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BY ELECTRONIC SUBMISSION

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RE: Comments to CMS-1695-FC

On behalf of LUGPA, we thank you for the opportunity to comment on the Hospital Outpatient Prospective Payment System ("OPPS") and Ambulatory Surgery Center ("ASC") Payment System Final Rule for 2019 (the "Final Rule").[1] Our focus is on an unintended consequence of migration of HCPCS code 50590 (extracorporeal shockwave lithotripsy; "ESWL") from APC 5375 to 5374. This change would jeopardize ESWL as a viable treatment option for kidney stones in the ASC setting and likely have a disproportionate effect on access to care in rural communities. We also comment on CPT Code 53854 (transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy) which, as with other procedures with similar clinical indications and resource use, is more appropriately assigned to APC 5374 than APC 5373.

As we explain more fully below, our concern is not necessarily with CMS's reassignment of ESWL services (HCPCS Code 50590) from APC 5375 to APC 5374. We recognize the Agency's discretion to reassign procedures within APCs as long as the reassignment maintains clinical and resource homogeneity within the APC. Our concern - and one that we believe CMS did not take into account in the Final Rule - is that the cost architecture of ESWL services is fundamentally different than virtually all other procedures assigned to APC 5374. Simply put, ESWL is an equipment-intensive procedure with the costs of furnishing the service in an ASC more closely approximating the costs of the service in the outpatient hospital setting. As such, ESWL, particularly in the ASC setting where the procedure is most commonly furnished on leased (as opposed to capital) equipment, is akin to device-intensive procedures for which CMS announced changes to payment methodology in the Final Rule "to better capture costs for procedures with significant device costs."[2] Accordingly, if ESWL remains in APC 5374, CMS should set the

[1] 83 Fed. Reg. 58818 (Nov. 21, 2018).
[2] Id. at 58944.

ASC payment rate at a higher percentage of the OPPS rate than is most commonly used within that particular APC.

We did not have an opportunity to share this input with CMS in our comments on the Proposed Rule, because CMS provided no indication until publication of the Final Rule that it intended to make such sweeping changes to the family of Urology APCs. Nevertheless, CMS can still adjust the ASC payment for Code 50590 for CY 2019 so that payment in the ASC setting more closely approximates the payment made when ESWL services are furnished in the hospital outpatient setting.

As we explain in Part II(C) below, the Agency can make this adjustment in one of several ways. First, CMS can keep HCPCS Code 50590 in APC 5374 but adjust the ASC payment to a higher percentage of the OPPS rate to account for the equipment-intensive nature of the procedure. Second, CMS can place Code 50590 in a newly-created APC 5374A with a payment rate in between the rates set for APCs 5374 and 5375. Third, CMS can undo the changes in assignments within the Urology APCs that the Agency announced, without advanced notice, in the Final Rule - and do so either for ESWL alone (Code 50590) or for all effected urology procedures - until the Agency can consider the implications that the payment changes will have on access to ESWL in the ASC setting.

Regardless of which route CMS takes, the Agency should consider payment for ESWL services in the context of the Agency's broader goal of lowering costs to the Medicare program and Medicare beneficiaries for services that can be delivered with the same level of quality in ASCs as compared to the outpatient hospital setting. In the Final Rule, CMS took action - such as in finalizing the proposal to apply the hospital market basket update to ASC payment system rates - that could *encourage* the migration of services from the hospital setting to the ASC setting and *increase* the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus, promoting better beneficiary access to care.[3] As the Agency stated: "[t]o the extent it is clinically appropriate for a beneficiary to receive services in a lower cost setting, we believe it would be appropriate to continue to develop payment incentives and remove payment disincentives to facilitate this choice."[4] In so doing, CMS accomplishes its goal of "maximize[ing] patient choice to obtain services at a lower cost to the extent feasible."[5]

CMS should demonstrate its commitment to these principles by adjusting payment for ESWL services in the ASC setting to ensure the viability of this non-invasive treatment option for Medicare beneficiaries, particularly in rural communities across the country where access to treatment for kidney stones is often limited.

As we explain in Part III, we believe that CMS erred by assigning new CPT Code 53854 (transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy), which describes the Rezum Therapy procedure for treatment of benign prostatic hyperplasia ("BPH"), to APC 5373. It is clear that if not reassigned to APC 5375, the Rezum Therapy should at least be placed in APC 5374 with two other BPH procedures CPT Code 53852 (transurethral destruction of prostate tissue; by radiofrequency thermotherapy) and CPT Code 53850 (transurethral destruction of prostate tissue; by microwave thermotherapy). From a clinical and resource perspective, these three BPH procedures should be assigned together to APC 5374.

