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September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies Proposed Rule (CMS-1751-P)[1]

Via Electronic Submission

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) 2022 Medicare Physician Fee Schedule ("MPFS") Proposed Rule (the "Proposed Rule").

LUGPA writes to express our concerns regarding the conversion factor reduction for CY 2022, which will have a detrimental impact on providers' ability to ensure access and quality care for Medicare beneficiaries during an ongoing COVID-19 public health emergency (PHE). Although LUGPA acknowledges that the conversion factor reduction is largely due to a legislative sunset, we urge the agency to explore exercising its regulatory authority to mitigate the impact of the reduction until Congress can renew payment relief for providers.

Additionally, LUGPA strongly opposes the Center for Medicare and Medicaid Services' (CMS') proposed updates to non-physician clinical labor (RVUs). Based on analysis performed by The Moran Company, CMS' proposed updates would dramatically impact payment of procedures that are performed in a non-facility setting and that have a significant cost component attributable to equipment and supplies. In turn, this will have a disproportionate impact on non-facility providers who specialize in furnishing equipment-and-supply dependent care, including standard treatment modalities in both urology and radiation oncology used to treat some of the most common urologic conditions.

LUGPA supports CMS' proposed site-neutrality payment policy for evaluation and management (E/M) codes; transparency efforts to include clinician affiliations with non-hospital facilities, such as end-stage renal disease (ESRD) facilities, on the Department of Health and Human Services' (HHS') Compare Tools; and the proposed updates to Stark regulations governing indirect compensation

[1] "CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies," 86 Fed. Reg. 39104 (July 23, 2021).

arrangements. Furthermore, LUGPA endorses CMS' proposal to launch the MIPS Value Pathway (MVP) program in 2023, though we have some concerns about the lack of opportunities for urology as a specialty to participate both Advanced Payment Models (APMs) and the novel MVP program.

Our comments, which are discussed in more detail below, can be distilled into the following calls for action:

- CMS should consider all options under its existing statutory authority to mitigate the impact associated with the removal of the temporary increase to conversion factor, including any options that phase-in the reduction.
- CMS should not proceed with its proposed update of the data source that informs the agency's valuation of non-physician clinical labor costs in the calculation of practice expense (PE) relative value units (RVUs) until CMS is able to appropriately assess the proposed update's impact on procedures performed in the non-facility setting and beneficiary access.
- CMS should continue with its proposal to launch MVPs, and we urge CMS to consider opportunities for urologist participation in the program.
- CMS should proceed with expanding public reporting of clinician affiliations on Compare Tools to include non-hospital facilities, such as ESRD facilities.
- CMS should proceed with updating Stark regulations to help physicians navigate indirect compensation arrangements.

I. BACKGROUND ON LUGPA

The Large Urology Group Practice Association (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 complementary priorities of: (1) the promotion 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. LUGPA was thereby able to ensure that its providers had an opportunity to advocate on behalf of their patients and their specialty at a national level. 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 (ref 2018 PUF data). 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 redirect 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 typicallymore convenient 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 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. LUGPA practices have embraced value-based care models, and the organization was among the first to create a physician-focused payment model. As such, LUGPA has served

consistently in developing and promoting a high-quality, cost-effective alternatives for care as a counterbalance to the cost increases associated with the trend towards consolidation of health care services.[3,4]

LUGPA's mission has been to provide and maximize access to the resources, technology, management tools and advocacy efforts to optimize the ability of independent practice urologists and their clinical partners to provide integrated, comprehensive care for patients with acute and chronic GU conditions. During the global Public Health Emergency (PHE), LUGPA's mission was expanded to provide crucial resources to independent physician practices so as to enable continuity of outpatient services, even as the nation's inpatient capacity was overrun by patients stricken with COVID-19. In the During this unprecedented crisis, LUGPA's team worked in Congress to advocate on behalf of all independent practice providers as emergency funding measures to sustain critical medical infrastructure were considered, in assisting membership with guidance regarding the applicability ofand access to government assistant programs subsequently, by coordinating sourcing of personal protective equipment, and by providing crucial safety data to its members.[5] Through these and other efforts, LUGPA helped ensure that vulnerable populations continued to be able to access life-saving urological services.[6]

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.

I. LUGPA URGES CMS TO EXPLORE EXERCISING ITS REGULATORY AUTHORITY TO MITIGATE THE IMPACT OF THE REDUCED CONVERSION FACTOR.

In response to the COVID-19 pandemic and PHE, Congress provided a 3.75% increase in MPFS payment amounts for services furnished between January 1, 2021 and December 30, 2021.[7] Congress further required that the payment increase "shall not be taken into account" for determining fee schedule payment rates for subsequent years,[8] thereby ensuring that the temporary increase could not be factored into the annual update methodology used by CMS. Accordingly, the conversion factor calculation for CY 2022, without the one-year 3.75% increase, will equal 33.5848.[9]

The temporary conversion factor increase was part of a national effort to support providers that were reeling from 2020's impact on the healthcare system, including mandatory shutdowns to some of providers' most profitable elective services, supply shortages, necessary and costly care delivery transformations to telehealth for providers, and an abrupt refocus on care delivery for COVID-19 patients. Providers in several subspecialties experienced a significant decline in outpatient visits during the spring of 2020,[10] and it is likely that several providers are still feeling the financial strain of this reduction. As providers work to ensure the highest levels of care and while mitigating the risk of spreading COVID-19, exhaustion of the resources needed to perform

[3] 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.

