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BY ELECTRONIC SUBMISSION

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Room 5512, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: Comments to OIG-0803-N

Dear Ms. Edwards:

On behalf of LUGPA, we thank you for the opportunity to comment on the Request for Information ("RFI") Regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty.[1] We appreciate the seriousness with which the U.S. Department of Health and Human Services ("HHS") is responding to the need to modernize our country's health care fraud and abuse laws. We agree that HHS will not be able to achieve its goal of "transform[ing] the healthcare system into one that pays for value,"[2] unless the statutory and regulatory provisions that act as barriers to coordinated care are addressed. In fact, we testified alongside Deputy Secretary Hargan on this exact issue in July 2018 before the House Ways & Means Subcommittee on Health, noting the critical importance of modernizing fraud and abuse laws to promote the transition from fee-for-service to value-based care in the Medicare program and in our healthcare system more broadly.[3]

In this RFI, the Office of Inspector General ("OIG") is properly focusing on many of the same issues that the Centers for Medicare and Medicaid Services ("CMS") focused on in its RFI relating to modernization of the federal physician self-referral ("Stark") law.[4] As OIG noted, there is a clear intersection between the Stark law with its strict liability standard and the Anti-Kickback Statute ("AKS") and its "knowing and willful standard."[5] Congress created both laws decades ago in response to the risk for abuse in a fee-for-service payment system—a fundamentally

[1] 83 Fed. Reg. 43607 (Aug. 27, 2018).
[2] Id. at 43608.
[3] Testimony of Dr. Gary Kirsh, LUGPA Immediate Past President & Chair of LUGPA Alternative Payment Model Task Force, Hearing before the U.S. House of Representatives Ways and Means Subcommittee on Health, "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program" (July 17, 2018) ("LUGPA Cong. Testimony").
[4] 83 Fed. Reg. 29524 (June 25, 2018).
[5] 83 Fed. Reg. at 43611.

different structure than the one that a bipartisan Congress created through the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA").[6] MACRA demands care coordination across sites of service and the development of value-based care delivery models; and, yet, our fraud and abuse laws were not updated in MACRA or since its passage.

Given how critical these issues are to the continued viability of independent urology (and other specialty) practices, we submitted comments to CMS in response to its RFI on Stark reform[7] and submit comments now to OIG in response to this RFI. Much like with the Stark law, targeted changes to the AKS need to be made through modification of existing safe harbors and/or creation of new safe harbors, to allow for the development and operation of innovative care delivery systems—across medical specialties and sites of service—that will improve outcomes and decrease cost. These reforms are especially critical, given that violations of the AKS can give rise to civil, criminal and administrative penalties,[8] and can serve as the basis for a violation of the False Claims Act[9] that, in turn, can trigger civil damages and administrative penalties that could bankrupt a medical practice. Although certain changes to the Stark law and AKS will need to occur through legislation such as the bipartisan Medicare Care Coordination Improvement Act of 2017,[10] we believe that OIG can make meaningful modifications to the AKS through its existing regulatory authority.

Although, the AKS has a "knowing and willful" standard, unlike Stark's strict liability test, the penalties are much more severe and can be both civil and criminal.

We agree with OIG that an analysis of whether (and how) to modify the AKS should begin with an examination of specific care delivery models that are adversely impacted by the law. Accordingly, in Part I, we provide concrete examples of alternative payment models ("APMs") and other novel financial arrangements that LUGPA member practices have developed and wish to develop in the future. We believe that these examples are the types of value-based arrangements that Congress envisioned when it passed MACRA, but the potential arrangements have hit a roadblock in the form of outdated aspects of the AKS (under OIG's jurisdiction) and the Stark law (under CMS's jurisdiction). In Part II, we discuss the targeted changes to the AKS that are needed to ensure that independent, integrated specialty practices can continue delivering high quality, coordinated care in the post-fee-for-service era.

As we present in more detail below (and as a complement to the proposals we presented to CMS in connection with modernizing the Stark law), LUGPA recommends that OIG take the following steps to modernize the AKS:

- Create a single, comprehensive waiver of the AKS as a rule published in the Code of Federal Regulations for participants in any bona fide APM;
- Create a new safe harbor under the AKS that would encourage the development and protect the operation of APMs and other value-based payment arrangements and clarify how existing safe harbors may be applied to APMs involving independent specialty practices;

[6] Pub. L. 114-10, enacted April 16, 2015.
[7] See Comment Letter from LUGPA President Neal D. Shore, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Administrator Seema Verma, CMS-1720-NC (Aug. 24, 2018).
[8] 42 U.S.C. § 1320a-7b.
[9] 31 U.S.C. § 3729.
[10] S. 2051 & H.R. 4206, 115th Congress (2017-2018).

- Create a new safe harbor under the AKS that would protect arrangements that support patient adherence to a treatment regimen that has been recommended by the patient's health care provider; and
- Support passage of the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for aligning the reform of the AKS and Stark law.

