October 5, 2020

Seema Verma
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 2021 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems Rule [CMS-1736-P]

Dear Administrator Verma,

On behalf of the Large Urology Group Practice Association (LUGPA), we thank you for the opportunity to comment on the CY 2021 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Payment System Proposed Rule (the "Proposed Rule").[1] Our comments focus on supporting the Centers for Medicare & Medicaid Services' (CMS) proposals regarding site-neutrality and 340B payment policy. Moreover, consistent with LUGPA's commitment to ensuring that physicians have access to all clinically appropriate treatment modalities for all disease states, we specifically recommend that CMS ensure appropriate payment for extracorporeal shockwave lithotripsy (ESWL) by amending the device-intensive procedure policy applicable to certain procedures in the ASC setting.

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 154 urology group practices in the United States, with more than 2,200 physicians who, collectively,

[1] 85 Fed. Reg. 48772 (Aug. 12, 2020).

provide approximately 40% of the nation's urology services.[2]

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 adapt more readily and thus are better equipped to 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. This includes patients 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. LUGPA supports CMS' policies that promote site-neutral payment under the OPPS.

A. CMS' proposed payment changes for Part B drugs acquired under the 340B program are appropriate measures to more accurately reflect the resources and acquisition costs that 340B covered entities incur.

In the CY 2018 OPPS/ASC Final Rule, CMS finalized a policy to pay for Part B drugs acquired under the 340B program at ASP - 22.5% instead of ASP + 6%. CMS stated that its goal in adopting the payment policy change was to make Medicare payments for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs, while recognizing the intent of the 340B program to allow covered entities to stretch scarce resources for the benefit of their vulnerable patient populations.

Based on a hospital acquisition cost survey of covered entities, CMS proposes to increase the payment reduction for Part B drugs acquired under the 340B program from -22.5% to -28.7%.[4] In the alternative, CMS proposes to maintain the -22.5% payment reduction, which was based on of a MedPAC analysis identifying 22.5% as a conservative minimum discount that 340B entities receive when they purchase drugs under the 340B program.[5] It is notable that the current CMS approach has been upheld by the United States Court of Appeals for the D.C. Circuit (*American Hospital Association v. Azar*, No. 19-5048 (D.C. Cir. 2020)).

LUGPA supports CMS' proposed increase to the payment reduction from -22.5% to -28.7%, or in the alternative, CMS' maintenance of the existing payment reduction of -22.5%. The role that 340B covered entities have in furnishing quality care to vulnerable communities is critical, and CMS' payment policy under Medicare Part B for 340B-acquired drugs preserves Congress' intent that 340B covered entities have access to favorable pricing, while at the same time ensuring that

[2] 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/MedicareProvider- Charge-Data/Physician-and-Other-Supplier.html.
[3] 85 Fed. Reg. at 48890.
[4] *Id.*

Medicare payment to 340B covered entities is reflective of such their exclusive access to heavily discounted prices. Therefore, although Medicare payment to 340B covered entities for Part B drugs will be lower than it would be otherwise, the reduced Medicare payment is merely reflects the significantly discounted acquisition cost that 340B covered entities enjoy and avoiding creating an artificial windfall for 340B covered entities that is associated with the purchase of 340B drugs at ASP + 6%. 340B hospitals will still reap profits on drugs provided to commercially insured and cash-pay patients.

B. CMS' proposed elimination of the Inpatient Only (IPO) and expansion of the ASC Covered Procedure List helps to eliminate barriers to physician clinical decision-making and enhance patient access.

CMS proposes to eliminate the inpatient only list (IPO), which was created in 2000 to identify services that require inpatient care because of the invasive nature of the procedure and CMS' view that such procedures would, in every case, be performed in an inpatient setting.[6] In light of significant developments in the practice of medicine since the creation of the IPO list that blur the previous delineation between inpatient v. outpatient services, CMS now proposes to eliminate the IPO list over three years.[7]

On a related note, CMS is proposing to add additional procedures to the ASC covered procedures list (ASC-CPL), a list that identifies procedures which may be performed in the ASC setting without posing a significant safety risk to Medicare beneficiaries and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care by midnight following the procedure.[8] CMS is also proposing to revise its criteria for determining which procedures to add to the ASC-CPL, which could increase the ASC-CPL list for CY 2021 by 11 procedures under the standard criteria, or by 270 procedures under the alternative criteria.[9]

LUGPA generally supports both proposals as they relate to the IPO and ASC-CPL list because they remove a barrier for physicians in exercising their clinical judgement as to which setting of care is most appropriate for a given patient. The IPO list places an unnecessary regulatory barrier on physicians' ability to apply their clinical knowledge and experience to each unique patient. As CMS recognizes, there have been significant advancements in the practice of medicine since the creation of the IPO list, and physicians require the flexibility to determine how to best care for their patients. Elimination of the IPO list supports that flexibility.

