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September 17, 2021

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

RE: CY 2022 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule [CMS-1753-P]

Via Electronic Submission

Dear Administrator Brooks-LaSure,

On behalf of the Large Urology Group Practice Association (LUGPA), we appreciate the opportunity to comment on the CY 2022 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Proposed Rule (the "Proposed Rule").[1] 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.[1]

LUGPA's longstanding position is that site neutrality should be one of CMS' primary guiding principles in determining payment policy under the OPPS. Site neutrality promotes beneficiary access to items and services in a more convenient and cost-effective setting of care, and it generally empowers patients to take a more active role in their care as they also have a wider selection of outpatient-based providers from which to seek care.

In keeping with our longstanding support for site neutral policy proposals, we write to support the Centers for Medicare & Medicaid Services' (CMS) proposed continuation of its payment policy for Part B drugs acquired under the 340B program. However, we oppose CMS' proposed reversal of the elimination of the Inpatient Only (IPO) list and urge CMS not to reinstate the IPO list, given that it runs contrary to the agency's commitment to site neutrality. We also support the agency's proposed increase to the civil monetary penalties associated with hospital non-compliance with price transparency requirements, and we support CMS' continued application of the productivity-adjusted hospital market basket

[1] "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals," 86 Fed. Reg. 42018 (Aug. 4, 2021) [hereinafter CY 2022 OPPS Proposed Rule].

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

update to the ASC PPS, which the agency implemented in the CY 2019 OPPS/ASC final rule. Finally, LUGPA reiterates its longstanding concern and request for payment reform for extracorporeal shock wave lithotripsy performed in the ASC setting.

By way of summary, we recommend as follows:

- **CMS should maintain site neutrality as a primary guiding principle in setting OPPS/ASC payment policy and it should continue promoting site neutral payment under the OPPS/ASC PPS.**
  The enactment of § 603 of the Bipartisan Budget Act (BiBA) represents a clear indication that Congress supports site neutrality under Medicare. CMS has advanced Congress' intent over the past several years, such as by imposing site neutral payment for E&M services furnished in off-campus provider-based departments in 2019. These policies eliminate the unwarranted financial incentives that lead to the provision of services in the hospital setting when those same services could be performed in a safe and cost-effective manner in another setting, such as an ambulatory surgical center or a physician's office. We urge CMS to continue such policies into the future.

- **CMS should proceed with its previously finalized initiative to eliminate the inpatient only (IPO) list and expand the ASC covered procedure list (CPL)**.
  Terminating the IPO list and expanding the ASCP CPL will help eliminate barriers to physician clinical decision-making while also enhancing patient access to care. Moreover, such policies are consistent with CMS' stated intent of migrating items and services from the HOPD to the ASC setting where they may be performed safely, conveniently, and more cost-effective.

- **CMS should continue its payment policy for Part B drugs acquired under the 340B program.**
  The explosive growth that the 340B program has experienced in the last decade, particularly among hospital covered entities, strongly suggests that hospitals are exploiting the 340B program to generate higher profits. We believe that CMS' ASP -22.5% payment policy 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.

- **CMS should finalize its proposal to increase the civil monetary penalty amounts for hospitals that are not in compliance with transparency requirements**.
  LUGPA is deeply concerned that hospitals appear to be engaging in a callous calculation. We believe that CMS' proposed scale, based on hospital bed amounts, will serve as an effective enforcement measure. By ensuring hospital compliance, CMS will ensure that patients can make informed decisions about their healthcare.

- **CMS should continue to apply the productivity-adjusted hospital market basket update to the ASC PPS.**
  The productivity-adjusted hospital market basket update supports the appropriate shifting of items and services to the ASC, which is generally a more cost-effective and convenient setting for patients. Moreover, the hospital market basket update more appropriately tracks changes in prices of healthcare inputs that ASCs actually use, rather than a basket of largely irrelevant consumer goods.

