December 31, 2019

**BY ELECTRONIC SUBMISSION**

Joanne Chiedi, Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Room 5521, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: Comments to OIG-0936-AA10-P

Dear Ms. Chiedi:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements ("AKS Proposed Rule").[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.

LUGPA agrees that HHS will not be able to achieve its goal of "transforming our healthcare system into one that pays for value,"[2] unless the statutory and regulatory provisions that act as barriers to coordinated care are addressed. The proposals that the Office of Inspector General ("OIG") has made to add new AKS safe harbors and expand existing ones, when combined with the important changes that CMS recently proposed to the Stark law,[3] are critical to advancing the transition to value-based care and improving the coordination of patient care.

LUGPA and its member practices have been championing the transition from fee-for-service to value-based care models since passage of the bipartisan Medicare Access and CHIP Reauthorization Act in 2015 ("MACRA").[4] In addition to submitting comments in response to OIG's and CMS's respective Requests for Information Regarding the AKS and Stark law, we testified alongside Deputy Secretary Hargan before the House Ways & Means Subcommittee on Health, noting the critical importance of modernizing fraud and abuse laws to promote the shift from

[1] 84 Fed. Reg. 55694 (Oct. 17, 2019).
[2] Id. at 55694.
[3] 84 Fed. Reg. 55766 (Oct. 17, 2019) (referred to herein as "Stark Proposed Rule").
[4] Pub. L. 114-10, enacted April 16, 2015.

fee-for-service to value-based care in the Medicare program and in our health care system more broadly.[5]

LUGPA appreciates that OIG and CMS coordinated with one another in developing their respective proposed rules. There is a clear intersection between the Stark law with its strict liability standard and the AKS and its "knowing and willful standard." Congress created both laws decades ago in response to the risk of abuse in a fee-for-service payment system—a fundamentally different structure than the one Congress created through MACRA. MACRA demands care coordination across sites of service and the development of value-based care delivery models; 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 are submitting comments to CMS in response to the Stark Proposed Rule at the same time we are submitting these comments in response to the AKS Proposed Rule.

We agree with OIG that targeted changes to the AKS need to be made through modification of existing safe harbors and through the 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,[6] and can serve as the basis for a violation of the False Claims Act[7] that, in turn, can trigger civil damages and administrative penalties that could bankrupt a medical practice. OIG was right to acknowledge in the Proposed Rule that the threat of such severe liability under the AKS (and the Stark law) is having a chilling effect on the development and implementation of value-based care delivery models.[8]

In a recent webinar presented by the American Bar Association, Assistant Inspector General for Legal Affairs Robert DeConti explained that OIG's threefold objective in proposing changes to the AKS is to "empower patients, facilitate care coordination, and accelerate the transition to value-based care."[9] We were particularly grateful to hear from Mr. DeConti—and to see in the AKS Proposed Rule—that the new and modified safe harbors apply equally across sites of service—whether it be a hospital or health system or an independent specialty group practice such as LUGPA's member integrated urology practices. With the cost of care continuing to skyrocket in the hospital setting, it is imperative that modifications to fraud and abuse laws protect care delivery in the high quality, lower-cost medical practice setting.

We believe that OIG's proposals for modernizing the AKS are good for patients and good for our healthcare system as a whole. In Part II, we provide OIG with concrete examples of the types of value-based arrangements that LUGPA member practices have developed—and wish to continue developing in the future—for which the new and expanded AKS safe harbors are needed. We believe that these examples are the types of value-based arrangements that Congress envisioned when it passed MACRA,

---

[5] 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").

[6] 42 U.S.C. § 1320a-7b.

[7] 31 U.S.C. § 3729.

[8] See 84 Fed. Reg. at 55695 (noting that the broad reach of the AKS and Stark law are "potentially inhibiting beneficial arrangements that would advance the transition to value-based care").

[9] Comments of Robert DeConti, Assistant Inspector General for Legal Affairs, U.S. Department of Health and Human Services Office of Inspector General, ABA Webinar, "Head Start: What you Need to Know about the Newly Proposed Anti-Kickback Statute Regulations) (Nov. 5, 2019).

