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June 27, 2016

**BY ELECTRONIC SUBMISSION**

Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

RE: Comments to CMS-5517-P

Dear Acting Administrator Slavitt:

On behalf of LUGPA, we thank you for the opportunity to comment on the Proposed Rule Implementing the Merit-Based Incentive Payment System (“MIPS”) and the Alternative Payment Model (“APM”) Incentive Under the Physician Fee Schedule, and Establishing Criteria for Physician Focused Payment Models (“PFPMs”) (collectively, the “Proposed Rule”)<sup>1</sup> to be operated by the Centers for Medicare and Medicaid Services (“CMS” or “the Agency”).

We commend CMS for its efforts to develop a workable policy framework consistent with the goals of the Medicare Access and CHIP Reauthorization Act (“MACRA”).<sup>2</sup> We also recognize the difficulty in developing a system that makes sense for the wide breadth of practice types and settings in which physicians and other healthcare professionals furnish care. CMS has responded to this complex task by creating certain new areas of flexibility, particularly with respect to revised rules for the Electronic Health Record program (or “Advancing Care Information” category). Unfortunately, there are elements of CMS’s proposed policy that will make it difficult for independent specialty practices that have the capacity to create meaningful APMs to participate fully in the payment system created by MACRA.

Our comments set forth simple suggestions that CMS can implement to ensure that specialty providers, generally, and integrated urology practices, in particular, are able to participate meaningfully in the MIPS, APM incentive, and other programs under MACRA. In brief, we ask CMS to do the following:

<sup>1</sup> 81 Fed. Reg. 28162.

<sup>2</sup> Pub. L. 114-10 (2015).



- Improve the transparency of the model approval process used by the Center for Medicare and Medicaid Innovation (“CMMI”) to provide greater certainty for group practices proposing new APMs.
- Clarify that an Advanced APM can set a benchmark other than the “total cost of care,” so that specialty-focused models can develop, and provide certain other clarifications of the Advanced APM rules.
- Use the CMMI waiver to ensure that participants in APMs that start after 2019 are not unduly discouraged from becoming Qualifying Participants.
- Provide Clinical Practice Improvement Activities that are more meaningful to urologists and other independent specialty practices, and do not allow the “topped out” rules to penalize specialty practices.
- Provide more information on how patients will be attributed to single-specialty practices for purposes of measuring resource use, and how patient relationship codes will interact with the proposed primary care-focused “two-step” attribution process.
- Withhold inclusion of Part D expenditures in the Agency’s calculation of resource use.
- Exercise caution in the use of USPSTF recommendations in constructing quality measures for the MIPS.
- Remove Agency-created barriers to provider alignment and collaboration in the physician self-referral (“Stark”) law regulations, including ending the Agency’s prohibition on “under arrangements” collaboration between hospitals and physician groups in the context of APMs.

## 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, developing new business opportunities, 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 118 urology group practices in the United States, with more than 2,000 physicians who, collectively, provide approximately 30% 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-

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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>.

effective delivery of medical services, as well as better meet the economic and administrative obstacles to successful practice. LUGPA practices often include other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care through a convenient one-stop shop for the patient. 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 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 Should Revise Processes to Accelerate the Development of Advanced APM Models**

Under the MACRA Proposed Rule, providers are strongly incentivized to move to APMs, but CMS has yet to develop an adequate infrastructure to ensure that models are reviewed in a timely manner and that those entities that submit models for consideration, including independent specialty practices, receive meaningful feedback. We believe it is critical that the APM approval process not be perceived as a “black box” into which proposals are submitted without guidance on the timeframe in which the Agency will review and approve or disapprove a submitted APM proposal or the rationale for why certain proposals are rejected. These issues will become even more serious as CMS can anticipate receiving an ever-increasing number of proposals for specialty-specific models. And, the need for improvements in the evaluation and approval process is urgent, given that MACRA establishes increasingly stringent standards for QPs every year.

### **A. Independent Urology Practices Have Limited Access to Specialty-Focused Care Models, And Existing CMMI Processes Need Improvement to Develop Such Models.**

There is currently no CMMI-approved model for urology; and, in part, this reflects the historical barriers specialists experience under the CMMI model approval process. Of the CMMI models currently focused on changing physicians' treatment patterns, the vast majority are ACO models (based on management of the entirety of a patient population's care) or bundled payment programs based on management of care associated with and following an inpatient hospital procedure.<sup>4</sup> Although CMMI solicited comments on options for specialty-focused models in early 2014, the Agency has never issued any official notice or proposed rule responding to these comments.<sup>5</sup> Since that time, CMMI has issued only two narrowly-focused specialty models—one for oncology services and the other for joint replacement services.<sup>6</sup> CMMI has not explained why the Agency chose to focus on these specialties rather than others. Little feedback is available on this

<sup>4</sup> CMMI, Innovation Models, <https://innovation.cms.gov/initiatives/index.html#views=models>.

<sup>5</sup> CMMI, Request for Information on Specialty Practitioner Payment Models, <https://innovation.cms.gov/files/x/specialtypractmodelsrfi.pdf>.

<sup>6</sup> CMMI, Specialty Practitioner Payment Model Opportunities, <https://innovation.cms.gov/initiatives/Specialty-Practitioner/>.

process, as CMMI stated that it will not “respond to every idea submitted,” in its proposal submission process.<sup>7</sup>

However, independent groups support the notion of urology-centric APMs. The Brookings Institution and Mitre, working under a CMS contract, have identified urology as one of the top-ten “most promising” specialties for CMMI to explore.<sup>8</sup> They speculated that prostate cancer could be a strong possibility for a novel payment model given the high Medicare spending associated with treatment of the disease, variability in care and costs, a number of treatment decision points, existing guidelines for various stages of the disease, and well-defined risk factors. However, Brookings was unable to identify a workable general model for prostate cancer given that, in some patients, there can be an unpredictably long period of time between initial diagnosis and need for treatment. LUGPA is already working to develop a global APM around the treatment of newly diagnosed prostate cancer; however, in addition to such comprehensive models, Brookings speculated that CMMI may wish to develop more granular models focused on specific forms of localized or metastatic cancer, or to include prostate cancer in later oncology-focused models.

One example of such a granular model not discussed by Brookings that has the potential for enormous cost savings is management of sepsis complicating prostate biopsies. The diagnosis of prostate cancer is contingent upon the performance of a prostate biopsy; the most common method of doing so is via a trans-rectal approach with a variety of different guidance mechanisms. The most significant complication of this procedure is infection; these infections generally require hospitalization and may be life-threatening in nature. Historically, the rate of sepsis following prostate biopsy without antimicrobial prophylaxis has been shown to be approximately 8%, but this was reduced to 3.1% with a single dose of pre-procedure antibiotics.<sup>9</sup> The advent of more virulent, multi-drug resistant organisms has led to concerns that, internationally, these infection rates are increasing.<sup>10</sup> LUGPA practices demonstrated as much as a 70.3% reduction in post-prostate biopsy sepsis rates after adoption of a standardized antibiotic prophylaxis regimen utilizing loco-regional patterns of bacterial resistance.<sup>11</sup> Data suggests that the average cost of inpatient management of sepsis ranges from as low as \$16,103 per episode where aggressive sepsis protocols have been successfully implemented<sup>12</sup> to as

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<sup>7</sup> CMMI, Share Your Ideas, <https://innovation.cms.gov/Share-Your-Ideas/index.html>.