- **CMS should ensure adequate payment for extracorporeal shock wave lithotripsy (ESWL) in the ASC setting by amending its device-intensive procedure payment policy.** The capital costs associated with ESWL do not vary based on whether the procedure is performed in the ASC or HOPD setting. Consistent with our comments over the years, CMS must reform payment for ESWL if the agency is committed to advancing its site neutral priorities because the existing payment framework is crippling ASC's ability to furnish ESWL and undermining a safe, convenient, and cost-effective site of care for patients to access ESWL. LUGPA reinforces its CY 2021 recommendations of amending the device-intensive procedure policy as applied to ESWL.

I. Background on LUGPA

The Large Urology Group Practice Association (LUGPA) was formed in 2008 as a way to facilitate communication between independent urology-focused (GU) groups of ten or more providers. This served the complementary priorities of: (1) the promotion clinical and operational benchmarking to guide best practices (2) the establishment and promulgation of quality guidelines, and (3) the utilization of resources for advocacy and communication in the legislative and regulatory arena to ensure that these providers also had an opportunity to advocate on behalf of their patients and their specialty. Since that time, LUGPA has expanded its mission to incorporate any group practice who shares the foundational principles of commitment to providing integrated and comprehensive GU services to those impacted by genitourinary diseases and conditions. LUGPA has gained membership steadily; it currently includes 150 urology group practices in the United States, representing more than 2,100 physicians who, collectively, provide approximately 35% of the nation's Medicare urology services.(ref 2018 PUF data). Furthermore, LUGPA's members provide the majority of the GU care delivered in the independent physician office setting.

As health care reform efforts in the US have evolved to direct focus towards the development and promotion of outcome driven, "best-practice" patient care delivered in the most cost-effective setting, LUGPA practices have consistently been leaders in innovative and adaptive care models. Expanding both the range of procedures and the integration of care that can be safely and effectively provided in the more convenient and cost-effective independent physician setting has resulted in demonstrable concomitant reduction in the cost of care delivery, as well as improved outcomes. In addition, LUGPA practices have been at the forefront of adopting team-based healthcare, with the inclusion of other physician specialists and a variety of advanced practice providers, maximizing both convenience and accessibility to expert treatment for a broad spectrum of GU conditions. LUGPA practices have embraced value-based care models, and the organization was among the first to create a physician-focused payment model. As such, LUGPA has served as a high-quality, cost-effective alternative to cost increases associated with the consolidation of health care services.[3,4]

LUGPA's mission has been to provide and maximize access to the resources, technology, management tools and advocacy efforts that optimize the ability of urological surgeons and their clinical partners in the independent setting to provide integrated, comprehensive care for patients with acute and chronic illnesses affecting the GU system. During the global Public Health Emergency (PHE) LUGPA's mission was expanded to provide crucial resources to independent physician practices that enabled continuity of outpatient services even as the nation's inpatient capacity was overrun by patients stricken with COVID-19. Whether facilitating understanding and

[3] Scheffler RM, Arnold DR, Whaley CM. Consolidation trends in California's health care system: impacts on ACA premiums and outpatient visit prices. Health Affairs. 2018 Sep 1;37(9):1409-16.

[4] Capps C, Dranove D, Ody C. The effect of hospital acquisitions of physician practices on prices and spending. Journal of health economics. 2018 May 1;59:139-52.

access to government assistant programs, coordinating sourcing of personal protective equipment, or providing crucial safety data to its members.[5] Through these and other efforts, LUGPA helped ensure that vulnerable populations continued to be able to access life-saving urological services.[6]

LUGPA will continue to work on behalf of its membership to ensure that the critical role of independent GU practices is recognized and optimized as we work to expand access to current and up-to-date treatment alternatives in the most cost-effective setting.

II. LUGPA supports payment policies that promote site-neutral payment under the OPPS, which includes the elimination of the IPO list and expansion of the ASC CPL and continuation of the 340B payment cuts.

A. The IPO list erects unnecessary barriers to access and impedes physicians' ability to harness the rapid pace of innovation to provide the safest, most cost-effective, and convenient care to their patients.

