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September 18, 2018

**BY ELECTRONIC SUBMISSION**

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: Revised Comments to CMS-1693-P (originally submitted  
9/10/2018)

Dear Administrator Verma:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Physician Fee Schedule (“MPFS”) and Quality Payment Program (“QPP”) Proposed Rule for 2019 (the “Proposed Rule”).<sup>1</sup> CMS has done something that happens too infrequently in the formulation of health policy—the Agency listened to physicians and issued proposals to support the doctor-patient relationship and enhance the overall patient experience. You heard our concerns and have taken action “by streamlining documentation requirements to focus on patient care and by modernizing payment policies so seniors and others covered by Medicare can take advantage of the latest technologies to get the quality care they need.”<sup>2</sup>

In this comment letter, we focus on those proposals that we believe will have the most significant impact on independent urology group practices and the patients we serve. With one limited exception that we describe below, we believe that CMS should finalize all of the historic changes the Agency has proposed to the evaluation and management (“E/M”) visit code sets—not merely the proposals that ease documentation burdens but also the proposal to create a single payment rate for level 2 through 5 E/M visits. Although some in the medical community have suggested that there are unanswered questions and potential unintended consequences of the payment proposal, our data analysis is very much in line with CMS’s analytics and confirms that the proposed revaluation of E/M visits for new and established payments is wholly appropriate.

<sup>1</sup> 83 Fed. Reg. 35704 (July 27, 2018).

<sup>2</sup> See Statement of CMS Administrator Seema Verma (July 12, 2018), available at <https://www.cms.gov/newsroom/press-releases/cms-proposes-historic-changes-modernize-medicare-and-restore-doctor-patient-relationship> (last accessed Sept. 5, 2018).

The only aspect of the E/M proposal that we believe should not be implemented is the proposed reduction of payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit. We fully recognize the need to maintain budget neutrality through implementation of the E/M proposals, but we believe that the more appropriate way to do so is for CMS to exercise its authority under Section 603 of the Bipartisan Budget Act of 2015 (“BBA”) by equalizing payment rates for E/M visits between non-excepted, off-campus provider-based departments and physician offices.

As we explain in further detail below, we offer the following comments with respect to the balance of the Proposed Rule:

- We ask that CMS eliminate the proposed cut in reimbursement for prostate biopsy services (HCPCS Code G0416) and establish a valuation for G0416 that is based on an objective analysis of the growing complexity associated with work actually done in reviewing prostate tissue collected through prostate needle biopsies;
- We ask that CMS not finalize its proposal to reduce the wholesale acquisition cost-based payments for Part B drugs from the 6% add-on currently in place to 3 percent;
- We ask CMS to equalize payment rates between non-excepted off-campus PBDs and physician offices on a procedure-by-procedure basis, but, if the Agency is not prepared to do so for CY 2019, at an absolute minimum, CMS should reduce the PFS Relativity Adjuster for non-excepted items and services furnished by non-excepted off-campus PBDs from 40% to 25% of the OPPS payment rate;
- We support CMS’s efforts to modernize Medicare physician payment for communication technology-based services, including through the creation of coding for remote evaluation of pre-recorded patient information for new and established patients (HCPCS Code GRAS1) and through the payment of inter-professional consultations performed via communications technology (CPT Codes 994X6, 994X0, 99446, 99447, 99448, 99449);
- We ask CMS to maintain flexibility with respect to Electronic Health Record certification requirements and delay the requirement of using the 2015 Edition CEHRT until the 2020 MIPS performance year to allow additional transition time for completing this process; and
- Although we generally support CMS’s proposed updates to the Quality Payment Program (“QPP”), we ask that the Agency (i) reconsider its proposals with respect to the elimination of extremely topped out measures and the removal of process measures, and (ii) maintain the weight of the cost performance category at 10 percent for the CY 2021 MIPS payment year.

## 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 145 urology group practices in the United States, with

more than 2,100 physicians who, collectively, provide approximately 35% of the nation's urology services.<sup>3</sup>

Integrated urology practices are able to monitor health care outcomes and seek out medical “best practice” in an era increasingly focused on medical quality and the cost-effective delivery of medical services. Additionally, these practice models can better overcome the economic and administrative obstacles to successful, value-based care. LUGPA practices often include advanced practice providers and other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care with added patient convenience. LUGPA's mission is to provide urological surgeons committed to providing integrated, comprehensive care the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system, including men with prostate, kidney and bladder cancer, in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, regulatory agencies, and legislative bodies.

## **II. CMS's Proposed Changes to the Documentation, Coding and Valuation of E/M Visits Are Consistent with the Administration's Goal of Putting the Patient First and Should be Implemented Effective January 1, 2019.**

In the Proposed Rule, CMS has identified and proposed a solution to one of the most vexing aspects of the MPFS—the documentation guidelines and associated payment structure and valuation of E/M visits. CMS has long recognized that “the E/M visit code set is outdated and needs to be revised and revalued.”<sup>4</sup> LUGPA shares this view.

Review of literature supports CMS taking bold steps to modernize the E/M visit code set. At present, the mechanism by which physicians interact with the electronic health record (“EHR”) is clearly recognized as burdensome and time consuming, undermining the potential advantages associated with utilization of these systems.<sup>5,6</sup> Indeed, it is estimated that physicians typically spend more than half their workday interacting with the EHR rather than the patient.<sup>7</sup> This burden has been documented as a strong contributor to physician burnout,<sup>8</sup> particularly in older physicians.<sup>9</sup> Furthermore, the documentation requirements to generate CPT codes for appropriate reimbursement may expose practitioners to additional medico-legal liability.<sup>10</sup> Clearly, E/M documentation guidelines are administratively burdensome and out of touch with the current practice of medicine, and CMS is correct to re-examine the structure of the code set and its attendant valuation.

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<sup>3</sup> Centers for Medicare and Medicaid Services, *Medicare Provider Utilization and Payment Data: Physician and Other Supplier*, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html> (last accessed Sept. 8, 2018).

<sup>4</sup> 83 Fed. Reg. at 35832 (citing 81 Fed. Reg. 46200 and 76 Fed. Reg. 42793).

<sup>5</sup> Collier R. Rethinking EHR interfaces to reduce click fatigue and physician burnout. *CMAJ: Canadian Medical Association Journal*. 2018; 190(33):E994-E995.

<sup>6</sup> Hingle S. Electronic Health Records: An Unfulfilled Promise and a Call to Action. *Ann Intern Med*; 165:818–819.

<sup>7</sup> Arndt BG, Beasley JW, Watkinson MD, et al. Tethered to the EHR: Primary Care Physician Workload Assessment Using EHR Event Log Data and Time-Motion Observations. *Annals of Family Medicine*. 2017; 15(5):419-426.

<sup>8</sup> Shanafelt TD, Dyrbye LN, West CP. Addressing Physician Burnout: The Way Forward. *JAMA*. 2017; 317(9):901–902.

<sup>9</sup> Khairat S, Burke G, Archambault H, et al. Perceived Burden of EHRs on Physicians at Different Stages of Their Career. *Appl Clin Inform*. 2018 Apr; 9(2):336-347.

<sup>10</sup> Mangalmurti SS, Murtagh L, Mello MM. Medical malpractice liability in the age of electronic health records. *N Engl J Med*. 2010 Nov 18; 363(21):2060-7.

We appreciate that this Administration is willing to act boldly on such an important topic. The Agency crystalized the importance of its E/M proposal as follows:

“[a]llowing practitioners to choose the most appropriate basis for distinguishing among the levels of E/M visits and applying a minimum documentation requirement, together with reducing the payment variation among E/M visit levels, would significantly reduce administrative burden for practitioners, and would avoid the current need to make coding and documentation decisions based on codes and documentation guidelines that are not a good fit with current medical practice.”<sup>11</sup>

We agree with CMS and divide our comments into four parts. First, we address CMS’s proposed changes to E/M documentation guidelines. Second, we examine the proposed restructure of the E/M code sets and associated revaluations, presenting a robust data analysis that further confirms the appropriateness of the Agency’s proposal. Third, we respond to the Agency’s proposed incorporation of multiple procedure payment reduction (“MPPR”) policies into the overarching changes to E/M coding and payment. Finally, we address the timing of when CMS should implement its proposals on E/M visits.

#### **A. CMS’s Proposed Changes to E/M Documentation Guidelines Will Reduce Administrative Burden and Enable Physicians and Other Practitioners to Focus on the Patient.**

In fleshing out its proposal to reshape documentation guidelines for E/M visits, the Agency’s simplest statement might also be its most profound:

“Our primary goal is to reduce administrative burden so that the practitioner can focus on the patient.”<sup>12</sup>

CMS asked stakeholders to offer their opinions “as to whether our E/M visit proposals would, in fact, support and further the goal.”<sup>13</sup> To be clear, we can think of few changes CMS could make in the MPFS that would have a more positive impact on practitioners’ ability to focus on patients, rather than paperwork, than the revisions the Agency is proposing to E/M documentation guidelines. The providers in our LUGPA member practices strongly concur with CMS’ prediction that the documentation changes will “allow practitioners to exercise greater clinical judgment and discretion in what they document, focusing on what is clinically relevant and medically necessary for the patient.”<sup>14</sup>

We also agree with CMS’s proposal to give practitioners maximum flexibility in selecting the mechanism they use in documenting E/M visits. Practitioners will be allowed to continue using the 1995 and 1997 E/M guidelines if they so choose, but they will also have the option of documenting E/M visits based on medical decision-making (“MDM”) or time as the basis for determining the appropriate level of E/M visit. For those practitioners who decide to remain with the current documentation framework or MDM, there will be an enormous benefit to having to document only to support the medical necessity of the visit and to provide documentation associated with current level 2 CPT visit codes (99202 & 99212). This change alone will have a profound impact on our ability, as caregivers, to focus our attention on the patient rather than paperwork.