Furthermore, continued additions to the ASC-CPL further recognizes that advancements in the practice of medicine is enabling beneficiaries to receive quality and safe medical care in settings that are significantly more convenient and at a lower cost. Additionally, continued additions to the ASC-CPL further acknowledges advancements in the practice of clinical medicine, expanding beneficiary access to high quality care in lower cost and generally more convenient settings. As discussed in more detail below, however, we emphasize that it is not enough to add services to the

[6] *Id.* at 48909.
[7] *Id.* at 48910.
[8] *Id.* at 48955-56.
[9] *Id.* at 48962-63.

ASC-CPL—CMS must also ensure that such services are adequately paid for to ensure beneficiary access.

It is imperative that in conjunction with expanding the list of Medicare-payable services on the ASC list, CMS eliminate the additional scaling factor, referred to as the ASC weight scalar, which is intended to maintain budget neutrality. This feature is discretionary and has only served to increase payment differentials between ASC and HOPD procedures. Adding new eligible codes to the ASC system without eliminating the current scalar will only penalize currently provided procedures in the ASC, including high volume urological procedures. While the conversion factor provides an average update of 2.7 percent across the payment system, the application of the ASC scalar reduces the average increase for high-volume services, thereby penalizing ASCs for successfully transitioning care away from the HOPD setting.

There is no evidence of growing differences in capital and operating costs in the two settings to support this growing payment differential. By maintaining budget neutrality in silos, instead of looking at HOPDs and ASCs collectively, the positive impact of the conversion factor alignment is negated, and CMS will not achieve the long-term savings desired.

III. LUGPA urges CMS to ensure adequate payment for extracorporeal shock wave lithotripsy (ESWL) in the ASC setting by amending its device-intensive procedure payment policy.

A. ESWL is an effective, non-invasive medical procedure that can safely be performed in the ASC setting but has historically been underutilized due high equipment acquisition costs coupled with site-of-care payment disparities.

ESWL (HCPCS 50590) involves the administration of shock waves generated by a lithotripter under the direction and supervision of a physician. Shock waves penetrate the skin and tissue to reach kidney stones and break them into small fragments so they can be passed. Lithotripsy can safely treat urinary tract stones, potentially preventing painful renal colic that often requires narcotics, urinary obstruction that can result in loss of renal function, septicemia, and the need for more invasive endoscopic or percutaneous alternatives. Given its non-invasive nature, ESWL has historically been almost performed safely in the ASC setting with great efficiency.

Despite its clinical benefits, ESWL is significantly underutilized in the ASC setting. As we have pointed out in numerous comment letters submitted in response to prior rulemakings, CMS has adopted payment changes for ESWL in the past several years that have contributed to significant payment shortfalls for ASCs that furnish ESWL, as summarized below in Table 1. In particular, CMS' payment policy for ESWL furnished in the ASC setting fails to take into account the device-intensive nature of ESWL, and more specifically, how the fair market acquisition of the necessary ESWL equipment (i.e. the use of the lithotripter) does not vary based on whether it is used in the hospital outpatient department (HOPD) or the ASC setting. CMS has long recognized that ESWL is fundamentally different in terms of equipment used than other procedures that treat stone disease of the urinary tract, but the agency's payment policy fails to account for these differences.[10]

[10] 66 Fed. Reg. 59856, 59862 (Nov. 30, 2001) ("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

Year	APC	OPPS Rate (ASC Rate)	Geometric Mean Cost
2018	5375	$3,705.77 ($1,757.24)	$3,245.23
2019	5374	$2,926.18 ($1,368.08)	$3,265.14
2020	5374	$3,018.20 ($1,372.67)	$3,147.26
2021 (Proposed)	5374	$3,123.80 ($1,396.56)	$3,493.05

