.

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[16] *See* MedPAC, *Chapter 15: Moving beyond the Merit-based Incentive Payment System*, Report to the Congress: Medicare Payment Policy (March 2018), available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch15_sec.pdf ("The Commission believes that the MIPS program impedes the movement toward high-value care. MIPS will not succeed in helping beneficiaries choose clinicians, in helping clinicians collectively change practice patterns to improve value, or in helping the Medicare program to reward clinicians based on value.").

[17] CY 2025 MPFS Proposed Rule, at 62596.

[18] *Id.*

Accordingly, we ask that CMS continue to simplify the MIPS program while maintaining flexibilities for reporting until stakeholders can identify and address the operational barriers of MVPs and all clinicians can optimally report via MVPs. Relatedly, LUGPA encourages CMS to provide education and funding to specialty societies to promote selection of, and to defray the costs of developing, relevant and clinically valuable measures for use in both traditional MIPS and MVPs.

Regarding the proposed modifications to the *Advancing Cancer Care MVP*, LUGPA supports including measures Q102 and Q495 (*Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients* and *Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood*). We do not support removal of Q144 (*Oncology: Medical and Radiation - Plan of Care for Pain*) because we believe it is additive, rather than duplicative, of Q143, and the two measures should be used together in the context of advanced cancer care.

Beginning in performance year (PY) 2025, CMS proposes to remove the 7-point cap for selected topped out measures and to make this determination on an annual basis. Generally, LUGPA supports CMS's efforts to address inequity in the MIPS program due to limited measure choice, and we therefore appreciate CMS's consideration of scoring changes for topped out measures. However, LUGPA believes that many measures only appear to be topped out, due to the reporting incentives inherent in the MIPS program. Thus, we ask that CMS lift the 7-point cap for all measures used in the program, thereby potentially encouraging clinicians to report on specialty-specific measures rather than relying on cross-cutting measures. Furthermore, LUGPA is concerned that the proposed list of selected measures excludes QCDR measures, which fill critical gaps in measurement by providing access to measures that are meaningful and relevant for specialists. Therefore, we urge CMS to remove the 7-point cap for QCDR measures, at minimum for those where measure choice is limited. In addition, while we understand CMS's desire to analyze trends on an annual basis, we believe potentially "switching out" the 7-point cap on an annual basis would be confusing to clinicians. As reporting remains complicated and onerous, particularly for smaller practices without a large administrative infrastructure, we urge CMS to simplify and clarify as much as possible to allow the broadest participation.

CMS proposes to leave the performance threshold at 75 points for PY 2025 and maintain its current policies for PY 2025 through PY 2027, so the performance threshold will be the mean of the final scores for all MIPS eligible clinicians from a prior period. LUGPA strongly supports CMS's proposal to retain the performance threshold at 75 points for PY 2025. Additionally, we continue to believe that incremental increases in the threshold will not result in increased attention to quality and subsequent improvements in care. Therefore, LUGPA urges CMS to retain a 75-point performance threshold beyond PY 2025.

IX. CMS Should Codify its Efforts to Ensure Payment Parity for Telehealth Services.

LUGPA has long been a proponent for the expansion of availability, coverage, and payment of telehealth services under the Medicare program. We applauded CMS's swift implementation of increased flexibilities following the declaration of the COVID-19 PHE, which enabled providers, including LUGPA members, to maintain continuity of care for their patients. Telehealth facilitates access to care for some of our most vulnerable Medicare beneficiaries, such as those with mobility challenges. Under § 1834(m)(2)(A) of the Act, payments to a distant-site practitioner must be equal to payment for the service if furnished without telecommunications.

In February 2023, the AMA CPT Editorial Panel added a new E/M subsection to the draft CPT codebook for Telemedicine Services. The Panel amended the E/M subsection to include 17 audio-visual or audio-only E/M codes. CMS declined to add these services to the Medicare Telehealth Services List, which already contains audio-only and audio-video telemedicine E/M codes. In the CY 2025 Proposed Rule, CMS explains that, should it accept the AMA's recommendations to add 16 of the new telemedicine E/M codes to the Medicare Telehealth Services List, CMS would need to establish equivalent RVUs for the telemedicine E/M codes to the corresponding non-telehealth services to satisfy the § 1834(m) payment requirements. However, CMS does not

"believe that there is a programmatic need to recognize the audio/video and audio-only telemedicine E/M codes for payment under Medicare," and instead proposes to assign the AMA's newly developed codes a Procedure Status indicator of "I" to note there is a more specific code that should be used for Medicare purposes, which in this case would be one of the existing O/O E/M codes currently on the Medicare Telehealth Services List, when billed correctly (i.e., to identify the beneficiary location, indicate audio-only administration, etc.).