[3] Id. at 59075-79.
[4] Id. at 59076.
[5] Id. at 59077.

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 urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, 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 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.[6]

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. Additionally, these practice models can better overcome the economic and administrative obstacles to successful, value-based care. LUGPA practices often include advanced practice providers and other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care with added patient convenience. 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, including men with prostate, kidney and bladder cancer, 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, regulatory agencies, and legislative bodies.

II. CMS's Decision to Cut Reimbursement for Extracorporeal Shockwave Lithotripsy (Code 50590) by More than 20% in the ASC Setting Jeopardizes Access to Cost-Efficient, Non-Invasive Kidney Stone Treatment.

CMS's dramatic cut in reimbursement for ESWL in the ASC setting - without any advanced notice to stakeholders in the Proposed Rule - threatens to jeopardize the ability of independent ASCs to continue furnishing this critically important treatment option for kidney stones. As we explain in detail below, CMS needs to increase the ASC payment for Code 50590 for CY 2019 or else face the unintended consequences of lithotripsy procedures shifting into the higher-cost outpatient hospital setting and, in rural communities, losing non-invasive ESWL as a treatment option altogether. As CMS recognized in the Final Rule, such shifts in site of service from the lower cost non-hospital setting to higher cost HOPDs are "unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in a higher cost setting."[7] That is precisely the situation with respect to ESWL services.

[6] Centers for Medicare and Medicaid Services, *Medicare Provider Utilization and Payment Data: Physician and Other Supplier*, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html (last accessed Dec. 22, 2018).

[7] 83 Fed. Reg. at 59006.

A. Cutting Reimbursement for Code 50590 Without Warning or Stakeholder Input Threatens Access to ESWL Treatment, Especially in Rural Communities.

LUGPA acknowledges CMS's authority to update APC assignments for HCPCS codes, and we recognize that the Agency has the obligation to do so at least annually.[8] However, we believe that notification in the Proposed Rule providing the opportunity for stakeholder comment is an essential part of this process, particularly when the Agency is contemplating dramatic change in reimbursement for a procedure. This is especially true for a service as commonly performed as ESWL. CMS's action with respect to ESWL is even more surprising in this instance, because the Agency had identified in the Proposed Rule certain urologic procedure codes that it was evaluating for potential reassignment within the family of Urology APCs and HCPCS Code 50590 was not one of them. Specifically, CMS had proposed changes to the codes for treatment of benign prostatic hyperplasia ("BPH") and solicited stakeholder input on those changes. With that advanced notice, stakeholders filed comments with respect to the BPH codes, CMS took the stakeholder input into account, and the Agency finalized proposed APC assignments for the procedures described by HCPCS Codes 53850 and 53854, as well as a revision to the APC assignment for the procedure described by HCPCS Code 53852 (from APC 5375 to APC 5374).[9] Leaving to one side the merits of those assignment decisions, none was surprising from a *process* standpoint; CMS followed its notice and comment rulemaking procedures.

In stark contrast - and with no advanced notice in the Proposed Rule - CMS explained in the Final Rule that:

> "based on the public comments received for the reassignment for all three benign prostatic hyperplasia treatment procedures, we reviewed the procedures assigned to the family of Urology APCs for this final rule with comment period and made some modifications to more appropriately reflect the resource costs and clinical characteristics of the services within each APC grouping. Specifically, we revised the APC assignment of the procedures assigned to the family of Urology APCs to more appropriately reflect a prospective payment system that is based on payment groupings and not code-specific payment rates, while maintaining clinical and resource homogeneity."[10]

Even though just three years ago the Agency agreed with our comments to the OPPS Proposed Rule for CY 2016 and placed HCPCS Code 50590 in APC 5375 (rather than in APC 5374 as originally proposed),[11] CMS has now moved Code 50590 into APC 5374. We do not believe that the reassignment must be undone to preserve the viability of ESWL in the ASC setting. To be clear, CMS should not construe this as LUGPA agreeing with CMS's decision to shift Code 50590 from APC 5375 to APC 5374, but rather a recognition that immediate reconfiguration of APC assignments after issuance of the OPPS Final Rule might prove technically difficult. Accordingly, our desire is to propose alternative solutions that will ensure continued access to ESWL services in the ASC setting without necessarily disturbing the APC designation for ESWL.