CMS Administrator Verma's remarks regarding modification of the Stark law apply with equal force to OIG's consideration of changes to the AKS: we must "leave in place the law's important protections for our beneficiaries—and for the trust fund—while not penalizing providers who are taking brave steps away from fee-for-service."[11] LUGPA member practices are taking those steps and look forward to working with OIG, CMS, HHS, and Congress to help develop responsible reforms to health care fraud and abuse laws, including the AKS and Stark law, to remove roadblocks to the development of value-based care models.

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.[12]

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.

LUGPA and its member practices were early proponents of the shift from fee-for-service to value-based payment models and, since passage of MACRA, we have been advocating for targeted reforms of health

[11] Remarks by CMS Administrator Seema Verma at the American Hospital Association Annual Membership Meeting, Washington DC (May 7, 2018), available at https://www.cms.gov/newsroom/fact-sheets/speech-remarks-cms-administrator-seema-verma-american-hospital-association-annual-membership-meeting.

[12] 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.

care fraud and abuse laws that are critical to MACRA's success. Specifically, we have (i) submitted comments in response to Congressional and Agency inquiries on the topic;[13] (ii) spearheaded support in the medical community for the Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206), which has been endorsed by 25 physician organizations representing 500,000 doctors;[14] and (iii) testified in Congress on the subject of modernizing health care fraud and abuse laws to support value-based care delivery models.[15] In short, we have been highly engaged on the important issues on which OIG has sought comment in the RFI.

II. LUGPA Member Practices Are at the Forefront of Developing the Types of APMs and Other Value-Based, Coordinated Care Models Contemplated by MACRA.

Much like the Stark law, the AKS[16] has not kept pace with the evolution of care delivery models and payment paradigms established since passage of MACRA more than three years ago. The lack of modifications to these laws has been particularly harmful to independent specialty practices and the patients we serve. The need for reform is evident as studies are confirming that independent practices are commonly the highest value site-of-service. In this Part I, we briefly summarize why it is so important for OIG to promote the role of independent practices in value-based care delivery and then, in response to OIG's request,[17] we set forth specific examples of APMs and other novel financial arrangements that LUGPA member practices are "designing to promote care coordination and value" for the benefit of our patients and the Medicare program.

A. Independent Specialty Practices Play an Important and Unique Role in the American Healthcare System.

Protecting the independent practice model is critical to the continued viability of our healthcare system, generally, and the Medicare program, in particular, as this provides an important counterbalance to less convenient, more expensive hospital-based care. First, physicians in LUGPA's member practices and other independent physician specialty practices provide high quality, cost-efficient care to a wide range of patients, including in underserved and rural communities. Second, these practices reduce healthcare costs and represent competition to increasingly consolidated hospital systems,[18] as evidenced by data demonstrating that healthcare costs increase significantly when physician groups are acquired by hospitals

[13] See, e.g., Comment Letter from LUGPA President Gary M. Kirsh, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to The Honorable Orrin G. Hatch, Chairman, U.S. Senate Committee on Finance and The Honorable Kevin Brady, Chairman, U.S. House of Representatives Committee on Ways and Means, "Modernizing the Stark Law" (Jan. 29, 2016); Comment Letter from LUGPA President Gary M. Kirsh, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Acting Administrator Andrew Slavitt, CMS-5517-P (June 27, 2016) pp. 15-21; Comment Letter from LUGPA President Gary M. Kirsh, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Acting Administrator Andrew Slavitt, CMS-1631-P (Sept. 8, 2015) pp. 14-21.

[14] See Letter from American Medical Association, LUGPA and 22 other national medical societies to The Honorable Robert J. Porman and The Honorable Michael F. Bennett in Support of S. 2051 (Nov 1. 2017); Letter from American Medical Association, LUGPA and 22 other national medical societies to The Honorable Larry Buschon, MD, The Honorable Raul Ruiz, MD, The Honorable Kenny Marchant, The Honorable Ron Kind in Support of H.R. 4206 (Nov 1. 2017).

[15] LUGPA Cong. Testimony, supra n.3.

[16] 42 U.S.C. § 1320a-7b.

[17] 83 Fed. Reg. at 43609.

[18] See e.g., David M. Cutler, Ph.D. and Fiona Scott Morton, Ph.D., Hospitals, Market Share, and Consolidation, 310(18) JAMA 1964 (November 13, 2013); 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.

and even more dramatically when physician groups are acquired by hospital systems.[19] Third, and perhaps most relevant to payment paradigms in a post-fee-for-service era, independent physician groups have been shown to provide higher quality and lower cost care in Medicare risk-sharing arrangements when compared to care provided in hospital-based settings.[20]

In an era in which cost savings and value-based care are increasingly vital considerations, one might predict that independent physician specialty practices would be at the heart of innovative care models. Unfortunately, this is not the case, with ACOs and other integrated care systems lagging in their inclusion of physician specialists.[21] This is not surprising given the fact that waivers of health care fraud and abuse laws since passage of the Affordable Care Act and MACRA have focused on hospitals, health systems and primary care. As a result, physicians in private practice have been stymied in their ability to achieve MACRA's goals of care coordination, quality improvement and resource conservation outside of formal ACOs. Recent research indicates that, since 2012, the number of hospital-employed physicians increased by 50 percent.[22] Without targeted changes to the AKS and Stark law that will facilitate the development and operation of value-based care models across sites of service, the trend of physicians being driven out of independent practice and into the higher-cost hospital setting will continue and, almost certainly, worsen.