While LUGPA wholeheartedly supports CMS's endorsement of the need to reimburse telehealth-administered services at parity with in-person services, due to CMS previously establishing equivalency criteria for care delivered virtually and care delivered in-person, LUGPA believes that requiring a modifier will only increase coding complexity. This will, in turn, increase the likelihood of denials by private insurers and serve to inhibit ongoing adoption of remote monitoring and health care delivery. Credible and responsible telehealth services require significant IT investment, modifications in practice, workflow and staffing changes, and provider adjustments in clinical practice and to support data collection. Utilization of a modifier only increases the complexity of Explanations of Benefits (EOBs), coding, and billing. LUGPA respectfully requests that CMS not finalize the modifier requirement for these excluded telehealth-specific E/M codes while complying with the Act's requirement that payments to a distant-site practitioner must be equal to payment for the service if furnished without telecommunications.

X. CMS Should Finalize its Proposed Telehealth Flexibilities.

The PHE-related telehealth flexibilities established under § 4113(e) of the CAA, 2023 are scheduled to expire on December 31, 2024. In comments for the CY 2024 MPFS Proposed Rule, LUGPA expressed concern that CMS would end certain telehealth flexibilities, including (1) permitting certain telehealth services to be furnished via audio-only communications technology, and (2) allowing requirements for "direct supervision" to be met via virtual presence, among other proposals.

In the CY 2025 MPFS Proposed Rule, CMS proposes several telehealth flexibilities. Among these, CMS proposes to (1) add two-way, real-time, audio-only communications technology to the regulatory definition of "interactive *telecommunications* system," starting January 1, 2025; and (2) extending the definition of "direct supervision" to include audio and video communications technology for a subset of services through 2025. CMS additionally proposes to continue its efforts to ensure payment parity for telehealth services.

A. CMS Should Finalize its Proposal to Permit Audio-Only Communication Technology to Meet the Definition of an 'Interactive Telecommunications System.'

Section 1843(m) of the Act specifies the circumstances under which CMS pays for services usually furnished in-person but instead administered via telecommunications technology. Pursuant to 42 C.F.R. § 410.78(a)(3), an "interactive communications system" is "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner." During the COVID-19 pandemic and declared PHE, CMS used its emergency regulations and waiver authority, under § 1135(b)(8) of the Act, to permit the use of audio-only modalities to furnish services described by audio-only telephone E/M services for behavioral health counseling and education services. Section 4113(e) of the CAA, 2023 further extended the types of services that can be furnished using audio-only technologies. These flexibilities are scheduled to expire on December 31, 2024.

In the CY 2025 MPFS Proposed Rule, CMS proposes to revise § 410.78(a)(3) to permanently include two-way, real-time audio-only modalities in the definition of an "interactive telecommunications system." Under this policy, telehealth services could be furnished to beneficiaries in their homes if the distant-site practitioner can technically use audio and visual modalities, but the patient is incapable or does not consent to use video technology. Further, CMS proposes to require use of CPT modifier "93" and, for RHCs and FQHCs, Medicare

modifier "FQ," to verify these conditions have been met. LUGPA thanks CMS for its proposal to utilize its regulatory authority to continue to allow audio-only telehealth services. We respectfully request that CMS finalize its proposal to revise § 410.78(a)(3) to allow audio-only telehealth modalities.

B. CMS Should Extend the Definition of 'Direct Supervision' to Include Audio-Video Communications Technology for a Subset of Services Through CY 2025, and Permanently Define 'Direct Supervision' to Include Audio-Video for a Subset of 'Incident-to' Services.

Under Medicare Part B, certain services must be furnished under specific minimum levels of supervision by a physician or practitioner. For professional services furnished "incident to" the services of the billing physician or practitioner (42 C.F.R. § 410.26) and many diagnostic tests (§ 410.32), "direct supervision" is required. "Direct supervision" has historically been defined as the physician or practitioner being physically present in the office suite and "immediately available" to furnish assistance and direction throughout the performance of the procedure.[19] However, during the COVID-19 PHE, CMS expanded the definition of "immediately available" to allow the physician/provider to establish a "virtual presence through audio/video real-time communications technology (excluding audio-only)."[20] The CAA, 2023 extended the time period during which these practitioners could bill for Medicare telehealth services through December 31, 2024; traditional "immediate availability" would apply after this date.