As illustrated below, the magnitude of the proposed APC reassignment will profoundly alter reimbursement for ESWL services:

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[8] See 42 U.S.C. § 1395L(t)(9) (directing 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").

[9] 83 Fed. Reg. at 58899-58901.

[10] Id. at 58900.

[11] Comment Letter from LUGPA President Gary M. Kirsh, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Acting Administrator Andrew Slavitt, CMS-1633-P (Aug. 31, 2015), pp. 2-8; OPPS Final Rule for CY 2016, CMS-1633-FC, 80 Fed. Reg. 70298, 70409-11 (Nov. 13, 2018).

Year	APC	Payment Rate	Geometric Mean Cost
2018	5375	$3,705.77	$3,245.23
2019	5374	$2,926.86	$3,265.14
Dollar change		($778.91)	$19.91
% Change		-21.02%	0.61%

Table 1: 2018 and 2019 Reimbursement for ESWL Based on APC Change

To be sure, a 21% cut in reimbursement for ESWL under the OPPS fee schedule, notwithstanding a 0.61% increase in the geometric mean cost for the procedure, is troubling, particularly when CMS has provided no explanation or data supporting the change. The far bigger issue, however, and the one that compels LUGPA to urge Agency action for CY 2019, is that ESWL will not remain a viable treatment option in the ASC setting unless the Agency increases the ASC payment for this equipment-intensive procedure to approximate more closely the payment in the outpatient hospital setting.

CMS has long recognized that extracorporeal shockwave lithotripsy is fundamentally different in terms of type of equipment used than other procedures that treat renal calculi (i.e., kidney stones). This is evidenced by the following excerpt from the OPPS Final Rule for CY 2002 delineating the difference between ureteroscopy with lithotripsy (Code 52353) and ESWL (Code 50590) as rationale for CMS electing to keep CPT Code 52353 in APC 0163 rather than moving it to APC 0169:

> "Although both codes involve lithotripsy, the type of equipment used in the two procedures is very different. Clinically, the surgical approach used for code 52353 and the resources used (e.g., anesthesia and operating room costs) are much more similar to other procedures in APC 0163 than to those for code 50590. Additionally, the median cost for code 50590, which was $700 higher than that of code 52353, is dependent on the widely variable arrangements hospitals make for use of the extracorporeal lithotriptor."[12]

Perhaps most importantly, CMS acknowledged that there are a variety of arrangements used by hospitals to obtain lithotripsy services. Although facilities may indeed purchase and amortize the equipment, the reality is that a substantial number of institutions rely on outside contractors to provide ESWL machinery and this same variability is true in the ASC setting. Although CMS reduced facility payments in the ASC setting based on assumptions regarding certain reduced costs, as further discussed in Part II(C) below, there is no basis to assume that these cost efficiencies extend to lower machine acquisition costs for lithotripters. To the contrary, ASCs are subject to the same fair market value constraints as any other facilities when it comes to acquisition of lithotripsy equipment and payment for ESWL services in the outpatient hospital and ASC settings needs to reflect that reality.

And yet, for CY 2019, CMS has set the ASC payment rate for ESWL at $1,366.84 (46.7% of the OPPS rate of $2,926.86). At that rate, ESWL will no longer be a viable alternative in the ASC setting to more invasive and higher cost ureteroscopy. Moreover, to the extent patients continue to choose ESWL for treatment of kidney stones, cases will invariably shift into the more expensive and less convenient hospital setting; unfortunately, in sites that rely on ESWL rental arrangements, this option may well be closed to patients. This could particularly limit access to care in rural environments where the ability to seek care at an alternative facility may well be limited.

[12] CY 2002 OPPS Final Rule, CMS-1159-F2, p. 59862 (Nov. 30, 2001).

B. The Cut in Reimbursement for Code 50590 in the ASC Setting Conflicts with CMS's Broader Policy Goal of Avoiding a Shift in Site of Service When Beneficiaries Can Safely Receive the Same Services in a Lower Cost Setting.

CMS should re-evaluate its decision on payment for ESWL in the ASC setting in light of the broader policy objectives that the Agency articulated in the OPPS Final Rule. Ever since passage of Section 603 of the Bipartisan Budget Act ("BBA") of 2015,[13] CMS has consistently articulated the goal of "attaining site neutral payments to promote a level playing field."[14] The Agency reaffirmed this commitment in the MPFS rulemaking process for 2019, noting that payment policy "should ultimately equalize payment rates between non-excepted off-campus provider-based departments ("PBDs") and physician offices to the greatest extent possible."[15] The Agency also took on the issue in the OPPS Proposed Rule for 2019, proposing steps to align payments between excepted and nonexcepted off-campus PBDs.[16] CMS's decision with respect to ESWL procedures, which jeopardizes access to the procedure in the ASC setting, stands in marked contrast to other steps CMS took in the OPPS Final Rule.