B. Medicare Beneficiaries and the Healthcare System Will Benefit Significantly from the APMs and Other Novel Financial Arrangements Being Developed by Independent Urology Practices.

LUGPA member practices are working on behalf of their patients to develop innovative care delivery models. The problem, however, is that much of these efforts cannot be operationalized unless and until certain modifications are made to the AKS and Stark law. And while the Secretary can provide waivers on a case-by-case basis for *approved* APMs, organizations wishing to engage in APM development find themselves in a proverbial Catch-22: they cannot test an APM in the real world without waivers, yet these waivers cannot be granted unless there is an approved APM. Organizations may spend months (sometimes years) of work, resources and substantial investments designing an APM, but it remains a theoretical, mathematical model whose impact on actual patient care and healthcare financing is unknown without testing in the clinical environment.

For the benefit of our patients, LUGPA's member practices are eager to move from the theoretical to the practical. Doing so is exactly what the architects of MACRA expected of us and, yet, we remain thwarted by the looming threat of criminal liability and crushing financial penalties under the AKS that have not been modified in response to the evolution of our health care delivery system. The following examples—culled from many submissions provided by LUGPA practices—illustrate how modernizing the AKS and

[19] 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.

[20] 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 (identifying cost savings of 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).

[21] John W. Peabody and Xiaoyan Huang, A Role for Specialists in Resuscitating Accountable Care Organizations, Harvard Business Review (November 5, 2013), available at: https://hbr.org/2013/11/specialists-can-help-resuscitate-accountable-care-organizations/.

[22] Physicians Advocacy Institute. Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012-2016. Accessed at: http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/2016-PAI-Physician-Employment-Study-Final.pdf.

Stark law with respect to APMs and other novel financial arrangements will benefit Medicare beneficiaries (and other patients).

1. A LUGPA practice in the Northeast was unable to develop an episode of care that would reduce infectious complications from 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. Episodes of care surrounding prostate biopsy would be an excellent opportunity for APM development because significant savings and improved patient care can be achieved by minimizing infections, which are all too common. This episode could include professional services, facility fees, anatomic pathology services, and imaging services across multiple sites of service. In addition, expanding the prostate biopsy bundle to include total cost of care for a period of two-to-four weeks after the biopsy would allow for shared savings between hospitals and providers to develop cooperatively protocols to reduce episodes of sepsis after prostate biopsy. This is a particularly worthy goal, given that the advent of more virulent, multi-drug resistant organisms has led to concerns that, internationally, these infection rates are increasing.[23]

The cost savings associated with such a prostate bundle could be significant. 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[24] to as high as $94,737 per episode in patients who had prior antibiotic exposure in the prior 90 days.[25] The rate of infection after prostate biopsy is reported to be as high as 4.1%,[26] and the most recent Medicare data shows that urologists performed 111,905 prostate biopsies in 2016.[27] Given this data, Medicare expenditures to manage this complication could exceed $250 million annually.[28]

The LUGPA practice referenced above developed a care pathway that would reduce average costs of prostate biopsy episode of care by nearly 70%; however, the practice found that there exists no mechanism to distribute shared savings from this model in a logical—and compliant—fashion that avoids risk under the AKS's criminal liability provisions prohibiting individuals or entities that knowingly or willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under Federal health care programs. In particular, a prostate biopsy episode of care could involve care coordination—and the related distribution of shared savings—across multiple entities (and referral sources) such as a urology group practice, a free-standing pathology lab, and a free-standing imaging facility. After legal review, attempts to create this care model were abandoned as impermissible.

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[23] 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.

[24] 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.

[25] 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.

[26] Averch T, Tessier C, Clemens JQ et al. AUA Quality Improvement Summit 2014: Conference Proceedings on Infectious Complications of Transrectal Prostate Needle Biopsy. Urol. Pract. 2015 July; 2(4):172-80.

[27] 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

[28] A 4.1% rate of infectious complications requiring hospitalization for 111,905 prostate biopsies yields 4,588 inpatient stays to manage this issue. The average of the high ($94,737) and low ($16,103) costs to manage an episode of septicemia is $55,420. The product of this average ($55,420) and projected number of inpatient stays (4,588) yields $254.3 million in average potential expenditures.