Table 1: OPPS and ASC Reimbursement for ESWL Procedures

To explain further, ESWL is a non-invasive ambulatory procedure that *is completely dependent upon the utilization of a lithotripter machine by highly trained specialist in urology surgery trained in this technique*. ESWL lithotripters are very expensive and urologists generally lease this equipment rather than purchase it, with initial outlay estimated in excess of $500,000 to purchase a machine and $65,000 annually to maintain the equipment. Industry data suggests that, of nearly 41,000 Medicare ESWL procedures reported annually, over 75% were performed on leased ESWL lithotripters.[11] Industry survey data indicates that mean per case costs of lithotripsy equipment is approximately $1,750. Therefore, although some facilities may purchase and amortize ESWL equipment, the reality is that the vast majority of institutions rely on outside contractors to provide ESWL equipment on an "as needed" basis, which on average costs approximately $1,750 per patient.

As can be seen from Table 1, however, CMS' payment for ESWL furnished in the ASC setting effectively assumes that ASCs can furnish ESWL at lower costs, which is true only insofar as one excludes the costs of acquiring access to lithotripters. The cost of lithotripters does not change depending on whether they are used in the HOPD or ASC setting, and yet they represent the primary tool for urologists to furnish ESWL—without a lithotripter ESWL simply cannot be performed. Thus, assuming an industry-reported mean cost of $1,750 mean per case costs of lithotripsy equipment, ASCs currently incur several hundreds of dollars of losses for each ESWL procedure they perform under the existing payment framework. Meanwhile, HOPDs are reimbursed for ESWL at a significantly higher payment, which serves to shift ESWL procedures towards the costlier HOPD site-of-care, increasing costs to the healthcare system and to beneficiaries, and overall reducing beneficiary freedom of choice to receive medical care in the setting that is most convenient and clinically appropriate for their circumstances.

Industry data indicates that it is these payment challenges and discrepancies that are the primary driver of decreased ESWL utilization in the ASC setting. By 2019, reassignment of ESWL to APC 5374 resulted in a decline of 13.4% in ESWL cases performed in the ASC setting.[12] An overwhelming number of urology practices (94.7%) indicated that inadequate reimbursement for

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 lithotripter.")

[11] Council for Urologic Interests, internal data, personal communication.

[12] Council for Urologic Interests, internal data, personal communication; LUGPA survey of 145 urology practices re ESWL ownership and utilization, 11/2019; 96 practice respondents from 35 states comprising nearly 2,000 practitioners.

ESWL in the ASC setting was the primary reason for the decline in ESWL utilization.[13,14] Many urology practices have also indicated that they have deferred discontinuing ESWL services pending potential resolution of payment challenges in this rulemaking, and that should payments not be adequate, these practices will stop furnishing ESWL in ASCs to Medicare beneficiaries going forward. As highlighted by Figure 1, even at the highest volume centers, the cost for furnishing ESWL exceeds current ASC reimbursement, which brings into focus that the access challenges are most pronounced for small and rural practices that have less patient volume.

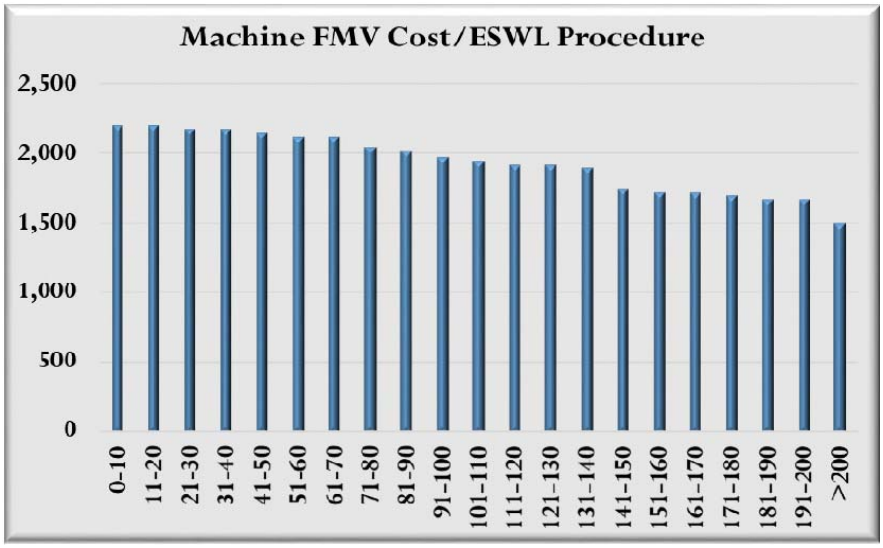

Figure 1: Lithotripter Fair Market Value Cost/Number of ESWL Procedures[15]