[4] 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.

[5] 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.

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

[7] *See* § 101, Division N, Consolidated Appropriations Act, 2021, Pub. L. No. 116-260 (Dec. 27, 2020).

[8] *See* § 1848(c)(2)(B)(iv)(V).

[9] 86 Fed. Reg. at 39529-30.

[10] Ateev Mehrotra et al, The Impact of COVID-19 on Outpatient Visits in 2020: Visits Remained Stable, Despite a Late Surge in Cases, The Commonwealth Fund (Feb. 21, 2021), available at: https://www.commonwealthfund.org/publications/2021/feb/impact-covid-19-outpatient-visits-2020-visits-stable-despite-late-surge.

at this level could have a negative downstream impact on patients. Small and solo physician offices in particular might not have the financial capability to retain staff or purchase costly equipment, which could result in early retirement and premature office closures, thereby reducing patient access to care.

Though many Americans have chosen to get vaccinated, the COVID-19 pandemic is not over, and cases are still being reported throughout the United States.[11] Providers, particularly those in COVID-19 "hotspots," may have already exhausted their resources and are working to furnish care during surges in COVID-19 cases notwithstanding. Providers who are still trying to recoup from losses they endured in 2020, and who are still facing challenges from the pandemic, will experience further hardship from the reduced conversion factor.

We understand the impact of our commentary with respect to the conversion factor is necessarily limited, as this is determined by statute, not rulemaking. However, this reduction is a devastating cut that will have a negative impact on the entire practice of medicine. We request that CMS consider all possible options to mitigate the negative impact of this reduction on providers.

II. LUGPA URGES CMS TO NOT FINALIZE ITS PROPOSAL TO UPDATE THE NON-PHYSICIAN CLINICAL LABOR COSTS USED IN THE CALCULATION OF PRACTICE EXPENSE RELATIVE VALUE UNITS FOR CY 2022 UNTIL THE AGENCY ADEQUATELY CONSIDERS THE UPDATE'S IMPACT ON PROCEDURES PERFORMED IN THE NON-FACILITY SETTING.

A. CMS' anticipated specialty-level clinical labor pricing impact disguises the pricing update's dramatic payment reductions for non-facility urological procedures that involve significant supply and equipment costs.

CMS proposes to update the data source the agency uses to capture non-physician clinical labor costs as direct resource inputs[12] in the calculation of Practice Expense (PE) Relative Value Units (RVUs).[13] CMS uses Bureau of Labor Statistics (BLS) wage data and other supplementary sources to assign clinical labor "rates per minute" to non-physician staff types involved in the provision of PFS services.[14] CMS proposes to update this BLS wage data source from 2002 levels to the most current BLS data available (2019) for use in CY 2022 rate setting.

As this update reflects a 17 year span[15] in the underlying source of wage data, nearly all non-physician clinical labor staff types are proposed to receive a pricing update ranging from 7% to 130%.[16] This proposed pricing update results in a significant increase, more than 25%, in the amount of value attributed to *clinical labor* in the PFS PE RVU methodology. This proposal also thereby increases total direct costs within the PFS system, resulting in redistribution of value across PFS services and has a "significant effect" on the valuation of many codes, particularly those that reflect a greater share of equipment and supply costs.[17]

By way of background, in CMS' PE RVU methodology, aggregate direct costs are made "budget neutral" as a policy decision. This increase accordingly triggers an offsetting reduction that is applied through the "direct scaling adjustment" within the PE RVU calculation. In CY 2021 rate setting, the direct scaling adjustment is .5916. This means that for every $100 in direct costs, CMS incorporates ~$59 into the PE RVU calculation. In CY 2022 proposed rate setting, the direct

[11] *See* Johns Hopkins University, Coronavirus Resource Center, available at: https://coronavirus.jhu.edu/data.
[12] Direct resource inputs include: non physician clinical labor, single use medical supplies and capital equipment directly attributable to the provision of an individual service.
[13] 86 Fed. Reg. at 39118-23.
[14] In the calculation of PE RVUs, CMS captures clinical labor costs as the product of the number of minutes the staff type is typically involved in the provision of the service and the per minute staff type wage rate as per BLS data.
[15] 2002 BLS data versus 2019 BLS data.
[16] 86 Fed. Reg. at 39120.
[17] *Id.* at 39562.

scaling adjustment decreases to .4468.[18] If finalized, this means that in CY 2022 for every $100 in direct costs, CMS incorporates ~$45 into the calculation of PE RVUs. As this direct scaling adjustment is applied consistently across all direct cost inputs, those services and specialties with a larger share of direct costs attributed to supplies and equipment are disproportionately affected by the budget neutral implications and redistribution effects of this proposal.