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 III, we provide comments on certain of the proposed definitions of key terms that are at the heart of the proposed AKS safe harbors. In Part IV, we comment on (i) the three proposed safe harbors for protection of Value-Based Arrangements ("VBAs"), (ii) the proposed safe harbor for patient engagement, (iii) the proposed safe harbor for CMS-sponsored models, and (iv) the modifications to the existing safe harbor for personal services and management contracts. We believe that each of these proposals should be finalized with limited modifications.

## I. LUGPA

In 2008, when physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the purpose of enhancing communication between large urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 154 urology group practices in the United States, with approximately 2,200 physicians who, collectively, provide nearly 40% of the nation's urology services.[10]

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 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 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;[11] (ii) spearheaded support in the medical community for the Medicare Care Coordination Improvement Act of 2019 (S. 966 & H.R.

[10] Centers for Medicare and Medicaid Services, Medicare Provider Utilization and Payment Data: Physician and Other Supplier, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html (last accessed Sept. 14, 2019).

[11] 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.

2282), which has been endorsed by 25 physician organizations representing 500,000 doctors; (iii) testified in Congress on the subject of modernizing health care fraud and abuse laws to support value-based care delivery models;[12] and (iv) submitted comments in response to OIG's and CMS's respective Requests for Information regarding the AKS/Beneficiary Inducements Civil Monetary Penalty and Stark law.[13] In short, we have been highly engaged on the important issues on which OIG seeks comment in the Proposed Rule.

## II. LUGPA Member Practices Are at the Forefront of Developing the Types of APMs and Other Value-Based, Coordinated Care Models for Which the Proposed Changes to the Anti-Kickback Statute Are Needed.

Much like the Stark law, the AKS[14] has not kept pace with the evolution of care delivery models and payment paradigms established since passage of MACRA more than four 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 II, we briefly summarize why it is so important for OIG, when finalizing the Proposed Rule, to ensure that the newly added and revised safe harbors promote the role of independent practices in value-based care delivery. Next, we present concrete examples of value-based care delivery models that LUGPA member practices are designing to promote care coordination and value for the benefit of our patients and the Medicare program. These are the type of care delivery and payment models for which the revisions to the AKS (and Stark law) are so critical. Finally, we explain how the threat of civil and criminal liability under the False Claims Act and AKS will continue to paralyze LUGPA member practices from operationalizing innovative care delivery models until OIG's newly proposed safe harbors (and proposed revisions to existing safe harbors) are finalized and take effect.

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

It is critical that OIG's changes to the AKS be of practical utility not only for ACOs, health systems and hospitals, but for the tens of thousands of physicians caring for patients in the independent urology (and other specialty) practice setting. Protecting and promoting 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,[15] as evidenced by data demonstrating that healthcare costs increase significantly when physician groups are acquired by hospitals and even more dramatically when

[12] LUGPA Cong. Testimony, supra n.5.

[13] See Comment Letter from LUGPA President Neal D. Shore, MD and LUGPA Health Policy Chair Deepak A. Kapoor, MD to Susan Edwards, HHS-OIG, OIG-0803-N (Oct. 26, 2018); 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).

[14] 42 U.S.C. § 1320a-7b.

[15] 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.

physician groups are acquired by hospital systems.[16] 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.[17]

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.[18] 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.[19] Without targeted changes to the AKS and Stark law to 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. OIG Finalizing the Newly Proposed Safe Harbors and Revisions to Existing Safe Harbors Will Enable Medicare Beneficiaries and the Healthcare System to Benefit from the Value-Based Arrangements Being Developed by Independent Urology Practices.

We cannot overstate the need for OIG to finalize its proposed changes to the AKS as soon as possible in order to support innovative care delivery models. LUGPA member practices have been working on behalf of their patients to develop such models, but the problem is that much of these efforts cannot be operationalized until OIG finalizes the proposed changes to the AKS (and CMS finalizes the proposed changes to the Stark law). And while the Secretary can provide waivers on a case-by-case basis for *approved* APMs, organizations wishing to develop APMs find themselves in a proverbial Catch-22: they cannot test APMs 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.

The need for prompt action by OIG (and CMS with respect to the Stark Law) is underscored by the complete dysfunction of CMMI's APM approval process. CMMI has yet to approve a single APM of the 16 models the Physician-Focused Payment Model Technical Advisory Committee ("PTAC") has recommended for testing or implementation over the past three years. Last month, two long-standing

---

[16] 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.