B. The COVID-19 pandemic has further exacerbated ASC challenges in furnishing ESWL, even as ESWL represents an opportunity to address the significant backlog resulting from the infection control protocols necessitated by the COVID-19 pandemic.

The COVID-19 pandemic has significantly strained the financial integrity of ASCs as public health experts and governments have encouraged, or in some cases required, health care providers to dramatically reduce outpatient services in order to prevent avoidable transmission of COVID-19 and many patients were encouraged to remain in their homes. As an elective procedure, ESWL has been squarely impacted by these developments, seeing a significant decline during the course of the pandemic. Council for Urological Interests (CUI) data indicates that there has been a 30% decline in ESWL utilization in the ASC setting over the same period last year.[16] Moreover, utilization of ESWL is expected to continue to suffer even as elective surgeries resume across the country due to the need for providers to meet current demand for outpatient services while addressing case backlog. Intermittent virus outbreaks are also likely to further disrupt providers' recoveries and access to ESWL.

Even as ESWL is further marginalized in the ASC setting by the COVID-19 pandemic, however, peer reviewed literature suggests that, when indicated, ESWL is likely the safest intervention for

[13] Council for Urologic Interests, internal data, personal communication.
[14] LUGPA survey of 145 urology practices re ESWL ownership and utilization, 11/2019; 96 practice respondents from 35 states comprising nearly 2,000 practitioners.
[15] Health Care Associates Inc., ESWL Fair Market Analysis; prepared for the Council for Urologic Interests.
[16] Council for Urologic Interests, internal data, personal communication.

kidney stones during the COVID-19 pandemic.[17] The volume of patients with kidney stones in HOPDs is significant, but institutional providers are disincentivized from shifting to the ASC setting because of reimbursement concerns. Because ESWL can be performed faster and more consistently than other alternatives, appropriate ASC reimbursement could significantly improve providers' ability to address patient backlog attributable to the COVID-19 pandemic.

In short, a growing number of patients in need of ESWL lack an actual location to receive the service, either because of restrictions imposed that are in response to the COVID-19 pandemic, or provider struggles to adequately meet current demand because of case backlog attributable to the COVID-19 pandemic. This serves to compound the current economic disincentives to provide ESWL in the first place. Nevertheless, ESWL poses clear advantages in safety and efficiency that could directly improve providers' ability to furnish needed urologic care during the COVID-19 pandemic. However, in order to do so, this requires that CMS ensure adequate payment in the ASC setting for ESWL procedures.

C. CMS can improve access to ESWL in the ASC setting and reduce system costs by establishing alternative criteria for qualification as a device-intensive procedure.

As discussed above, the performance of ESWL is inherently device-dependent because ESWL cannot be performed in the absence of a lithotripter. However, CMS' payment to ASCs fails to recognize this reality because CMS reduces payment to the ASC based on a percentage of the OPPS payment rate made to HOPDs, even though the fair market acquisition value for this equipment is not different at the or HOPD setting. As a result, ASCs are significantly underpaid for ESWL, which shifts ESWL procedures to the costlier HOPD site-of-care in direct contravention of CMS' stated policy that "[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."[18]

LUGPA believes that CMS can adequately address appropriate payment for ESWL when furnished in the ASC setting by leveraging its existing device-intensive procedure policy. Currently, CMS' device-intensive procedure policy only applies to procedures that involve implantable devices assigned a CPT/HCPCS code that must be surgically inserted or implanted and have a device offset of greater than 30 percent when calculated according to the standard OPPS ASC rate setting methodology.[19] In applying this device offset requirement to ESWL, using industry survey data indicating that the mean equipment acquisition cost is $1,750, we can estimate that the cost of a lithotripter represents approximately 50% of the geometric mean cost of APC 5374[20] Therefore, ESWL would otherwise meet the definition of a device-intensive procedure but for not involving an implantable/insertable device identified by a specific CPT code.

