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August 31, 2015

BY ELECTRONIC SUBMISSION

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on CMS-1633-P

Dear Acting Administrator Slavitt:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals Under the Hospital Inpatient Payment System; CY 2016 Proposed Rule (CMS-1633-P), published in the July 8, 2015 Federal Register (the "Proposed Rule").¹ These comments principally address LUGPA's concerns regarding the reclassification of urologic ambulatory payment classifications (APCs), particularly the classification of certain lithotripsy procedures to treat kidney stones as well as prostate laser procedures used for treatment of benign prostatic hyperplasia (BPH), a condition commonly referred to as enlargement of the prostate gland.

I. LUGPA

In 2008, when physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the purpose of enhancing communication between large groups, allowing for benchmarking of operations, promoting quality clinical outcomes, developing new business opportunities, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 118 urology group practices in the United States, with more than 2,000 physicians comprising more than 25 percent of the nation's practicing urologists.

¹ 80 Fed. Reg. 39200 (July 8, 2015).

Integrated urology practices are able to monitor health care outcomes and seek out medical “best practice” in an era increasingly focused on medical quality and the cost-effective delivery of medical services, as well as better meet the economic and administrative obstacles to successful practice. LUGPA’s mission is to provide urological surgeons committed to providing integrated, comprehensive care the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, and regulatory agencies and legislative bodies.

Over the past several years, LUGPA has taken an active role in providing CMS and other governmental agencies, including the Medicare Payment Advisory Commission (MedPAC), the Government Accountability Office (GAO) and the Congressional Budget Office (CBO), critical data and other information regarding diagnostic and therapeutic modalities used in providing urologic care to Medicare beneficiaries. On numerous occasions, LUGPA representatives have met with senior leaders in all of these agencies, as well as with members of Congress, to discuss peer-reviewed and other empirical studies of the utilization of various modalities for diagnosing and treating urologic conditions, including prostate cancer, in Medicare beneficiaries. In addition, LUGPA has provided comments to CMS on the Medicare Shared Savings Program/Accountable Care Organizations proposed rule and continues to take a leadership role with respect to proposed bundled payment systems for delivery of high quality, cost-efficient urologic services.

We hope to continue the relationship we have established with CMS, MedPAC, GAO, CBO and others by providing meaningful commentary to agency reports, inquiries, and proposals. Thus, we respectfully provide the following comments on CMS-1633-P.

II. CMS Should Provide Greater Clarity on its Re-Classification of APCs and Consider Creating a New Level Between APC 5374 and APC 5375.

We support CMS’s ongoing effort to re-organize the current APC system to better reflect clinical coherence and resource utilization. And, we agree with CMS that consecutively numbering the APCs will enhance public understanding of the APC groups and “make it easier for [the public] to communicate to the agency about issues concerning APCs.”² At the same time, LUGPA believes that the current process would benefit, and the public would be even more capable of providing meaningful comment, if CMS provided additional information on the specific clinical factors and resource commonalities used to designate these groups. In addition, we believe CMS’s goals would be better served with a new level between APC 5374 and APC 5375 in which to place certain services that do not fit neatly into either APC.

² *Id.* at 39257.

A. CMS Should Explain in Greater Detail its Rationale for Grouping Procedures Into Specific APCs.

Last year, CMS announced its intention to undertake a “major restructuring and consolidation” of APCs.³ CMS explained that its aim was to regroup procedures within APCs in order for the services within each newly-configured APC to be “more comparable clinically and with respect to resource use.”⁴ CMS began the project with a reclassification of APCs for ophthalmic services (consolidated from 24 to 13 APCs) and female reproductive procedures (consolidated from 7 to 5 APCs) and cited 42 U.S.C. § 1395L(t)(9) as authority for the changes.⁵ That statutory provision calls upon the agency to review and revise, not less than annually, the OPPS payment components, “to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.”⁶ Notwithstanding the dictates of § 1395L(t)(9), CMS did not cite or include a specific analysis of these factors as a basis for reorganizing the APCs, nor did the Agency provide information regarding the criteria used to distinguish between various levels of treatments and procedures that were being placed into newly created APCs.