Previously, CMS expressed concern about abruptly reverting to a pre-PHE policy that defined "direct supervision" as requiring a supervising practitioner to be physically present. CMS in the CY 2025 MPFS Proposed Rule explains that an immediate reversion may create a barrier to access for many services, such as incident-to services, and that supervising practitioners would need time to reorganize their practice patterns effectively. CMS acknowledges the widespread utilization of this flexibility but notes the necessity for certain services to be furnished under direct supervision, especially if complications require immediate intervention by the supervisor. Therefore, CMS proposes to extend the definition of "direct supervision" to allow for the supervising practitioner to be present and "immediately available" via real-time audio and visual interactive telecommunication through December 31, 2025.

Additionally, CMS proposes to permanently define "direct supervision" to include audio-visual communications for a subset of services, which are generally furnished by "auxiliary personnel," pursuant to § 410.26(a)(1). The applicable incident-to services are: (1) provided by auxiliary personnel employed by and working under the direct supervision of the billing practitioner, and for which the underlying HCPCS is assigned a PC/TC indicator of "5"; and (2) services described by CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient that may not require the presence of a physician or other qualified health care professional*). CMS proposes to adopt the definition of direct supervision for "inherently" lower-risk services.[21] For all other services, the flexibilities to include audio and visual telecommunications will be extended through December 31, 2025.

LUGPA values the flexibility to offer such care at the clinical judgment of the billing physician or practitioner, and therefore we urge CMS to continue the virtual presence flexibility through December 31, 2025, and to make permanent this flexibility for the identified incident-to services. The virtual presence flexibility allowed our physician practices to expand and improve beneficiary access to care by removing literal physical barriers to access. While LUGPA does not see "virtual presence" ever fully supplanting in-person services, we certainly anticipate that ongoing technological advances may increase the amount, complexity, and acuity of

[19] 42 C.F.R. § 410.32(b)(3)(ii).

[20] *Id.*

[21] CY 2025 MPFS Proposed Rule, at 61634 ("services that are inherently lower risk" are defined as services "that do not ordinarily require the presence of the billing practitioner, do not require direction by the supervising practitioner to the same degree as other services furnished under direct supervision, and are not services typically performed directly by the supervising practitioner.").

care to be delivered remotely as an adjunct to proximate resources, with exciting implications for patient access and quality improvement.

XI. CMS Should Cautiously Approach Implementation of Transfer of Care Modifiers for Global Packages to Avoid Confusion and the Inadvertent Creation of Burdensome Documentation Requirements on Community Providers.

For CY 2025, CMS proposes to broaden the applicability of the transfer of care modifiers for global packages and require mandatory use of the -54, -55, and -56 modifiers for all 90-day global surgical packages when a practitioner, or another provider in the same group practice, expects to furnish only the pre-operative service, procedure, or postoperative portions of a global package. This includes circumstances where there is a formal, documented transfer of care or an informal (but expected) transfer. Under this policy, practitioners billing for a global package procedure code with modifier -54 and other practitioners in the group practice would be able to bill during the global period for any E/M procedure(s) that are unrelated to the global package. CMS is additionally proposing a global surgical add-on code, GPOC1, to be billed during the postoperative 90-day period after the procedure. CMS anticipates this code will be billed once during that timeframe, when the patient is seen for an O/O E/M procedure related to the recent surgical procedure, by a physician who did not furnish the surgical procedure.

LUGPA supports CMS's goal to track informal transfers of care to ensure that global modifiers are used as intended in these circumstances. However, LUGPA respectfully requests that CMS delay the implementation of any reimbursement changes associated with this policy until CY 2026 so it can work with LUGPA and other stakeholders to refine the policy to ensure it achieves its intended application without creating an inadvertent burden on smaller and community practices. We are concerned that, under this policy, all providers involved in furnishing care in a defined interval would be obligated to account for information dependent on access to a full and comprehensive review of records and/or a patient and their family's ability to understand and recount that a relevant intervention occurred during said interval. Moreover, this policy would place a burden on patients to remember certain procedures performed within 90 days, which could be particularly challenging for patients with certain conditions and/or cognitive limitations. Additionally, patients who undergo complex procedures can and do experience unanticipated complications that sometimes necessitate further intervention. Simply put, providers cannot reasonably be expected to predict a given patient's outcomes before furnishing procedures; it is simply not possible. While LUGPA supports efforts to advance value-based care, we urge CMS not to alter the proposal for implementation to allow further evaluation.

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On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the CY 2025 MPFS Proposed Rule. Please feel free to 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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