<sup>8</sup> Brookings/MITRE CMS Alliance to Modernize Healthcare, Specialty Payment Model Opportunities Assessment and Design: Preliminary Assessment of Model Opportunities, December 10, 2013, [http://www2.mitre.org/public/payment\\_models/Prelim\\_Assess\\_Other\\_Model\\_Opps.pdf](http://www2.mitre.org/public/payment_models/Prelim_Assess_Other_Model_Opps.pdf).

<sup>9</sup> Kapoor DA, Klimberg IW, Malek GH, et al. Single-dose oral ciprofloxacin versus placebo for prophylaxis during transrectal prostate biopsy. *Urology* 1998; 52:552–558

<sup>10</sup> Loeb S, Carter HB, Berndt SI, Ricker W, Schaeffer EM. Complications after prostate biopsy: data from SEER-Medicare. *J Urol*. 2011 Nov;186(5):1830-4

<sup>11</sup> Averch, T., Tessier, C., Clemens, J.Q., et al., 2015. AUA Quality Improvement Summit 2014: conference proceedings on infectious complications of transrectal prostate needle biopsy. *Urology Practice*, 2(4), pp.172-180).

<sup>12</sup> Shorr AF, Micek ST, Jackson WL, et al. Economic implications of an evidence-based sepsis protocol: Can we improve outcomes and lower costs? *Crit Care Med*. 2007 May;35(5):1257-62.

high as \$94,737 per episode in patients who had prior antibiotic exposure in the prior 90 days.<sup>13</sup> As such, implementation of these protocols produced cost savings between \$10,660,186 and \$62,715,894 over 6 years in a single LUGPA practice.

LUGPA and its member practices are ready to partner with CMMI in developing models along these lines. Unfortunately, CMMI has produced limited guidance regarding its process for analyzing and approving models proposed by external stakeholders. The Agency's sole statement of its approval process to date is a two-page set of "Model Design Factors" that provide general principles under which CMMI will evaluate a model.<sup>14</sup> These include extremely high level statements of policy goals such as "extent of clinical transformation," "potential for quality improvement," "probability of model success," and "scalability." However, we understand the Agency uses a much more robust internal process. The Government Accountability Office's analysis illustrates a complex internal approval process used by CMMI that involves careful evaluation of proposed models against detailed "Portfolio Criteria," resulting in a formal proposal that is evaluated by other departments within CMS.<sup>15</sup> CMMI has made little of this material available to the public. For example, while a summary of the Portfolio Criteria may be found through a search of the CMMI website this summary is not linked conspicuously on the site.<sup>16</sup> CMMI provides no information regarding the relationship between the "Portfolio Criteria" and "Model Design Factors," and neither set of standards describes any objective, quantitative criteria. At the same time, it appears that CMMI uses a cumbersome committee-based process to evaluate a model's potential areas of overlap with other departments within CMS, and must obtain approval from every office in CMS in order to move forward with a model.<sup>17</sup> As a result, entities developing APMs have very little actionable information with which to develop models relevant to CMMI.

Although it is expensive and time-consuming to develop an APM, MACRA places this kind of payment model at the heart of payment reform. As a result, the relatively informal process that CMMI has used to date in communicating to the public its evaluation of proposed models is no longer adequate and certainly not sustainable. CMMI can significantly improve the predictability of this process with a small number of simple procedural changes.

***Specifically, CMMI should improve the transparency and predictability of its model approval process (and CMS should apply similar standards to the Physician-Focused Payment Models) as follows:***

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<sup>13</sup> Micek S, Johnson MT, Reichley R, et al. BMC Infect Dis. An institutional perspective on the impact of recent antibiotic exposure on length of stay and hospital costs for patients with gram-negative sepsis. 2012 Mar 13;12:56.

<sup>14</sup> CMMI, Model Design Factors, <https://innovation.cms.gov/Files/x/rfi-websitepreamble.pdf>.

<sup>15</sup> Government Accountability Office, "CMS Innovation Center: Early Implementation Efforts Suggest Need for Additional Actions to Help Ensure Coordination with Other CMS Offices," ("GAO CMMI Report"), p. 39-41, <http://www.gao.gov/assets/660/650119.pdf>.

<sup>16</sup> CMMI, "Our Portfolio Criteria," <https://innovation.cms.gov/about/our-portfolio-criteria/index.html#collapse-potential>.

<sup>17</sup> GAO CMMI Report at p. 28.

- *CMMI should publish a set of objective financial and/or quality standards that it will use to evaluate a model. For example, if CMMI intends to adopt the Advanced APM standard for approved models going forward,<sup>18</sup> it should clarify this metric.*
- *CMMI should adopt the approach used elsewhere within CMS with respect to regulated entities subject to complex standards (such as Qualified Health Plans offered under the Health Insurance Marketplace) and provide freely available calculators and other resources,<sup>19</sup> so that entities developing an APM can easily model various options for participation.*
- *CMMI should commit to providing entities that submit models a definitive “yes or no” answer within a reasonable timeframe and no later than 90 days after submission.*
- *CMMI should provide specific, meaningful feedback for rejected models and indicate how deficiencies can be rectified.*

**B. CMS Proposes Standards Governing the Eligibility of Advanced APMs That Will be Difficult for Providers to Apply and Will Discourage Participation in Advanced APMs.**

In the Proposed Rule, CMS sets forth standards to determine whether an APM can qualify as an “Advanced APM,” in part by accepting “financial risk” for monetary losses above a certain benchmark that is “more than a nominal amount.”<sup>20</sup> We recognize that the varying nature of current and proposed APM models poses a challenge for CMS to develop meaningful oversight standards. At the same time, however, we believe that Congress intended to allow models relevant to physician specialty groups to become Advanced APMs. The Proposed Rule is silent on a number of important issues critical to ensuring that independent specialty practices will be able to develop and participate in Advanced APMs. We seek clarification on these proposed standards and we suggest a number of changes that would facilitate participation by a broader range of physician specialties. Specifically, we seek confirmation that an Advanced APM is **not** required to base the “benchmark” used to evaluate the cost of care upon the “total cost of care” measure currently used by the ACO programs, but is instead able to define a customized benchmark relevant to the particular specialty that is the subject of the Advanced APM.

LUGPA is studying an APM including clinical decision support tools, clinical protocols, and advanced analytics to assist in targeted interventions for prostate cancer. Treatment for prostate cancer can take many forms, ranging from active surveillance to clinical interventions using chemotherapy, hormone therapy, or radiation.<sup>21</sup> As a result, a model

<sup>18</sup> 81 Fed. Reg. at 28296-28307.

<sup>19</sup> See e.g., the Minimum Value Calculator, developed by CMS to allow insurance companies to calculate whether their plans offered adequate actuarial value in compliance with federal rules. <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/mv-calculator-methodology.pdf>

<sup>20</sup> See 42 U.S.C. § 1395L(z)(3)(D) and 81 Fed. Reg. at 28305.