The IPO list was created in 2000 to identify services that require inpatient care because of the invasiveness of the procedure(s) and CMS' view that such procedures would, in every case, be performed in an inpatient setting.[7] However, in light of significant developments in medicine since the creation of the IPO list that blur the previous delineation between inpatient and outpatient services, CMS proposed and then finalized its determination to phase out the list during a three-year period.[8] During CY 2021, CMS first removed 298 procedures from the list. In our comments responding to the CY 2021 OPPS Proposed Rule, LUGPA expressed support for CMS' decision to eliminate the IPO list. CMS also added 267 surgery or surgery-like codes to the ASC CPL, which LUGPA also supported.

In the CY 2022 OPPS Proposed Rule, CMS cites stakeholder opposition to eliminating the IPO list and proposes to reverse its decision by halting its elimination and adding the 298 services back to the IPO list.[9] Furthermore, CMS is proposing to codify the criteria used to determine whether a procedure should be removed from the IPO list:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that we have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC list.[10]

[5] Kapoor DA, Latino K, Hodes G, et al. The Impact of Systematic Safety Precautions on COVID-19 Risk Exposure and Transmission Rates in Outpatient Healthcare Workers. Rev Urol. 2020;22(3):93-101.
[6] Harris RG. After COVID-19, LUGPA More Important Than Ever. Rev Urol. 2020;22(2):75-76
[7] 85 Fed. Reg. at 48909.
[8] 85 Fed. Reg. at 48910; 85 Fed. Reg. at 86093.
[9] 86 Fed. Reg. at 42156.
[10] *Id.* at 42155.

Simultaneously, CMS is reversing the addition of 258 surgical procedures to the ASC CPL, determining that such procedures are inappropriate for the ASC setting taking into account the typical Medicare beneficiary.[11] CMS is seeking comments on these proposals.

LUGPA opposes CMS' proposed reinstatement of the IPO list. LUGPA supported CMS' finalized decision to eliminate the IPO list because it would 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.

Moreover, the IPO list also erects an unnecessary barrier to the timely adoption of innovative technology as the gears of government, including the IPO list determination process, grind slowly relative to the blistering pace of technological innovation; technology has evolved more rapidly than government's ability to track it. The healthcare intelligence firm Sg2 projects that 85% of all healthcare procedures will be performed on an outpatient basis by 2028.[12] As CMS has noted, the agency "is committed to ensuring Medicare beneficiaries have access to new cures and technologies that improve health outcomes."[13] The proposed policy directly contravenes this stated commitment of the agency.

Furthermore, healthcare professionals have the clinical training to determine whether health services can be performed safely and effectively in the outpatient setting. Indeed, CMS itself has recognized that 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.

Not only does the elimination of the IPO list and expansion of the ASC CPL promote beneficiary access to safe and convenient sites of care while expanding access to innovation, it also contributes to *significant* savings in Medicare spending. The Ambulatory Surgery Center Association (ASCA) and researchers at the University of California-Berkeley analyzed Medicare data in 2013 and determined that between 2008 to 2011, ASCs reduced costs to the Medicare program by $7.5 billion, including $2.3 billion in 2011 alone.[14]

A more recent 2020 analysis that updates the 2013 analysis determined that for the eight-year period between 2011 to 2018, ASCs generated $28.7 billion in savings.[15] The yearly savings increased from $3.1 billion in 2011 to $4.2 billion in 2018, resulting from a growth in the number of ASC procedures and the widening gap between HOPD and ASC payment rates.[16] Projected savings between 2019 to 2028 are expected to also increase year-after-year as they did between 2011 to 2018, with an average annual growth rate of 10.9% and reaching approximately $12.2 billion in 2028.[17] In short, the migration of services to the ASC setting generates well documented savings in Medicare spending, and so long as CMS maintains adequate payment in the ASC setting (such as by using the hospital market basket index), such savings are expected to only increase.

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[11] *Id.* at 42208.

[12] Olderog, A., Slama, L. (2018). Predicting Health Care Utilization Over the Decade. Presented at the 2018 Evolution of Surgery Summit, Washington DC. https://www.ascassociation.org/2018-sg2-report.

[13] 86 Fed. Reg. 2987 (Jan. 14, 2021).