Unfortunately, in the Proposed Rule for CY 2016, the same lack of clarity affects CMS’s proposed changes in APC classifications of urologic codes from the current 16 APCs down to just 7 newly created APCs. CMS provides the general rationale that its revised APCs “more appropriately categorize all of the urology procedures and services within an APC group such that the services within each proposed newly configured APC are comparable clinically and with respect to resource use.”⁷ But CMS sheds very little additional light on the policy rationale underlying the specific decisions it made—why, for example, CMS created 7 new APCs (rather than 6, 8 or 10) or why certain procedures were categorized into the top of one APC versus the bottom of the next highest APC.

We urge CMS to provide more detailed information on its reasoning for combining certain groups of procedures together in the course of its ongoing “major restructuring” of APCs. In particular, practicing urologists—and by extension, our patients—would be better served with greater information regarding the policy rationale for determining that certain APC groupings are more coherent than others, and the likelihood of future reclassifications. Greater transparency is critical, because the rationale for certain of CMS’s grouping choices in the Proposed Rule is not evident—either from the text of the Proposed Rule or the groupings themselves.

B. CMS Should Create an APC Level Between APC 5374 and 5375.

LUGPA supports CMS’s effort to reclassify urologic codes within APCs to achieve greater equivalency from a clinical and resource-use perspective, but we are concerned that, in certain instances, the groupings CMS has proposed fail to achieve this goal. **Of the 277 urologic CPT codes assigned to the 7 newly created APCs, 163—nearly**

³ 79 Fed. Reg. 40916, 40981.

⁴ *Id.*

⁵ *Id.*

⁶ 42 U.S.C. § 1395L(t)(9).

⁷ 80 Fed. Reg. 39200, 39263.

60%—of those CPT codes are proposed to be grouped into APC 5374. This APC now covers a wide variety of endoscopies, surgical procedures, stone removal, and laser surgery. Conversely, certain of the other newly created APCs are extremely narrow—APC 5376, for example, only contains 7 procedures. It is difficult to see how this distribution achieves the goals of clinical or resource coherence, and CMS has unfortunately not explained its reasoning.

The division between APC 5374 and APC 5375 is particularly dramatic with respect to reimbursable amounts. Procedures performed in hospital outpatient departments under APC 5374 are reimbursed at \$2,529.65, while procedures performed under APC 5375 are reimbursed at \$3,890.28. This significant jump between the APCs severely disadvantages certain procedures whose actual costs are at the upper end of APC 5374. For example, CPT Code 50590 (lithotripsy, extracorporeal shock wave (“ESWL”)) is currently paid under APC 0163 at \$3,112.54 in hospital outpatient departments; the reclassification under APC 5374 will mean a cut of \$582.89 per procedure.⁸ A summary of the reimbursement and cost basis for CPT 50590 is presented in Table 1.⁹

Table 1: Cost and Reimbursement Changes for CPT 50590, 2015-16

	APC	Payment Rate	Geometric Mean Cost
2015	0163	\$3,113.76	\$3,126.56
2016 (proposed)	5374	\$2,529.65	\$3,103.57
Dollar change		-\$584.11	-\$22.99
% Change		-18.8%	-0.7%

In other words, the decrease in reimbursement for this non-invasive treatment to fragment kidney stones will be more than 25 times greater than the reduction in cost basis for this procedure. The proposed reorganization of APCs therefore has the result of triggering a large reimbursement cut for an important procedure purely due to CMS choosing to place CPT 50590 into APC 5374 instead of in APC 5375.

LUGPA recognizes that CMS faces a challenge in classifying procedures that, from a clinical and resource perspective, exist at the outermost limit of one of the newly created APCs. We recognize that the answer might not necessarily be for CMS to shift ESWL into APC 5375, but we do ask CMS to recognize that its decision to create 7 (as opposed to 8, 9 or 10) new APCs was arbitrary. Rather than having CMS choose between two APCs—5374 and 5375—neither of which might accurately capture ESWL from a clinical and resource perspective, **LUGPA proposes that CMS should create an**

⁸ In ambulatory surgery centers, CMS proposes that codes under APC 5374 will be reimbursed at \$1,401.11, while those procedures performed under APC 5375 are reimbursed at \$2,001.46.