A perfect example is CMS's decision to finalize its proposal to align payments for clinic visit services across excepted and non-excepted off-campus PBDs and to do so in a non-budget neutral manner.[17] As CMS noted, this policy will result in an estimated cost savings of $380 million, with approximately $80 million of that amount saved by Medicare beneficiaries in the form of reduced copayments.[18] This concrete step addresses hospitals' ongoing incentive to purchase physician practices and shift care into excepted PBDs that benefit from higher payments under the OPPS.[19] Payment policy that makes it impossible to continue furnishing ESWL services in the lower cost ASC setting, particularly in rural communities with less access to such services, is fundamentally at odds with CMS's objective of protecting the independent practice model from being subsumed by more expensive hospital-based care.

CMS's action in the Final Rule with respect to payments for 340B-acquired drugs and biologicals is another example of the Agency adjusting payments to avoid care shifting into higher cost settings. LUGPA commends CMS for leveling the playing field with respect to payment for 340B-acquired drugs between excepted and non-excepted off-campus PBDs by reducing reimbursement for separately payable, covered outpatient drugs and biologicals acquired under the 340B program and used in the nonexcepted off-campus PBD setting from ASP + 6 percent to ASP minus 22.5 percent.[20] The Final Rule eliminates the "significant incongruity between the payment amounts for these drugs depending upon where (for example, excepted or nonexcepted PBD) they are furnished."[21] Such payment discrepancies based on site of service - and the "perverse incentive" that such discrepancies create for hospitals to circumvent the OPPS payment adjustment by furnishing 340B-acquired drugs in nonexcepted off-campus PBDs where Medicare currently makes payment for those drugs at ASP + 6 percent - are precisely what Congress intended to eliminate through Section 603 of the BBA of 2015.[22]

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[13] Public Law 114-74 (2015).
[14] See, e.g., 82 Fed. Reg. at 33985.
[15] 83 Fed. Reg. 35704, 35742 (July 27, 2018).
[16] 83 Fed. Reg. 37046, 37138-50 (July 31, 2018).
[17] 83 Fed. Reg. at 59013.
[18] Id. at 59014.
[19] Id. at 59011.
[20] Id. at 59021.
[21] OPPS Proposed Rule for CY 2019, 83 Fed. Reg. at 37146.
[22] OPPS Final Rule for CY 2019, 83 Fed. Reg. at 59017, 59021.

The importance of preserving access to ESWL services in the lower cost ASC setting is also clear from the principles that led CMS to finalize its proposal to apply the hospital market basket update to ASC payment system rates.[23] As the Agency explained:

> "The Administration recognizes the value that ASCs may bring to the Medicare Program that results in the delivery of efficient, high-quality care to beneficiaries at a lower cost…. Both beneficiaries and the Medicare Program benefit from reduced expenditures when a beneficiary's clinical needs allow for a procedure to be performed in lower cost settings such as ASCs relative to hospital outpatient departments."[24]

CMS is not merely trying to preserve access to care in the lower-cost ASC setting; rather, the Agency is affirmatively "exploring ways to align payments with the costs of care and to *incentivize* use of the most efficient and clinically appropriate sites of care, including hospital outpatient departments, ASCs, and physician offices."[25] The Agency's decision to apply the hospital market basket update to ASC payment system rates instead of continuing to apply the Consumer Price Index for all urban consumers ("CPI-U") offers the perfect illustration of CMS's effort to encourage the migration of clinically appropriate care into the ASC setting:

> "We believe providing ASCs with the same rate update mechanism as hospitals could encourage the migration of services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus promoting better beneficiary access to care. We believe that it is important to encourage such migration of services and that this policy would give physicians and patients greater choice in selecting the best care setting."[26]

The principles that led CMS to finalize its proposals regarding payment for clinic visit services and 340B-acquired drugs and, even more relevantly, the application of the hospital market basket update to ASCs, apply with equal force with respect to payment for ESWL services in the ASC setting.

C. CMS Should Increase Reimbursement for Code 50590 in the ASC Setting for Calendar Year 2019 to More Accurately Reflect the Cost of Performing the Procedure.