[14] "Reducing Medicare Costs by Migrating Volume from Hospital Outpatient Departments to Ambulatory Surgery Centers," ASCA (Oct. 4, 2020), https://higherlogicdownload.s3.amazonaws.com/ASCACONNECT/fd1693e2-e4a8-43d3-816d-17ecfc7d55c1/UploadedImages/Reducing_Medicare_Costs_Study/Reducing_Medicare_Costs_by_Migrating_Volume from_HOPDs_to_ASCs.pdf.

[15] *Id.* at 8.

[16] *Id.*

[17] *Id.* at 9.

CMS indicated that, in part, they were responding to comments with respect to patient safety issues in the ASC vs. HOPD setting. This contravenes current literature which indicated that in general, patients treated in an ASC are less likely to be admitted to a hospital or visit an emergency room a short time after outpatient surgery.[18] Importantly, data indicates that specifically for urology, introduction of an ASC into a market was not associated with increases in hospital admission or mortality.[19]

LUGPA therefore urges CMS to continue with its previously finalized decision to eliminate the IPO list and expand the ASC CPL as planned, and not to reinstate the IPO list (nor codify an IPO list elimination criteria) or reverse course on the expansion of the ASC CPL as proposed in the CY 2022 OPPS rule.

B. CMS' proposed maintenance of the current payment rate for Part B drugs acquired under the 340B program reflects the resources and acquisition costs incurred by 340B covered entities.

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. In the CY 2022 Proposed Rule, CMS proposes to maintain the -22.5% payment reduction to ASP.[20]

LUGPA supports CMS' proposed maintenance of the existing payment of ASP -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 Medicare payment to 340B covered entities takes into account covered entities' exclusive access to heavily discounted drug prices.

The explosive growth of the 340B program in the last decade strongly suggests that hospitals have are exploiting 340B pricing to generate significant profits with little oversight on how they are spent. The Medicare Payment Advisory Commission (MedPAC) found that the 340B program grew relatively slowly between 1992 and 2005 to include roughly 583 participants.[21] However, by 2014, the 340B program exploded and grew by 367% in just nine years after the enactment of the Medicare Modernization Act (MMA) of 2003. Hospitals recognized that 340B program participation enabled them to maximize profits under the new ASP-based payment methodology established under the MMA. This can be seen most clearly in the oncology space, where the share of chemotherapy infusions administered in 340B hospital outpatient departments increased by 770% between 2004 to 2014, rising from 3% to 23.1%.[22] Today, roughly 40% of all acute care

[18] Munnich EL, Parente ST. Returns to specialization: Evidence from the outpatient surgery market. J Health Econ. 2018 Jan;57:147-167.

[19] Suskind AM, Dunn RL, Zhang Y, et al. Ambulatory surgery centers and outpatient urologic surgery among Medicare beneficiaries. Urology. 2014 Jul;84(1):57-61.

[20] 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*, 967 F.3d 818 (D.C. Cir. 2020)) and that the Supreme Court will hear arguments on the case during the 2022 Term.

[21] Report to the Congress: Overview of the 340B Drug Pricing Program. MedPAC, May 2015.

[22] Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014. Milliman, April 2016.

hospitals in the United States participate in the 340B program.[23] There should be no doubt that participation in the 340B program represents a lucrative membership club for hospitals.

CMS' proposed ASP -22.5% reduction in the Medicare payment amount merely reflects the significantly discounted acquisition cost that 340B covered entities enjoy on Part B drugs and avoids contributing to an artificial windfall for 340B covered entities associated with a payment of ASP + 6%. 340B hospitals will continue to have access to heavily discounted drug prices.

As discussed in our comments for the CY 2021 OPPS Proposed Rule, LUGPA also supports CMS' initiatives to implement site-neutrality policies under the OPPS/ASC payment systems. We believe that the payment reduction for 340B-acquired drugs, among other policies, are 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.