<sup>21</sup> See National Comprehensive Cancer Network, NCCN Guidelines Version 2.2016 Prostate Cancer Updates.

could be developed that would compare the quality outcomes and spending associated with urologists' performance in selecting appropriate care for a population of patients and could require participating urologists to take financial responsibility for the risk of expenditures "beyond a nominal amount" *for the management and complications of therapy for this particular disease*. Such a model appears to fit within the statutory standard for APMs, but the model cannot be adopted **unless physicians can be evaluated on the basis of a clinically relevant set of services**. We seek confirmation from CMS that an Advanced APM may properly base its benchmark on this kind of clinically relevant subset.

Establishing a specialty specific benchmark is important because, under the Proposed Rule, CMS would create expanded standards to determine whether an APM required entities to accept "financial risk," and whether such risk was beyond a "nominal amount." Of these two elements, the "nominal amount" rule could pose significant problems depending upon the benchmark used by the APM.<sup>22</sup> In sum, CMS proposes that an APM would meet the "nominal risk" standard if: 1) the APM (or its participants) must repay at least 30% of the marginal amount at risk (i.e., the dollars in excess of the benchmark amount); 2) the APM is at risk for repaying at least 4% of expected expenditure (i.e., the benchmark amount); and 3) any minimum loss rate policy is limited to the initial 4% of expenditures above the benchmark.<sup>23</sup>

Depending on the benchmark used, this "nominal risk" standard could pose a significant barrier for APMs seeking Advanced APM status—particularly if they are led by physicians. Although neither MACRA nor CMS regulation has explicitly defined the term "benchmark," we think it is significant that all of the ACO models CMS proposes to include in its list of Advanced APMs use the same benchmark: **the "total cost of care."**<sup>24</sup>

Although we understand CMS's rationale for developing a "total cost of care" metric, we are concerned that a total Medicare spending metric could require providers to assume financial responsibility for care that may be far outside the given provider's area of expertise. Moreover, a total Medicare spending standard can only be managed effectively by those physicians who can control a beneficiary's overall care. As patients may choose to seek services at lower-value facilities than recommended by the APM participant, even primary care physicians could incur costs that are simply outside of their control. At present, the only sites of service that could adhere to a "total cost of care" metric would be consolidated health care systems *with their own insurance products* that can regulate patient choice through co-insurances and deductibles. Very few entities anywhere in the country fit this description, and we do not believe Congress intended to constrain the development of specialty-specific APMs in this manner. That said, as specialists who often serve as the principal caregivers for serious disease states, we embrace our role in managing costs and assuming risk for the entirety of care for those conditions, including the use of ancillary and inpatient services.

<sup>22</sup> An APM would generally meet the financial risk standard so long as it requires repayment (or other financial penalties) if its expenditures exceed the benchmark. See 81 Fed. Reg. at 28304.

<sup>23</sup> 81 Fed. Reg. at 28306.

<sup>24</sup> See e.g., 42 C.F.R. § 425.602.

Notably, CMS implies that alternative benchmarks are possible. In its discussion of the “nominal amount” standard, the Agency states that the benchmark means: “the amount of Medicare expenditures (**which can vary as to the involvement of Parts A and B depending upon the APM**) above which an APM Entity owes losses and below which an APM Entity earns savings.”<sup>25</sup> Alternatively, the “nominal risk” standard for bundled payment arrangements will be based on the target price established by the applicable bundle. Although this suggests a degree of flexibility, we do not believe it provides a clear enough statement that CMS will accept models using a benchmark other than the “total cost of care” used for each of the ACO models approved as Advanced APMs.

We do not believe Congress intended to foreclose APMs focused on specialty management of diseases such as prostate cancer. The broader definition of “nominal risk” would create significant new incentives for physician participation in these models, but a rule requiring an APM to assume the risk of losses based on total Medicare expenditures would discourage physician-only APMs of any type, because physicians would potentially be exposed to large hospital cost overruns that the physicians have little or no ability to influence or control. CMS could easily resolve this issue by allowing APMs the flexibility to define the benchmark they will use and then require each APM to accept risk “beyond a nominal amount” based on that benchmark.

*Accordingly, we request that CMS allow Advanced APMs to meet the “nominal risk” standard with respect to a clinically relevant subset of the total Medicare expenditures of attributed beneficiaries, rather than requiring the use of overall Medicare expenditures.*

### **C. CMS Should Use Its Existing Statutory Authority to Encourage An Appropriately Broad Group of Physicians, Including Independent Urology Practices, to Participate in APMs.**

ACO programs provide urologists with few opportunities to participate, given that ACOs require management of a patient’s entire healthcare experience, much of which is outside the control or influence of urologists. Moreover, under existing ACO programs, patients are attributed based solely on primary care services. As a result, existing ACO models will not properly credit modifications to *urology* care that improve outcomes or lower costs for the treatment of genitourinary conditions, even if such modifications require significant investments by physicians. As a practical matter, with all of these limitations, the vast majority of urology practices (and physician specialists in general) will have no viable opportunity to participate in Advanced APMs under the favorable eligibility rules in place during calendar year 2017.

At the same time, we expect that CMS’s establishment of “ground rules” for Advanced APMs will encourage the development of many new models that can become Advanced APMs. Future Advanced APM models will likely be better aligned with urology (and other specialty) practices. Unfortunately, by the time such models are approved, MACRA will already have required providers to show that a majority of reimbursement (or a large percentage of patients) are treated through such an APM. MACRA’s five percent bonus

<sup>25</sup> 81 Fed. Reg. at 28305. Emphasis added.



will not encourage many urologists to participate in a newly designed Advanced APM if a condition of receiving the bonus is that, by the time the APM is available, the APM must immediately become the source of 75% of the physician's reimbursement. Indeed, CMS is already facing a similar timing problem as it has acknowledged that the Proposed Rule will be finalized after the application deadline passes for participation in an APM in 2017.<sup>26</sup>

CMMI has the power to solve this problem in the form of its broad authority granted in the ACA to waive sections of the Social Security Act in order to test new models (including APMs).<sup>27</sup> Given that CMS considers the shift away from fee-for-service payments to APMs to be a core part of the new payment system, it would be appropriate for the Agency to use the waiver to smooth the transition to new Advanced APM models in future years.<sup>28</sup>

*Accordingly, we ask that CMMI exercise its authority to waive the application of 42 U.S.C. § 1395L(z)(2), such that participants in APMs approved by CMMI after 2017 receive a transition period in which such participants' QP eligibility is determined under the eligibility criteria for calendar year 2017.*

### **III. Required Reporting Under the MIPS Does Not Address Concerns of Independent Urology Practices.**

The Proposed Rule's sections implementing the MIPS are as much or more of a concern for independent urology practices as those sections applicable to APMs. All providers who do not become QPs will be graded automatically under the MIPS, unless they fall into one of the limited exclusions.<sup>29</sup> The MIPS represents a significant break from prior Medicare practice by establishing a new composite score used to evaluate every eligible clinician (EC) on the basis of four categories:

- 1) quality;
- 2) resource use;
- 3) "advancing care information" through the use of EHR; and
- 4) CPIAs.<sup>30</sup>

We commend CMS for designing a workable system by which these extremely broad categories can be translated to a meaningful score and for proposing options that may be available to ECs who are specialty physicians. However, in certain respects, the standards are heavily linked to primary care practice metrics that specialty physician practices cannot incorporate in a clinically meaningful way and, hence, should not be the basis by which specialty practices are measured. Below, we present additional detail on these areas and suggest ways in which the Agency can ensure that it does not inadvertently penalize urologists and other specialty physicians.