2. A LUGPA practice in the Mid-Atlantic was unable to development a radiation oncology joint venture with hospitals systems.

About two-thirds of all cancer patients undergo radiation therapy at some point during the course of their disease.[29] Data suggests that, nationally, there is broad variation in the administration of radiation therapy; factors unrelated to the individual patient account for the majority of such variations in the cost of radiation therapy, indicating potential inefficiency in health care expenditure.[30] Given this, communities would be better served through consolidation and elimination of unnecessary, expensive services. Part of this strategy ideally involves a variety of stakeholders, each of which could participate in such a model in a value-based ecosystem.

With the intent of preventing oversaturation of services, the practice entered good faith negotiations with a regional hospital system to develop a radiation joint venture that would have created clinical pathways, outcome measures and management relationships that would have lowered overall costs for radiation. The hospital system could not remunerate the practice for those efforts or develop an appropriate distribution of shared savings without potentially running afoul of the AKS. Despite the opportunity to achieve better outcomes, improve adherence to clinical pathways and lower cost, the project was abandoned.

3. A LUGPA practice in the Southeast was thwarted from collaborating in a virtual group setting.

There is ample data supporting the notion that vertical integration of physicians and hospitals increase cost without any commensurate increase in quality.[31] Indeed, the probability of system abuse is so high that one researcher suggested that these arrangements "facilitate the payment of what are effectively kickbacks for inappropriate referrals."[32] This can result in devastating costs to patients through increased deductible and co-insurance payments.

The Southeastern market in which this LUGPA practice furnishes care contains five hospital systems providing care to patients with two of these hospitals controlling the vast majority of patient lives. Over 90% of physicians in this market are employed by the hospitals. Not only are internal referrals for higher-cost services within the hospital network encouraged, hospital-employed physicians risk financial penalties if they refer patients for services outside of the system network, even if those services can be delivered more conveniently and at a lower cost in a non-hospital setting. In an effort to remedy this serious problem, a group of physicians who were not employed by the hospitals sought to align services by forming a virtual group for reporting under the Merit-Based Incentive Payment System ("MIPS").[33] Although CMS has encouraged the formation of virtual groups through recent rulemaking, including among individual physician specialists and specialty group practices, no provision was made for the creation of financial risk-sharing models within these groups. The upside gain in MIPS reporting did not cover the administrative costs of developing clinical pathways and reporting mechanisms, nor did it outweigh the risk of potentially crippling liability under the AKS that could attach to the distribution of shared savings achieved through

[29] Yamada Y. Cancer Rehabilitation: Principles and Practice 2009 New York, NY Demos Medical Publishing.
[30] Paravati AJ, Boero IJ, Triplett DP, et al. Variation in the Cost of Radiation Therapy Among Medicare Patients With Cancer. J Oncol Pract. 2015 Sep; 11(5):403-9.
[31] Post B, Buchmueller T, Ryan AM. Vertical Integration of Hospitals and Physicians: Economic Theory and Empirical Evidence on Spending and Quality. Med Care Res Rev. 2018 Aug; 75(4):399-433.
[32] Baker LC, Bundorf MK, Kessler DP. Vertical integration: hospital ownership of physician practices is associated with higher prices and spending. Health Aff (Millwood). 2014 May; 33(5):756-63.
[33] 82 Fed. Reg. at 30027-34.

greater care coordination. As a result, the attempt to create an economically viable competitive counterbalance to the dominant hospital systems in the region failed.

4. A LUGPA practice in the Northeast faces challenges in coordinating service lines across specialties.

Data illustrating the trend towards increased acquisition of physician practices by hospitals[34] belie statistics suggesting that hospitals lose an average of $128,000 per employed physician.[35] Indeed, these losses have been described as "an artifact of accounting, because hospitals frequently do not attribute any bonus for meeting 'value-based' contract targets, or incremental hospital surgical, imaging, and lab revenues to physician practice income."[36] This ability to cost shift physician compensation affords hospitals an often insurmountable competitive advantage in recruiting physicians which can lead to virtual monopolies in healthcare services. Measurement of the Herfindahl-Hirschman Index data suggests that this market share domination can vary widely by specialty.[37]

An integrated urology group practice in a market where the majority of community-based breast surgeons were being acquired by hospitals sought to provide an opportunity for the few remaining non-aligned breast specialists to remain independent. Unfortunately, given the reduction in surgical fees, the professional reimbursement for these surgeons did not approach the compensation package offered by the local hospital systems. The urology practice had integrated radiation oncology services but offers neither advanced imaging nor chemotherapy service; all four of these services (surgical oncology, medical oncology, radiation oncology and diagnostic imaging) are essential to development of a fully integrated breast cancer center of excellence. The urology group sought to partner with medical oncologists and radiologists to create a joint venture specifically to create such a breast cancer center of excellence. However, this integration, which would have allowed the breast surgeons to continue to utilize vastly less expensive services, was thwarted, in part, by the difficulty in creating a legal structure that would be fully compliant with the AKS. After six months of expensive legal research, which did not result in a viable proposal, the breast surgeons commenced soliciting offers from hospitals.