We appreciate the meeting in December of 2019, and the subsequent dialog with CMS in which we reviewed the above issues. As per our previous discussions, we believe that CMS can craft

[17] Fakhr YA, Aghamir SM. "Urinary stone management during the COVID-19 pandemic: a suggested approach and review of literature." *Therapeutic Advances in Urology*. 2020 Aug; 12:1756287220939513.
[18] 83 Fed. Reg. 37046, 37173 (July 31, 2018); *see also* E.O. 13813 – "Promoting Healthcare Choice and Competition Across the United States," (Oct. 12, 2017).
[19] 42 C.F.R. 416.171(b)(2).
[20] ([$1,750] ÷ [$3493.05] = [50%]).

alternative criteria to the existing device-intensive procedure criteria that would apply to an extremely limited number of device-intensive procedures that do not otherwise meet the current device-intensive procedure policy, but are inherently device-intensive notwithstanding, like ESWL. As per CMS's request that we provide input into criteria that would allow for appropriate reimbursement for certain procedures (including ESWL), We propose the following alternative criteria to qualify as a device-intensive procedure:

- The procedure cannot be performed without the equipment/device;
- The equipment/device is typically obtained on an "as-needed" basis rather than purchased or leased by the entity providing the care;
- The fair-market lease or rental cost in an HOPD or ASC setting is not materially different for either site of service;
- The fair-market lease or rental cost of the equipment precludes performing the service at an appropriate margin in an ASC setting; and
- The procedure is most appropriately done on an ambulatory basis for the majority of patients.

Our proposed solution maintains ESWL in APC 5374, but adequately considers the market realities of ASCs and ESWL by aligning Medicare payment with the ESWL procedure's device-intensive aspects. Applying CMS methodology in 2021 of subtracting device cost from the geometric mean cost and then scaling service costs, we estimate that an appropriate payment in the ASC setting for ESWL should be closer to $2,344.83, which is still significantly lower than the HOPD payment amount of $3,123.80 for 2021. Industry data suggests that only approximately 20% of ESWL services are performed at the ASC setting,[21] and it is anticipated that use will further decline amongst those presently performing Medicare ESWL in ASC setting. LUGPA data[22] suggests that of those presently performing ESWL in the ASC setting, 60% were not aware of current Medicare reimbursement rates at their center while others indicated that they deferred discontinuing ESWL services pending potential resolution of payment issues in current rulemaking. Should payments not be adequate they would be compelled to stop ASC ESWL for Medicare beneficiaries going forward.

LUGPA believes that our proposed policy change is consistent with CMS' goal of expanding site-neutral payment policies, where appropriate, in order to maximize beneficiary choice, enhance clinical decision-making, and reduce costs. Even at the enhanced payment level suggested above, we can anticipate that given access, beneficiaries would choose to have ESWL at a more cost efficient site of service. The table below illustrates potential system savings should 25, 50 or 75 percent of cases currently performed at the HOPD setting migrate to the ASC at the above cost parameters:[23]

% Migration to ASC	25%	50%	75%
Cost Savings	$ 6,387,800.00	$12,775,600.00	$19,163,400.00

Table 2: Potential Costs Savings Resulting From ESWL Migration from HOPD to ASC Setting

[21] Op cit., Council for Urologic Interests personal communication
[22] Op cit., LUGPA member ESWL survey
[23] Assumes % migration of 41,000 Medicare ESWL cases (of which 80% are presently performed in the HOPD setting), based on HOPD reimbursement of $3,123 and ASC payment of $2,344.

Failure to act could serve to substantially increase system costs—given that ASC payments are proposed to be $1,727 lower in the ASC setting, a migration of even half the cases currently done in the ASC setting to the HOPD would increase system costs by over $ 7 million in 2021. **We urge CMS to act in the final rule by finalizing our proposed alternative criteria for application of the device-intensive procedure payment policy to procedures like ESWL.**

D. Amending the device-intensive procedure payment policy is within the agency's authority to revise its proposals.

Revising the current device-intensive procedure policy would be in accordance with the statutory and judicial standards governing notice and comment rulemaking. The Administrative Procedure Act (APA) at 5 U.S.C. § 553(b)(3) and (c) generally requires a notice of proposed rulemaking to include "either the terms or substance of the proposed rule or a description of subjects and issues involved" and "[a]fter notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments."