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<sup>11</sup> 83 Fed. Reg. at 35837.

<sup>12</sup> Id. at 35838.

<sup>13</sup> Id.

<sup>14</sup> Id.

Ultimately, though, we believe it will be CMS's proposal to allow practitioners to use time as the single factor in selecting the E/M visit level that will have the most positive impact on our ability to focus our attention on patient care. The proposal is as effective as it is simple—permitting the practitioner to use the amount of time he or she personally spends face-to-face with the patient as the basis for documenting the E/M visit, regardless of whether counseling or care coordination dominate the visit.<sup>15</sup>

We also support the other common-sense changes that CMS has proposed to the documentation and billing guidelines for E/M visits:

- With respect to documentation of history and exam for established patients, practitioners would only be required to focus their documentation on what has changed since the last visit or on pertinent items that have not changed;
- With respect to new and established patients, practitioners would no longer be required to re-enter information in the medical record regarding the chief complaint and history that are already entered by other staff or the beneficiary;
- With respect to the billing of same-day visits by practitioners of the same group and specialty, the blanket prohibition would be removed in light of the increased number and granularity of practitioner specialties and a desire to enhance patient convenience by avoiding the scheduling of E/M visits on two separate days.

In short, CMS's proposed changes to documentation and billing guidelines for E/M visits will greatly reduce clinical burden and enhance a patient-centric approach to care.

#### **B. CMS Has Correctly Recalibrated the Coding Structure and Payment Rates for New and Established Patient E/M Visit Levels 2 through 5.**

CMS correctly recognized that the challenges associated with the E/M code sets extend beyond the documentation guidelines and include the payment structure itself; LUGPA applauds CMS for its thoughtful approach to this issue.

To further research this, LUGPA conducted an analysis of every CPT code referable to every urologist who billed Medicare in 2016.<sup>16</sup> A separate analysis was conducted for patient visits based on site of service (facility vs. office). Within each site of service, RVU streams for new/established patients were segregated (CPTs 99201-99205, 99211-99215). Using the zip code information attached to each NPI number, we indexed every NPI number to its unique 2019 GPCI and compared that to its corresponding 2018 GPCI. Using the standard formula for calculation of total RVU,<sup>17</sup> we calculated the change in RVUs for all E/M codes at each site of service. As providers may have services at more than once site of service, RVUs for each NPI for office and facility visits were cross-referenced and summed to create total RVU change for every NPI number. From this, descriptive statistics and histograms were generated. This procedure was carried out for the changes to base E/M codes. As urology was identified by CMS as being eligible to use

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<sup>15</sup> Id. at 35837.

<sup>16</sup> Medicare Provider Utilization and Payment Data: Physician and Other Supplier PUF CY2016. Accessed at: <https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/utc4-f9xp/data>.

<sup>17</sup> Total RVU = (Work RVU \* Work GPCI) + (Practice Expense RVU \* Practice Expense GPCI) + (Malpractice RVU \* Malpractice GPCI).

the add-on HCPCS code GCG0X, a similar procedure as described above was carried out for E/M codes with GCG0X as well. RVU data used for the calculation is depicted in the tables below.<sup>18</sup>

Base RVU Adjustments, New						Base RVU Adjustments, Established				
Year	CPT	RVU Component				CPT	RVU Component			
		Work	Office PE	Facility PE	MP		Work	Office PE	Facility PE	MP
2019	99201	0.48	0.7	0.21	0.02	99211	0.18	0.48	0.08	0.01
	99202	1.9	1.69	0.8	0.14	99212	1.22	1.25	0.52	0.08
	99203	1.9	1.69	0.8	0.14	99213	1.22	1.25	0.52	0.08
	99204	1.9	1.69	0.8	0.14	99214	1.22	1.25	0.52	0.08
	99205	1.9	1.69	0.8	0.14	99215	1.22	1.25	0.52	0.08
2018	99201	0.48	0.73	0.23	0.05	99211	0.18	0.42	0.07	0.01
	99202	0.93	1.11	0.42	0.08	99212	0.48	0.72	0.2	0.04
	99203	1.42	1.48	0.6	0.15	99213	0.97	1.02	0.41	0.07
	99204	2.43	2	1.01	0.22	99214	1.5	1.44	0.62	0.1
	99205	3.17	2.39	1.32	0.29	99215	2.11	1.84	0.88	0.15

**Table 1: Base RVU Values used for Calculation**

Base RVU Adjustments, New + GCG0X						RVU Adjustments Established + GCG0X				
Year	CPT	RVU Component				CPT	RVU Component			
		Work	Office PE	Facility PE	MP		Work	Office PE	Facility PE	MP
2019	99201	0.48	0.7	0.21	0.02	99211	0.18	0.48	0.08	0.01
	99202	2.15	1.8	0.91	0.16	99212	1.47	1.36	0.63	0.1
	99203	2.15	1.8	0.91	0.16	99213	1.47	1.36	0.63	0.1
	99204	2.15	1.8	0.91	0.16	99214	1.47	1.36	0.63	0.1
	99205	2.15	1.8	0.91	0.16	99215	1.47	1.36	0.63	0.1
2018	99201	0.48	0.73	0.23	0.05	99211	0.18	0.42	0.07	0.01
	99202	0.93	1.11	0.42	0.08	99212	0.48	0.72	0.2	0.04
	99203	1.42	1.48	0.6	0.15	99213	0.97	1.02	0.41	0.07
	99204	2.43	2	1.01	0.22	99214	1.5	1.44	0.62	0.1
	99205	3.17	2.39	1.32	0.29	99215	2.11	1.84	0.88	0.15

**Table 2: Base RVU Values used for Calculation, including HCPCS Code GCG0X**

The cumulative changes in total RVUs for all sites of service for new and established patient visits as suggested in the Proposed Rule are depicted in the graphics below:

<sup>18</sup> For clarity, we relied on the RVU components for HCPCS Code GCG0X listed in Addendum B in performing our data analysis (Work 0.25, Office PE 0.11, Facility PE 0.11, and Malpractice 0.02) which differ from those listed in the body of the Proposed Rule, 83 Fed. Reg. at 35842 (Work 0.25, PE 0.07, and Malpractice, 0.01).

For 8,651 urologists identified as having billed Medicare for any new or follow-up patient visits in 2016, the mean change was a mere 74.8 RVUs with a median value of 49.3 RVUs. The data revealed a marked degree of kurtosis (5.5); a 75.9% of urologists nationally would see impact of just +/- 400 RVUs.

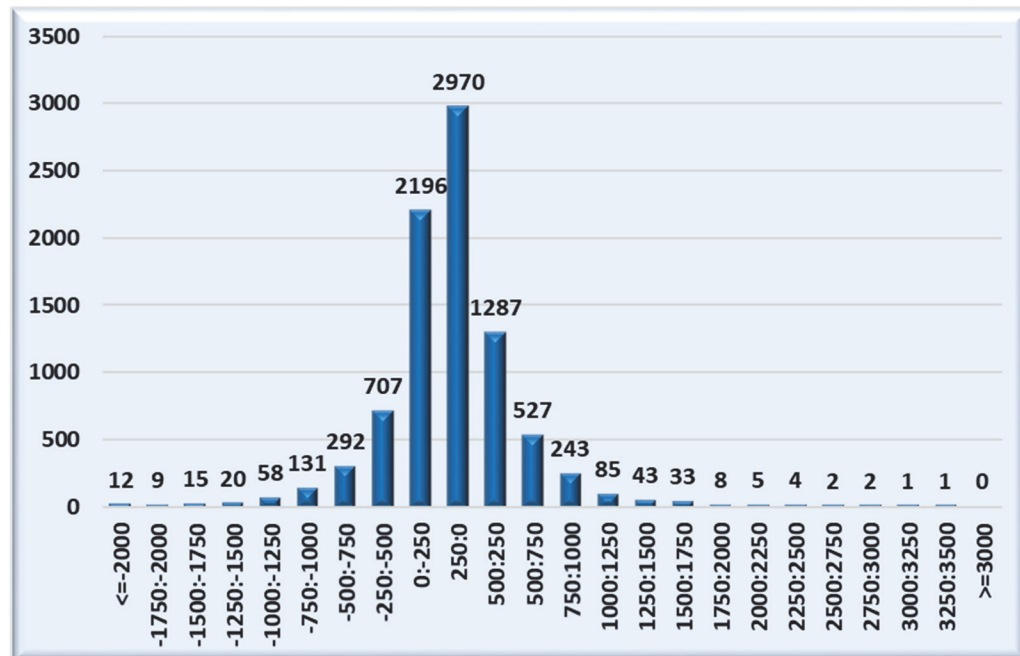


Figure 1: Effect of Proposed E/M Code Change on Urologists

When the base RVU adjustment is combined with HCPCS code GCG0X, the mean change in RVUs increases to 426.3 RVUs with a median increase of 310.7 RVUs, with only 7.4% of urologists seeing negative adjustments. Despite this, the overall change is still modest - 64.9% of urologists would have gains of 600 RVUs or less.