5. A Western LUGPA practice cannot create practice efficiencies in a hospital outpatient surgical department.

There exists substantial price disparities between ambulatory surgical centers ("ASCs") and both inpatient and outpatient hospital departments.[38] This has led to an increased number of ASCs and a concomitant

[34] Physicians Advocacy Institute. Op. Cit. p 8.
[35] MGMA Cost Survey: 2016 Report Based on 2015 Data. Accessed at: https://www.mgma.com/resources/products/mgma-2016-practice-operations-report.
[36] Goldsmith J, Hunter A, Strauss, A. Do Most Hospitals Benefit from Directly Employing Physicians? Harvard Business Review; May 29, 2018. Accessed at: https://hbr.org/2018/05/do-most-hospitals-benefit-from-directly-employing-physicians.
[37] Capps C, Dranove D, Ody C. The effect of hospital acquisitions of physician practices on prices and spending. J Health Econ. 2018 May; 59:139-152.
[38] Commercial Insurance Cost Savings in Ambulatory Surgery Centers. Prepared by Healthcare Bluebook for the Ambulatory Surgical Center Association. Accessed at: https://www.healthcarebluebook.com/explore-downloads/ascsavings.pdf.

increase in the number of procedures performed at this site of service,[39] a trend observed as well in the urology space.[40]

A LUGPA practice with close ties to a local community hospital sought to develop an agreement whereby the urologists would manage the cost of the urology surgical suites. Pathways were to be put in place to standardize selection and monitor utilization of supplies within the operating room. Additional quality and efficiency metrics were developed including measurement of operating room turnover time, monitoring of surgical infection and hospital admission rates as well as tracking patient satisfaction. Cost savings that resulted from this program were to be utilized to help the hospital negotiate more competitively with ASCs while simultaneously creating shared savings that could be used to attract additional providers to bring cases to the facility. Despite extensive background work, the urology group and hospital were unable to implement the proposal due to compliance concerns arising under the AKS.

III. The Anti-Kickback Statute Requires Targeted Changes to Protect Independent Specialty Practices that Seek to Deliver High Quality, Coordinated Care in a Value-Based Payment System.

A. The Criminal and Civil Liability that Attach to Violations of the Anti-Kickback Statute Stifle Innovation.

The risk of criminal and civil liability under the AKS is arguably the single greatest barrier to independent urology (and other specialty) practices achieving MACRA's dual goals of coordinated and value-based care. The AKS makes it a criminal and civil offense for a person to "knowingly and willfully solicit[] or receive[] *any remuneration*…directly or indirectly, overtly or covertly, in cash or in kind…in return for referring an individual to a person" for the furnishing of any service paid for under a federal health care program.[41] The AKS is violated even if the remuneration was provided only in part to induce referrals.[42] In addition, a violation of the AKS can trigger a violation of the False Claims Act ("FCA"), which imposes civil penalties on any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[43]

Damages and penalties for violating the AKS and FCA can be severe. The AKS has criminal penalties that provide for fines up to $25,000 and/or imprisonment for up to five years,[44] and civil penalties of $10,000 to $50,000 per instance of unlawful remuneration and referral, plus up to three times the amount of kickback paid, and exclusion from Federal health care programs.[45] For its part, the FCA provides for civil penalties of $5,500 to $21,500 per false or fraudulent request or demand for payment, plus up to three times the amount of damages sustained by the government.[46] The FCA damages provisions can add up to staggering amounts, even for modest violations. For example, if an entity submits 50 false claims totaling

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[39] Dyrda L. 16 financial and operational trends for ASCs. Becker's ASC Review, May 2, 2017. Accessed at: https://www.beckersasc.com/asc-turnarounds-ideas-to-improve-performance/16-financial-and-operational-trends-for-ascs.html.

[40] Patel H, Matlaga B, Ziemba J. Trends in the Setting and Cost of Ambulatory Urological Surgery: An Analysis of Five States in the Healthcare Cost and Utilization Project J Urol 2018; 199(4) sup, p. e1022.

[41] 42 U.S.C. § 1320a-7b(b)(1) (emphasis added); *see also id.* § 1320a-7a(7).

[42] United States v. Borrasi, 639 F.3d 774, 782 (7th Cir. 2011); United States v. LaHue, 261 F.3d 993, 1003 (10th Cir. 2001).

[43] 31 U.S.C. § 3729(a)(1)(B).

[44] 42 U.S.C. § 1320a-7b(b).

[45] Id. § 1320a-7a(a).

[46] 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5 (increasing the per-claim penalties to $11,000-21,563 for violations that occurred after Nov. 2, 2015).

$50,000, that entity could be liable for up to $150,000 (triple damages on the $50,000 in false claims) plus $275,000 to $1,075,000 in per violation penalties ($5,500 to $21,500 for each of the 50 false claims submitted).