Here, although CMS indicated that it was not proposing changes to its device-intensive procedures policy,[24] it did extensively describe its current device-intensive policy and the agency's historical flexibility in amending it.[25] Furthermore, CMS made various proposals regarding payment for urology-related APCs,[26] indicating that CMS is aware of the need to make refinements to payment for urology services, which include ESWL. Therefore, CMS put the public on notice regarding the amenability of both its device-intensive procedure policy and payment for urology services. Moreover, in providing a 60-day comment period, CMS has provided commenters with the ability to comment on both policies.

Were CMS to choose an alternative that it did not initially propose would be consistent with standard agency practice, and is well within CMS' authority under the APA. For example, had CMS stated that it was not changing the reimbursement status of a particular drug (e.g., in the hospital inpatient setting, eligibility for Medicare new technology add-on payments), then received comments opposing its proposal, CMS would clearly have the authority to alter the reimbursement status in the Final Rule. Indeed, CMS regularly reverses its position in rulemaking. For example, the 2017 Physician Fee Schedule final rule saw CMS reverse its position on more than a half dozen proposals it had made in the proposed rule.[27] Another example can be found in the fiscal year 2015 Federally Qualified Health Centers Final Rule, where CMS established a new set of G-codes in the final rule, acknowledging that the agency did not propose the coding additions in the proposed rule and was adding them in sole response to comments.[28]

[24] 85 Fed. Reg. at 48865 ("For CY 2021, we are not proposing any changes to our device-intensive policy.").
[25] *Id.* at 48863-65.
[26] *Id.* at 48842.
[27] *See*, CMS, Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017, Final Rule, 81 Fed. Reg. 80170, 80170 (Nov. 15, 2016).
[28] CMS, Prospective Payment System for Federally Qualified Health Centers (FQHC), Final Rule with comment period, 79 Fed. Reg. 26436, 25456-58 (May 2, 2014) (CMS established HCPCS G-codes for FQHCs to report and bill FQHC visits to Medicare under the FQHC PPS, noting that billing procedures for the G codes would be made through program instruction. While establishing the G-codes, the Agency also acknowledged that it "did not propose the establishment of G codes in the proposed rule, nor did [CMS] receive public comments specifically

Here, CMS will undoubtedly receive multiple comments from stakeholders to amend its device-intensive procedure policy, in addition to refining payment for urology services. As alluded to above, LUGPA and other stakeholders have consistently urged CMS to reform payment for ESWL for several years in a row. CMS has indicated that it does not anticipate making changes to its device-intensive procedure policy, but that refinements to payment for urology services are appropriate. Accordingly, it is within CMS' discretion as an agency subjecting its policies to notice-and-comment rulemaking to adopt suggested alternatives in the Final Rule, including the alternative of amending its device-intensive procedure policy to ensure appropriate payment for a certain group of services, including ESWL.

E. Revising the device-intensive procedure policy would be a logical outgrowth of the Proposed Rule.

Adopting alternative criteria for qualifying as device-intensive is consistent with how courts have interpreted an agency's notice and comment obligations under the APA. Courts have implemented § 553(b)(3) through the "logical outgrowth" doctrine. Under this doctrine, "while an agency may promulgate final rules that differ from the proposed rule . . . a final rule is a logical outgrowth of a proposed rule only if interested parties should have anticipated that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period."[29] In the case of Medicare regulations, section 1871(a)(4) of the Act expressly requires compliance with the "logical outgrowth" test. Courts have stated that section 1871(a)(4) of the Act, which prohibits the Secretary of Health and Human Services from finalizing "a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule", imposes "notice and comment requirements on the Secretary's substantive rulemaking similar to those created by the APA."[30]

When analyzing whether a final rule is a logical outgrowth of the proposed rule, courts apply the "standard functionally by asking whether the purposes of notice and comment have been adequately served . . . that is, whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule."[31] In the case of the device-intensive procedure policy and payment for urology services, the agency has extensively discussed both topics and thus a new round of notice and comment would certainly not be the first opportunity interested parties have to offer comments to persuade the agency to modify its rule.