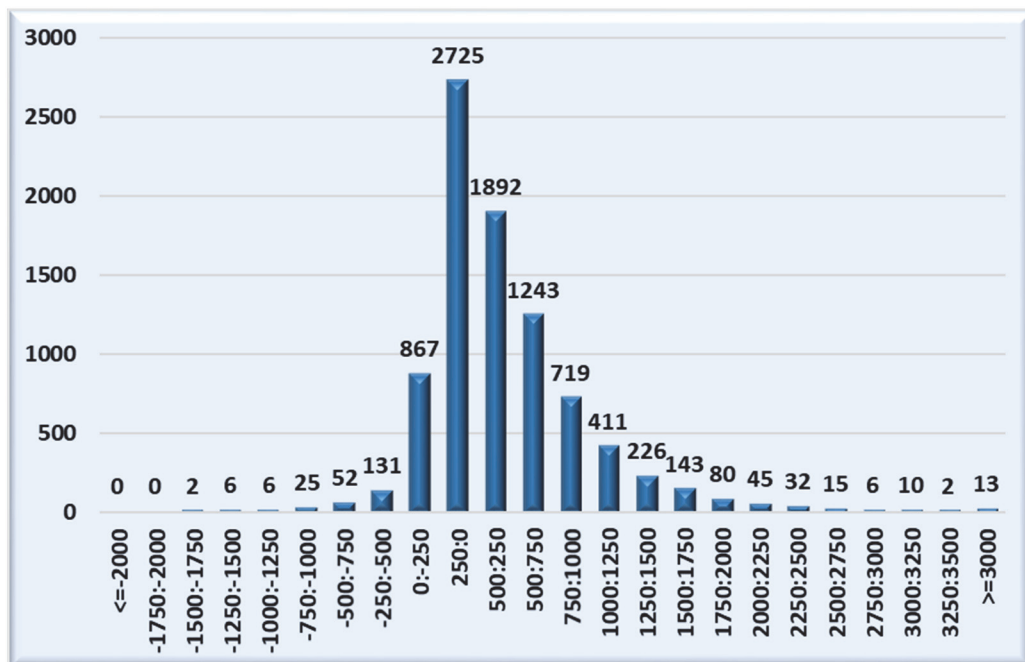
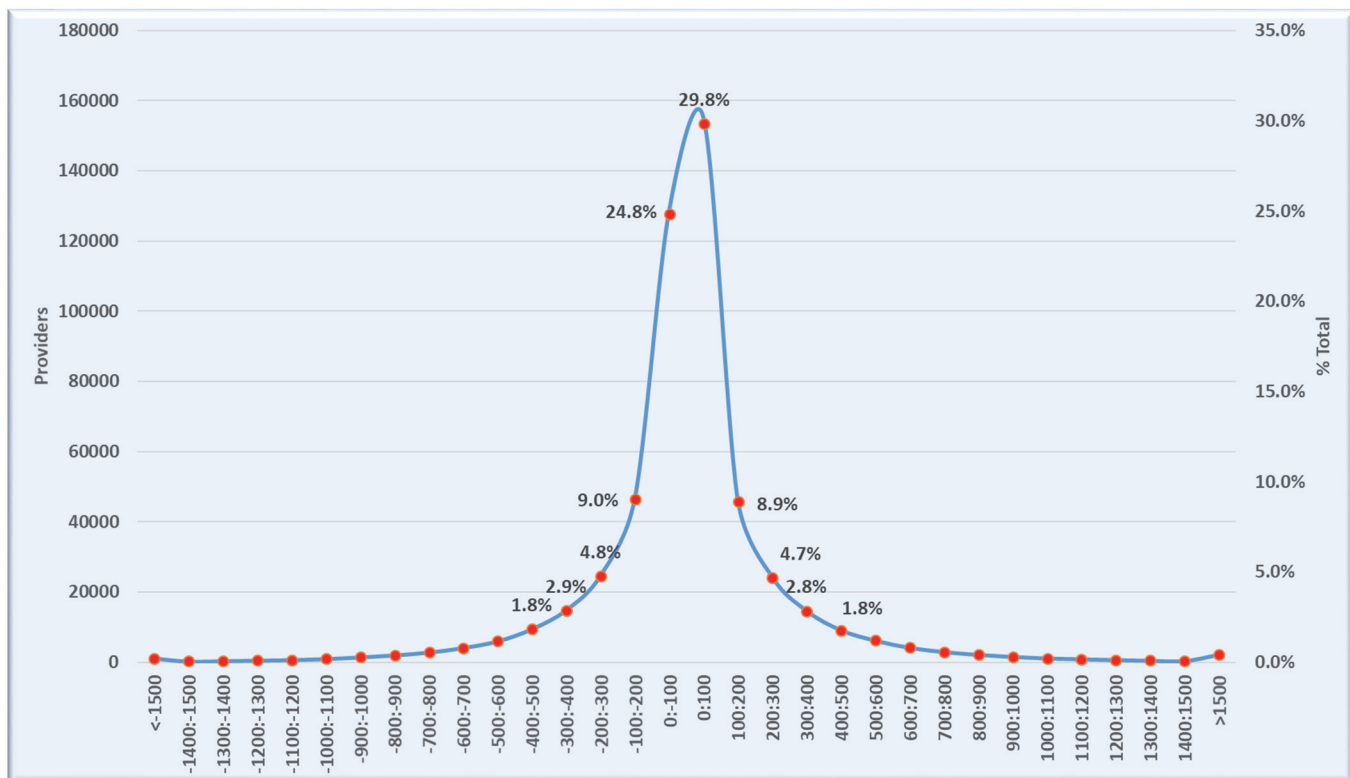


Figure 2: Effect of Proposed E/M Code Changes on Urologists, Including Code GCG0X

Given the benefit to its member practices, however modest, LUGPA certainly has a parochial interest in encouraging CMS to implement the E/M rule change as proposed. That said, as an organization, we understand that there is concern on the part of some stakeholders regarding the potential impact of this proposal on providers in general, and we recognize that CMS has an obligation to ensure that any change does not disproportionately impact subsets of providers.

For that reason, before endorsing the changes to the E/M code sets in the Proposed Rule, LUGPA extended its analytics to include all outpatient new and established patient office visits in the outpatient setting (CPT Codes 99201-05 & 99211-15) for all NPI numbers with any such encounters in 2016. We employed the same methodology as we had used in analyzing the impact of the Proposed Rule on the subset of NPI numbers associated with urology. The results are depicted in the figure below:



**Figure 2: Effect of Proposed E/M Code Change on all Providers, no Add-on Codes**

This analysis comprised approximately 248 million patient visits for 518,892 providers identified as having billed Medicare in 2016 for the above-described CPT codes. The results of this comprehensive review underscore CMS's thoughtful approach in developing this proposal. The mean impact of compressing payment for E/M codes for level 2-5 visits is a mere 8.04 RVUs/provider with a median change of only 5.85 RVUs/provider. Remarkably, 91.4% of providers will see a change of +/- 300 RVUs or less with over half of providers (54.6%) remaining within +/- 100 RVUs of their baseline values. If we focus on only those providers who face reductions from baseline RVUs under the old coding system, we see that only 8.8% of providers will face a decrease of 300 RVUs or more, with less than half these (4.0%) subject to decreases of 500 RVUs or more.

While providers with a proposed decrease of 300 RVUs or more comprise just 8.8% of physicians, when considering E/M visits for new and established patients in both facility and office sites of service, this group performed 21.5% of level 4 or 5 E/M visits. In fact, level 4/5 E/M visits accounted for 85% of total encounters; for the balance of providers, level 4/5 E/M visits accounted for 38.2% of encounters.

Given this data, it is easy to understand why certain stakeholders have expressed concern with respect to potential disincentives to see more complex patients under the new coding scheme; however, careful analysis suggests that this concern may be unfounded. CMS suggests that, for level four and five E/M codes, providers would document the visit to a level two, "plus either of the proposed add-on codes (HCPCS codes GPC1X or GCG0X) depending on the type of patient care furnished, and could bill one unit of the proposed prolonged services code (HCPCS code GPRO1) if they meet the time threshold for this code."<sup>19</sup> The following tables modify the information provided in Table 2 above by adding the additional time modifier GPRO1:<sup>20</sup>

<sup>19</sup> 83 Fed. Reg. at 35847.

<sup>20</sup> Data in Table 2 is modified by adding 1.17 work, 0.63 office PE, 0.51 facility PE and 0.07 malpractice RVUs.