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<sup>26</sup> *Id.* at 28305.

<sup>27</sup> 42 U.S.C. § 1315a(d)(1).

<sup>28</sup> 81 Fed. Reg. at 28166.

<sup>29</sup> QPs, certain Partial QPs, newly enrolled providers or groups, and groups with a low volume of patients are excluded from reporting under the MIPS. See 81 Fed. Reg. at 28177-8.

<sup>30</sup> 42 U.S.C. § 1395w-4(q)(2)(A).

### **A. CMS Should Modify the “Topping Out” Rules to Provide Meaningful Feedback and a Transition Period.**

In the initial implementation years, the “quality” component of MIPS has the largest weight. CMS proposes that most ECs will be required to report on a minimum of six quality metrics (or a full set of specialty metrics), plus one “cross-cutting” metric;<sup>31</sup> and we note that the Agency has proposed a meaningful set of urology-specific *base* quality measures.<sup>32</sup> In general, we believe most LUGPA members will be able to meet this standard.

However, CMS also proposes a set of “topped out” rules that may penalize physician practices *even if they fully comply with these reporting standards*. Under these rules, an EC would not receive full credit under MIPS for reporting a measure that is widely reported by other providers.<sup>33</sup> Instead, CMS will apply a downward adjustment to such a quality measure based on the degree to which other providers report high performance on the measure. This is inappropriate for at least two important reasons.

First, such a process would penalize ECs for the reporting choices made by wholly unrelated entities. If a quality metric is properly designed to capture a clinically relevant aspect of specialty practice, and the EC submits data on that metric in good faith, it is unfair to suggest that the EC provides lower quality care simply because that particular measure proved popular among all ECs.

Second, as CMS itself acknowledges, many of the measures it has made available to providers are “topped out”—approximately half of all measures are “topped out” and certain process measures have a median score of 100% success.<sup>34</sup> Although we understand this complicates CMS’s scoring efforts, the fact remains that the Agency itself requires reporting of a minimum number of measures. It is unfair and inconsistent with the statute to penalize an EC for complying with these mandatory reporting rules. For example, CMS has only proposed eight urology measures available to every urologist in any site-of-service. Given this limited number, it is reasonable to expect that many measures will be “topped out”—not because they are clinically irrelevant, but because urologists have few options to achieve compliance with CMS reporting rules.

*Accordingly, we ask CMS to modify the “topped out” measure rules to ensure that providers are not penalized without notice of a metric’s “topped out” status, and that specialty practices are not penalized due to the lack of available metrics.*

### **B. CPIAs Are Too Heavily-Focused on Primary Care.**

CPIAs are one of the four basic components of the MIPS score. In initial years, CMS proposes to weight this category as 15% of the total score.<sup>35</sup> Unfortunately, CPIAs share

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<sup>31</sup> 81 Fed. Reg. at 28186.

<sup>32</sup> *Id.* at 28521-2.

<sup>33</sup> *Id.* at 28253.

<sup>34</sup> *Id.*

<sup>35</sup> *Id.* at 28261.

many of the problems of cross-cutting measures insofar as they are focused predominantly on primary care and public health activities that are not realistically part of most urologists' (or other specialists') practices. CPIAs are evaluated on a 60-point scale, with ECs earning more points for "high-priority" measures. As such, under the weighted scoring system used by CMS, physicians will be able to achieve the highest score for this category with a smaller number of "high-priority" than "low-priority" measures. For example, a group practice could receive full credit for the CPIA category by reporting just three "high-priority" measures; the same group would need to report six "medium-priority" measures to achieve the same score.<sup>36</sup>

The problem, however, is that few "high-priority" measures are available for urologists. Most are heavily focused on care management measures that are more relevant to primary care, such as measures related to the management of diabetes or the integration of mental or behavioral health services. Of the eleven "high-priority" measures, only four are generally applicable to a wide range of physician groups.<sup>37</sup>

*Accordingly, we ask that CMS convene a specialty workgroup including urologists in independent practice to identify additional high-quality measures demonstrating meaningful CPIAs for various specialties, including urology.*

### **C. CMS Should Be Careful In Incorporating Recommendations From the United States Preventive Service Task Force In Quality Measures.**

CMS proposes to evaluate newly proposed MIPS quality measures based in part on whether they are associated with a USPSTF recommendation.<sup>38</sup> In its present form, the USPSTF process lacks a mechanism for significant input from specialty physicians most experienced in the disease states studied. For example, The USPSTF panel that issued a "D" grade for PSA testing did not include representatives with clinically meaningful experience in urology, urologic oncology, radiation oncology or medical oncology, and relied upon studies with serious methodological flaws.<sup>39</sup> LUGPA has previously expressed concerns about the incorporation of recommendations by the USPSTF, most recently in response to the proposed electronic clinical quality measure ("ECQM") on prostate-specific antigen ("PSA") tests.<sup>40</sup> We appreciate that CMS heeded the concerns raised by LUGPA, the American Urological Association, and others, and did not use the USPSTF's "D" grade for PSA testing as a basis for adopting a quality metric to assess "unnecessary screening for prostate cancer using PSA." Until the USPSTF recommendation process is substantially reformed, we believe that CMS should proceed with great caution before incorporating any future USPSTF recommendations into MIPS quality measures.

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<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> 81 Fed. Reg. at 28194.

<sup>39</sup> *Id.*

<sup>40</sup> LUGPA Comments to CMS Regarding Non - Recommended PSA - Based Screening, November 20, 2015.

#### **IV. CMS's Proposed Resource Use Rules Appear to Disadvantage Urologists and other Specialty Physicians.**

##### **A. The Method of Patient Attribution Appears to Be Adopted From the Shared Savings Program's Primary-Care Focused Methodology.**

Patient attribution refers to the process by which CMS identifies the group of patients whose healthcare expenditures will be used to calculate an EC's resource use. This process is especially complicated for physician specialists because a specialist's contact with a patient may be infrequent, while still being of vital importance to that patient's health. It would be inappropriate to evaluate the resource use associated with every patient seen by the specialist, because many of the resources would be incurred in connection with totally unrelated health expenditures. At the same time, it may be challenging to determine the factors that would allow a patient's care to be attributed to a particular specialist, rather than to a primary care physician or other physician involved in the patient's care.