⁹ Centers for Medicare and Medicaid Services, “Costs for Hospital Outpatient Services, by HCPCS code for CY 2016,” available at: <https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1633-P-OPPS-Cost-Statistics.zip> (“2016 NPRM Cost Statistics”) and “Costs for Hospital Outpatient Services, by HCPCS code for CY 2015,” available at: <https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1613-FC-Cost-Stats.zip> (“2015 Cost Statistics”).

additional APC—an APC 5374A—that would better capture the cost of providing ESWL to Medicare beneficiaries. This would be a more reasonable method to achieve CMS’s goal of encouraging clinical coherence and similar resource utilization without risking de facto reimbursement cuts as a result.

The creation of an APC 5374A containing only CPT Code 50590 is thoroughly justified by actual cost and utilization data. As noted below, large variations in the number of codes assigned to particular APCs already exist in the CMS’s proposed classifications, with almost 60% of CPT codes grouped under APC 5374:

Table 2: Number of CPT Codes in Proposed APCs.¹⁰

APC	Number of HCPCS Codes	As % of Total
5371	17	6.1%
5372	25	9.0%
5373	48	17.3%
5374	161	58.1%
5375	11	4.0%
5376	7	2.5%
5377	8	2.9%
Grand Total	277	100.0%

The APCs are also unbalanced in terms of number of procedures furnished. Under CMS’s proposal, **nearly half of the urology procedures would fall under APC 5374.**

Table 3: Urology Procedures Performed in Each APC.¹¹

APC	Procedure Count	As % of Total
5371	85,789	11.8%
5372	134,491	18.4%
5373	110,124	15.1%
5374	350,926	48.1%
53750	31,464	4.3%
5376	4,846	0.7%
53760	4,760	0.7%
53770	7,168	1.0%
Grand Total	729,568	100.0%

¹⁰ Centers for Medicare and Medicaid Services, “Addendum B.-Proposed OPPS Payment by HCPCS Code for CY 2016,” available at:

<https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1633-P-OPPS-Addenda.zip>.

¹¹ 2016 NPRM Cost Statistics.

At the same time, there is compelling evidence that CPT 50590 should be treated separately from the rest of APC 5374 in order to properly characterize resource use. Table 4 below shows the frequency, median cost, and mean cost of the ten most commonly performed CPT Codes in the proposed APC 5374. Note that CPT 50590 is the second most frequently performed—and has the third-highest median and mean cost—of the procedures grouped in APC 5374.¹² Moreover, from the perspective of the practical use of APCs by providers, note that ESWL procedures alone (42,597; Table 4 below) are nearly the same as the total number of procedures furnished under all CPT Codes assigned to APC 5375, 5376 and 5377 *combined* (48,238; see Table 3 above). **This combination of high frequency and high costs makes it appropriate to assign ESWL to its own APC.**

Table 4: Count, Median Cost, and Mean Cost of Top 10 Procedures in APC 5374 Ranked by Volume of Services.¹³

HCPCS	Units	As % of Total	Median Cost	Median Cost Rank	Geometric Mean Cost	Mean Cost Rank
52332	63918	18.0%	\$ 2,142.76	8	\$ 2,161.64	8
50590	42597	12.0%	\$ 3,159.88	3	\$ 3,103.57	3
52601	25826	7.0%	\$ 3,338.32	2	\$ 3,374.78	2
52234	22110	6.0%	\$ 2,222.48	7	\$ 2,219.30	7
52648	19815	6.0%	\$ 3,589.54	1	\$ 3,623.11	1
52235	19793	6.0%	\$ 2,478.90	6	\$ 2,496.60	6
52204	17423	5.0%	\$ 1,964.67	10	\$ 1,925.15	10
52352	12233	3.0%	\$ 2,554.85	5	\$ 2,583.97	5
52240	11011	3.0%	\$ 2,868.67	4	\$ 2,907.67	4
52224	10930	0.03	\$ 2,039.43	9	\$ 1,997.94	9
	350908 ¹⁴	100.0%	\$ 2,631.61 ¹⁵		\$ 2,632.99 ¹⁶	

Global cost data also supports placement of ESWL in its own, newly created 5374A. As is illustrated in Table 5, here again, ESWL is second in overall cost to providers of all CPT Codes assigned to APC 5374, accounting for 12.9% of overall provider procedure costs under this APC.

¹² Note that we comment in Part III below on the code with the highest median and mean cost among the procedures assigned to APC 5374—CPT Code 52648.

¹³ 2016 NPRM Cost Statistics.

¹⁴ This represents total procedures in proposed APC 5374, not total in column.

