September 27, 2019

BY ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P

Re: File Code-CMS-1717-P

Dear Madams and Sirs:

The Council for Urological Interests ("CUI") is pleased to have the opportunity to provide comments on the Medicare Final Rule with Comment Period for 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2020 Proposed Rule"). CUI is an organization comprising providers of the technical portion of an array of urology procedures, including lithotripsy, to hospitals and ambulatory surgery centers. Over the past twelve months, CUI members have helped both rural and urban hospitals and ASCs perform tens of thousands of shock wave lithotripsy (SWL) procedures on Medicare beneficiaries. Based upon our reading of the 2019 Final Rule, CUI Members performed approximately 80% of the SWL procedures in CMS's database. Most physicians who work with CUI members are board-certified urologists. Although now retired from the active practice of Urology, I am a board-certified urologist who has personally performed over one thousand (1000) SWL procedures. Physicians who work with members of CUI are certified to perform practically all of the procedures in the urology APCs.

As noted on January 2, 2019 in our public comment to CMS's 2019 Final Rule (2019 Comment), incorporated herein by reference, CMS has blatantly ignored its obligation to comply with the APA notice-and-comment requirements for impacted parties. After being shocked by the November 2, 2018 Final Rule's shifting of SWL (CPT 50590) to APC 5374, , CUI submitted

a Freedom of Information Act request (FOIA) to try to gain an understanding of why CMS's 2019 Final Rule was inconsistent with its 2019 Proposed Rule. The definition of "clinicially comparable" for the treatment of kidney stones is SWL and ureteroscopy with lithotripsy (URSL: CPT 52353 & CPT 52356). Indeed since the inception of the APC grouping, SWL and URSL have been appropriately linked together in APC 5375.

On November 7, 2018, we requested the underlying cost information for SWL under the FOIA. Despite requesting that we receive the data in time for the submission of our 2019 Comment in January, and despite the 20-business-day response required by law, we have never received any information from CMS. And the FOIA was filed three hundred and twenty-four (324) days ago.

In addition, we reached out to CMS staff to get a meeting to understand why CMS would issue a proposed rule on July 25, 2018, without a single word about possible restructuring of APC 5375 by dropping the high volume SWL into APC 5374, and then issue a final rule barely ninety days later having shifted SWL into APC 5374. With the negative impact directly aimed at CUI members, CMS intentionally failed to give the affected parties any chance to make public comment. Furthermore, CMS staff refused to meet unless CUI could show a flaw in their methodology and stated, "the sole rationale was the cost data reflecting CMS's calculation of average geometric mean cost (GMC) of required resources." A sleight of hand by CMS: show us how our methodology was wrong but we are not going to show you our data.

In the 2020 Proposed Rule, CMS continues to ignore its mandate to create APCs with clinically homogeneous procedures. SWL remains in APC 5374, separated from its sister procedures USRL in APC 5375. Yet comparison of the geometric mean costs of SWL and the blended and weight adjusted geometric means costs for URSL in CMS's published CPT cost

data for 2019 Proposed and 2019 Final reveals a SWL/URSL ratio of 0.775 in the Proposed data set and 0.774 in the Final data set. There was no meaningful change in the geometric mean cost relationship between SWL and URSL to support CMS's APC restructuring.

Frustrated by CMS's inaction in response to a FOIA, CUI formally applied for a Data Use Agreement (DUA) to research CMS's methodology in the last three HOPPS and ASC Payment Systems rules. After approval, and payment of twelve thousand dollars ($12,000) for information that should be available at no cost to the public, we received Limited Data Sets (LDS) for 2018 Final, 2019 Proposed, 2019 Final, and 2020 Proposed. Unfortunately, the methodology formula supplied in CMS materials was flawed and thus there was no way to validate CMS's calculations or the accuracy of cost data upon which CMS relied. At least one major hospital with a large number of SWL cases confided that they could not find any hospital expenses in their cost submission for 50590. But the inability to accurately evaluate the LDS prevented detailed analysis of the accuracy of cost reports of facilities for which CUI members provide SWL services "under arrangement." In addition, CMS's help-line for LDS questions went unanswered on multiple occasions.