RVU Adjustments Including HCPCS Codes GCG0X and GPRO1, New Patients							
Year	CPT	RVU Components				Total RVUs	
		Work	Office PE	Facility PE	MP	Office	Facility
2019	99201	0.48	0.7	0.21	0.02	1.2	0.71
	99202	2.15	1.8	0.91	0.16	4.11	3.22
	99203	2.15	1.8	0.91	0.16	4.11	3.22
	99204	3.32	2.43	1.42	0.23	5.98	4.97
	99205	3.32	2.43	1.42	0.23	5.98	4.97
2018	99201	0.48	0.73	0.23	0.05	1.26	0.76
	99202	0.93	1.11	0.42	0.08	2.12	1.43
	99203	1.42	1.48	0.6	0.15	3.05	2.17
	99204	2.43	2	1.01	0.22	4.65	3.66
	99205	3.17	2.39	1.32	0.29	5.85	4.78
Change	99201	0	-0.03	-0.02	-0.03	-0.06	-0.05
	99202	1.22	0.69	0.49	0.08	1.99	1.79
	99203	0.73	0.32	0.31	0.01	1.06	1.05
	99204	0.89	0.43	0.41	0.01	1.33	1.31
	99205	0.15	0.04	0.1	-0.06	0.13	0.19

Table 3: RVU Values used for Calculation Including HCPCS Codes GCG0X and GPRO1, New Patients

Base RVU Adjustments, Including HCPCS Codes GCG0X and GPRO1, Established Patients							
Year	CPT	RVU Components				Total RVUs	
		Work	Office PE	Facility PE	MP	Office	Facility
2019	99211	0.18	0.48	0.08	0.01	0.67	0.27
	99212	1.47	1.36	0.63	0.1	2.93	2.2
	99213	1.47	1.36	0.63	0.1	2.93	2.2
	99214	2.64	1.99	1.14	0.17	4.8	3.95
	99215	2.64	1.99	1.14	0.17	4.8	3.95
2018	99211	0.18	0.42	0.07	0.01	0.61	0.26
	99212	0.48	0.72	0.2	0.04	1.24	0.72
	99213	0.97	1.02	0.41	0.07	2.06	1.45
	99214	1.5	1.44	0.62	0.1	3.04	2.22
	99215	2.11	1.84	0.88	0.15	4.1	3.14
Change	99211	0	0.06	0.01	0	0.06	0.01
	99212	0.99	0.64	0.43	0.06	1.69	1.48
	99213	0.5	0.34	0.22	0.03	0.87	0.75
	99214	1.14	0.55	0.52	0.07	1.76	1.73
	99215	0.53	0.15	0.26	0.02	0.7	0.81

Table 4: RVU Values used for Calculation Including HCPCS Codes GCG0X and GPRO1, Established Patients

Adding those codes into the analysis results in net positive RVU changes for both level four and five E/M codes; this should ameliorate the concerns of those stakeholders concerned about the impact on providers who perform services on more complex patients requiring additional face-to-face time during E/M visits.

**C. CMS's Proposal to Implement an E/M Multiple Procedure Payment Reduction to Achieve Budget Neutrality is at Odds with the Agency's Commitment to Putting the Patient First and Should Be Rejected in Favor of Valuing E/M Visits in a Site-Neutral Manner.**

As part of its proposal to make payment for E/M level 2 through 5 visits at a single PFS rate, CMS proposes to reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit.<sup>21</sup> CMS acknowledges that, through application of the MPPR, the Agency is seeking to “maintain[] work budget neutrality” in the overall E/M proposal.<sup>22</sup> Although we recognize the need to ensure budget neutrality, we are concerned that this approach is not the most appropriate method to accomplish this goal risks two unintended consequences: (i) potentially undercompensating providers for appropriate practice expenses when procedures are performed the same day as an E/M visit; and (ii) misaligning payment incentives for providers to perform services in a manner most convenient to the patient.

The MPPR was established on the premise that efficiencies exist in practice expense (“PE”) and pre- and post-surgical physician work. In the Proposed Rule, CMS suggests that “the efficiencies associated with furnishing an E/M visit in combination with a same-day procedure are similar enough to those accounted for by the surgical MPPR to merit a reduction in the relative resources of 50 percent.”<sup>23</sup> LUGPA respectfully disagrees with this assertion. Fundamentally, the resources used for procedures commonly performed the same day as E/M visits (typically associated with a 0-day global) are distinct from those used to provide the E/M service.

Urology provides an excellent example of this in the management of non-muscle invasive bladder cancer. Periodic cystoscopy is the mainstay management of this disease, as even low-grade tumors have a substantial rate of recurrence.<sup>24</sup> It is not uncommon for bladder cancer to exist concurrently with other urologic conditions; indeed, the concurrent presence of benign prostatic hyperplasia (BPH) and bladder cancer is well documented.<sup>25</sup> The follow-up regimen and services performed for each of these unrelated disease states are substantially different and require fundamentally different resources. In the 2019 MPFS Proposed Rule, a diagnostic cystoscopy (CPT Code 52000) has a total non-facility national RVU value of 5.27, which means that a 50% reduction would yield 2.635 RVUs. At the proposed 2019 conversion factor, this is a reduction in payment of \$94.99. However, there is virtually no overlap between services provided in the routine management of BPH and in a diagnostic cystoscopy for the purpose of following bladder cancer. LUGPA submits that applying the MPPR in instances such as this is not appropriate.

An overarching theme of our comments to the proposed MPFS is enhancing the patient experience. An additional concern with respect to application of the MPPR in the context of E/M services is the misalignment of incentives that would result from implementation of such a proposal. Although many such examples exist where this could occur, for the sake of consistency, we again cite the management of

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<sup>21</sup> 83 Fed. Reg. at 35841.

<sup>22</sup> Id. at 35841 (noting that application of a 50 percent MPPR to E/M visits furnished as separately identifiable services in the same day as a procedure would reduce expenditures under the PFS by approximately 6.7 million RVUs, which can then be allocated toward the values of the add-on codes that reflect the additional resources associated with E/M visits for primary care and inherent visit complexity).

<sup>23</sup> Id.

<sup>24</sup> Chang S, Boorjian S, Chou R et al. Diagnosis and Treatment of Non-Muscle Invasive Bladder Cancer: AUA/SUO Guideline. *J Urol* 2016;196(4), 1021-1029.

<sup>25</sup> Dai X, Fang X, Ma Y, Xianyu J, et al. Benign Prostatic Hyperplasia and the Risk of Prostate Cancer and Bladder Cancer: A Meta-Analysis of Observational Studies. Mubarak. M, ed. *Medicine*. May 2016; 95(18):e3493, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4863764/> (last accessed Sept. 8, 2018).

transitional cell carcinoma. As stated above, due to the high risk of recurrence, patients with transitional cell carcinoma undergo routine interval diagnostic cystoscopy. This procedure has an associated 0-day global—by definition, this entails (i) no pre-operative period; (ii) no post-operative days; and (iii) the visit on day of procedure is generally not payable as a separate service.<sup>26</sup> This is appropriate as the cognitive aspect of counseling the patient with respect to the indication and risks of the procedure is included in the CPT code. However, this is not appropriate in instances where new pathology is found at the time of the procedure; the cognitive aspect of counseling the patient with respect to options regarding management of the disease is clearly a separately identifiable service. At present, such consultation (in the above example it may include discussions of intravesical chemotherapy or further surgical intervention) may be performed and appropriately reimbursed the same day using the -25 modifier if it is convenient and appropriate to do so. Restricting this—as CMS is proposing through application of the MPPR—inappropriately devalues the services provided the same day.

We suggest an alternative approach that is more consistent with CMS’s goals for modernizing the Medicare program. Over the last three years, CMS has taken important steps to implement Section 603 of the Bipartisan Budget Act of 2015 (“BBA”), the purpose of which is to establish a site neutral payment policy for newly acquired, provider-based, off-campus hospital outpatient departments within the Medicare program.<sup>27</sup> In fact, in enacting the BBA, “Congress was reacting to findings such as those reported by GAO that Medicare paid \$58 to \$86 more when an evaluation and management visit was performed in an HOPD compared to a physician office, depending on the HCPCS code billed, even though these beneficiaries were no sicker than those seen in a physician’s office.”<sup>28</sup> As CMS looks to achieve budget neutrality with respect to its E/M proposal, we urge the Agency to adopt a more holistic view of the Medicare program and—consistent with the authority Congress granted CMS to implement the BBA—achieve actual payment neutrality for E/M visits across sites of service.

We believe that such an approach is in keeping with CMS’s overarching payment policy goals for the Medicare program. As the Agency explained in the Proposed Rule:

“We continue to believe the amendments made by section 603 of the Bipartisan Budget Act of 2015 were intended to eliminate the Medicare payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPI for items and services they furnish there. Therefore, we continue to believe the payment policy under this provision should ultimately equalize payment rates between non-excepted off-campus PBDs and physician offices to the greatest extent possible....”<sup>29</sup>

Equalizing payment rates for E/M visits across the HOPD and office settings is a more appropriate approach to maintaining budget neutrality than applying an E/M multiple procedure payment reduction, particularly when viewed from the patient’s perspective. Importantly, in Section 603 of the BBA, Congress granted CMS the authority to take such a step with respect to the valuation of E/M visits in non-excepted,

<sup>26</sup> Medicare Learning Network, Global Surgery Booklet, available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/GlobalSurgery-ICN907166.pdf> (last accessed Sept. 8, 2018).

<sup>27</sup> P.L. 114-74.

<sup>28</sup> Letter from Committee on Energy and Commerce, U.S. House of Representatives to Francis J. Crosson, M.D., Chairman, Medicare Payment Advisory Commission (Aug. 30, 2018)(E&C Committee Letter), citing GAO-16-189, “Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform,” available at <http://www.gao.gov/products/GAO-16-189> (last accessed Sept. 5, 2018).