Furthermore, as the relative size of the direct cost pool is based on 2006 data, determining whether or not direct costs constitute the same percentage of overall practice expenses as they did almost two decades ago would require a new physician practice cost survey. **Given the difference in practice modality and the profound change in technology, it is simply not possible that the relative percentage of direct costs for physician services in 2022 is the same as in 2006**. **Since CMS has already acknowledged that the PPIS data is outdated and has begun to contemplate updating PPIS data and even overhauling the PE methodology, it would be irresponsible for CMS to update clinical labor inputs in an outdated framework at this time.** Exercising circumspection would serve the dual purpose of minimizing the disruption of an already anticipated near term subsequent revision and also avoid, as an inadvertent consequence, a shift of supply or equipment intensive procedures away from lower cost and more accessible sites of service, as illustrated in more detail below.

Although CMS estimates that the anticipated clinical labor pricing effect on the specialty of urology is a 1% decrease and estimates that the combined impact of all CY 2022 PFS proposals on the specialty of urology is 0% (not taking into account the expiration of the conversion factor increase), CMS' analysis ignores the clinical labor pricing effects on services provided in a non-facility setting that have a larger share of supply or equipment costs compared to labor, which is discussed in further detail below.

B. CMS' specialty-level impact analysis (Table 123) fails to take into account the disparate impact on non-facility v. facility procedures for urology.

LUGPA enlisted The Moran Company (TMC) to analyze the impact of CMS' proposed clinical labor pricing update on specific urology codes payable in the non-facility setting to better understand the impact that the update would have on independent physicians' ability to furnish care to their patients in safe, cost-effective, and convenient non-facility-based settings.

At the outset, Table 1 below summarizes the impact of CMS' proposed clinical labor update on urology. Consistent with CMS' estimates, TMC also estimates that the proposed update will have a more or less neutral impact on urology at a specialty-level, but TMC further divides this impact between the non-facility and facility settings and finds a neutral impact on the non-facility setting, and a slight 1% increase in the facility setting. However, this sets aside the reduction in the conversion factor reduction for CY 2022, which, when included, contributes to an approximate total 4% cut in the non-facility setting and 3% cut in the facility setting.

Table 1: Estimate of Impact of 2022 Proposed Rule Policies on Total Allowed Charges[19]

	TMC Replication of CY 2022 Impact			Incl. Conversion Factor Reduction		
Specialty	Total	NF	F	Total	NF	F
Urology	0%	0%	1%	-4%	-4%	-3%

[18] This decrease in the direct scaling adjustment is driven by the clinical labor pricing update, however, also reflects changes in volume as well as other changes in direct costs including the final year of the transition to market based pricing for supply and equipment inputs.

[19] The full analysis is attached as Appendix A, Tab 1.

In order to establish whether there was significant variability within the specialty in the anticipated "net" impact of 0% as a result of the clinical labor update, TMC's analysis demonstrated that the increase in payments for certain E&M codes (99201-99215), which together represent the largest share of the total codes billed by urology, were effectively "balancing out" the other reductions that urology was experiencing. Thus, as shown in Table 2, if the E&M codes are removed from the specialty impact analysis, urology experiences a total reduction of -1%, with the impact on non-facility payments declining -3%, as opposed to netting zero according to CMS' analysis. In other words, increases in payment for E&M codes distorts the impact on urology at a specialty-level, and it hides the fact that the clinical labor update will be particularly punitive against providers who specialize in equipment/supply-intensive procedures.

Table 2: Estimate of Impact of 2022 Proposed Rule Policies on Total Allowed Charges - with and without E&M[20]

	TMC Replication of CY 2022 Impact			Without E&M Codes (99201-99215)		
Specialty	Total	NF	F	Total	NF	F
Urology	0%	0%	1%	-1%	-3%	1%

TMC also considered the impact on urology if the clinical labor update was *not* finalized to determine the reimbursement that these specialties would forgo if CMS were to finalize the clinical labor update. Table 3 below removes the clinical labor update from the specialty-level payment estimates for urology. Without the clinical labor updates, urology would experience a total increase of 1% for CY 2022, with 2% in the non-facility setting and approximately 0% in the facility setting.

Table 3: Estimate of Impact of CY 2022 Proposed Rule Policies (Without Clinical Labor Update)[21]

	TMC Replication of CY 2022 Impact			*Without Clinical Labor Update*		
Specialty	**Total**	**NF**	**F**	**Total**	**NF**	**F**
Urology	0%	0%	1%	1%	2%	0%

C. Further service-level analysis in urology demonstrates devastating payment reductions for procedures with a greater share of equipment and supply costs.