In short, the threat of criminal and civil penalties that attach to violations of the AKS and FCA is paralyzing. On the one hand, MACRA demands that independent urology practices share resources and coordinate care with potential referral sources across different sites of serve and, yet, such efforts expose these practices to company-ending criminal and civil liability.

In the face of such exposure, it is not possible for HHS to achieve its goal of "foster[ing] arrangements that would promote care coordination and advance the delivery of value-based care,"[47] unless OIG makes targeted changes to the AKS. HHS Deputy Secretary Hargan recognized the seriousness of the issue in recent Congressional testimony when he noted that it is critical that health care fraud and abuse laws "aren't strangling innovation and new models of care that will be for the benefit of the American people."[48]

As a practical matter, however, that is precisely what is happening. More than three years beyond passage of MACRA, barriers to clinical and financial integration posed by the AKS (and the Stark law) are proving more onerous than originally perceived, and the vision of MACRA and value-based care delivery is in jeopardy. According to CMS, currently only five percent of physicians are even participating in an APM. More troubling, there are almost no APMs in the pipeline. In the two-and-a-half years that the Physician-Focused Payment Model Technical Advisory Committee ("PTAC") has been operational, only 26 APMs have been submitted for review. Of these 26 submissions, only four have been recommended for implementation and six for limited scale testing. Moreover, not a single PTAC-recommended APM has been enacted by CMS. This past summer, PTAC cancelled its meeting for lack of submitted APM proposals. Although there are many factors contributing to the lack of APM submissions and approvals, there is no question that the risk of criminal liability under the AKS,[49] the risk of civil monetary penalties,[50] and the risk of exclusion from federal health care programs and liability under the FCA[51] are paralyzing for independent specialty practices seeking to participate in APMs and other value-based payment arrangements.

Fortunately, Congress created a mechanism through which OIG can create safe harbors under the AKS as a set of "evolving rules that would be updated periodically to reflect changing business practices and technologies in the health care industry."[52] These discrete modifications to the AKS, when combined with targeted regulatory and legislative changes to the Stark law,[53] will allow for the development of arrangements between providers to share resources and create referral pathways that enable the distribution of shared savings across health care entities.

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[47] 83 Fed. Reg. at 43608.
[48] See Testimony of HHS Deputy Secretary Eric Hargan, Hearing before the U.S. House of Representatives Ways and Means Subcommittee on Health, "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program" (July 17, 2018).
[49] 42 U.S.C. § 1320a-7b.
[50] Id. §1320a-7a.
[51] Id. § 1320a-7b; 31 U.S.C. § 3729-33.
[52] 83 Fed. Reg. at 43608, citing H.R. Rep. No. 100-85, Pt. 2, at 27 (1987).
[53] See Comment Letter from LUGPA President Neal D. Shore, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to CMS Administrator Seema Verma, CMS-1720-NC (Aug. 24, 2018), pp. 17-18.

B. OIG Should Exercise its Regulatory Authority to Establish a Single, Comprehensive Waiver of the AKS for Participants in APMs that Adopts the Same Flexible Approach Used in the ACO Waivers or, at a Minimum, Create a New Safe Harbor Under the AKS that Would Encourage the Development and Protect the Operation of APMs and Other Value-Based Payment Arrangements.

A healthcare marketplace in which all or most physicians are effectively *required* to accept risk and closely collaborate with hospitals and other health care entities will be difficult to sustain under the AKS's existing safe harbors. It is inappropriate for physician specialists caring for Medicare beneficiaries in independent medical practices to face burdens in this new post-FFS payment system that OIG has eliminated—through the grant of broad waivers and other regulatory flexibility—for primary care physicians and hospitals.

Currently, the most common Medicare APMs are ACOs. However, existing ACO models are effectively closed to physician specialists 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. Consequently, only 30 percent of ACOs are physician-only and, of these, almost all are primary care.[54] As we showed in Part I(B) above, LUGPA and its member practices have been developing potential APM models and other novel financial arrangements that would provide meaningful opportunities for urologists and other physicians to collaborate across sites of service in order to improve care delivery and reduce expenditures.

The most comprehensive effort to address the problematic nature of the AKS and Stark law is the set of waivers produced for ACOs.[55] These waivers, adopted in 2011 and recently extended, represent a significant departure from the exacting provisions of the AKS and Stark law. Simply stated, the waivers provide broad protection to physicians and entities who are participating (or intend to participate) in the Medicare Shared Savings Program ("MSSP") or certain initiatives proposed by the Center for Medicare and Medicaid Innovation ("CMMI"). These flexible waivers cover ACOs' operations (the "participation" waiver) *and* the activities of the physicians and entities preparing to join or create an ACO (the "pre-participation" waiver).[56] HHS also believed it was necessary to waive each ACO's distribution of shared savings to entities inside and outside the ACO (as long as those savings are used for activities reasonably related to the purposes of the ACO).[57]