LUGPA believes that CMS can fix the problem with the ASC payment rate for ESWL in one of three ways for CY 2019. As we explain below, it is not necessary to move ESWL out of APC 5374 to protect access to ESWL services in the ASC setting. Our focus is on ensuring that, regardless of the APC to which CMS assigns the procedure, services for ESWL are not interrupted in the ASC setting. The three options available to CMS are as follows:

1. Keep HCPCS Code 50590 in APC 5374 but adjust the ASC payment to a higher percentage of the OPPS rate to account for the equipment-intensive nature of the procedure;
2. Place Code 50590 in a newly-created APC 5374A with an ASC payment rate set in between the rates set for APCs 5374 and 5375;

[23] Id. at 59075-79.
[24] Id. at 59075-76.
[25] Id. at 59076 (emphasis added).
[26] Id. at 59079.

3. Undo the change in APC assignment for ESWL - either by shifting that one procedure code (HCPCS Code 50590) back to APC 5375 or by undoing all changes in assignments within the Urology APCs that were announced in the Final Rule, without any prior warning, and solicit stakeholder input on assignments within the family of Urology APCs as part of the CY 2020 OPPS rulemaking process.

Regardless of which option CMS chooses, it is critical that the Agency carefully scrutinize the unique cost architecture of ESWL services to ensure that payment in the ASC setting is not set so low as to force ESWL procedures out of the lower cost ASC setting and into the higher cost outpatient hospital setting. The Medicare program and its beneficiaries lose in that situation.

1. **Keep ESWL in APC 5374 But Adjust the ASC Payment Rate to a Higher Percentage of the OPPS Rate to Account for the Equipment-Intensive Nature of the Procedure.**

CMS can fix the problem with the ASC payment rate for ESWL services while keeping HCPCS Code 50590 in APC 5374. To do so, however, CMS will need to adjust the ASC payment rate to approximate more closely the payment for the identical service in the outpatient hospital setting. We believe that the equipment-intensive nature of ESWL compels such an adjustment. The changes that the Agency made in the Final Rule to payment for device-intensive procedures can serve as a guide for how (and why) to make such an adjustment.

ESWL shares many of the same characteristics as procedures deemed to be "device intensive" and for which the Agency sets ASC payment at a higher percentage of OPPS payments than other procedures assigned to the same APCs as device-intensive procedures. To be clear, we understand that ESWL is not "device intensive" insofar as that term is limited to procedures involving the surgical insertion or implantation of a device.[27] Yet, CMS's rationale for liberalizing the "device-intensive" procedure policy for CY 2019 should apply with equal force to a procedure such as ESWL for which the cost of equipment (i.e., the lithotripter) has such a profound impact on the overall cost of delivering the service.

CMS recognizes that device-intensive procedures require special handling with respect to payments in an ASC setting. Indeed, we applaud CMS's actions to expand access to services in the ASC setting by easing the requirements for a procedure to be considered device intensive, both by reducing the non-service requirement to 30% as well as by eliminating the requirement that a device remain within a patient's body after completion of the procedure.[28]

Consistent with those policy changes, CMS designated 358 HCPCS Codes payable under the OPPS as device-intensive procedures.[29] In each instance, CMS examined the device and service portions of the procedures separately in recognition of the fact that it would be inappropriate to apply the ASC conversion factor to the device cost included in the OPPS payment rate for the procedure. The specifics of the methodology are worth repeating here given their relevance to how CMS can set a more appropriate ASC payment rate for ESWL while keeping the procedure in APC 5374:

> "We apply the device offset percentage based on the standard OPPS APC ratesetting methodology to the OPPS national unadjusted payment to determine the device cost included in the OPPS payment rate for a device-intensive ASC covered

[27] Id. at 58945.
[28] Id. at 58948.
[29] Addendum P to OPPS Final Rule for CY 2019, *available at* https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1695-FC-2019-OPPS-FR-Addenda.zip (last accessed Dec. 21, 2018).

> surgical procedure, which we then set as equal to the device portion of the national unadjusted ASC payment rate for the procedure. We calculate the service portion of the ASC payment for device-intensive procedures by applying the uniform ASC conversion factor to the service (nondevice) portion of the OPPS relative payment weight for the device-intensive procedure. Finally, we sum the ASC device portion and ASC service portion to establish the full payment for the device-intensive procedure under the ASC payment system."[30]

All told, CMS applied this payment methodology to 358 HCPCS codes across 51 APCs; in each instance, the ASC payment rate for the device-intensive procedure exceeds the mode payment rate for the particular APC.[31] Eight of the 358 device-intensive procedures are urology procedures; ESWL is not one of them. Indeed, ESWL is assigned a device offset of only 1.21 percent. Given the OPPS reimbursement rate of $2,926.86 for APC 5374, this amounts to a mere $35.42.