As alluded to above in the case of E&M codes, focusing on specialty-level payment impact obfuscates the disparate payment impact at the service-level for procedures which contain a greater share of supply and equipment costs and thus that do not benefit as much from higher labor costs factors. Table 4 below summarizes the proposed clinical labor update's impact on the top 13 CPT codes billed by urologists in the non-facility setting. Quite notably, the percentage difference between CY 2021 and CY 2022 payment rates for these codes ranges from -10% to 16%, with 85% of the 13 CPT codes experiencing a payment reduction, and the costliest CPT codes experiencing the greatest magnitude of payment reductions.

[20] The full analysis is attached as Appendix B, Tab 1.
[21] The full analysis is attached as Appendix C.

Table 4: Comparison of CY 2021 and Proposed CY 2022 Non-Facility Payment Rates (top 13 codes by volume)[22]

HCPCS	Description	2021 Total NF Payment	2022 Total NF Payment	2021-2022 Differential
51798	Us urine capacity measure	$10.47	$12.09	16%
52000	Cystoscopy	$241.11	$226.03	-6%
51741	Electro-uroflowmetry first	$14.31	$14.44	1%
51702	Insert temp bladder cath	$65.25	$61.12	-6%
51720	Treatment of bladder lesion	$91.07	$87.66	-4%
51700	Irrigation of bladder	$80.95	$74.89	-7%
51701	Insert bladder catheter	$46.76	$44.00	-6%
51705	Change of bladder tube	$99.79	$96.39	-3%
51784	Anal/urinary muscle study	$67.34	$63.48	-6%
51797	Intraabdominal pressure test	$192.61	$174.64	-9%
55700	Biopsy of prostate	$256.46	$233.41	-9%
52310	Cystoscopy and treatment	$320.67	$307.97	-4%
51729	Cystometrogram w/vp&up	$405.46	$365.07	-10%

The payment reductions caused by the clinical labor update are even starker when one examines fourteen urological CPT codes billed as global services that principally rely on equipment and supplies. Table 5 below indicates that for *all* fourteen procedures, the 2022 supply costs *exceed* the 2022 PE payments, and **only for five of these procedures does the total payment for the procedure cover the supply costs (alone)**. Indeed, for five CPT code 52442 (*Cystourethro w/ addl implant*) is a case in point (highlighted below) and describes a procedure that relies on an implantable device that itself accounts for a significant share of the costs associated with the procedure. The procedure is disproportionately affected by the clinical labor update such that, not only will providers be underwater with respect to the 2022 PE payments, but the *total* payment for the procedure will not even cover the costs of the supplies required to perform said procedure! Indeed, if the clinical labor update is finalized, CPT code 52442 will experience a -22% payment reduction.[23]

In addition to the above, the payment reductions result in consequences clearly contradictory to the fundamental principle of the RBRVS which states "that payments for physician services should vary with the resource costs for providing those services and is intended to improve and stabilize the payment system while providing physicians an avenue to continuously improve it."[24] As further illustrated in Table 5, **the payment realignment proposed by the agency results in a serious imbalance, in which the total payment for a procedure performed by a physician can actually be lower than the payment for the professional work component alone**. This will create payment imblances that fundamentally undermine the premise that the RBRVS system can create payment equivalency between services with comparable resource use between specialties, and as we will discuss shortly, profound discrepancies between sites of service.

[22] For a full analysis, see Appendix D, Tab 3.
[23] *See* Appendix D, Tab 1.
[24] RBRVS overview. Accessed at: https://www.ama-assn.org/about/rvs-update-committee-ruc/rbrvs-overview

Table 5: Codes Where CMS Accepted Direct Cost of Supplies is Greater than Non-Facility PE Payment Rate[25]

HCPCS	Description	2022 NF PE Payment	2022 Total NF Payment	2022 Supply Costs	Net Margin	2022 wRVU Fee	Margin vs. wRVU Fee
52442	Cystourethro w/addl implant	$758	$796	$875	($79)	$34	($113)
51797	Intraabdominal pressure test	$136	$136	$163	($27)	$27	($54)
55874	Tprnl plmt biodegrdabl matrl	$2,454	$2,566	$3,093	($527)	$102	($629)
53855	Insert prost urethral stent	$529	$591	$607	($16)	$55	($71)
53860	Transurethral rf treatment	$2,000	$2,149	$2,309	($160)	$133	($293)
51797	Intraabdominal pressure test	$145	$175	$163	$12	$27	($15)
52441	Cystourethro w/implant	$1,004	$1,155	$1,095	$60	$134	($74)
53854	Trurl dstrj prst8 tiss rf wv	$1,305	$1,528	$1,401	$127	$199	($72)
53850	Prostatic microwave thermotx	$1,098	$1,302	$1,141	$161	$182	($21)
53852	Prostatic rf thermotx	$1,051	$1,273	$1,081	$192	$199	($7)
50389	Remove renal tube w/fluoro	$341	$382	$357	$25	$37	($12)
55873	Cryoablate prostate	$4,681	$5,192	$5,098	$94	$457	($363)
50592	Perc rf ablate renal tumor	$2,351	$2,591	$2,421	$170	$220	($50)
50705	Ureteral embolization/occl	$1,573	$1,722	$1,685	$37	$135	($98)

All in all, for a 158 code set of urology procedures, the proposed clinical labor updates will result in an aggregate payment reduction of nearly $38 million for non-facility-based procedures.[26]

D. LUGPA opposes the finalization of the proposed clinical labor update and urges CMS, prior to taking any action, to consider the impact of the proposed update on the agency's broader goal of migrating services to the non-facility-setting.