Courts have found that "a final rule represents a logical outgrowth where the NPRM expressly asked for comments on a particular issue or otherwise made clear that the agency was

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requesting such codes," and as such, in the Final Rule with Comment, the Agency invited comment.) Separately, we note that in the CY 2016 PFS Final Rule, 80 Fed. Reg. 70886, 71321 (Nov. 16, 2015), CMS declined to make any revisions to its regulatory text defining "remuneration," noting that the Agency had not proposed any "regulatory revisions in the proposed rule" and that its preamble discussion to the proposed rule was a statement of CMS' existing policy." This, however, can be distinguished from the present situation where no revisions to the regulatory text are needed.

[29] *Intl Union, UMW v. MSHA*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (internal quotations and citations omitted).

[30] *Select Specialty Hosp. - Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13 (D.D.C. 2011).

[31] *American Water Works Ass'n v. EPA*, 40 F.3d 1266 (D.C. Cir. 1994) (emphasis added) (internal quotations and citations omitted).

contemplating a particular change."[32] Finalizing a revision to its device-intensive procedure policy fits comfortably within these standards. The agency in the Proposed Rule is proposing one approach—maintaining its current policy—as opposed to the approach of potentially changing the criteria applicable under its device-intensive procedure policy. The comment period is serving its statutory purpose of allowing interested parties to offer comments on whether the Agency's proposal to keep its current policy in place for now is wise, or whether it should adopt alternative criteria as submitted by commenters. Whatever approach, if finalized, would represent a logical outgrowth of CMS' proposal.

An agency's solicitation of comments on a particular issue in the proposed rule has frequently been found to pass muster under the logical outgrowth test. In *International Union v. MSHA*, 626 F.3d 84 (D.C. Cir 2010), the Mine Safety & Health Administration (MSHA) proposed that refuge chambers for miners provide 60 cubic feet per miner, but specifically sought comment on these proposed values, particularly in low mining heights. The agency ultimately finalized a volume requirement of 30 cubic feet per miner for refuge chambers in mines with heights of 36 inches or less. The D.C. Circuit concluded that the final rule was a logical outgrowth of the proposed rule because "MSHA's proposed rule identified the problem of low height mines and specifically solicited detailed comments on it."[33]

Similarly, in *City of Portland v. EPA*, 507 F.3d 706 (D.C. Cir. 2007), the EPA proposed three surface water treatment options for systems with existing uncovered reservoirs—to 1) cover the reservoirs; 2) treat the effluent from the reservoirs for viruses, but not for a parasite called Cryptosporidium; and 3) implement a state-approved risk mitigation plan. The agency then finalized a very different scheme under which these cities had to either 1) cover the reservoirs or 2) treat the effluent for viruses and Cryptosporidium. The court, however, held that the final rule was a logical outgrowth of the proposed rule. The court reasoned that the agency had fulfilled the logical outgrowth standard by stating in the proposed rule that it "continued to be concerned about contamination occurring in uncovered finished water storage facilities" and requesting comment on whether 1) it was appropriate to allow systems with uncovered reservoirs to implement a risk management plan or treat effluent for viruses instead of covering the facility; and 2) if systems treat the effluent, whether such treatment should be required to include Cryptosporidium instead of merely viruses.[34]

Moreover, in *Natural Resources Defense Council, Inc. v. Thomas*, 838 F.2d 1224 (D.C. Cir. 1988), the court examined an EPA rulemaking in which the agency had initially proposed that for demonstrations of the pollution reduction capabilities of smoke stacks that exceeded a certain height, each source would assume a baseline emissions rate based on either existing technology-based emissions limits, existing State Implementation Plan limits, or limits based on a formula. The agency proposed that which baseline was applicable would depend on what limits were

[32] *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009).
[33] *Int'l Union v. MSHA*, 626 F.3d 84, 96 (D.C. Cir 2010).
[34] *City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007) (emphasis added). EPA's first two questions in the "Request for Comments" section of that portion of the proposed rule asked: "Is it appropriate to allow systems with uncovered finished water storage facilities to implement a risk management plan or treat the effluent to inactivate viruses instead of covering the facility?" and "If systems treat the effluent of an uncovered finished water storage facility instead of covering it, should systems be required to inactivate Cryptosporidium . . . [since it has] been found to increase in uncovered storage facilities?" (emphasis added).