<sup>29</sup> 83 Fed. Reg. at 35741-42.

off-campus provider-based departments (“PBDs”). By designating the PFS as the appropriate fee schedule for services rendered by non-excepted PBDs, CMS has the ability to go beyond its current application of a PFS Relativity Adjuster (proposed at 40% for a second straight year) and actually set equal payment rates for E/M visits in the physician office versus non-excepted PBD setting. Taking such a step is wholly appropriate given that, as noted above, Congress enacted Section 603 of the BBA in response to the payment disparity between E/M visits in the PBD and physician office settings.<sup>30</sup>

This Administration’s commitment to putting the patient first should signal the end of payment policies that result in patients incurring greater out-of-pocket expenses when they receive identical services in the outpatient hospital setting as compared to their own physicians’ offices. And given that the “primary goal” of the E/M documentation and coding changes is to enable the practitioner to “focus on the patient,”<sup>31</sup> we do not believe that CMS should implement a policy that would incentivize practitioners to break apart E/M visits and procedures that otherwise would occur for the convenience of the patient on the same day.

**D. With the Exception of the MPPR Proposal, CMS Should Implement the Remainder of the Documentation and Payment Rate Modifications Effective January 1, 2019.**

We are aware that certain stakeholders are urging CMS to break apart the documentation and valuation components of the overall E/M proposal and move forward only with the changes to the documentation guidelines. LUGPA does not share this view and agrees with CMS that the proposed documentation changes for E/M visits are “intrinsically related” to the Agency’s proposal to simplify PFS payment for E/M visits.<sup>32</sup>

Respectfully, we believe that the argument to implement the documentation changes for CY 2019 but push off the interrelated payment changes until CY 2020 rings hollow. If anything, modification of systems and protocols to implement the more flexible documentation guidelines (even if voluntary) strikes us as the change that would take longer to implement than a change in the valuation of Level 2 through Level 5 E/M visits for new and established patients.<sup>33</sup> In fact, if CMS finalizes the entirety of its E/M proposal, practitioners’ coding practices would not change because they “would still bill the CPT code for whichever level of E/M service they furnished.”<sup>34</sup> The only difference is that practitioners would be paid at the single PFS rate for E/M visit levels 2 through 5 for new and established patients. Furthermore, as these changes do not extend to commercial payors at this time, it will be necessary to maintain the current documentation level to bill appropriately for services rendered outside of the Medicare program.

While an analysis of the impact on providers is critical to ensure adequate resources exist to perform patient care functions, LUGPA feels that such an analysis overlooks an extremely important component to this questions, that is, the impact on the patient. It has been clearly established that implementation of an EHR adversely affects the patient experience;<sup>35</sup> LUGPA strongly supports changes that facilitate interaction between patient and provider.

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<sup>30</sup> E&C Committee Letter.

<sup>31</sup> 83 Fed. Reg. at 35838.

<sup>32</sup> Id. at 35835.

<sup>33</sup> As CMS noted, because its proposed documentation changes for E/M visits would be optional, “practitioners could choose to continue to document these visits using the current framework and rules,” thereby mitigating any need to delay implementation. Id. at 35848.

<sup>34</sup> Id. at 35839.

<sup>35</sup> Meyerhoefer CD, Sherer SA, Deily ME, et al. Provider and patient satisfaction with the integration of ambulatory and hospital EHR systems. *J Am Med Inform Assoc.* 2018 Aug 1;25(8):1054-1063.

Although some have argued against implementation of the payment changes because of unnamed “potential unintended consequences,”<sup>36</sup> we believe the full proposal should be implemented effective January 1, 2019, precisely because of its intended consequences—the dramatic streamlining and simplification of the documentation requirements and payment amounts associated with E/M visits. We view—as we believe CMS does—that minimizing documentation requirements and simplifying the payment structure are two sides of the same coin and should not be implemented in piecemeal fashion.

### **III. CMS Continues To Value Prostate Biopsy Services in a Manner that Does Not Reflect Clinical Practice and Is Not Based on Objective Data, Contradicting the Position of the RUC and Relevant Specialty Societies.**

CMS has changed the method by which pathologists are expected to code for analysis of prostate biopsies six times in the last nine years.<sup>37</sup> In many cases, these changes were made on an interim final basis without an opportunity for notice and comment. This frequent intervention has led to widespread confusion, to the point that the RUC was unable to obtain a valid survey of physicians to determine proper valuation for analysis of prostate biopsy.<sup>38</sup> LUGPA has commented on several of CMS’s policy changes over the last several years.<sup>39</sup> These changes have led to significant reductions in reimbursement for the examination of prostate biopsy samples—a critical element in the diagnosis of the most common solid tumor diagnosed in men which is a leading cause of cancer death in the United States.<sup>40</sup> Worse, CMS’s cuts in reimbursement are based upon incorrect assumptions and logical inferences, rather than on objective data collected from clinicians, and are being made at a time when the complexity of analyzing prostate biopsies is growing.

The changes in coding and valuation of prostate biopsy services reflect CMS’s misguided efforts to define the “anomalous relationship” between the a base pathology code (CPT Code 88305) associated with the study of potentially cancerous tissue, and prostate biopsy techniques which necessarily collect a large number of cores.<sup>41</sup> This was reviewed in significant detail in our comments to the 2016 MPFS Final Rule.<sup>42</sup> At a high level, the history is as follows:

- There are two distinct clinical techniques used to obtain prostate tissue samples to assess the presence of prostate cancer: 1) Prostate Needle Biopsy (“PNB”) is an initial biopsy technique generally consisting of twelve samples, each of which must be studied carefully to determine the existence of cancer;<sup>43</sup> 2) Prostate Saturation Biopsy (“PSB”) is a follow-up or confirmatory biopsy technique consisting of 40-80 cores, typically used for high-risk men to assess the type of

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<sup>36</sup> See Letter from American Medical Association et al. to CMS Administrator Seema Verma re: CMS-1693-P, p. 1 (Aug. 27, 2018).

<sup>37</sup> See Medicare Physician Fee Schedule rules for 2009 (73 Fed. Reg. 38502, 38520 (July 7, 2008)), 2013 (77 Fed. Reg. at 69074), 2014 (78 Fed. Reg. at 74320), 2015 (79 Fed. Reg. 67548, 67581 (Nov. 13, 2014)), 2016 (80 Fed. Reg. at 71058), and 2017 (81 Fed. Reg. 80170, 80349-50 (Nov. 15, 2016)).

<sup>38</sup> May 2015 American Medical Association / Specialty Society RVS Update Committee Summary of Recommendations, p. 1909.

<sup>39</sup> See LUGPA Comments to the 2015 MPFS Proposed Rule, 2016 Final Rule, 2017 Proposed Rule and 2018 Proposed Rule.

<sup>40</sup> Cancer Facts & Figures 2018, available at <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2018/cancer-facts-and-figures-2018.pdf>.

<sup>41</sup> See 81 Fed. Reg. at 80349.

<sup>42</sup> LUGPA Comments to 2016 MPFS Final Rule.

<sup>43</sup> See NCCN Guidelines Version 2.2015, Prostate Cancer Early Detection, [http://www.nccn.org/professionals/physician\\_gls/pdf/prostate\\_detection.pdf](http://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf) at PROSD-3; see also Kapoor DA, Bostwick, DG, Mendrinos, SE, et al. Utilization Trends and Positive Biopsy Rates for Prostate Biopsies in the United States: 2005 to 2011. *Reviews in Urology*, 15(4): 1-17 (2013).

therapy that is most appropriate (or active surveillance).<sup>44</sup> Because the presence of cancer is often already established when PSB is indicated, fewer samples obtained through PSB require the same degree of analysis that is required for samples collected through PNB.

- Prior to 2009, pathologists billed for analysis of prostate tissue by submitting a distinct claim for CPT Code 88305 for each core analyzed.
- In the 2009 MPFS, CMS created a new set of G-codes to capture pathological analysis of prostate biopsy samples.<sup>45</sup> HCPCS Code G0416 was associated with analysis of samples collected through PSB. Because only a minority of cores obtained through PSB involves potentially cancerous tissue, CMS valued G0416 based on a combination of reimbursement rates associated with CPT Codes 88304 and 88305.<sup>46</sup>
- From 2014-2015, CMS combined the analysis of all prostate biopsy samples into a single code—G0416—meaning this code covered analysis of cores obtained through PNB as well.<sup>47</sup> Although every sample obtained through PNB requires the identical in-depth analysis associated with CPT Code 88305, and PNB is more common than PSB, CMS did not revise the valuation of G0416 to reflect this change in the intensity of pathology services.
- In the 2015 MPFS, CMS determined that the valuation of CPT Code 88305 should be reduced, in part because it no longer captured services associated with prostate biopsy.<sup>48</sup> As a result, no CPT Code currently captures the type of complex analysis associated with samples obtained by PNB.
- In 2015, the RUC attempted to survey physicians to determine comparable codes. It found that the degree of change in this area was so significant that physicians were unable to identify consistent comparable codes, finding that the survey results were “flawed and provide invalid estimates of physician work and time.”<sup>49</sup>

In 2015, the RUC and every relevant specialty society took the same position with regard to reimbursement for prostate biopsy services. Each stated that prostate biopsy services should be reimbursed through multiple instances of a properly valued CPT Code 88305, just as had been the case prior to 2009.<sup>50</sup> In LUGPA’s comments to the 2016 MPFS Final Rule, we argued that CMS should refrain from revaluing this code until the RUC or CMS can obtain objective information about the work and practice expense of this service based on a valid survey of physicians.<sup>51</sup> We continue to believe this is the best approach.