CMS proposes that it will measure resource use using three measures adapted from the existing value-based modifier program:

- 1) the total per capita cost of care;
- 2) the hospital-based Medicare Spending Per Beneficiary measure; and
- 3) care episode groups reflecting total costs for a specific set of services.<sup>41</sup>

We restrict our comments to the total per capita cost of care and care episode group categories. For these measures, CMS proposes a "two-step" attribution system adopted from the one in place in the MSSP. Our concern is that the nature of this attribution system will inaccurately model 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>42</sup> But, we fail to see how a primary care-based attribution methodology is appropriate for a payment policy intended to evaluate all physicians, including specialists. As CMS has acknowledged, it is difficult to see many specialty group practices being attributed patients under this methodology;<sup>43</sup> yet, this raises serious questions about the treatment of such practices under the MIPS. If CMS does not attribute the Agency's proposed minimum of twenty cases to a TIN,<sup>44</sup> what are the practice's responsibilities under the MIPS? It would be unreasonable to penalize specialty practices for failing to satisfy the resource use element of the MIPS score on these grounds. This is particularly problematic for urology, because even though urology is not a primary care specialty, urologists certainly are the principal caregivers of the genitourinary tract. As such, the decision-making by urologists in terms of resource utilization, referral patterns and clinical pathways deserve to be uniquely captured;

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<sup>41</sup> 81 Fed. Reg. at 28198.

<sup>42</sup> Medicare Value Modifier Fact Sheet, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Attribution-Fact-Sheet.pdf>.

<sup>43</sup> 81 Fed. Reg. at 28199.

<sup>44</sup> *Id.* at 28200.

urology practices should not have to rely on primary care attribution to develop value metrics to assess physician performance.

*We urge CMS to modify the attribution process to recognize the unique contribution specialty practices make to efficient care.*

### **B. CMS's Proposed Episode-Based Groups Do Not Take into Account Important Aspects of Independent Practice.**

CMS proposes a new set of resource use measures called “care episode groups.” These groups are extremely important because they appear to be the only measure of resource use that is directly linked to specific elements of clinical performance relevant to a given physician specialty. As such, they are distinct from the other cost measures that capture *total* costs, including expensive, acute hospitalization costs for totally unrelated conditions. Care episode groups have special importance for urologists and other specialty physicians because, generally, these physicians are not in a position to influence all facets of a patient's care. As such, this metric would potentially allow specialists to demonstrate the specific value provided with respect to a defined, clinically relevant set of services.

We are concerned, however, that the care episode groups CMS proposes are heavily linked to inpatient hospital services. The episode groups fall into two categories—“acute” and “procedural.”<sup>45</sup> Acute episode groups are explicitly triggered by an inpatient code, while procedural groups may be triggered by a code in any setting CMS proposes two episode groups for urology: prostatectomy for prostate cancer and transurethral resection of the prostate (“TURP”) for BPH;<sup>46</sup> yet, CMS has only established prostatectomy trigger codes that may be performed in the inpatient setting.<sup>47</sup> As a result, the prostatectomy group is triggered by an inpatient claim containing any of the “trigger codes” defined by CMS.<sup>48</sup>

Although we understand this is a first attempt to establish a care episode group system, we urge CMS to establish a broader range of care episode groups that are meaningful for providers across sites of service—not just those furnishing care in the inpatient hospital setting. As an example, one of the glaring omissions in the care episode group process is a lack of support for acute surgical services provided in ambulatory surgical centers—recognized as providing high quality, efficient and cost effective care when compared to hospitals.<sup>49,50</sup> As the Office of Inspector General (“OIG”) has observed, services

<sup>45</sup> CMS Episode Groups Summary, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/Episode-groups-summary.pdf>.

<sup>46</sup> 81 Fed. Reg. at 28204 and 28207. Note that TURP is listed under the “gastrointestinal” section; we believe this is simply an error on CMS's part.

<sup>47</sup> Cf. CY 2015 Ambulatory Surgical Center Final Rule, Addendum AA and CMS Episode Group List, Method A, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-Feedback.html>.

<sup>48</sup> 81 Fed. Reg. at 28204.

<sup>49</sup> Munnich, E.L. and Parente, S.T., 2014. Procedures take less time at ambulatory surgery centers, keeping costs down and ability to meet demand up. *Health Affairs*, 33(5), pp.764-769.

performed in ASCs were responsible for an estimated \$7 billion in Medicare savings between 2007 and 2011.<sup>51</sup> But, as CMS explained in its description of methodology for the care episode groups, attributing patients to acute care episode groups will *only* be based on the source of inpatient evaluation and management codes.<sup>52</sup> This would specifically disadvantage specialty physicians who care for patients in the more convenient, less expensive independent practice and ambulatory surgery center settings and potentially create MIPS penalties for physicians who do not practice exclusively within the hospital setting.

***Accordingly, CMS should establish care episode groups that can be triggered by ASC services and allow patient attribution for these care episode groups to be based on services delivered in ASCs.***

### **C. CMS Should Not Include Part D Expenditures in its Calculation of Resource Use.**

CMS should exercise the discretion Congress granted the Agency under MACRA and not incorporate Medicare Part D expenditures into its analysis of patient resource use.<sup>53</sup> Urologists and other physician specialists are frequently responsible for managing the care of patients with late-stage cancer or other complex diseases or chronic conditions that require use of life-saving (or life-prolonging) medications that have no generic or other clinical alternatives. It would be inconsistent with the triple aim to penalize specialists for providing clinically appropriate care, simply because higher-acuity conditions must be treated with expensive drugs. Absent any clinical quality metrics used to determine the impact that these Part D medications have on health outcomes and quality of life, CMS should defer inclusion of these expenditures in any calculation of the MIPS resource use metric.

### **V. LUGPA Applauds the Significant and Needed Flexibility CMS Created in the Electronic Health Record Rules.**

The EHR meaningful use program has been the source of much frustration for independent practices, particularly small practices that have expended significant capital and been subjected to substantial CMS reporting obligations in connection with EHR systems that have not provided the expected benefits. As a result, we were grateful to see that CMS has added needed flexibility to this process as part of the Advancing Care Information component of the MIPS composite score. The shift to a category-based

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<sup>50</sup> Carey, K., 2015. Price Increases Were Much Lower In Ambulatory Surgery Centers Than Hospital Outpatient Departments In 2007–12. *Health Affairs*, 34(10), pp.1738-1744.

<sup>51</sup> Office of Inspector General, “Medicare and Beneficiaries Could Save Billions if CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates,” Report A-05-12-00020 (April 2014), <http://oig.hhs.gov/oas/reports/region5/51200020.pdf>.

<sup>52</sup> 81 Fed. Reg. at 28201. CMS proposes to use the attribution approach defined in “Detailed Methods of the 2014 Supplemental Quality and Resource Use Reports (QRURs),” <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/Detailed-Methods-2014SupplementalQRURs.pdf>.

<sup>53</sup> See e.g., 42 U.S.C. § 1395w-4(r)(5)(C).

score that allows groups to achieve “partial credit” for implementing various elements of an EHR system (rather than the prior “all or nothing” system), will greatly reduce the burden on independent practices.<sup>54</sup> We commend CMS for this approach.