Although we recognize that ESWL does not meet the criteria to be deemed a "device-intensive procedure," there are important similarities between equipment-intensive ESWL and device-intensive urologic procedures that warrants an upward adjustment in the ASC payment rate for ESWL to approximate more closely the payment made for ESWL in the outpatient hospital setting. The argument is particularly compelling given the nature of the lithotripter equipment used in the ASC setting.

A recent survey estimated that ESWL services are furnished to approximately 33,000 Medicare beneficiaries each year on mobile lithotripter units brought to hospitals and ASCs.[32] These facilities often do not own the lithotripters; they are leased units and, therefore, they are not the type of equipment for which depreciation and financing expenses are recoverable as depreciable assets.[33] And, given the high capital costs of the devices, there are typically far fewer procedures performed in a single facility in the ASC setting. This means that the per-use cost of the lithotripter unit is often higher in the ASC setting than in hospital outpatient departments as there are far fewer procedures over which to spread the cost of the equipment. The fact that lithotripters are rarely, if ever, depreciable assets in the ASC setting is not something that we believe has been factored into the setting of the ASC payment rate for Code 50590.

2. **Appropriately Recognize ESWL's Unique Resource Use by Restoring it to a Unique APC**

CMS has long recognized that ESWL is a unique procedure. Prior to 2016, HCPCS code 50590 was the only procedure within APC 0169. Indeed, as we have previously noted, based on the unique nature of ESWL and the multiple methods by which facilities acquire this equipment, CMS resisted inclusion of other HCPCS codes within APC 0169. However, commencing in 2016, CMS reclassified urologic codes within APCs with an intent to achieve greater equivalency from a clinical and resource-use perspective.[34] We expressed concern that, initially, CMS assigned ESWL to APC 5374, which would have resulted in an 18.8% reduction in reimbursement.[35] At that time, we proposed two solutions, to either move ESWL to

[30] Id. at 58947.
[31] The 358 HCPCS Codes have an average device offset of 47.3%, which works out to an average offset of $5,228.61.
[32] Russell Newman, President HealthTronics Inc., Personal Communication.
[33] See CMS Pub. 15-1, The Provider Reimbursement Manual – Part 1, Ch. 1–Depreciation, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929.html (last accessed Jan. 2, 2019).
[34] Comment Letter from LUGPA President Gary M. Kirsh, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Acting Administrator Andrew Slavitt, CMS-1633-P (Aug. 31, 2015).
[35] Id.

APC 5375, or preferably, restore ESWL to its prior status by creating an intermediate APC, 5374A, that would more accurately reflect the unique nature of this service.[36]

Although our preference was that ESWL continue to be recognized as a unique service, we were gratified that in the OPPS Final Rule for CY 2016 CMS recognized that the costs of ESWL would not be adequately reimbursed in APC 5374 and opted to move the procedure to APC 5375. Conversely, we were discouraged that in the OPPS Final Rule for CY 2019 CMS, without advance stakeholder notice, opted to move ESWL to APC 5374, particularly since the difference between APC 5374 and APC 5375 is particularly dramatic with respect to reimbursable amounts.[37] This move is particularly confounding as the geometric mean cost for ESWL has changed from $3,126.36 when classified in APC 0169 to $3,265.14 in the 2019 Final Rule, an increase of 4.4%.

LUGPA recognizes that CMS faces a challenge in classifying procedures that, from a clinical and resource perspective, exist at the outermost limit of an APC. We ask that CMS recognize that its decision eliminating the unique APC for ESWL in 2016 created challenges for ESWL reimbursement; the impact on the high or low end of geometric mean costs is amplified by the high volume of service performed for this procedure. Rather than continuing to face the struggle of over- or under-reimbursing this procedure by placing it into an APC that is unlikely to capture ESWL from a clinical and resource perspective, **LUGPA urges CMS to create an additional APC 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.

Analysis of the OPPS Addenda reveals that there are 19 instances in which CMS recognizes the unique characteristics of a particular HCPCS code and assigned the code to an individual APC.[38] Recognition of ESWL as a unique service is consistent with both CMS's historical and current approach to lithotripsy services. Until its elimination, APC 0169 was uniquely assigned to HCPCS code 50590, reflecting CMS's recognition that there was variability in the methodology by which facilities access lithotripsy equipment. Although APC 0169 has been deleted, CMS continues to recognize the uniqueness of lithotripsy services in its assignation of revenue codes. Of the many hundreds of revenue codes assigned, LUGPA was only able to identify two that were associated with a single urologic procedure, 0723 (neonatal circumcision) and 0790 (lithotripsy).