In trying to better understand CMS's process in annually updating costs of procedures, we looked into CMS's own 2019 description of APCs on its website and how it "packages" hospital costs. Quoting the CMS website:

> "Packaging," or grouping integral, ancillary, supportive, dependent and adjunctive services into the payment for the associated primary procedure or service, is a critical OPPS feature. Packaging encourages better use of hospital resources. Medicare makes no separate packaged service payments. Some types of packaged items and services include:
>
> - All supplies
> - Ancillary services
> - Anesthesia

- Operating and recovery room use
- Clinical diagnostic laboratory tests
- Procedures described by add-on codes

The importance of inaccurate or incomplete cost reports from hospitals, as noted in the example above, is obvious when "packaging" is critical to CMS's determination of geometric mean costs and resource use. Again, the inability to use the LDS to validate CMS's data is critical to trying to answer the question of why CMS chose to restructure APC 5375 without advanced notice.

Blocked by CMS' lack of responsiveness and transparency and not knowing of its accuracy, CUI turned to CMS's published CPT cost data for 2018, 2019, and Proposed 2020 to try and understand CMS's actions. First, geometric mean costs for URSL have risen by 5.5%, while SWL costs have risen only 1.1% during that time. Second, the total geometric mean costs of SWL to URSL in Proposed 2019 rule was 62%, whereas in the 2019 Final rule three months later it was essentially unchanged at 61%. Third, in 2020 Proposed, CMS shows the total URSL costs increasing to almost $230 million while SWL costs fall to less than $125 million. Fourth, in 2020, CMS plans to pay 99% of URSL's geometric mean cost compared to only 93% of SWL's costs. Of course, such a differential was easy to obtain simply by moving SWL out of APC 5375 into APC 5374 and paying $1,100 less for every CPT 50590. But as noted above, change in geometric mean costs did not explain CMS's reshuffling of APCs. So what did CMS do?

CMS will likely point to the following statement in the 2019 Proposed Rule as justification, and claim that it gave proper notice to impacted parties:

> "Taking into account the APC changes that we are proposing to make for CY 2020, we reviewed all of the APCs to determine which APCs would not meet the requirements of the 2 times rule. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for

> affected APCs: ● Resource homogeneity; ● Clinical homogeneity; ● Hospital outpatient setting utilization; ● Frequency of service (volume); and ● Opportunity for upcoding and code fragments."

Yet no where did CMS publicly disclose that they were going to disregard clinical homogeneity and move SWL into the lower APC 5374 in order to make APC 5374 total costs appear more balanced when compared to APC 5375. In fact, CPT 50590 comprises 73% of the case volumes in APC 5374.

One could speculate that "budget neutrality" was somehow CMS's justification for SWL's shift, but a closer look at APCs 5374 and 5375 in 2017, 2018, and 2019 is enlightening. From looking at the 2017 and 2018 Final rulings, the total payouts for APCs 5374 and 5375 have a consistent ratio, with increasing cost year over year:

2017 Final
5374 - $300 mil
5375 - $632 mil (SWL included)
Both - $932 mil

2018 Final
5374 - $322 mil
5375 - $719 mil (SWL included)
Both - $1.04 bil

Taking the volumes from the 2019 Final ruling, but using the APC classifications from the 2019 Proposed ruling, we see this trend continue:

2019 Proposed (with 2019 Final volumes)
5374 - $331 mil
5375 - $768 mil (SWL included)
Both - $1.10 bil

While several CPT codes were shifted from 5375 to 5374 for the 2019 Final ruling, SWL comprised 73% of the total claim volume. No codes were moved into 5375 from 5374. By

dropping SWL into APC 5374, the total payments for it appear much closer to the total payments for APC 5375. Yet the cumulative total payments of the two APCs was only marginally lower than total payments for the same APCs in 2018.