LUGPA urges the agency to not finalize its proposed clinical labor update until the agency has adequately assessed the impact of such an update on non-facility providers and their ability to furnish cost-effective and quality care in a more convenient setting for their patients. Although LUGPA recognizes that adjusting non-physician clinical labor costs to better reflect current levels is an important improvement to ensure the integrity of the Medicare physician fee schedule, TMC's analysis demonstrates that such an update has system-wide ramifications that need to be better understood and mitigated prior to implementation. TMC's analysis in the urology space illustrates a dynamic that the proposed clinical labor update would significantly disadvantage non-facility providers who perform equipment/supply-intensive procedures, and because this dynamic is driven by CMS' policy decision to maintain the relative size of the direct and indirect cost pool based on 2006 data and outdated PPIS data, LUGPA is certain that the mechanical application of the clinical labor updates will have similar effects across all other specialties.

Moreover, CMS' proposed clinical labor update would also undermine the agency's commitment and actions to migrate services away from higher-cost, facility-based sites of care towards cost-effective, non-facility based sites of care. Although, when performed in the non-facility setting, these supply and equipment cost intensive procedures provide significant cost savings for Medicare due to the reduction in overhead and labor costs,, the cost to obtain equipment and

[25] *See* full analysis at Appendix E, Tab 2.
[26] *See* Appendix C, Tab 2.

supplies is typically the same across sites of care. Procedures that have a greater share of supply and equipment costs are some of the most financially challenging for providers to perform in the non-facility setting as the costs are often quite large.. Given their economies of scale, however, HOPDs and other institutional settings are better able to absorb and diffuse the costs of equipment and supplies across their budgets, while for non-facility-based physicians, some of the equipment and supplies they employ may represent the single largest capital expenditure they have.

This dynamic is plainly reflected in the significant variability in payment amounts for urological procedures that can be performed across the HOPD, ASC, and physician office setting. Table 6 below illustrates that CMS' proposed CY 2022 payment changes, particularly the proposed clinical labor update and expiration of the conversion factor increase, will cause double-digit payment reductions in the physician office across the vast majority of 20 of the most commonly billed urological procedures (excluding E&M codes) when compared to CY 2021. **However, in the HOPD setting, every *single* procedure of the 20 analyzed will experience a payment increase. The effect of this is self-evident: procedures that could and had migrated to the non-facility setting will now revert back to the facility setting, ballooning Medicare spend, increasing beneficiary out-of-pocket costs, and otherwise aggravating the beneficiary experience along the way.**

Table 6: Percentage Change in CY 2021-2022 Payments For Select Procedures Based on Site of Care

CPT Code	Description	2022 Proposed ($)			2021-2022 Difference (%)		
		Total HOPD	Total ASC	Total Office	Total HOPD	Total ASC	Total Office
52000	Cystoscopy	669.41	380.05	226.03	2.4%	2.8%	-10.4%
52442	Cystourethro w/addl implant	8,517.35	7,287.14	795.96	2.5%	2.7%	-26.3%
55874	Tprnl plmt biodegrdabl matrl	4,690.79	3,193.22	2,565.54	2.5%	2.8%	-24.0%
53854	Trurl dstrj prst8 tiss rf wv	2,224.04	1,209.15	1,528.11	2.2%	2.4%	-23.1%
52441	Cystourethro w/implant	4,733.44	3,704.83	1,154.65	2.5%	2.6%	-23.6%
55700	Biopsy of prostate	1,967.79	952.90	233.41	2.4%	3.0%	-12.3%
52224	Cystoscopy and treatment	3,355.59	1,642.19	723.75	2.5%	3.1%	-17.4%
51728	Cystometrogram w/vp	668.07	321.41	343.91	2.4%	-9.3%	-14.1%
52281	Cystoscopy and treatment	1,990.29	975.40	310.66	2.4%	3.0%	-13.2%
51797	Intraabdominal pressure test	#N/A	29.22	174.64	#N/A	#N/A	-14.0%
51729	Cystometrogram w/vp&up	683.85	336.85	365.07	2.3%	-9.1%	-13.7%
53850	Prostatic microwave thermotx	3,517.14	1,463.63	1,302.08	2.4%	-16.6%	-23.3%
52310	Cystoscopy and treatment	1,988.94	974.06	307.97	2.4%	3.0%	-7.6%
51700	Irrigation of bladder	302.59	82.28	74.89	2.3%	-4.8%	-10.6%
51702	Insert temp bladder cath	#N/A	25.19	61.12	#N/A	#N/A	-10.6%
52287	Cystoscopy/chemodenervation	2,005.40	990.51	369.10	2.4%	2.9%	-10.9%
52214	Cystoscopy and treatment	3,328.73	1,615.33	691.51	2.5%	3.1%	-17.8%
51720	Treatment of bladder lesion	315.69	98.06	87.66	2.2%	-1.8%	-7.3%
51705	Change of bladder tube	324.75	114.52	96.39	2.2%	-1.5%	-7.0%
51784	Anal/urinary muscle study	#N/A	55.08	63.48	#N/A	-3.7%	-9.5%