However, in an effort to address CMS’s identification of G0416 as a misvalued code, the RUC recommended that CMS apply the PE RVUs associated with CPT Code 88305 to G0416.<sup>52</sup> LUGPA disagreed because: 1) it is not appropriate to use the PE RVUs associated with CPT Code 88305 when

<sup>44</sup> NCCN Guidelines Version 2.2015, Prostate Cancer Early Detection, [http://www.nccn.org/professionals/physician\\_gls/pdf/prostate\\_detection.pdf](http://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf) at MS-20; see also Role of Transperineal 3-Dimensional Pathologic Mapping of the Prostate—A 4-Year Experience. *Urology*. 2007 Dec; 70(6) Sup 1: S27-S35.

<sup>45</sup> 73 Fed. Reg. at 69751.

<sup>46</sup> Id. CMS assumed that 15% of the samples taken through PSB require “considerable clinical expertise to differentiate and distinguish carcinoma from hyperplasia” associated with CPT Code 88305, while the remaining 85% of samples required “confirmation of prostate tissue and interpretation indicating the presence of cancer or not” associated with CPT Code 88304.

<sup>47</sup> See 78 Fed. Reg. at 74318-21.

<sup>48</sup> 79 Fed. Reg. at 67581.

<sup>49</sup> May 2015 American Medical Association / Specialty Society RVS Update Committee Summary of Recommendations, p. 1909. (“May 2015 RUC Recommendations”).

<sup>50</sup> Id.

<sup>51</sup> LUGPA Comments on 2016 MPFS Final Rule at p. 12.

<sup>52</sup> Id.

that code had been revalued in 2014 to reflect the shift of prostate biopsy services into G0416; and 2) the RUC continued to apply CMS's initial assumption that only 15% of the samples covered under G0416 required complex pathological examination.<sup>53</sup>

In the MPFS Proposed Rule for CY 2017, CMS proposed to modify the valuation of G0416 without acknowledging the breadth of services covered.<sup>54</sup> Notably, the College of American Pathologists and American Society of Cytopathology presented information to the RUC sufficient to meet its "compelling evidence" standard, such that the RUC recommended a wRVU of 4.0 for this code.<sup>55</sup> Nevertheless, CMS rejected that recommendation and proposed to adjust the wRVUs for G0416 based on the wRVUs of CPT Code 88305.<sup>56</sup> Accordingly, CMS used the intra-service time ratio between G0416 and 88305 to arrive at a proposed wRVU amount of 3.60. Notwithstanding opposition from the RUC and the physician community, CMS finalized a wRVU of 3.60 for HCPCS Code G0416 for CY 2017, maintained that same level of wRVU for CY 2018, and is proposing to do so again for CY 2019.

We do not believe that HCPCS code G0416 can be valued correctly until CMS stops treating "CPT code 88305 [a]s the basis for HCPCS code G0416."<sup>57</sup> But, CPT Code 88305 is only "the basis" for HCPCS Code G0416 in the sense that, historically, a single instance of CPT Code 88305 had been billed for each core analyzed. Thus, prior to 2009, analysis of prostate biopsy services was represented by twelve to eighty claims for CPT Code 88305 (depending on whether PNB or PSB was used to collect samples). CMS is continuing to use the wRVUs associated with a single instance of 88305, *which has been revalued to factor out prostate biopsy services*, and then apply this amount to G0416 based on the ratio of intra-service time between G0416 and 88305. CMS took this approach for each of the last two years, and the Agency appears to be applying the same approach for CY 2019.

Although CMS no longer allows the use of a single unit of CPT Code 88305 to be submitted for each sample studied for a prostate biopsy, a comparison of the existing wRVUs for 88305 and CMS's proposed wRVUs for G0416 illustrates the magnitude of this change. Current consensus clinical guidelines suggest that for optimal detection of prostate cancer, 12 unique samples of the prostate are necessary, each obtained from a different area of the prostate in a template pattern.<sup>58</sup> The table below illustrating the 2018 and proposed 2019 base RVUs for HCPCS code G0416 and CPT Code 88305 demonstrates the ongoing disconnect between CMS payment policy and universally accepted practice standards:

Code	Description	CY 2019 Proposed			CY 2018 Actual			2018 - 2019 RVU Delta		
		Global	PC	TC	Global	PC	TC	Global	PC	TC
G0416	Prostate biopsy, any mthd	10.66	5.09	5.57	12.07	5.14	6.93	-11.7%	-1.0%	-19.6%
88305	Tissue exam by pathologist	2.00	1.09	0.91	1.95	1.11	0.84	2.6%	-1.8%	8.3%

Table 5: 2018 Actual vs. 2019 Proposed RVUs for HCPCS Code G0416 and CPT Code 88305

CMS continues to value the professional component of HCPCS Code G0416 at a level that would equate to fewer than five instances of CPT Code 88305. **Even more troubling, CMS is proposing to reduce the technical component of HCPCS code G0416 from approximately 8.3 to merely 6.1 instances of**

<sup>53</sup> May 2015 RUC Recommendations at 1931, 1934-1937.

<sup>54</sup> 81 Fed. Reg. at 46263.

<sup>55</sup> Id. Specialty societies must present "compelling evidence" to the RUC to demonstrate that a code established by CMS should be revalued. See 74 Fed. Reg. 61738, 61942 (November 25, 2009).

<sup>56</sup> 81 Fed. Reg. at 46263.

<sup>57</sup> See 81 Fed. Reg. at 46263.

<sup>58</sup> Bjurlin MA, Wysock JS, Taneja SS. Optimization of Prostate Biopsy: Review of Technique and Complications. The Urologic clinics of North America. 2014;41(2):299-313. doi:10.1016/j.ucl.2014.01.011.

**CPT Code 88305 – a reduction of 16% (after having made a 19% reduction from CY 2017 to CY 2018).**

There is no dispute that the standard of care is to analyze at least 12 tissue cores to properly assess for the presence of prostate cancer. Furthermore, the dependence on sophisticated histopathological reads has continued to increase—this is particularly true when clinicians counsel patients on the appropriateness of active surveillance. In 2013, NCCN guidelines stratified organ-confined prostate cancer into four risk categories; very low, low, intermediate and high.<sup>59</sup> Of these groups, only the “very low” risk category required consideration of the number of cores positive and volume of cancer present in each core (fewer than three cores positive with less than 50% cancer in each core). The current version of NCCN (Version 2.2018)<sup>60</sup> now stratifies organ confined prostate cancer into *six* subgroups, and, of these, three require assessment of the number and degree of positivity of individual cores. Notably, these three categories are those for which active surveillance could be appropriate. As a result, technical and professional precision in assessing cores is more critical than ever in stratifying patient risk.

We do not believe CMS took into account these changing clinical standards for evaluation of prostate cancer as the Agency proposed additional reductions in RVUs. The proposal creates a clear disconnect between prevailing clinical protocols and the valuation of G0416 and, even worse, undermines the goal of encouraging active surveillance for newly diagnosed patients with prostate cancer. This is greatly disappointing, given LUGPA practices’ commitment to encouraging active surveillance as evinced by the development and submission of the only urological disease specific APM to the Physician-Focused Payment Model Technical Advisory Committee (“PTAC”).

We are concerned that the continued reduction in reimbursement for G0416 does not take into account the significant differences in diagnosing prostate cancer as compared to other types of cancer. To be clear, we have come to believe that it was appropriate for CMS to create distinct pathology codes based on type of cancer; the problem, though, is in failing to build into the valuation of G0416 the growing complexity—as dictated by the most recent NCCN guidelines—of analyzing the number of cores with prostate cancer and the percentage of each core containing prostate cancer that is so critical to the accurate staging of a patient’s disease. The task involved in analyzing prostate biopsies is fundamentally different than for the majority of other cancers for which therapeutic decision making is predicated on a binary assessment of whether cancer is present or not coupled with histopathological grading and/or staging. In addition to these functions, reporting the number of positive specimens and percent of cancer involvement in each specimen is a critical component to ensuring proper stratification of risk to properly counsel the patient on choosing the most appropriate course of therapy. CMS’s valuation of G0416 does not take this significant difference into account.

As proposed, HCPCS code G0416 would have a global RVU value of only 44.4% of the global RVU value of 12 instances of CPT code 88305 (which already has been devalued as described above by excluding prostate biopsy). CMS cannot plausibly claim that a change in laboratory processing technique justifies such a reduction, given that the Agency is actually proposing to *increase* the TC component of CPT 88305 from 0.84 RVUs to 0.91 RVUs. Data suggests that only about half of eligible men newly

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<sup>59</sup> NCCN Guidelines Version 1.2013: Prostate Cancer. Initial Prostate Cancer Diagnosis, Staging Workup, Recurrence Risk (PROS-1).

<sup>60</sup> NCCN Guidelines Version 2.2018: Prostate Cancer. Risk Stratification and Staging Workup (PROS-2).



diagnosed with prostate cancer actually elect active surveillance.<sup>61</sup> Although this is a multi-factorial problem, CMS at least should facilitate the identification of eligible patients by appropriately compensating providers and establishing a valuation for G0416 that is based on an objective analysis of the work actually done in reviewing prostate tissue collected through PNB and that takes into account the growing complexity of analyzing prostate biopsies as dictated by current NCCN guidelines.