3. **Restore ESWL to APC 5375, either individually, or as a group.**

While we acknowledge CMS's authority and obligation to review APC assignation on an annual basis, we believe that stakeholder input is of critical importance to provide feedback from those directly impacted by regulatory changes. Our view is concordant with that of the Agency, as CMS itself states:

> "The nation is best served by fostering participation that represents a broad range of perspectives - including patients and caregivers - and representation from key stakeholders relative to a specific medical condition, patient population, and/or care delivery setting. Enhancing existing activities and promoting broader engagement

[36] Id.
[37] For CY 2019, procedures performed in hospital outpatient departments under APC 5374 will be reimbursed at $2,926.86, while procedures performed under APC 5375 will be reimbursed at $4,020.54.
[38] Op. Cit. Addendum P to OPPS Final Rule for CY 2019.

> are critical to an ongoing and successful partnership among organizations developing measures."[39]

As such, we were profoundly disappointed when CMS announced in the Final Rule - without warning or opportunity for stakeholder input - that it had reviewed the procedures assigned to the family of Urology APCs for the Final Rule with comment period and made "some modifications" to reflect more appropriately the resource costs and clinical characteristics of the services within each APC.[40] This is a dramatic deviation from the last time CMS considered sweeping changes to APC assignments for urologic procedures, when the Agency provided stakeholders with warning in the OPPS Proposed Rule for CY 2016. As part of that earlier rulemaking process, CMS carefully examined the appropriate APC assignment for ESWL, solicited stakeholder input, and made a conscious decision to place HCPCS Code 50590 in APC 5375 based on input from LUGPA and other stakeholders.

What is particularly troubling is that the changes made - particularly the shift of ESWL from APC 5375 to APC 5374 - undermine CMS's efforts to encourage the migration of services from the hospital setting to the ASC setting and increase the presence of ASCs in health care markets or geographic areas where previously there were none or few, thus promoting better beneficiary access to care.[41] We have to believe this is an unintended consequence and one that should be reversed for CY 2019.

CMS has two options in this regard. At a minimum, the Agency should shift HCPCS Code 50590 back to APC 5375 for CY 2019. Alternatively, CMS should undo all of the assignment changes within the family of Urology APCs, restoring the HCPCS Codes to their CY 2018 APC assignments. The second option is more consistent with CMS's historic approach of soliciting stakeholder comment on changes in APC assignments. LUGPA would welcome the opportunity to serve as a resource to CMS in early 2019 as the Agency analyzes which of the changes in APC assignments to propose as part of the OPPS Proposed Rule for CY 2020.

III. CMS's Decision to Assign Rezum Therapy (CPT Code 53854) to APC 5373 Does Not Adequately Reflect the Cost of the Procedure, and the Agency Should Reassign Rezum Therapy to APC 5374 to Achieve Clinical and Resource Homogeneity with Other Procedures to Treat BPH.

In the Final Rule, CMS analyzed the assignments for three clinically similar procedures for treatment of benign prostatic hyperplasia ("BPH") - CPT Code 53854, which is known as Rezum Therapy, and CPT Codes 53852 and 53850.[42] All three procedures are within the same family of codes involving transurethral destruction of prostate tissue, with the primary difference being the energy sources used to shrink or destroy prostate tissue: CPT Code 53854 by radiofrequency, generated water vapor therapy; CPT Code 53852 by radiofrequency thermotherapy; and CPT Code 53850 by microwave thermotherapy. Notwithstanding the clinical and resource homogeneity of the three BPH procedures, CMS assigned Rezum Therapy (CPT Code 53854) to APC 5373, thereby designating the procedure as a Level 3 Urology service, while assigning CPT Codes 53852 and 53850 to APC 5374, thereby designating those procedures as Level 4 Urology services.

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[39] "Importance of Stakeholder Engagement to CMS," *available at* https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/How-CMS-Engages-You.html (last accessed Dec. 22, 2018).
[40] 83 Fed. Reg. at 58900.
[41] Id. at 59096.
[42] 83 Fed. Reg. at 58899-58901.

The assignment of Rezum Therapy to APC 5373 is wrong on two levels. First, the procedure bears little resemblance from a clinical or resource perspective to the other procedures denominated "Level 3" Urology services. Second, the assignment to APC 5373 ignores the substantial similarities to the two other BPH procedures denominated as Level 4 Urology services.