In summary, if finalized, the proposed clinical labor update will create substantial unintended consequences, such as delayed or reduced patient access to services; the reduction or elimination of treatments appropriately furnished in office settings with reallocation to facility settings; disincentives to the development of innovative medical procedures that enable efficiencies in the office; and an increase in overall costs to Medicare due to impediments to patient access to less costly in-office sites of service. LUGPA strongly encourages CMS to postpone these proposed payment changes to more fully assess their impact and consider alternatives that better serve the goals of improving health equity and patient access, including potentially waiting until the agency is able to overhaul its PE methodology as planned. Specifically, it is critical that CMS not create incentives that will necessitate a shift from the in-office setting to the more costly and less accessible facility setting.

E. The proposed payment changes will impact the delivery of integrated radiation oncology services performed by LUGPA practices and will confound the purpose of the radiation oncology demonstration project.

LUGPA was an early proponent of developing alternative payment models and other value-based payment structures for use in treating patients with Genitourinary malignancies,and we are highly appreciative of the efforts CMS has made to design an RO Model. Indeed, the APM submitted by LUGPA for treating newly diagnosed patients with prostate cancer included global payments for radiation therapy.[27] We are in favor of CMS testing a value-based care delivery model for the purpose of enhancing the quality of cancer care, reducing overall Medicare expenditures, and reducing administrative burdens placed on providers, and we have interacted extensively with the agency to refine the model, which is set to launch on January 1, 2022.

That said, finalizing the clinical labor update would significantly impact all providers participating in the RO Model, including independent free-standing radiation oncology centers, radiation centers integrated into multi-specialtty groups, and also those hospital-based providers of radiation oncology services included in the mandatory demonstration project. Under the RO Model, episode-based payment rates for TC services provided by Model are "trended" using a blend of the updates otherwise applicable under the hospital outpatient prospective payment system (HOPPS) and PFS. If the payment changes in both the 2022 HOPPS and 2022 PFS Proposed Rule are finalized without revision, the episode based payments made to almost 1000 demonstration participants—including hospital participants whose Medicare payment would otherwise increase—will be decreased by approximately 10% below the episode rates that have been proposed. This occurs at a time when these RO Model Participants may well be experiencing substantially increased administrative costs to comply with the extensive and novel RO Model requirements. Taken in tandem with these factors, the implication of the reduction in Medicare payments, estimated at $140 million in a single year as a consequence, cannot be overstated.[28]

Moreover, implementing these payment reductions without change would completely undermine CMS' ability to credibly assess the impact of the RO Model. It is impossible to quantify in advance the impact that payment reductions of this magnitude will make on delivery of radiation services provided by non-institutional radiation oncology providers in traditional Medicare fee-for-service markets which serve as benchmarks, functioning as the "control arm" for the RO Model. It is elementary to study design that it is essential to eliminate or at least minimize confounding variables in the control arm of a study.

As noted, other immediate factors make it particularly misguided at this moment to adopt a policy with such significant implications. While manifold, the most salient of these include the presence

[27] LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer submitted to Physician-Focused Payment Model Technical Advisory Committee (July 5, 2017), *available at* https://aspe.hhs.gov/system/files/pdf/255906/LUGPAAPM.pdf

[28] Diane Millman, AFROC Washington Counsel. Powers, Pyles, Sutter & Verville, P.C,Personal Communication

of an ongoing PHE which has, in many cases, utterly swamped hospital resources, deferring all but the most emergent levels of care along with the anticipated implementation of a radiation oncology demonstration program (RO Model) on January 1, 2022. Specifically as it pertains to the RO Model, the coincident reimbursement reduction related to the PE RVU recaluculation would render the impacts of the program impossible to determine, thereby obviating its purpose. The magnitude of the logistics associated with implementation and monitoring of the RO project by providers of radiation services as well as by CMS' vendors is further reason we strongly encourage CMS to reconsider updating non physician labor costs at this time.

F. To the extent that CMS moves forward with updating the non-physician clinical labor costs, LUGPA urges CMS to phase-in implementation beginning CY 2023 because CY 2022 is an inappropriate year to implement discretionary and significant payment changes which will only compound other payment challenges for providers, including the reduction in the conversion factor, ongoing adjustment to updated equipment and supply costs, and the ongoing COVID-19 pandemic.

If CMS is intent on finalizing the proposed clinical labor updates notwithstanding the adverse impact it will have on beneficiary access to equipment/supply-intensive procedures furnished in a more convenient and cost-effective non-facility site of care, we agree with the agency that a 4-year implementation phase-in is appropriate. However, we urge CMS to begin the 4-year phase-in CY 2023 as opposed to CY 2022 to allow providers to recover from several years involving a flurry of payment challenges.