#### **IV. CMS Should not Finalize its Proposal to Reduce WAC-based Payments for Part B Drugs to a 3 Percent Add-on.**

We are concerned that CMS's proposal to utilize a 3 percent add-on in place of the current 6 percent add-on for wholesale acquisition cost (WAC)-based payments for Part B drugs<sup>62</sup> will negatively impact access to new drugs that urologists use as a last-line defense for treating cancers that are unresponsive to existing treatments. Citing to a MedPAC report to Congress, CMS suggests that "percentage-based add-on payments for expensive drugs may create an incentive for the use of those drugs."<sup>63</sup> But the cited MedPAC Report noted that "it is difficult to know the extent to which the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue."<sup>64</sup> The MedPAC report included no evidence suggesting that the add-on percentage to WAC-based payments is affecting drug utilization. LUGPA urges CMS not to reduce the 6-percent add-on for WAC-based payments without examining more closely the potential financial impact on specialty practices—particularly smaller practices and those in rural areas—that might not be able to negotiate sufficiently favorable pricing to continue making these drugs available to their cancer patients.

At present, the current reimbursement for pharmaceuticals is only nominally wholesale acquisition cost (WAC) plus 6%; when the impact of sequestration is considered, this amounts to WAC plus 4.3%. CMS is proposing to cut Medicare Part B reimbursement for new cancer drugs and other specialty therapies to the rate of list price plus 3%; when the sequester cut is included this actually results in a premium of only 1.35%, for the first six months a drug is on the market. We are concerned that this payment cut for new cancer therapies will result in drug manufacturers actually increasing WAC list prices so that their new products will not be at a competitive disadvantage to existing products which are reimbursed at average sales price (ASP) plus 6%.

#### **V. LUGPA Applauds CMS's Efforts to Modernize Medicare Physician Payment for Communication Technology-Based Services.**

Much like its efforts to reform E/M documentation, coding and payment policies, CMS has listened to practitioners and developed a series of proposals to modernize another aspect of the MPFS—communication technology-based services.<sup>65</sup> We support the common-sense proposals the Agency has put forward to expand access to telehealth services within the current statutory framework and to pay appropriately for services that take full advantage of communication technologies. We also believe that these proposals advance HHS's broader objective of facilitating care coordination within the Medicare

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<sup>61</sup> Kapoor DA, Shore ND, Kirsh GM et al. The LUGPA Alternative Payment Model for Initial Therapy of Newly Diagnosed Patients With Organ-confined Prostate Cancer: Rationale and Development. *Rev Urol.* 2017;19(4):235-245.

<sup>62</sup> 83 Fed. Reg. at 35854-55.

<sup>63</sup> *Id.* at 35854, citing MedPAC Report to the Congress: Medicare and Health Care Delivery System, June 2015 ("MedPAC June 2015 Report"), available at <http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf> (last accessed Sept. 8, 2010).

<sup>64</sup> MedPAC June 2015 Report, pp. 61-62.

<sup>65</sup> 83 Fed. Reg. at 35722.

program.<sup>66</sup> We focus on two of those proposals here—remote evaluation of pre-recorded patient information (HCPCS Code GRAS1) and inter-professional Internet consultation (CPT Codes 994X6, 994X0, 99446, 99447, 99448, 99449).

**A. CMS Should Finalize Its Proposal to Create Specific Coding for Remote Evaluation of Pre-Recorded Patient Information (HCPCS Code GRAS1) and Should Extend the Proposal to Cover New Patients.**

CMS is taking an important step in modernizing the MPFS by proposing to make separate Medicare payments when a physician uses “store and forward” communication technology, specifically in the form of pre-recorded patient-generated still or video images.<sup>67</sup> Not only does creation of HCPCS Code GRAS1 facilitate the timely assessment of patient conditions, it will help patients avoid unnecessary office visits and, as importantly, provide physicians with a tool to ensure that patients come in for needed office visits. We agree with the Agency that the proposed coding and separate payment for this service is “consistent with the progression of technology and its impact on the practice of medicine in recent years, and would result in increased access to services for Medicare beneficiaries.”<sup>68</sup>

It is for those very reasons that we believe CMS should extend the proposal so that it not only covers established patients—as currently contemplated—but also covers new patients. CMS identified dermatology and ophthalmology as two specialties that could benefit from the extension of the proposal to cover new patients.<sup>69</sup> Extending HCPCS Code GRAS1 to cover new patients would also be of value in urology, providing us with a timely way to assess patients with conditions such as hematuria (i.e., blood in the urine). If the urologist determines that the patient needs to be seen for an office visit based on the use of “store and forward” technology, the remote service would be considered bundled into the in-person E/M office visit.

**B. CMS Should Finalize Its Proposal to Pay Separately for Inter-professional Consultations Performed Via Communications Technology (CPT Codes 994X6, 994X0, 99446, 99447, 99448, 99449).**

This proposal is yet another example of CMS developing modifications to the MPFS that reflect the medical practice trend “away from an episodic treatment-based approach to one that involves patient-centered care management.”<sup>70</sup> Inter-professional consultation is critical to accurate and timely diagnoses and development of treatment plans. The six new codes foster coordinated care among primary care physicians and specialists as well as across medical specialties. And, as CMS noted, the proposed code set makes sense for patients by obviating the need for separately scheduled visits to obtain specialist input that, in certain instances, can be obtained via a phone or internet-based interaction between a treating and consulting physician.

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<sup>66</sup> See, e.g., Medicare Program; Request for Information Regarding the Physician Self-Referral Law, CMS-1720-NC, 83 Fed. Reg. 29524, 29524 (June 25, 2018).

<sup>67</sup> 83 Fed. Reg. at 35724-25.

<sup>68</sup> Id. at 35725.

<sup>69</sup> Id.

<sup>70</sup> Id.

## **VI. CMS Should Equalize Payment Rates Between Non-Excepted Off-Campus PBDs and Physician Offices on a Procedure-By-Procedure Basis; at an Absolute Minimum, the Agency Should Lower the PFS Relativity Adjuster from 40% to 25% of the OPFS Payment Rate.**

This Administration has shown a willingness to take bold steps to safeguard the Medicare program, and we believe that such action should be taken to equalize payment rates across the hospital outpatient department (“HOPD”) and physician office settings. CMS took important, initial steps towards achieving site-neutral payment structures following passage of the BBA of 2015, but we believe that momentum has now stalled as evidenced by the Agency’s proposal to maintain a PFS Relativity Adjuster of 40 percent of the OPFS payment rate for CY 2019 rather than moving more boldly to equalize payment rates across sites of service.

There is little doubt that hospital-physician consolidation is driving up the cost of health care in the Medicare program.<sup>71</sup> And there appears to be consensus that the more appropriate way to address this consolidation and to bring down the overall cost of care is through equalizing payment rates across sites of service. As Dr. Mark Miller, the Executive Director of the Medicare Payment Advisory Commission (MedPAC), stated in Congressional testimony in December 2014:

“In principle, the Medicare program should pay the same amount for the same service, regardless of the setting in which it is provided, unless payment differentials are justifiable by differences in patient mix, provider mission (e.g., maintaining stand-by capacity for emergencies), or other justifiable factors.”<sup>72</sup>

For its part, CMS has consistently articulated the goal of “attaining site neutral payments to promote a level playing field.”<sup>73</sup> As noted above, CMS reaffirmed this commitment in the CY 2019 Proposed Rule when it noted that payment policy “should ultimately equalize payment rates between non-excepted off-campus PBDs and physician offices to the greatest extent possible.”<sup>74</sup>

But for the last two years—and proposed again for CY 2019—CMS is maintaining the vestiges of an inherently unequal payment structure by applying a downward scaling factor known as the “PFS Relativity Adjuster” to payments for non-excepted items and services furnished in non-excepted off campus PBDs.<sup>75</sup> CMS’s proposal for CY 2019 is to maintain the PFS Relativity Adjuster at the same level as is currently in place for CY 2018—40 percent.

LUGPA renews its call for CMS to actually equalize payment rates between non-excepted off-campus PBDs and physician offices and to do so on a procedure-by-procedure basis. The Agency needs to take that step in order to promote competition across sites of service and protect access to the high quality and more cost-efficient care furnished in independent urology (and other specialty) practices.

At a minimum, if CMS does not establish a payment policy for CY 2019 that equalizes payment rates between non-excepted off-campus PBDs and physician offices, the Agency should revise the PFS

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<sup>71</sup> June 2017 Report to Congress: Medicare and the Health Care Delivery System, Chapter 10, “Provider Consolidation: The Role of Medicare Policy,” available at [http://www.medpac.gov/docs/default-source/reports/jun17\\_reporttocongress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0), p. 289 (last accessed Sept. 8, 2018) (acknowledging that “physician-hospital vertical consolidation can also result in higher costs for Medicare and commercial insurers”).

<sup>72</sup> Miller ME. “Context for Medicare Payment Policy and Recommendations,” available at <http://docs.house.gov/meetings/IF/IF14/20141209/102787/HHRG-113-IF14-Wstate-MillerM-20141209.pdf> (last accessed at Sept 5, 2018).

<sup>73</sup> See, e.g., 82 Fed. Reg. at 33985.

<sup>74</sup> 83 Fed. Reg. at 35742.

<sup>75</sup> Id. at 35738-39.

Relativity Adjuster for non-excepted items and services furnished by non-excepted off-campus PBDs down to 25% of the OPPS payment rate (as opposed to maintaining the PFS Relativity Adjuster at 40% of the OPPS payment rate).<sup>76</sup>

To be clear, anything short of equalizing payment rates on a procedure-by-procedure basis will simply delay the Agency's stated "goal of attaining site neutral payments to promote a level playing field under Medicare between physician office settings and non-excepted off-campus PBDs."<sup>77</sup> But, the revision of the PFS Relativity Adjuster down to 25% for CY 2019 would be a meaningful step in the right direction and would put the Medicare program on the path to a truly site neutral payment structure that is critical to the ultimate success of the Medicare program.