As CMS noted in the CY 2019 OPPS rule, volume increases in services paid under OPPS were projected to increase by 5.3% that year at a cost of $75.3 billion, an increase of $20 billion in just a few years.[24] This happened notwithstanding the enactment of § 603 of the BiBA.[25] In order to address the rapid increase in the volume of services paid under the OPPS, CMS adopted additional policies designed to eliminate unwarranted financial incentives leading to the provision of services in the hospital setting when those same services could be safely and cost-effectively performed in another setting, such as a physician's office or an ambulatory surgery center. For example, in the 2019 OPPS rule, CMS capped reimbursement for evaluation and management services performed in the hospital setting (even those that had been grandfathered as a result of the enactment of § 603 of the BiBA) at the rates for those same services paid under the physician fee schedule. LUGPA strongly supported that policy in 2019 and is pleased to see that CMS has proposed to maintain that policy in the CY 2022 proposed rule.

III. LUGPA supports CMS' proposal to increase civil monetary penalties to hospitals for violations of the price-transparency requirements.

A. Raising the civil monetary penalties (CMP) from $300 per day to a minimum penalty amount adjusted by a hospital-specific "scaling factor," proposed to be a hospital's number of beds as specified in its cost report data, will improve compliance and promote access to information so patients can make informed decisions about their care.

In the CY 2020 Hospital Price Transparency Final Rule, CMS codified the requirement that hospitals make publicly available information on contractually negotiated rates that hospitals negotiate with payers for a set of 300 "shoppable services." As noted in the CY 2022 OPPS Proposed rule, "[the] final regulations were designed to begin to address some of the barriers that limit price transparency with a goal of increasing competition among healthcare providers to bring down costs."[26] Specifically, the Hospital Price Transparency Final Rule set a daily $300 maximum penalty for hospitals that did not comply with transparency requirements enumerated in 45 CFR § 180.[27]

[23] "340B," PhRMA (last accessed Aug. 26, 2021), https://www.phrma.org/policy-issues/340B.
[24] 83 Fed. Reg. 37046, 37139 (July 31, 2018).
[25] Pub. L. No. 114-74 § 603, 129 Stat. 584, 597 – 599 (Nov. 2, 2015)
[26] 86 Fed. Reg. at 42312.
[27] 84 Fed. Reg. at 65590.

In the CY 2022 OPPS Proposed rule, CMS expresses concern about what has been identified as a "high rate of hospital noncompliance" and proposes to address hospital noncompliance by using a scaling factor to increase the CMP amount "in a manner uniquely tailored to the noncompliant hospital."[28] CMS will use the noncompliant hospital's number of beds, per hospital cost-report data submitted to CMS, as the "scaling factor" to determine the uniquely tailored CMP amounts. Using this scale, CMS proposes to penalize noncompliant hospitals with 30 or fewer beds with a maximum daily CMP of $300; for noncompliant hospitals with 31 to 550 beds, the maximum daily CMP would be the amount of beds multiplied by $10; and for noncompliant hospitals with more than 550 beds, the maximum daily CMP amount would be $5,500.

LUGPA supports CMS' proposal to increase CMPs for noncompliance with the hospital-transparency requirements. There have been widespread media reports that hospitals are not only not complying with the rule, but that they are taking proactive steps to hide the information required by the rule.[29] In one survey of 500 hospitals subject to the transparency requirements, 471 of surveyed hospitals "did not fully post the prices they charge patients and the rates they have negotiated with insurers."[30] This represents a 94% non-compliance rate among the hospitals that were evaluated. The identified trend toward increased noncompliance is concerning, as it undermines patients' ability to make informed decisions about their healthcare. We believe the scaled CMP amount will serve to discourage hospital noncompliance, and that the scaled CMP amount is sufficiently targeted to be sensitive to each hospital's resources.

IV. LUGPA supports CMS' application of the hospital market basket index to update the ASC PPS as a common sense payment policy that promotes safe, convenient, and cost-effective care.

A. The hospital market basket index much more closely reflects the actual cost of providing healthcare to patients.

In the Proposed Rule, CMS proposes to continue to apply the hospital market basket index to update ASC PPS payment rates, as CMS currently does for HOPD payments.[31] CMS' proposal represents a continuation of a policy first implemented in the CY 2019 OPPS/ASC final rule. Historically, the ASC PPS has been updated by the consumer price index for all urban consumers (CPI-U), which tracks price changes in a sampling of consumer goods, of which only 9% have any relation to healthcare. In contrast, the hospital market basket index tracks price changes of a basket of goods and services that are directly related to healthcare, such as the cost of medical equipment, healthcare labor costs, etc. CMS indicated in 2019, and reiterates in the Proposed Rule, that it intends to update the ASC PPS using the hospital market basket update only until CY 2023 in order to assess the hospital market basket update's impact on migration of procedures from the hospital setting to the ASC setting, as well as any unintended consequences.