¹⁵ Weighted average of median cost for procedures displayed in Table 4.

¹⁶ Weighted average of geometric mean cost for displayed in Table 4.

Table 5: Frequency, Average Geometric Mean Cost, Mean Total Cost, and % of Total Medicare Spend Across APC 5374 for Top 10 Codes in APC 5374 by Volume.¹⁷

HCPCS	Units	Geometric Mean Cost	Total Cost to Provider	% Total Cost to Provider
52332	63918	\$ 2,161.64	\$ 138,167,705.52	13.5%
50590	42597	\$ 3,103.57	\$ 132,202,771.29	12.9%
52601	25826	\$ 3,374.78	\$ 87,157,068.28	8.5%
52648	19815	\$ 3,623.11	\$ 71,791,924.65	7.0%
52235	19793	\$ 2,496.60	\$ 49,415,203.80	4.8%
52234	22110	\$ 2,219.30	\$ 49,068,723.00	4.8%
52204	17423	\$ 1,925.15	\$ 33,541,888.45	3.3%
52240	11011	\$ 2,907.67	\$ 32,016,354.37	3.1%
52352	12233	\$ 2,583.97	\$ 31,609,705.01	3.1%
52224	10930	\$ 1,997.94	\$ 21,837,484.20	2.1%
Total	350908 ¹⁸	\$ 2,632.99 ¹⁹	\$ 1,025,813,796.46	100.0%

The data in Table 6 below further confirms that ESWL does not belong in a “catch-all” APC with 160 other procedures. The total Medicare expenditures for ESWL (\$107,755,501.05²⁰) accounts for (a) 12.1% of expenditures in APC 5374; (b) 7.8% of total Medicare urology expenditures; and (c) exceeds total expenditures for 4 entire APC classifications (5371,5372,5375O, and 5377O).

Table 6: Total Medicare Expenditures by proposed APC

APC	Total Medicare Spend	ESWL, as % APC Expenditure
5371	\$ 17,449,482.60	617.5%
5372	\$ 70,400,864.22	153.1%
5373	\$ 148,250,512.28	72.7%
5374	\$ 887,674,422.20	12.1%
5375O	\$ 122,403,769.92	88.0%
5376	\$ -	n/a
5376O	\$ 35,553,240.20	303.1%
5377O	\$ 103,773,859.84	103.8%
Grand Total	\$ 1,385,506,151.26	7.8%

Finally, it is important to remember that procedure frequency in any given APC is likely to vary widely by provider. Given the extremely large group of codes and wide range in costs assigned to APC 5374, there is a high risk that CMS’s groupings could lead to serious imbalances between providers. A more appropriate designation would be to

¹⁷ 2016 NPRM Cost Statistics.

¹⁸ This represents total procedures in proposed APC 5374, not total in column

¹⁹ Weighted average of geometric mean cost for displayed in Table 4

²⁰ 2016 NPRM Cost Statistics.

assign CPT Code 50590 to a newly designated APC 5374A with a reimbursement level established in between the currently proposed APC 5374 and APC 5375.

II. CMS Should Include Laser Vaporization Procedures to Treat Benign Prostatic Hyperplasia in APC 5375.

One unfortunate effect of CMS's lack of clarity in revaluing codes is that it is sometimes unclear why certain clinically similar procedures are assigned to different APCs. One example of this confusing separation is the set of laser procedures used in treating benign prostate hyperplasia ("BPH").

A. Background of BPH Laser Treatment Options

BPH is a common prostate condition associated with aging in men, characterized by an enlargement of the prostate that impedes urination. Historically, the most common approach to treating BPH was surgical. Although surgical interventions remain common, they raise the risk of morbidity, including bleeding, fluid absorption and associated transurethral resection syndrome, prolonged catheterization, urethral stricture, and bladder neck contracture.²¹ As a result, in recent decades a variety of treatments have been developed to treat BPH while minimizing invasive surgery. As typically classified, non-surgical BPH treatments fall into three categories: **coagulating**, **vaporizing**, and **enucleating**.