## **VII. CMS Should Maintain Flexibility with Respect to Electronic Health Record Certification Requirements.**

In requiring the use of 2015 Edition certified EHR technology ("CEHRT") beginning January 1, 2019,<sup>78</sup> we are concerned that CMS is underestimating the challenges that independent medical practices are confronting in transitioning EHR systems. Many physicians, particularly those in smaller and rural practices, need additional time to transition to the 2015 Edition CEHRT and we urge the Agency to delay the requirement of using the 2015 Edition CEHRT until the 2020 MIPS performance year to allow additional transition time for completing this process.

## **VIII. LUGPA Generally Supports CMS's Quality Payment Program Updates with Limited Modifications.**

CMS continues to advance the development of value-based care through rulemaking. LUGPA strongly supports this transition and looks forward to genuine opportunities for all practitioners to participate in reimbursement models that reward outcomes and patient experience over volume of services. That said, LUGPA continues to have concerns with respect to the relatively limited opportunity for urologists and other specialists to participate in risk sharing arrangements; for this reason LUGPA urges caution with respect to regulatory changes that may disadvantage subsets of providers disproportionately affected by the MIPS.

### **A. CMS's Proposals with Respect to Topped-Out Measures and Removal of Process Measures Unfairly Burden Physician Specialists.**

We continue to be concerned about the limited number of quality measures available to urologists and other physician specialists. There are two aspects of CMS's proposals that are not sufficiently sensitivity to the challenges being faced by specialists under the MIPS.

First, we do not believe CMS should finalize its proposals to incrementally remove process measures.<sup>79</sup> Until additional specialty-specific measures are created, CMS should not narrow the limited set of measures under which specialists are able to report.

Second, we are disappointed by the Agency's proposal to hasten the removal of measures that reach an extremely topped out status.<sup>80</sup> Under the proposal, CMS would be permitted to remove such measures in the next rulemaking cycle, thereby eliminating the extended timeframe for removing topped out measures.

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<sup>76</sup> Id. at 35740.

<sup>77</sup> 83 Fed. Reg. at 33985.

<sup>78</sup> 83 Fed. Reg. at 35912.

<sup>79</sup> 83 Fed. Reg. at 35900.

<sup>80</sup> Id.

As CMS previously recognized, CMS removing topped out measures “may impact the ability of some MIPS eligible clinicians to submit 6 measures and may impact some specialties more than others.”<sup>81</sup> This is certainly the case in urology. We do not believe CMS should start creating exceptions to the four-year lifecycle for removal of topped out measures that the Agency established in the CY 2018 MPFS Final Rule.

In fact, we believe that CMS should go one step further in creating protections for specialty practices under the MIPS. Instead of hastening the removal of an extremely topped out measure, the Agency should announce that a topped out measure specific to a given specialty shall not be removed until such time that a new measure has been finalized and implemented as a replacement within that specialty.

**B. The Weight of the Cost Performance Category Should Remain at 10 Percent for the CY 2021 MIPS Payment Year.**

LUGPA agrees with CMS that “measuring cost is an integral part of measuring value,” and we fully appreciate the significant impact that clinicians have on the cost of patient care.<sup>82</sup> With that said, we are too early in the process of developing cost measures to begin increasing the weight of the cost performance category. This is especially true in urology for which new measures have not yet been tested or finalized. The practical effect, then, is that urologists’ performance under the cost performance category will be based on the Total Per Capita Cost and Medicare Spending Per Beneficiary measures that we do not believe accurately reflect cost performance for physician specialists.

For these measures, CMS proposes to continue the “two-step” attribution system adopted from the one in place in the Medicare Shared Savings Program. Our concern is that the nature of this attribution system inaccurately models specialty care by excluding those patients for whom specialists deliver highly-efficient care.

The “two step” attribution process is designed to attribute patients solely on the basis of primary care services.<sup>83</sup> As we have noted in prior comment letters, we fail to see how a primary care-based attribution methodology is appropriate for a payment policy intended to evaluate all physicians, including specialists.<sup>84</sup> As CMS has acknowledged, it is difficult to see many specialty group practices being attributed patients under this methodology;<sup>85</sup> yet, this raises serious questions about the treatment of such practices under the MIPS. This is particularly true for urology. Although urologists are not primary care providers, the specialty serves as the principle caregiver of the genitourinary tract. CMS properly recognizes that E/M visits account for a substantial proportion of a urologist’s practice; however, these visits are constrained to the disease states managed by the specialty. This problem is further exacerbated by the limited opportunities for urologists to be exempted from cost measures via APM participation. By CMS’s own estimate, a mere 0.8% of practicing urologists qualified as APM participants in 2017.<sup>86</sup>

We contend that it is unjust to hold providers accountable for costs that are fundamentally out of their control. Accordingly, any increase in the weight of the cost performance category should await the

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<sup>81</sup> 82 Fed. Reg. at 30104.

<sup>82</sup> 83 Fed. Reg. at 35901.

<sup>83</sup> Medicare Value Modifier Fact Sheet, available at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Attribution-Fact-Sheet.pdf> (last accessed Sept. 8, 2018).

<sup>84</sup> See Comment Letter from LUGPA President Neal D. Shore, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Acting Administrator Andrew Slavitt, CMS-5517-FC, pp. 2-4 (Dec. 13, 2016).

<sup>85</sup> 81 Fed. Reg. at 28199.

<sup>86</sup> 81 Fed. Reg. 77008 (Nov. 4, 2016).

development of additional episodes of care or opportunities for participation in APMs for urologists and other physician specialists.

## IX. Request for Action

We thank CMS for the substantial work that went into the development of the Proposed Rule, particularly the transformative changes that the Agency is proposing to the E/M visit code sets. In support of its “Patients Over Paperwork Initiative,” CMS has listened to practitioners and redesigned coding, payment and documentation requirements that “are overly burdensome and no longer aligned with the current practice of medicine.”<sup>87</sup>

As a brief summary, our principal recommendations are that the Agency:

- with respect to E/M visits:
  - finalize the Agency’s proposals to lift restrictions related to E/M documentation by:
    - allowing practitioners to choose to document office/outpatient E/M visits using medical decision-making or time instead of applying the current E/M document guidelines;
    - expanding current options by allowing practitioners to use time as the governing factor in selecting visit level and documenting the E/M visit, regardless of whether counseling or care coordination dominate the visit;
    - expanding current options regarding the documentation of history and exam, to allow practitioners to focus their documentation on what has changed since the last visit or on pertinent items that have not changed, rather than re-documenting information, provided they review and update the previous information; and
    - allowing practitioners to simply review and verify certain information in the medical record that is entered by staff or the patient, rather than re-entering it.
  - finalize the proposal to eliminate the prohibition on billing same-day visits by practitioners of the same group and specialty;
  - finalize the proposal to simplify the payment for E/M visit levels 2 through 5 by paying a single rate for the level 2 through 5 E/M visits;
  - withdraw the proposed application of the MPPR that would reduce payment by 50 percent for the least expensive procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit and, instead, exercise the Agency’s authority under Section 603 of the BBA by equalizing payment rates for E/M visits across non-excepted PBDs and physician offices; and
  - with the exception of the MPPR proposal, implement the remainder of the documentation and payment rate modifications effective January 1, 2019;
- with respect to the valuation of prostate biopsy services, eliminate the proposed decrease in reimbursement for HCPCS Code G0416 and establish a valuation for G0416 that is based on an

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<sup>87</sup> 83 Fed. Reg. at 35839.

objective analysis of the work actually done in reviewing prostate tissue collected through prostate needle biopsies;

- with respect to payment for Part B drugs, refrain from finalizing the proposal to reduce WAC-based payments for Part B drugs from the 6% add-on currently in place to 3 percent;
- with respect to site-neutrality payment policy:
  - equalize payment rates between non-excepted off-campus PBDs and physician offices on a procedure-by-procedure basis; or
  - at an absolute minimum, reduce the PFS Relativity Adjuster for non-excepted items and services furnished by non-excepted off-campus PBDs from 40% to 25% of the OPSS payment rate;
- with respect to CMS's efforts to modernize Medicare physician payment for communication technology-based services:
  - finalize the creation of coding for remote evaluation of pre-recorded patient information (HCPCS Code GRAS1) and extend the proposal so that it not only covers established patients—as currently contemplated—but also covers new patients; and
  - finalize the proposal to pay for inter-professional consultations performed via communications technology (CPT Codes 994X6, 994X0, 99446, 99447, 99448, 99449);
- with respect to Electronic Health Record certification requirements, maintain flexibility and delay the requirement of using the 2015 Edition CEHRT until the 2020 MIPS performance year to allow additional transition time for completing this process; and
- with respect to the updates to the QPP, (i) reconsider proposals with respect to the elimination of extremely topped out measures and the removal of process measures, and (ii) maintain the weight of the cost performance category at 10 percent for the CY 2021 MIPS payment year.

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](mailto:dkapoor@impplc.com), or Howard Rubin at (202) 625-3534 or [howard.rubin@kattenlaw.com](mailto:howard.rubin@kattenlaw.com), if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



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