LUGPA supports CMS' continued use of the hospital market basket to update ASC PPS payment amounts. The statute does not require the adoption of any one specific annual update factor for the ASC PPS, but it does provide that in the absence of any such update factor as determined by CMS, payments must be increased by CPI-U.[32]

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[28] 86 Fed. Reg. at 42313.

[29] *See* Tom McGinty, Anna Wilde Matthews and Melanie Evans, "Hospitals Hide Pricing Data From Search Results," THE WALL STREET JOURNAL (March 22, 2021).

[30] Dan Diamond, "Nearly all hospitals flout federal requirement to post prices, report finds," WASHINGTON POST (July 16, 2021), https://www.washingtonpost.com/health/2021/07/16/hospital-cost-transparency/.

[31] 86 Fed. Reg. at 42230.

[32] *See* Social Security Act, § 1833(i)(2)(C)(i).

Although we understand that CMS' use of the hospital market basket is temporary and set to expire in CY 2023, we cannot comprehend why CMS would revert to CPI-U regardless of what the agency concludes following its assessment of the five-year hospital market basket update policy. LUGPA believe that the use of the hospital market basket update is a common sense update factor to use since it directly incorporates the cost of healthcare resources and inputs, as opposed to the CPI-U that barely reflects the cost of healthcare, which have consistently risen faster than the cost of consumer goods. Even if CMS' assessment concludes the worst case scenario, that the hospital market basket update had no impact on migrating procedures to the ASC setting, we do not see how that justifies updating a healthcare payment system with price changes that are virtually irrelevant with respect to the rising cost of healthcare. Reverting to the statutory default of CPI-U when CMS plainly has the authority to use a superior update factor effectively represents an abdication of CMS' responsibility to ensure access to ASC services through adequate payment to participating providers.

Therefore, we urge CMS to apply the hospital market basket update to the ASC PPS on a permanent basis to better align payments with the rising costs of healthcare and to help provide payment certainty to ASC providers.

V. 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.

In response to the CY 2021 OPPS/ASC proposed rule,[33] in addition to prior rulemakings, LUGPA submitted comments drawing CMS' attention to the significant payment challenges experienced by ASC providers for ESWL procedures (HCPCS 50590, APC 5374). In particular, we have highlighted that the vast disparity in payment for ESWL procedures in the HOPD versus the ASC settings fails to recognize the device-intensive nature of ESWL, and as a result, CMS' payment policy is impeding the migration of ESWL to the ASC where it can be safely and more conveniently performed on a more cost-effective basis. In the Proposed Rule, CMS once again does not propose to make any changes to ESWL payment rates, but LUGPA nevertheless reiterates our position that payment reform for ESWL procedures is needed, and CMS can leverage its existing device-intensive policy to that end.

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.* Lithotripters are very expensive and urologists and facilities 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.[34] 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.