2019 Final
5374 - $485 mil. (SWL included & represents 73% of volume)
5375 - $540 mil
Both - $1.03 bil

So by shifting SWL into APC 5374 without any prior notice, and absolutely no explanation as required by the Administrative Procedure Act, CMS was able to make APCs 5374 and 5375 appear more balanced. In fact, the sum of total payouts for the 2 APCs remained almost identical for 2018 and 2019, whether in the original proposed APC or the SWL shifted one. In other words, there seemed to be no "budget neutrality" justification for CMS's change to APC 5375.

Undoubtedly, the restructuring of APC 5374 raised the reimbursement for many procedures above their geometric mean costs. Apparently, all that was necessary was to target SWL's 40,000 cases and pay only 93% of its geometric mean costs. While their reasoning remains unclear, their intent is very clearly demonstrated. And yet not one word of forwarning to CUI members, who are providing services to thousands of vulnerable Medicare beneficiaries.

Under section 1833*l*(t)(2)(B) of the Medicare Act, services and procedures included in the same APC group must be comparable clinically and in terms of resource use. Procedures are not considered comparable regarding use of resources if the highest mean cost for a procedure within the group is more than two times the lowest mean cost for a procedure in the group. Clearly, the two times rule did not impact CMS's decision to move SWL into APC 5374.

CMS regulations do not appear to define what is "comparable clinically." Yet when it comes to surgical intervention of 90% of the kidney stones that require treatment, there is universal agreement that SWL and URSL are clinically comparable and homogeneous. Indeed, this comparability is codified in the American Urological Associations's Guidelines to the Surgical Management of Stone Disease (AUA Guidelines).

Perhaps a sleight of hand or perhaps innocent, CMS, in the above quote from the 2019 Proposed Rule, reversed the order of criteria used to evaluate APCs by stating "resource homogeneity" before "clinical homogeneity." Statutory language, on the other hand, places clinical homogeneity first, not second. Whether referenced first or second, however, CMS chose to ignore that key part of their statutory mandate. They simply turned a blind eye to the clinical homogeneity of SWL and URSL.

Interestingly, our analysis above suggests that they also ignored resource compatibility of these procedures, which had been consistently recognized in 2017, 2018, and 2019 Proposed. Yes, the costs of USRL have gone up faster than the costs of SWL. But it is not "lithotripsy" that raises the cost of URSL, but rather the invasiveness of the procedure that requires the placement of a ureteral stent in 90% of the patients for safety reasons. In fact, $609.16 of CPT 52356 geometric mean cost is placement of a stent, which is easily done since the surgeon already has instruments inserted in the patient's ureter.

SWL, on the other hand, requires the placement of a ureteral stent in less than 20% of cases. CPT 50590 is not bundled and simply covers shock wave lithotripsy. CUI members can

not insert or bill for ureteral stents in those 20% of cases for fear of violating the Stark Law. Yet the hospitals can and do bill separately under CPT 52322 for placement of those ureteral stents.

Even though safety and comfort concerns may drive the surgeon to place a ureteral stent immediately post-SWL, similar to post-URSL, there is a significant difference. As mentioned above, the surgeon is already poised inside of the ureter in URSL, making placement of a stent simple. SWL, however, is non-invasive and placement of a stent requires a totally new cystoscopy set up and repositioning of the patient. In other words, stent placement post-SWL is a totally new procedure. CPT 52322 billing is appropriate and is paid at a minimum of 50% of the APC rate ($3,059.21 under 2020 Proposed APC 5374). Using 2020 Proposed CPT cost data to recalculate the true geometric mean cost of SWL, including the 20% of stent placements, reveals a weighted average geometric mean cost of $3,655.83. A true apples to apples comparison, thus reveals that SWL and USRL remain both clinically and resource use homogeneous. Again, this critical factor goes unmentioned, let alone explained, as required by the APA. Why account for stents for URSL, and not SWL?