Coagulating procedures work by applying heat to prostate tissue. In these techniques, the heat causes tissue to coagulate, sealing blood and lymph vessels and leading to cell death.²² This dead tissue then falls from the viable tissue in a process called "sloughing."²³ There are a variety of ablative techniques, including direct application of heat through non-laser techniques, such as transurethral needle ablation (TUNA) or transurethral microwave thermotherapy (TUMT).²⁴ Laser techniques to apply heat in this manner include visual laser ablation of the prostate (VLAP) or holmium laser ablation of the prostate (HoLAP).²⁵

Enucleating procedures work by using a laser to cut the enlarged portion of the prostate gland. A morcellator is then used to mechanically destroy and remove this tissue.²⁶ The most common form of this technique is holmium laser enucleation of the prostate (HoLEP). Importantly, unlike coagulating treatments, enucleating treatments result in the immediate destruction and removal of prostate tissue.²⁷

²¹ Yakup Bostanci, Amir Kazzazi, et al., *Laser Prostatectomy: Holmium Laser Enucleation and Photoselective Laser Vaporization of the Prostate*, 15(1) *Reviews in Urology* 1 (2013).

²² New York Times Health, Prostate, Enlarged Overview, available at: <http://www.nytimes.com/health/guides/disease/enlarged-prostate/surgery.html?print=1>.

²³ *Id.*

²⁴ Levi A. Deters, et al., *Benign Prostatic Hypertrophy Treatment & Management*, Medscape (July 24, 2015), available at: <http://emedicine.medscape.com/article/437359-treatment#d11>.

²⁵ Rainer M. Kuntz, *Current Role of Lasers in the Treatment of Benign Prostatic Hyperplasia (BPH)*, 49 *European Urology* 961 (2006).

²⁶ Bostanci et al., at p. 1.

²⁷ Muta M. Issa, *The Evolution of Laser Therapy in the Treatment of Benign Prostatic Hyperplasia*, 7 (Supp. 9) *Reviews in Urology* S15 (2005).

Similarly, vaporizing procedures such as photoselective laser vaporization of the prostate (PVP), work by using a high-powered laser (typically the American Medical Systems GreenLight laser) to immediately destroy portions of enlarged prostate tissue.²⁸ The stronger, more directed laser allows the urologist to remove small pieces of tissue with less coagulation, causing an easier post-operative period.²⁹ This is the most commonly performed non-surgical intervention for BPH.

The AMA has acknowledged these three separate treatment options with three distinct CPT codes for laser surgery of the prostate. CPT Code 52647 covers laser coagulation, CPT Code 52648 covers laser vaporization of prostate tissue, and CPT Code 52649 covers laser enucleation of prostate tissue. Importantly, only CPT Codes 52648 and 52649 also cover any additional necessary transurethral resection (i.e., surgical removal) of the prostate.

B. CMS’s Proposal Inappropriately Groups Coagulating and Tissue Removal Procedures in Separate APCs.

In its restructuring of urologic APCs, CMS has proposed dividing one form of treatment for BPH from all others. While we agree with CMS’s recognition of tissue removal using laser enucleation as a more complex treatment than those that rely on coagulation and, hence, the placement of CPT Code 52649 for laser enucleation in APC 5375, we believe that CMS erred by placing CPT Code 52648 for laser vaporization in APC 5374 rather than in APC 5375.

Laser vaporization and enucleation are generally considered to be the leading laser treatments for BPH.³⁰ A recent evidence review identified PVP and HoLEP as the technologies most likely to become valid alternatives to the “gold standard” of surgical treatment.³¹ Vaporization and enucleation are both preferable to ablation techniques that induce coagulation because the dead tissue created by these older techniques can cause post-procedure complications.³² Indeed, certain analyses simply group enucleation and PVP together as alternate forms of vaporization.³³ Similarly, a recent review of clinical guidelines for Lower Urinary Tract Symptoms (including BPH) found that certain guidelines actually recommended that patients *avoid* coagulating treatments unless they have contraindications to “standard surgery,” which included both vaporization techniques and HoLEP.³⁴ The same review included HoLEP, transurethral vaporization of the prostate (TUVP), and PVP in a list of “other acceptable surgical options and almost equally effective as [traditional surgery].”³⁵

²⁸ *Id.*

²⁹ *Id.*

³⁰ Bostanci et al., at p. 2.

³¹ *Id.*

³² Issa at pp. S16-17.

³³ *Id.*

³⁴ Michael Erlano Chua, et al., *A Critical Review of Recent Clinical Practice Guidelines on the Diagnosis and Treatment of Non-Neurogenic Male Lower Urinary Tract Symptoms*, 9(7-8) Canadian Urological Association Journal E463, E467 (July-August 2015).