## **VI. CMS Should Exercise its Existing Statutory Authority to Take Immediate Action to Reform the Stark Law In Order to Support MACRA Implementation.**

In the 2016 Medicare Physician Fee Schedule proposed rule issued in July 2015, CMS asked the public to comment on “perceived barriers to achieving clinical and financial integration posed by the physician self-referral law generally,” or due to particular elements of the Stark law. CMS was right to solicit comment on these topics, but the barriers to which the Agency alluded a year ago are now a very real impediment to successful functioning of the MIPS and APM programs. As such, we believe it is critical for CMS to address, as part of its implementing regulations under MACRA, a limited set of Stark Law reforms that will enable physicians in independent practice to achieve the greater care coordination and integration of services that MACRA demands.

Every Medicare-participating physician in the country will now be evaluated on the basis of value-based metrics: either through the MIPS composite score (primarily based on quality, utilization of Electronic Health Records (EHR), and resource use measures) or through a formal APM. These new models of payment will require changes in the way that physicians organize their practices, structure compensation, and work with other entities to coordinate care. CMS recognized the inherent inconsistencies between coordinated care and existing Stark regulations, and responded by granting five distinct waivers to participating hospitals and physicians to shield them from the legal risks associated with ACO formation. Those waivers, however, fail to capture key aspects of the new payment structures created by MACRA, which obviously was not part of the health care policy lexicon more than 25 years ago when Stark was first developed.

Transformation in the model of care delivery is, of course, one of the core purposes of MACRA; and yet, the federal Stark Law, as currently formulated, severely restricts providers’ ability to collaborate with one another and develop these innovative care models. Moreover, as a strict liability statute, the Stark Law creates substantial compliance risk for providers who collaborate, unless they limit themselves to tightly-defined arrangements that are closely associated with the fee-for-service payment system.

Under the Proposed Rule, CMS would use providers’ performance in 2017 to assess the penalties and bonuses that would apply in 2019.<sup>55</sup> As such, physician practices face enormous pressure to work more collaboratively in order to meet the stringent requirements to be classified as “Advanced APMs.” The MACRA statute also requires that Qualifying Participants (“QPs”) must demonstrate that an ever-higher percentage of payment or patients comes from at-risk arrangements in each year.<sup>56</sup> Fortunately, under its existing statutory authority, CMS can implement common-sense modifications to the Stark Law that will encourage greater collaboration between physicians, practices, and

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<sup>54</sup> 81 Fed. Reg. at 28216 -7

<sup>55</sup> *Id.* at 28180.

<sup>56</sup> 42 U.S.C. § 1395L(z)(2).

other entities, which will help resolve this problem. Given the rapid schedule for implementation of MACRA, CMS must act now—in the Final Rule—to remove barriers to the alignment of physicians and entities that are attempting to meet these high standards under severe time pressure.

**A. CMS Should Use Its Regulatory Authority to Ensure that Group Practices Can Distribute Resources on the Basis of Activities Designed to Achieve the Goals of the MIPS.**

CMS should modify its Stark regulations to protect physician groups that seek to implement innovative compensation strategies that incentivize achievement of the MIPS goals of improved quality outcomes (and reporting thereof), more efficient resource use, adoption of EHR technology, and engagement in Clinical Practice Improvement Activities (CPIAs).<sup>57</sup> At present, the CMS group practice regulation requires that “no physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals,” unless such compensation fits one of the “special rules for productivity bonuses or profit shares.”<sup>58</sup>

Congress included general references to special rules for productivity bonuses and profit shares in the Stark statute.<sup>59</sup> The statutory standard provides:

“A physician in a group practice may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed or services incident to such personally performed services, so long as the share or bonus is not determined in any manner which is directly related to the volume or value of referrals by such physician.”

CMS has used its regulatory authority to flesh out in much greater detail what is meant by the “productivity bonus and profit share” provision. In its “Phase I” Stark rulemaking, CMS established that certain types of bonuses or profit shares would be deemed not to take into account the “volume or value of referrals.”<sup>60</sup> These deeming provisions, however, almost uniformly relate to volume-based (as opposed to value-based) measures. For example, CMS established that a **profit share** will be deemed not to take into account the volume or value of referrals if payment is: 1) distributed equally on a per-capita basis; 2) distributed on the basis of revenues attributed to non-DHS services; and 3) revenues from DHS are a *de minimis* part of the group’s total revenues and of each physician’s compensation.<sup>61</sup> Similarly, a **productivity bonus** will be protected if: 1) it is based on the physician’s total patient encounters or relative value units (RVUs); 2) it is based on the allocation of the physician’s compensation attributable to services that are not DHS; and 3) revenues from DHS are a *de minimis* part of the group’s total revenues and of each physician’s compensation.<sup>62</sup>

<sup>57</sup> *Id.* at § 1395w-4(q)(2)(A).

<sup>58</sup> 42 C.F.R. § 411.352(g).

<sup>59</sup> 42 U.S.C. § 1395nn(h)(4)(B).

<sup>60</sup> 66 Fed. Reg. 856, 908-10.

<sup>61</sup> 42 C.F.R. § 411.352(i)(1) and (2).

<sup>62</sup> *Id.* at (i)(3).



This creates a quandary for physician practices under the MACRA. On the one hand, CMS explicitly protects the distribution of profit shares and productivity bonuses by a group practice on the basis of certain measures of volume (either proportionately to non-DHS revenue or on the basis of RVUs). On the other hand, under the MIPS, the amount of reimbursement for each physician will be adjusted due to services provided wholly outside the physician practice because each group's resource use and performance on certain quality metrics will depend in part on the overall experience of attributed patients who may receive care from many providers *outside* a given group. The result is that group practices will be held accountable for the collective performance of all professionals who bill through their Tax Identification Number ("TIN") for the MIPS.<sup>63</sup> As a result, group practices will be more accountable for the management of the total performance of physicians who bill through the group's TIN than ever before—including the referral patterns of physicians to hospitals or other providers outside the group. Yet the Stark regulations, if left unchanged, do not permit a practice to encourage their physicians to comply individually with these new treatment protocols.

The problem is that CMS's "deeming" rules predate—and are therefore silent on—incentives for improved care coordination, partnership with high-quality physicians, and other mechanisms to improve quality, resource use, and CPIAs. This is particularly concerning for purposes of reporting resource use, because the Proposed Rule suggests that the resource use component of MIPS will partly reflect the total per capita Medicare Part A and B costs of any beneficiaries attributed to the group's eligible clinicians—not just any given physician's personally performed services.<sup>64</sup> Accordingly, a group's performance will depend upon better management of a physician's referral patterns, utilization of ancillary services, and collaboration with high-quality or cost-efficient partners. These activities are inherently different from measures of personal productivity (such as RVUs). As a result, the conflicting requirements of MACRA and the Stark Law inhibit group practices from structuring incentives that extend beyond a physician's personally performed services and take into consideration compliance with the group's population management objectives.

In crafting the "deeming" provisions of the Phase I rule, CMS noted that it had the ability to define other financial relationships as being outside the "volume or value" prohibition of the special rules. For example, the Agency noted (without implementing through regulation) that capitation arrangements would also be deemed not take into account the volume or value of referrals.<sup>65</sup> CMS should now revisit its 15-year-old regulation deeming certain forms of group practice compensation as not taking into account the "volume or value" of referrals to ensure that group practices may properly compensate physicians on the basis of meeting clinical benchmarks, referrals to high-quality or cost-efficient providers, and other measures relevant to the MIPS

***Specifically, CMS should clarify, through regulation, that the distribution of a productivity bonus or profit share on the basis of a physician's MIPS composite score***

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<sup>63</sup> 81 Fed. Reg. at 28178-9.