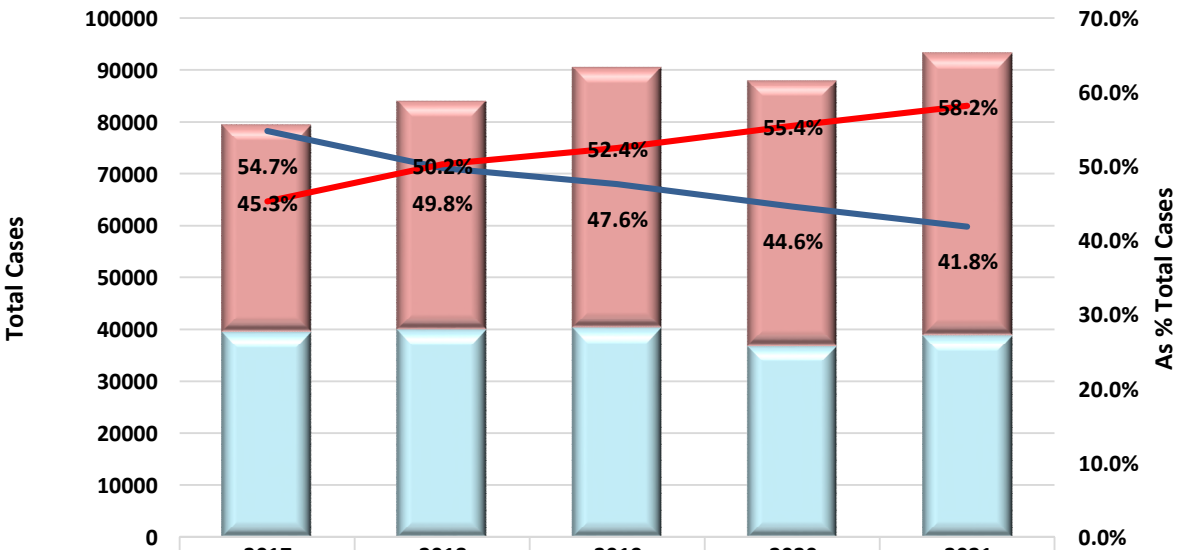
[33] https://lugpa.memberclicks.net/assets/docs/2020/LUGPA%20Comments%20to%20CMS%201376-P.pdf.
[34] Council for Urologic Interests, internal data, personal communication.

As can be seen from Table 1 below, 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.

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	5374	$3,123.80	$1,396.56	$3,493.05
2022 (Proposed)	5374	$3,157.78	$1,444.38	$3,407.71

Table 1: OPPS and ASC Reimbursement for ESWL Procedures

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.



	2017	2018	2019	2020	2021
52356	39945	44053	50203	51188	54320
50590	39554	39962	40351	36803	38864
50590 (%)	54.7%	49.8%	47.6%	44.6%	41.8%
52356 (%)	45.3%	50.2%	52.4%	55.4%	58.2%

Figure 1: ESWL v. Ureteroscopy/Lithotripsy Procedures, 2017-2022

The decline in utilization of ESWL is illustrated in Figure 1 above. When one compares ESWL to ureteroscopy/lithotripsy (HCPCS 52356), a common performed invasive procedure to remove kidney stones—this procedure is assigned to APC 5375. While ureteroscopy has its own intrinsic costs, it does not involve resource-intensive capital like a lithotripter machine. As illustrated

above, the percentage of total cases of ESWL has declined over the years, while the percentage of ureteroscopy/lithotripsy cases have increased. The inverse relationship between the incident of ESWL and ureteroscopy/lithotripsy is contemporaneous with shifts in reimbursement; indeed, the use of invasive ureteroscopy to treat stones during the COVID PHE *increased* even though hospital and HOPD access was extremely constrained. This lack of access to ESWL as a non-invasive option is precisely what the urologic community jointly expressed as a concern during our meetings with CMS last year.[35] Even though ESWL effectively achieves the same outcome as ureteroscopy/lithotripsy without requiring an invasive surgical procedure, beneficiaries are unable to access ESWL in the ASC setting because of payment shortfalls associated with APC 5374 under the ASC PPS.

To address the inadequacy in payment, LUGPA reiterates our CY 2021 OPPS/ASC recommendation that CMS amend its device-intensive procedure policy to accommodate the unique circumstances of ESWL, which involves high capital costs but does not involve an implantable device.[36] If this is not possible, an alternative mechanism to alter ESWL reimbursement in the ASC setting must be implemented.

VI. Conclusion

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,

R. Jonathan Henderson, MD
President

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[35] *See* LUGPA's CY 2021 Comments, *available at* **https://www.regulations.gov/comment/CMS-2020-0090-1233** (describing how the COVID-19 pandemic exacerbated ASC's challenges in furnishing ESWL even though ESWL could significantly address the backlog in kidney stone removal procedures attributable to the COVID-19 pandemic).

[36] *See id.* at 9.