Existing waivers, however, are of limited utility to integrated physician specialty practices because the MSSP is heavily weighted towards primary care. For example, beneficiary assignment to an MSSP ACO is determined based on where the beneficiary receives a plurality of his or her primary care services, with a preference for "primary care physicians" defined as internal medicine, general practice, family practice, and geriatric medicine.[58] Other specialties are considered only where a beneficiary has *no* primary care services furnished by any other primary care physician—whether inside or outside the ACO.[59] In addition, the set of quality metrics identified for MSSP ACOs is heavily weighted toward primary care case

[54] 2018 Medicare Shared Savings Program Fast Facts. Accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf.
[55] 76 Fed. Reg. 67992 and 79 Fed. Reg. 62356.
[56] Id. at 68000.
[57] Id. at 68001.
[58] See 42 C.F.R. § 425.402 and definition of "primary care physician" and "primary care services" at 42 C.F.R. § 425.20.
[59] Id.

management.[60] Moreover, a specialty practice that *does* serve as the basis for beneficiary assignment is forbidden from participating in another ACO.[61] In short, most independent specialty practices are unable to take full advantage of the ACO waivers authorized under the MSSP statutory authority at 42 U.SC. § 1395jjj(f).

At the time that ACO waivers were finalized in 2011, HHS noted that it would engage in extensive monitoring and consider additional program safeguards.[62] Since then, with the continued growth of ACOs, the Secretary has extended these waivers, solicited additional comment, and suggested that CMS and OIG would engage in further rulemaking.[63] In the seven years following the finalizing of the ACO waivers, these important policy changes have become fundamental parts of the healthcare payment system and represent a significant departure from the AKS's and Stark law's general prohibitions.

We believe the long tenure of the ACO waivers, their increasing incorporation into the daily practices of ACOs across the country, and the widespread familiarity they have achieved in the provider community are powerful arguments in favor of extending their protections to value-based care models developed by independent specialty practices. Moreover, despite HHS's warnings of increased monitoring, additional safeguards, and potential narrowing of the waivers, we are not aware of any significant patient or program abuse arising out of their use. Finally, we see no reason why OIG could not create the kind of tight integration between substantive program requirements and program integrity protections it achieved under the MSSP. If OIG is capable of crafting a set of policies that holistically support the full range of primary care-focused ACO business models, it should be able to expand this set of policies to facilitate the kind of far-reaching change contemplated by Congress in MACRA applicable to all physicians, regardless of specialty or site of service.

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. 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 AKS. The *ad hoc* approach reflected in OIG's current waiver policy is no longer appropriate given the integral nature of Advanced APMs to successful MACRA implementation. HHS—through OIG and CMS—now has extensive experience crafting waivers for ACOs and other arrangements, particularly for Advanced APMs. 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 an APM);
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.

[60] Centers for Medicare and Medicaid Services, "ACO Quality Metrics," available at: https://www.cms.gov /Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads /ACO-Shared-Savings-Program-Quality-Measures.pdf.
[61] See 42 C.F.R. §§ 425.402 and 425.306(b) and associated discussion in 80 Fed. Reg. 32692, 32750-32755.
[62] 76 Fed. Reg. 67992, 68008.
[63] 79 Fed. Reg. 62357.

Although we recognize that the details of these waivers as applied to a given program may require some adjustment to account for applicable safeguards, OIG has already developed a durable framework for a uniform and predictable waiver policy. Accordingly, we ask OIG to create a single, comprehensive waiver of the AKS as a rule published in the Code of Federal Regulations for participants in any bona fide APM.

While a comprehensive waiver of the AKS would be the most effective way to remove barriers to coordinated and value-based care, OIG can also exercise its regulatory authority to establish a new safe harbor for those seeking to develop and participate in APMs and other value-based payment arrangements that would shield them from prosecution or sanctions under the AKS. To be clear, we do not believe that a new safe harbor would be as effective in promoting care coordination as a broader waiver of the AKS, because the safe harbor mechanism would still require a transaction-by-transaction analysis of APMs and other value-based delivery models, including through the pursuit of costly and time-consuming advisory opinions from OIG. With that said, a new safe harbor focused on protecting participants in APMs—combined with clarification from OIG as to how existing safe harbors may be applied to APMs involving independent specialty practices—would be a positive step in support of HHS's Regulatory Sprint to Coordinated Care.

C. The Medicare Care Coordination Improvement Act of 2017 is a Critical Component of the Effort to Modernize Health Care Fraud and Abuse Laws and Is Worthy of OIG's Support.