³⁵ *Id.* at E468.

This year, CMS appropriately separated CPT Code 52649 from the CPT Codes associated with coagulating treatments, in apparent recognition of the greater complexity and efficacy of laser enucleation. CMS moved CPT Code 52649 into APC 5375, while leaving the CPT Codes associated with laser coagulation (52647), TUMT (53850), and TUNA (53852) in APC 5374. We agree that laser enucleation represents a process that is substantially different from these coagulating procedures, such that grouping them together would undermine clinical coherence. Laser enucleation involves the immediate destruction of tissue, with no residue of dead tissue. However, under this basis it is unclear why CMS has failed to classify the laser vaporizing procedures under CPT Code 52648 in this same APC 5375. There is no significant reason why PVP or TUVVP, which also result in immediate destruction of tissue, should be paid at a lower rate than laser enucleation. **On its face, the failure to include laser vaporizing procedures in APC 5375 appears to contradict CMS's stated goal of clinically coherent APCs.**

The exclusion of vaporizing procedures from APC 5375 also cannot be justified by dissimilar resource utilization. Our pricing review indicates that a widely used PVP system costs \$100,000 - \$125,000, with an additional cost of \$1,000 - \$1,200 for disposables. Similarly, a HoLEP system costs \$110,000 to \$125,000 with an additional cost of \$1,100 to \$1,300 for disposables. **In other words, the purchase and supply costs of typical vaporizing and enucleating laser treatments are nearly identical.**³⁶ In addition, CPT Code 52648 has the highest mean and median per-procedure cost of any CPT Code proposed for inclusion in APC 5374.³⁷ Laser vaporization is also highly utilized—this combination of cost and utilization means that **CPT Code 52648 is solely responsible for 7% of the overall cost of services in APC 5374.**³⁸ The similar cost structures of providing these services, and the fact that CPT Code 52648 is a true “edge case” at the upper end of the costs of procedures that have been proposed for grouping in APC 5374, strongly indicates that CPT Code 52648 should be grouped instead with procedures assigned to APC 5375.

VI. Request for CMS Action

Consistent with our comments above, LUGPA respectfully requests that CMS take the following specific actions in finalizing the Proposed Rule for CY 2016:

CMS should provide greater clarity on its policy rationale for grouping CPT Codes within newly created APCs. We are extremely concerned that CMS is undertaking a major restructuring of important payment policies without articulating clear standards for its changes. In particular, we are concerned that seemingly aberrant results triggered by the large cohort of CPT Codes placed in APC 5374 have not been supported by any specific discussion of the Agency's policy rationale. Moreover, we are concerned that CMS's reclassification of procedures in newly created APCs was not developed in light of the various statutory factors set forth in 42 U.S.C. § 1395L(t)(9). This lack of analysis makes it extremely difficult for our members to understand the rationale behind these revisions and provide meaningful comment on CMS's proposals.

³⁶ Comparison of a Greenlight XPS System using Greenlight MOXY Fiber to Lumenis 100W Holmium System using holmium fiber.

³⁷ See Table 4, above.

³⁸ See Table 5, above.

CMS should create a new APC 5374A to classify CPT Code 50590 (lithotripsy, extracorporeal shock wave (“ESWL”)). Important reimbursement decisions should not turn on CMS’s seemingly arbitrary decision to create seven (rather than eight) new APCs. This is particularly true for common and clinically significant procedures like ESWL. CMS should remedy the unjustified reimbursement cut to ESWL services by creating a more granular APC structure that appropriately classifies this service in an APC with a valuation set in between APC 5374 and APC 5375.

CMS should place CPT Code 52648 in APC 5375. Although CMS properly grouped laser enucleation methods into this higher APC, we believe clinical coherence and resource use requires that the more commonly-performed laser tissue removal methods using vaporization also be grouped into this APC instead of in APC 5374 where CPT Code 52648 has been proposed for assignment.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Rule. Please feel free to contact Dr. Kapoor at (516) 342-8170 or dkapoor@implc.com, or Howard Rubin at (202) 625-3534 or howard.rubin@kattenlaw.com, if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



Gary M. Kirsh, M.D.
President



Deepak A. Kapoor, M.D.
Chairman, Health Policy

cc: Marc Hartstein, CMS
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