<sup>64</sup> *Id.* at 28197-9.

<sup>65</sup> 66 Fed. Reg. at 910.

*(or a component thereof) is not deemed to take into account the volume or value of referrals.*

## **B. CMS Needs to Create a Predictable and Consistently Applied Set of Stark Law Flexibilities for APMs.**

### 1. CMS Should Establish a Single, Comprehensive Waiver of the Stark Law for Participants in APMs.

Currently, the most common Medicare APMs are ACOs. However, existing ACO models are effectively closed to physician specialties because these models require participants to manage a patient population's full spectrum of care in a manner that is fundamentally inconsistent with specialty practice. LUGPA and other groups are now developing potential APM models that CMMI could adopt to provide meaningful opportunities for urologists and other physicians to collaborate in order to improve care delivery and reduce expenditures.

Unfortunately, these efforts to develop APMs—precisely what MACRA wants physician organizations to be doing—are thwarted by a patchwork approach to CMS's waiver process that leaves physicians wondering which elements of the Stark Law, Anti-Kickback Statute, Civil Monetary Penalty, and other laws will apply, and which will be waived. A more predictable, comprehensive solution is required.

To date, CMS has not committed to the future availability of any waivers, refusing to issue such waivers through notice-and-comment rulemaking and including caveats that discourage provider reliance on such waivers. For example, the initial MSSP waivers stated that “[w]e plan to narrow the waivers . . . unless the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements.”<sup>66</sup> Even the waivers for the Next Generation ACO Model, issued in December 2015, warn that “[t]o the extent these payment mechanisms change, or other payment mechanisms are added in future Performance Years, these waivers may change or evolve with respect to those new elements.”<sup>67</sup>

In the context of isolated demonstration projects this piecemeal approach may have been adequate; however, MACRA's very structure pulls these projects into the heart of Medicare payment policy. As the Agency acknowledges, “[u]nder the incentives for participation in Advanced APMs, our goals . . . are to **expand the opportunities for participation in APMs, maximize participation in current and future Advanced APMs, create clear and attainable standards for incentives, promote the continued flexibility in the design of APMs, and support multipayer initiatives across the health care market.**”<sup>68</sup> In addition, CMS has now proposed a sweeping set of unified

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<sup>66</sup> 76 Fed. Reg. 67991, 68008.

<sup>67</sup> Notice of Waiver of Certain Fraud and Abuse Laws in Connection with the Next Generation Model, p. 7, <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Next-Generation-ACO-Model-Waiver.pdf>.

<sup>68</sup> 81 Fed. Reg. at 28169. Emphasis added.

standards for the Agency to use in evaluating the quality of a given APM.<sup>69</sup> In particular, the proposed Advanced APM rules create objective, stringent standards to ensure that participants in an Advanced APM are truly accepting the “downside risk” of failing to meet specified metrics.<sup>70</sup> Managing downside risk inherently requires tremendous coordination between physicians operating within a practice and, at times, across different practices and sites of service—coordination that is fundamentally hindered by the current application of the Stark law.

The *ad hoc* approach reflected in CMS’s current waiver policy is no longer appropriate given the central nature of Advanced APMs. CMS now has extensive experience crafting waivers for ACOs and other arrangements, particularly the subset of programs that would qualify as “Advanced APMs” under the Proposed Rule.<sup>71</sup> These waivers have certain features in common:

- 1) at a minimum, they protect relationships between participants when distributing shared savings (and may also waive “pre-participation” relationships undertaken in contemplation of entering a model);
- 2) they require bona fide participation in an APM as evidenced by a participation agreement, under which the ACO or other responsible entity remains in good standing; and
- 3) they require documentation of a bona fide determination by an ACO or other responsible entity’s governing body that the arrangement is reasonably related to program goals.

Although we recognize that the details of these waivers as applied to a given program may require some adjustment to account for applicable safeguards, CMS has already developed a durable framework for a uniform and predictable waiver policy.

***Accordingly, we ask CMS to create a single, comprehensive waiver of the Stark Law as a rule published in the Code of Federal Regulations for participants in any bona fide APMs as defined by the Proposed Rule.***

## 2. CMS Should Create an Exception to the Stark Law for Other Payer Advanced APMs.

Under MACRA, Congress clearly meant to transform healthcare beyond the narrow Medicare context. This is why participants in APMs may satisfy the QP eligibility standards beginning in the 2021 payment year (the 2019 performance year) by using an all-payer metric that reflects participation in non-Medicare APMs.<sup>72</sup> But participation in non-Medicare models raises its own set of concerns under the Stark Law, because payments under these models may be treated as “financial relationships” under the law. As a result, the distribution of shared savings, incentive payments, and the provision of infrastructure necessary to earn *non-Medicare* bonuses will also raise concerns under the

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<sup>69</sup> *Id.* at 28298.

<sup>70</sup> *Id.* at 28304-9.

<sup>71</sup> Of relevance to urology, these are the MSSP Tracks Two and Three and the Next Generation ACO program, each of which has received a Stark Law waiver under relevant statutory authority.

<sup>72</sup> 42 U.S.C. § 1395L(z)(2)(B).

Stark Law. Moreover, many of the Stark Law exceptions prohibit remuneration that reflects “other business generated” between a DHS entity and a physician, which may include private pay or Medicaid business.<sup>73</sup>

CMS only possesses the authority to waive the Stark Law for the MSSP and CMMI models, which arguably do not reach innovative payment arrangements developed entirely outside Medicare.<sup>74</sup> However, CMS possesses general regulatory authority to craft new exceptions, as long as they pose “no risk of program or patient abuse.”<sup>75</sup> The Agency has previously exercised this authority to create some of the most important Stark Law exceptions, including the general exception for “fair market value” arrangements.<sup>76</sup> And, in the six years since passage of the Affordable Care Act, CMS has gained substantial experience with developing a meaningful fraud and abuse framework for the distribution of shared savings through the waiver models. That experience, coupled with the detailed standards in the Proposed Rule for non-Medicare Other Payer Advanced APMs,<sup>77</sup> should give CMS the confidence that it can develop a workable exception posing “no risk of program or patient abuse.” Moreover, the Proposed Rule’s substantial focus on Other Payer Advanced APMs strongly suggests that CMS intends to protect participation in this kind of model to the same degree that MSSP or CMMI programs are protected.