Unintended Consequences Abound

Our 2019 comment elaborated on the efficiencies of the mobile provision of SWL services to urban and rural facilities, the high capital cost of lithotripters, the expertise of the lithotripsy technologists. There is no need of recounting it all here.

Rarely do hospitals own a lithotripter because their volume does not justify such a high capital cost. Instead they contract "under arrangement" with providers like CUI members who provide the lithotripter and a professional lithotripsy technologist to assist the surgeon in performing the kidney stone case at the facility. As a consequence, it would not be surprising if their cost reports for CPT 50590 were inaccurate. As noted above, one hospital CFO found no evidence of any hospital ancillary costs being included in his facility's report.

URSL equipment, on the other hand, is one hundred percent (100%) owned by the hospital. Hospital systems now own fifty percent (50%) of the doctors, who are under the system's scrutiny for revenue production. Is it any wonder why hospitals prefer URSL where they own the equipment, own the doctors, and get ninety-nine percent (99%) of their putative costs reimbursed for Medicare patients?

As CMS has incentivized URSL, university urology training programs have adopted the same bias. In speaking personally with over fifteen training program directors, each candidly admitted that their residents in training get very little exposure to SWL. Indeed, it is more "fun" for the residents and more economically rewarding for the health system for URSL to be the procedure of choice. The ninety day global window around SWL only increases the health systems' favoritism towards USRL. CMS's payment scheme institutionalizes a bias that is harmful for Medicare beneficiaries and, as we will show, CMS itself.

While CMS focuses on money spent for its Medicare beneficiaries' kidney stone treatments, the Medicare patient suffers the consequences of the aforementioned bias. Unquestionably, URSL has a higher complication rate than SWL. The AUA Guidelines note, "SWL is the procedure with the least morbidity and the lowest complication rate…." Nearly ninety percent (90%) of Medicare patients have an indwelling ureteral stent placed after URSL.

These stents lead to repetitive painful episodes, visits to the emergency room, infection, and unplanned admissions. Medicare patients describe their quality of life with an indwelling stent as very poor. And that is before a small percentage of patients suffer a tearing of the ureter or a severe stricture, both devastating injuries.

Most studies that have given patients an unbiased choice of either URSL or SWL have shown that patients favor the noninvasive and stentless aspects of SWL. But as noted above, the surgeon's training, skillset, immediate access, and institutional bias may all result in the patient receiving URSL.

As forewarned in our 2019 Comment, lack of access to SWL is another risk the Medicare beneficiary may face as a result of CMS's biased payment scheme. We are aware of multiple facilities, both rural and urban, that have discontinued SWL services for Medicare recipients. Facilities find it difficult to justify getting only 93% of their costs reimbursed for SWL when 99% of their costs are covered for URSL.

Ironically, CMS itself will suffer its own unintended consequence. The culprit: Unplanned Admissions post treatment. While a CUI study showed the unplanned admission (UPA) rate for high volume SWL centers was only 7%, multiple studies have pegged the UPA of URSL at 15%. Using published CMS 2020 Proposed CPT cost data and proposed APC payment rates, this UPA differential will cost CMS up to an extra $141,087,940 annually.

Remedy

For all of the above reasons and for all Medicare beneficiaries, we ask you to restore SWL (CPT 50590) to its clinically homogeneous home: APC 5375. At the same time, the true resource use for SWL should be recognized, just as it is for USRL. The placement of stents with SWL should be calculated into the mean geometric costs of SWL and paid appropriately. Doing

such would recognize the reality of the homogeneity of SWL and URSL: a fact recognized by all previous CMS regimes. Budget neutrality, as related to APCs 5374 and 5375, would not seem to be an issue. In fact, a strong case can be made that by eliminating the unintended consequences CMS has put in motion, a positive budget response is possible.

Sincerely,

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Chairman
Council for Urological Interests