OIG was right to take note of the "intersection" between the Stark law and AKS.[64] Just as physician practices are compelled to coordinate care across sites of service, modernizing of health care fraud and abuse laws to remove barriers to value-based care will require coordination not only between OIG and CMS, but also between HHS and Congress. We recognize that OIG and CMS have certain statutory limits to their regulatory authority to modify the AKS and Stark law, respectively, and that is why 25 diverse physician organizations—across specialties and sites of service—have endorsed the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206).[65]

We appreciate HHS's commitment to working with Congress on this legislation. Legislators across both sides of the aisle recognize—as does HHS—that physicians are unable to participate in APMs because of the barriers posed by the AKS and Stark law.[66] With respect to reform of the Stark law, Principal Deputy Administrator Kouzoukas noted during a Congressional hearing this past Spring that the concepts for Stark reform described by the lead sponsors of the Medicare Care Coordination Improvement Act are in line with similar concepts included in President Trump's FY 2019 budget.[67]

At its core, the bipartisan Medicare Care Coordination Improvement Act:

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[64] 83 Fed. Reg. at 43611.

[65] S. 2051 & H.R. 4206, 115th Congress (2017-2018), available https://www.congress.gov/bill/115th-congress/senate-bill/2051 & https://www.congress.gov/bill/115th-congress/house-bill/4206/text.

[66] See, e.g., Statements of H.R. 4206 Co-Sponsors, Rep. Kenny Marchant (R-TX) and Rep. Ron Kind (D-WI), Hearing before the U.S. House of Representatives Ways and Means Subcommittee on Health, "Implementation of MACRA's Physician Payment Policies" (March 21, 2018); see also Statement of H.R. 4206 Co-Sponsor, Rep. Larry Buschon, M.D. (R-IN), Hearing before the U.S. House of Representatives Energy & Commerce Committee, "MACRA and MIPS: An Update on the Merit-based Incentive Payment System" (July 26, 2018).

[67] Testimony of CMS Principal Deputy Administrator Demetrios Kouzoukas, Hearing before the U.S. House of Representatives Ways and Means Subcommittee on Health, "Implementation of MACRA's Physician Payment Policies" (March 21, 2018).

1. Establishes that the Secretary's waiver authority with respect to Civil Monetary Penalties and the Anti-Kickback Statute "shall apply with respect to covered APM entities to the same extent and in the same manner as such provisions apply with respect to accountable care organizations";[68]
2. Creates a new exception to the Stark law's physician ownership and compensation arrangement prohibitions designed to facilitate the development and operation of APMs so that physicians can test a proposed APM when it is submitted in writing and approved by the Secretary;[69] and
3. Expands CMS's authority to create additional exceptions to the Stark law's physician ownership and compensation arrangement prohibitions when the Secretary determines that the financial relationship does not pose a "significant risk of program or patient abuse, including those that would promote care coordination, quality improvement and resource conservation by physician practices."[70]

We believe that the Medicare Care Coordination Improvement Act is critical to the Administration's goal of "transform[ing] the healthcare system into one that pays for value."71 The Secretary cannot modify the scope of his own statutorily-created waiver authority; nor can CMS change the parameters—created by Congress—that permit CMS to add new exceptions to the Stark law. Such changes require Congressional action in the form of S. 2051 and H.R. 4206 as a complement to the steps OIG can take through its existing regulatory authority to modify and/or create new safe harbors to facilitate care coordination and support physicians' efforts to deliver better value and care to their patients.

IV. Request for Action

We thank OIG for the efforts it is making to address the impact and burden of the AKS, including the ways in which the AKS inhibits—and, in certain instances, prohibits—care coordination. Neither the AKS nor the Stark law need to be eliminated for our healthcare system to transition successfully from a fee-for-service to a value-based payment system. However, there are certain aspects of these laws that are anathema to the types of care delivery and financial models that Congress sought to unlock through MACRA. Although certain reform efforts, particularly with respect to the Stark law, will need to be achieved through legislation such as the bipartisan Medicare Care Coordination Act of 2017 (S. 2051/H.R. 4206), there are valuable steps that OIG can take, pursuant to its existing regulatory authority, to eliminate barriers to coordinated care.

As a brief summary, our principal recommendations are that OIG:

- Create a single, comprehensive waiver of the AKS as a rule published in the Code of Federal Regulations for participants in any bona fide APM;
- Create a new safe harbor under the AKS that would encourage the development and protect the operation of APMs and other value-based payment arrangements and clarify how existing safe harbors may be applied to APMs involving independent specialty practices;
- Create a new safe harbor under the AKS that would protect arrangements that support patient adherence to a treatment regimen that has been recommended by the patient's health care provider; and

[68] See H.R. 4206, Section 2(a); S. 2051, Section 2(a).
[69] See H.R. 4206, Section 2(c); S. 2051, Section 2(c).
[70] See H.R. 4206, Section 2(b); S. 2051, Section 2(b).
[71] 83 Fed. Reg. at 29524.

- Support passage of the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for aligning reform of the AKS and Stark law.

On behalf of LUGPA, we would like to thank OIG for providing us this opportunity to comment on the RFI. 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 OIG as it considers these issues.

Respectfully submitted,

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