As noted above, all Medicare providers are set to experience an across-the-board payment reduction as a result of the expiration of the temporary increase to the conversion factor under the Consolidated Appropriations Act, 2021. Compounding a conversion factor payment reduction with a clinical labor update that will disproportionately impact certain procedures over others unnecessarily injects additional hardship on struggling providers, particularly those practicing in non-facility settings.

Additionally, as CMS notes in the Proposed Rule, CY 2022 will be the final year of the 4-year phase-in that updated the equipment and supply costs to market-based pricing.[29] Not only are providers continuing to adjust to these ongoing changes, but it would be a failure in stewardship of the Medicare program for CMS to tack onto this uncertainty additional and complex payment changes and potentially distort the agency's evaluation of both the equipment and supply costs update and the clinical labor update.

Finally, LUGPA need not remind CMS that the COVID-19 pandemic has and will continue to strain the American health care system as variants continue to emerge and contribute to the resurgence of COVID-19 across the country. Along with the entire world, providers have uniformly experienced 2 years of disruption to their lives and the survival of their practices will continue to depend on transformations and continued adaptations to thedelivery of care that require additional expense as well as time to allow for implementation. LUGPA believes it would be tone-deaf and inconsistent with the lived experience of providers and patients to adopt a significant payment adjustment that disproportionately affects procedures involving equipment and supplies in the middle of an ongoing global pandemic.

LUGPA also fails to see how adopting a payment change that will steer a greater number of Medicare beneficiaries to institutional settings where there is a higher risk of COVID-19 contamination is consistent with public health protocols intended to reduce the spread of COVID-

[29] 86 Fed. Reg. at 39919.

19. Studies have shown that hospital spread of COVID-19 is led by *patients* rather than health workers because the facility effectively serves as a congregation area for COVID-19 patients.[30]

In summary, if CMS insists on moving forward with its proposed clinical labor update, it should, at the very least, phase-in implementation of the update beginning with CY 2023, and use CY 2022 to understand the viability of potential alternatives, including updates to the direct and indirect cost pools used under the agency's PE methodology.

III. LUGPA SUPPORTS THE TRANSITION FROM MIPS TO MVPS AND RECOMMENDS CMS EXPLORE INCLUDING OPPORTUNITIES FOR UROLOGISTS AND OTHER SPECIALTIES TO PARTICIPATE.

The Medicare and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (QPP), which launched two tracks for physician reporting, beginning with reporting year 2017/payment year 2019: the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (Advanced APMs).[31] MIPS eligible clinicians receive a payment adjustment based on their aggregated performance in four weighted categories—cost, quality, improvement activities, and Promoting Interoperability—while qualifying APM participants (QPs) can receive a payment adjustment and are exempt from MIPS reporting.[32]

CMS finalized its proposal to shift toward the MIPS Value Pathways (MVPs) in the CY 2020 MPFS Final Rule. In the CY 2022 Proposed Rule, CMS explains its plan to continue shifting toward the MIPS Value Pathways to "allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population," starting with the 2023 MIPS year.[33] CMS seeks to gradually implement MVPs for all specialties and subspecialties in the program and has plans to sunset the traditional MIPS program in the future. Of the seven proposed MVPs for implementation in 2023, one in particular—Optimizing Chronic Disease Management—contains the quality measure Q119: Diabetes Medical Attention for Nephropathy, which may have some overlapping applicability for urology.[34]

LUGPA commends CMS for shifting toward MVPs, which will allow for greater specialty and subspecialty participation. LUGPA welcomes the opportunity to work with CMS as it considers expanding opportunities for urologist and other specialty participation.

IV. LUGPA SUPPORTS CMS' PROPOSAL TO INCLUDE END-STAGE RENAL DISEASE (ESRD) FACILITY AFFILIATION REPORTING ON THE COMPARE TOOLS.

In the CY 2022 MPFS Proposed Rule, CMS proposes publicly reporting on Compare Tools, as hosted by HHS, clinicians' affiliations with certain facilities: long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities, skilled nursing facilities (SNFs), home health agencies, hospice, and end-stage renal disease (ESRD) facilities.[35] As CMS explains in the CY 2022 Proposed Rule, clinician profiles on HHS' "Compare Tools," available at https://www.medicare.gov/care-compare/ ("Care Compare") and data.medicare.gov, currently provide contact information, medical specialties, certifications, and affiliations with APMs, groups, and hospitals.[36] According to CMS, "user testing consistently shows that Medicare patients and caregivers find value in these types of information," and "website users have consistently noted the importance of understanding up front the relationships clinicians may have with facilities

[30] Mary Van Beusekom, "Study: Patients, not staff, source of most hospital COVID spread," Center for Infectious Disease Research and Policy (Aug. 24, 2021), https://www.cidrap.umn.edu/news-perspective/2021/08/study-patients-not-staff-source-most-hospital-covid-spread.
[31] 86 Fed. Reg. at 39263.
[32] *Id.* at 39337.
[33] *Id.* at 39337.
[34] *Id.* at 39892.
[35] *Id.* at 39466.
[36] *Id.* at 39468.