***Accordingly, CMS should exercise its general authority to develop regulatory exceptions to extend the protections of the ACO waivers to physicians and DHS entities that participate in Other Payer APMs.***

### **C. CMS Should Reconsider Rules for Services Provided “Under Arrangements” to Facilitate Coordinated Care.**

MACRA’s overall focus on management of the total cost of care (without regard to the site of service) creates enormous pressure for entities across various sites of service to collaborate with one another. However, regulatory changes to the Stark Law in recent years have made it more difficult for entities—particularly independent physician practices and hospitals—to offer services jointly that are not feasible for a single entity to operate. Most importantly, CMS’s changes to the definition of a “DHS entity” in 2008 either prohibited or greatly complicated “under arrangements” relationships in which a hospital and physician group jointly operates a service that neither could provide on its own. Following the rulemaking, physicians and hospitals were forced either to unwind

<sup>73</sup> See e.g., the exceptions for the rental of office space at 42 C.F.R. § 411.357(a)(5)(i), lease of equipment at 411.357(b)(4)(i), personal service arrangements at 411.357(d)(1)(v), physician recruitment at 411.357(e)(1)(iii), isolated transactions at 411.357(f)(1)(ii), arrangements with hospitals that are unrelated to DHS at 411.357(g)(3), “under arrangements” relationships with a hospital at 411.357(h)(5), nonmonetary compensation at 411.357(k)(1)(i), fair market value compensation at 411.357(l)(3), medical staff incidental benefits at 411.357(m)(1), indirect compensation arrangements at 411.357(p)(1)(i). This is an incomplete list representing the most commonly used compensation exceptions.

<sup>74</sup> 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1).

<sup>75</sup> 42 U.S.C. § 1395nn(b)(4).

<sup>76</sup> 42 C.F.R. § 411.357(l).

<sup>77</sup> 81 Fed. Reg. at 28330-4.

many of these relationships, including services that may have otherwise not been available, or to restructure these arrangements so as to comply with the new regulations. Compliance with the regulations generally restricts the degree of potential coordination that may be achieved (for example, by severely limiting the services provided by a joint-ventured entity so that it does not “perform” the DHS).

In the “under arrangements” context, a physician-owned entity enters into an arrangement (including a joint venture) with a hospital to provide medically necessary services to patients. CMS’s revised definition of the term “entity” required physicians to meet a Stark law ownership exception (which are extremely narrow) to continue to provide such services.<sup>78</sup> The ability to provide a full spectrum of services to patients is a core part of achieving the “triple aim” of enhanced population health, improved patient experience, and reduced per capita cost, particularly where a physician group is providing capital to support core services for a safety net system. Reasonable collaboration between a hospital and physician group should be encouraged if such collaboration serves to (a) ensure necessary services are available to avoid readmissions; (b) increase quality; (c) ease transitions between sites-of-service; or (d) provide more integrated care.

“Under arrangements” models can play an essential role to achieve the kind of close collaboration incentivized by MACRA. These models allow hospitals and physicians to negotiate clear, written rules surrounding the joint operation of a medically necessary service that would otherwise be impractical for either to offer on its own. In this way, a properly constructed, arms-length “under arrangements” model is *more* consistent with the policy rationale of the Stark Law than the kinds of vertically integrated hospital models that have flourished (often at the expense independent specialty care models) since CMS revised the definition of “entity.” For example, under the terms of the *bona fide* employment exception to the Stark Law, hospitals may pay employed physicians a bonus based on their productivity and may condition the physician’s employment on referrals within the hospital’s clinical network,<sup>79</sup> creating *de facto* compensation for DHS referrals.

Enhancing the ability for physician groups to create alternate payment methodologies in collaboration with hospitals will allow them to remain independent of the hospital. This is particularly relevant as:

1. Independent physician specialty practices provide high-quality, cost-efficient care to a wide range of patients, including in underserved and rural communities;
2. Independent specialty practices (such as LUGPA member group practices) reduce healthcare costs and represent competition to increasingly-consolidated hospital systems,<sup>80</sup> as evidenced by data demonstrating that healthcare costs increase

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<sup>78</sup> “Entity,” 42 C.F.R. § 411.351. See also 73 Fed. Reg. 48434, 48721.

<sup>79</sup> 42 C.F.R. § 411.357(c) and 42 C.F.R. § 411.354(d).

<sup>80</sup> David M. Cutler, Ph.D. and Fiona Scott Morton, Ph.D., Hospitals, Market Share, and Consolidation, 310(18) JAMA 1964 (November 13, 2013)

- significantly when physician groups are acquired by hospitals and even more dramatically when physician groups are acquired by hospital systems;<sup>81</sup> and
3. Perhaps most relevant to future payment paradigms, independent physician groups have been shown to provide higher quality and lower cost care in Medicare risk sharing arrangements when compared to those provided in hospital-based settings. These cost savings were as much as 35% for DHS services such as radiation therapy as well as for Part-B drugs when these services were performed in the independent group practice setting.<sup>82</sup>

*Accordingly, CMS should either amend the definition of “entity” or use its exception authority to clarify that bona fide “under arrangement” relationships designed to achieve a MIPS quality metric or a CPIA are permitted under the Stark Law.*

## **VII. Request for CMS Action**

We thank CMS for the substantial work that went into developing the Proposed Rule. Our comments are intended to assist the Agency in ensuring that MACRA implementation enables physicians—regardless of specialty and site of service—to participate in value-based payment structures for the benefit of our patients. As a brief summary, our principal recommendations are that the Agency:

- With respect to Advanced APM processes:
  - Change the CMMI model approval process to increase efficiency and provide greater certainty and transparency to group practices proposing APMs.
  - Clarify that an APM can use specialty-focused, rather than total Medicare, costs as the benchmark (subject to other Medicare program rules).
  - Clarify that an APM may meet the “nominal risk” standard with respect to a clinically relevant subset of Medicare enrollees.
  - Use the CMMI waiver to allow a transition period for providers to become QPs more easily for models that begin after 2017.
- With respect to MIPS reporting:
  - Work with urologists in independent practice to develop more meaningful cross-cutting measures and CPIAs for independent urology practice.
  - Exclude cross-cutting measures from the “topping out” rules.
  - Refrain from use of USPSTF recommendations in constructing quality measures until such time that specialty physicians are afforded the opportunity to substantively participate in the crafting of such recommendations.
- With respect to resource use:

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<sup>81</sup> Robinson JC, Kelly Miller K. Total expenditures per patient in hospital-owned and physician-owned physician organizations in California. *JAMA* 312.16 (2014): 1663-1669.

<sup>82</sup> McWilliams JM, Chernew ME, Zaslavsky AM, et al. Delivery system integration and health care spending and quality for Medicare beneficiaries. (2013) *JAMA internal medicine*, 173(15), 1447-1456.

- Clarify how patients would be attributed to single-specialty practices in light of patient relationship codes.
- Establish care episode groups that may be triggered by ASC or in-office services.
- Withhold inclusion of Part D expenditures in the Agency's calculation of resource use.
- Modernize the Stark Law through CMS's regulatory authority by:
  - Allowing group practices to distribute profits and productivity bonuses on the basis of activities designed to achieve MIPS or APM goals.
  - Creating a single comprehensive waiver for Advanced APMs.
  - Creating an exception for Other Payer Advanced APMs.
  - Allowing limited "under arrangements" joint ventures where tied to MIPS or APM goals.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Rule and we stand ready to assist CMS as it works to achieve the goals of MACRA. Please feel free to contact Dr. Kapoor at (516) 342-8170 or dkapoor@impplc.com, or Howard Rubin at (202) 625-3534 or howard.rubin@kattenlaw.com, if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



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