As the American Urological Association observed in its comment letter submitted in response to the Final Rule, the payment disparity between CPT Codes 53854, on the one hand, and CPT Codes 53852 and 53850, on the other hand, is inconsistent with the RVUs associated with these three procedures.[43]

CPT Code	Work RVUs	PE RVUs	MP RVUs	Total RVUs	2019 Payment	2019 APC	OPPS Payment	ASC Payment
53854	5.93	45.43	0.69	52.05	$1,875.88	5373	$1,739.75	$785.29
53852	5.93	37.39	0.65	43.97	$1,584.68	5374	$2,926.86	$1,347.37
53850	5.42	39.4	0.59	45.41	$1,636.58	5374	$2,926.86	$1,368.08

Table 2: Non-Facility RVUs, National Payments and APC Designation for Clinically Similar BPH Procedures

As the data reflects, the Work RVUs for Rezum Therapy are the same as for CPT Code 53852 and *higher* than for CPT Code 53850, and the PE and Malpractice RVUs are *higher* for Rezum Therapy than for either of the two other CPT Codes. We believe that this data would have supported an assignment of Rezum Therapy to APC 5375, but at a minimum, CMS should reassign Rezum Therapy to APC 5374 so that the procedure is classified with the two other BPH treatment procedures performed via transurethral destruction of prostate tissue. Such a change would result in all three minimally invasive BPH codes being grouped together – consistent with the Agency's charge of making APC assignments based on clinical and resource homogeneity.

IV. Request for Action

We are certain that CMS did not intend to jeopardize Medicare beneficiaries' access to non-invasive ESWL procedures in the ASC setting and risk shifting these cases into the higher-cost hospital outpatient setting or, even worse, risk access to the procedure altogether in rural communities. Unfortunately, this is precisely what will happen unless CMS takes action to remedy this for CY 2019.

For CY 2019, LUGPA believes it is critical that CMS increase payment for ESWL furnished in the ASC setting in order for Medicare beneficiaries, particularly in rural communities, to maintain access to non-invasive kidney stone treatment. CMS can make this adjustment without changing the APC assignment for ESWL or for any other procedures within the family of Urology APCs. Instead, CMS can keep HCPCS Code 50590 in APC 5374, but use its regulatory authority, borrowing from the methodology used to set ASC payment rates for more than 350 device-intensive procedures, to set the payment rate for equipment-intensive ESWL at a higher percentage of the OPPS payment rate than the percentage applied most commonly to other procedures within APC 5374. Making this limited change acknowledges the unique cost architecture of an equipment-intensive procedure such as ESWL for which the costs in an ASC setting - defined in largest part by the cost of the lithotripter machine - more closely approximate the costs in the outpatient hospital setting.

Other options exist for CMS to preserve access to ESWL in the ASC setting. The Agency can place Code 50590 in a newly-created APC 5374A with a payment rate in between the rates set for APCs 5374 and 5375. The Agency can also undo the change in assignment for ESWL - either by shifting that one procedure

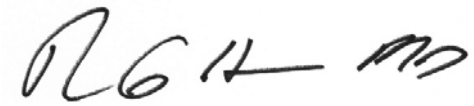
[43] See Comment Letter from American Urological Association to Administrator Verma, CMS-1695-FC (Jan. 2, 2019).

back into APC 5375 or by undoing all of the changes in assignments for the family of Urology APCs and revisit the assignments as part of the rulemaking process for the CY 2020 OPPS Fee Schedule. The latter option would be consistent with CMS's usual approach of soliciting stakeholder input and would avoid the unintended consequence of jeopardizing access to ESWL services in the ASC setting, particularly in rural communities.

CMS should also revise the APC assignment for the Rezum Procedure (CPT Code 53854; transurethral destruction of prostate tissue; by radiofrequency water vapor (steam) thermotherapy), shifting Code 53854 from APC 5373 to APC 5374 so that the procedure is grouped with two other minimally invasive BPH procedures that are similar from a clinical and resource perspective - CPT Code 53852 (transurethral destruction of prostate tissue; by radiofrequency thermotherapy) and CPT Code 53850 (transurethral destruction of prostate tissue; by microwave thermotherapy). The payment for Rezum Therapy in APC 5373, particularly in the ASC setting, bears little resemblance to the costs associated with the procedure and, at a minimum, the procedure should be reassigned to APC 5374 for CY 2019.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Final Rule. Please feel free to contact Dr. Kapoor at (516) 342-8170 or dkapoor@impplc.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,



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