where they perform services when searching for a clinician."[37] CMS further explains how user testing has revealed that hospital affiliation is important to patients and to caregivers, "since [patients] may be looking for a clinician to perform a procedure at a hospital or want to know the hospitals a clinician could potentially admit them if needed."[38]

LUGPA supports CMS' proposal to increase transparency and ensure that patients have adequate information when making decisions about their healthcare. These web tools are essential for patients and caregivers to make informed health decisions, and CMS' proposal to expand information on clinician affiliations with facilities other than hospitals would further enhance patient decision-making. LUGPA agrees with CMS' assessment that patients and caregivers would benefit from the ability to navigate between clinicians' profile pages to profile pages for facilities such as dialysis facilities.[39] Furthermore, institutionally affiliated providers may have mandates to use institutionally owned ancillary services, which can have a downstream effect of substantially higher costs to systems and for patients; information on such affiliations can help patients make informed decisions regarding costs.

V. LUGPA SUPPORTS CMS' PROPOSAL TO REVISE AND CLARIFY REGULATIONS ON INDIRECT COMPENSATION ARRANGEMENTS.

On December 2, 2020, CMS published the Modernizing and Clarifying the Physician Self-Referral Regulations (the "MCR") Final Rule, which established new exceptions to the physician self-referral law regarding "value-based" arrangements and updated the definition of indirect compensation arrangements.[40] In the CY 2022 MPFS Proposed Rule, CMS is proposing to revise 42 CFR § 411.354(c)(2) to clarify regulations for indirect compensation arrangements. Specifically, CMS proposes to include "any unbroken chain of financial relationships in which the compensation arrangement closest to the physician (or immediate family member of the physician) involves compensation for anything other than services that he or she personally performs" within the definition of "indirect compensation arrangement."[41]

Prior to the MCR Final Rule, an "unbroken chain of financial relationships" between a referring physician, or a member of the physician's immediate family, and the entity providing the health services satisfied the definition of an "indirect compensation arrangement" if all elements enumerated in § 411.354(c)(2) were present.[42] The MCR established a test for evaluating if "compensation varies with the volume or value of referrals or other business generated between the parties:" under the MCR, an indirect compensation arrangement is an "unbroken chain of financial relationships" between a physician, or immediate family member of the physician, and an entity with which the physician has a "direct financial relationship" and "receives aggregate compensation" from the entity that is either (1) not fair-market value; (2) calculated in a manner that incorporates the physician's referrals, or; (3) correlates positively to the physician's "generation of other business for the entity," and the entity must have actual knowledge of the physician's aggregate compensation and positive correlation(s).[43]

In the CY 2022 MPFS Proposed Rule, CMS explains how the test for analyzing chains of financial relationships inadvertently omitted "[c]ertain arrangements involving unit of service-based payment for the rental of office space or equipment."[44] CMS is proposing to include payments for office-space and equipment rentals within the definition of "anything other than services

[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] *See generally* 85 Fed. Reg. 77492.
[41] 86 Fed. Reg. at 39320.
[42] *Id.* at 39321.
[43] *Id.*
[44] *Id.* at 39322.

performed by the physician (or immediate family member)" for the purposes of analyzing an "unbroken chain of financial relationships."[45]

Furthermore, CMS is proposing to clarify certain definitions set forth in the MCR, namely "unit" and "services that are personally performed."[46] To help facilitate compliance with applicable self-referral laws, CMS is proposing a new regulation at § 411.354(c)(2)(ii)(B)(2) to identify a "unit," for the purposes of compensation: a "unit" can mean (1) a payment to the physician based solely on the amount of time during which the service is provided; (2) a payment based solely on the service provided, or; (3) a payment not based solely on the amount of time or solely on the service provided.[47] CMS is also proposing to codify a policy that services performed by persons other than the physician or family member—such as employees, independent contractors, supervisees, and group-practice members—are *not* considered to be "personally performed" by the physician or physician's immediate family member.[48]

LUGPA supports these proposals and thanks CMS for issuing the technical clarifications, which will help avoid any misdirection among membership.

VI. CONCLUSION

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the CY 2022 MPFS Proposed Rule. As noted above, we are deeply concerned about the reduction in the conversion factor, starting in CY 2022, and we urge CMS to consider all possible options to mitigate the impact of this reduction on providers. LUGPA also strongly counsels against adoption of the proposed clinical labor update. There is strong and pervasive empirical support that the update will have an adverse impact on those providers performing supply and equipment intensive procedures in non facility settings and, consequently, drive these procedures higher cost sites of service as well as to serve to confound the intended effect and results of the novel RO project scheduled for implementation on January 1, 2022.

Please feel free to contact Dr. Kapoor at (516)-342-8170 or dkapoor@impplc.com if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,

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[45] *Id.* at 39323.
[46] *Id.* at 39320.
[47] *Id.* at 39324.
[48] *Id.* at 39323.