already applicable to the source. Under the rule the agency ultimately finalized, however, the baseline for all sources would be a single technology-based limit based on new source performance standards (NSPS).[35] The court acknowledged that the final rule was "dramatically different" from the proposed rule.[36] However, the court held that the logical outgrowth standard was satisfied because "the germ of NSPS was there, as one of the possibly-applicable technology-based limits" and "public comments raised the possibility of adopting a single, technology-based limit."[37] Accordingly, the "NSPS assumption appears to have emerged from the agency's notice and comment process, as the agency responded to others' comments by stripping away the components of the original proposal that it concluded were more vulnerable."[38]

Here, the Proposed Rule's extensive discussion of the device-intensive procedure policy, including how the agency has amended it in recent years, indicates that CMS is open to making changes to its device-intensive procedure policy even if the agency is not specifically proposing any in the Proposed Rule. Moreover, CMS attention to appropriate payment for urology services in the Proposed Rule provides further reason to believe that CMS is open to adopting payment changes that address payment challenges under the OPPS and ASC payment systems. In short, stakeholders are on notice, as a result of the Proposed Rule, that there is far more than the "germ" of the possibility that the agency will reject its proposed approach—which is to do nothing with respect to the device-intensive procedure policy—and adopt certain changes that promote accurate payment for device-intensive procedures that do not currently qualify under the existing policy.

IV. Request for Action

LUGPA supports the numerous initiatives by CMS to implement site-neutrality policies under the OPPS/ASC payment systems, we which view as critical in stemming the tide of consolidation of physician services within the hospital setting while safeguarding the high quality, cost-efficient care furnished to Medicare beneficiaries by independent medical practices. We urge CMS to continue such policies, and to also address ongoing payment challenges with specific device-intensive procedures that are undermining CMS' overarching policy goal of site-neutrality.

By way of summary, we recommend that CMS:

- Implement its payment reductions for Part B drugs acquired under the 340B program.
    - We believe that CMS' proposal accurately reflects the costs actually incurred by 340B covered entities while preserving Congress' intent that 340B drugs have access to discounted pricing on covered outpatient drugs.

- Implement its proposal to eliminate the IPO list and to expand and/or otherwise revise the ASC CPL.
    - As CMS has recognized, advances in the practice of medicine have progressed rapidly and it makes little sense for CMS to impose artificial barriers on evolving clinical decision-making.

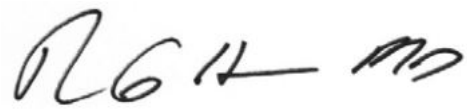
[35] *Natural Resources Defense Council, Inc. v. Thomas*, 838 F.2d 1224, 1242 (D.C. Cir. 1988).
[36] *Id.* at 1241.
[37] *Id.* at 1242-43
[38] *Id.* at 1243.

- CMS' proposed elimination of the IPO list and revisions to the ASC CPL serve to promote beneficiary choice and enhance clinical decision-making by allowing for the most appropriate site-of-care based on each patient's individual circumstances.

- Increase payment for ESWL furnished in the ASC setting by adequately accounting for the procedure's inherently device-dependent nature through slight modifications to CMS' existing device-intensive procedure payment policy.
  - LUGPA has previously recommended a range of proposals to CMS to address inadequate payment for ESWL in the ASC setting, and we have engaged the agency on multiple occasions regarding payment for ESWL.
  - Beneficiaries in small and rural communities have long experienced challenges in accessing ESWL because of the current payment framework, and COVID-19 has served only to further exacerbate those challenges.
  - **Our comments highlight not only the value of ESWL for patients, but also the potentially impactful role that adequate payment for ESWL in the ASC setting could have on enabling providers to better respond to the COVID-19 pandemic.**
  - We are confident that our proposed alternative device-intensive procedure criteria is narrowly tailored to impact only truly device-dependent procedures, and that CMS' finalization of such a policy in the Final Rule is within the agency's authority and represents a logical outgrowth of the Proposed Rule.

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@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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