[17] 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).

[18] 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/ (last accessed Dec. 12, 2019).

[19] Physicians Advocacy Institute. Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment 2012-2016, *available at* http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/2016-PAI-Physician-Employment-Study-Final.pdf (last accessed Dec. 12, 2019).

members of PTAC quit in frustration. Len Nichols, Director of the Center for Health Policy Research and Ethics at George Mason said, "I hope my resignation (and those of others) might spur a reexamination of departmental priorities and process so that a more fruitful process of taking physician payment reform ideas from the field may be created as soon as possible."[20] In announcing his own resignation, Harold Miller, CEO of the Center for Healthcare Quality and Payment Reform, echoed Mr. Nichols' comments by noting that "[s]adly not a single one of the models we have recommended is being implemented or tested by the Department of Health and Human Services, and the Secretary has stated none of them will be."[21]

That is why OIG's and CMS's approaches in the AKS and Stark Proposed Rules of allowing testing and implementation of VBAs without having to wait for APM approval by a government agency is so imperative. Physician practices, hospitals and other providers can engage in value-based delivery as soon as these rules are finalized as long as they comply with the prescribed requirements of the new AKS safe harbors and Stark exceptions.

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 Stark law with respect to value-based arrangements will benefit Medicare beneficiaries (and other patients) and underscore the need for OIG to finalize the proposed new and revised safe harbors. Each model is designed to enhance collaboration among providers—within practices, across specialties and sites of service—for the benefit of 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 the development of value-based arrangements 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.[22]

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

[20] Inside Health Policy: "PTAC Members Resign, Say Congress Needs to Step in and Fix Process," November 20, 2019, *available at* https://insidehealthpolicy.com/daily-news/ptac-members-resign-say-congress-needs-step-and-fix-process (last accessed Dec. 21, 2019).

[21] Id.

[22] 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.

aggressive sepsis protocols have been successfully implemented[23] to as high as $94,737 per episode in patients who had prior antibiotic exposure in the prior 90 days.[24] The rate of infection after prostate biopsy is reported to be as high as 4.1%,[25] and recent Medicare data shows that urologists performed 111,905 prostate biopsies in 2016.[26] Given this data, Medicare expenditures to manage this complication could exceed $250 million annually.[27]

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.

2. 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.[28] 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."[29] 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").[30] Although CMS has encouraged the formation of virtual groups through recent rulemaking, including

[23] 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.

[24] 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.

[25] 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.

[26] 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.

[27] 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.

[28] 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.

[29] 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.

[30] 82 Fed. Reg. at 30027-34.

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

3. 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[31] belie statistics suggesting that hospitals lose an average of $128,000 per employed physician.[32] 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."[33] 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.[34]

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.

4. 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.[35] This has led to an increased number of ASCs and a

[31] Physicians Advocacy Institute. Op. Cit. p 8.
[32] MGMA Cost Survey: 2016 Report Based on 2015 Data. Accessed at: https://www.mgma.com/resources/products/mgma-2016-practice-operations-report.
[33] 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.
[34] 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.
[35] 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.

concomitant increase in the number of procedures performed at this site of service,[36] a trend observed as well in urology.[37]

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 under the AKS.

### C. The Criminal and Civil Liability that Attach to Violations of the Anti-Kickback Statute Will Continue to Stifle Innovation Until OIG Finalizes the Newly Proposed Safe Harbors and Revisions to Existing Safe Harbors.

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. OIG correctly observed that such liability—whether "real or perceived"—creates a "barrier to promoting flexible industry-led innovations in the delivery of more efficient and better coordinated healthcare."[38] 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.[39] The AKS is violated even if the remuneration was provided only in part to induce referrals.[40] 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."[41]

Damages and penalties for violating the AKS and FCA can be severe. The AKS has criminal penalties that provide for fines up to $100,000 and/or imprisonment for up to ten years,[42] and civil penalties of tens of thousands of dollars per instance of unlawful remuneration and referral, plus up to three times the amount of kickback paid, and exclusion from Federal health care programs.[43] For its part, the FCA provides for civil penalties per false or fraudulent request or demand for payment, plus up to three times the amount of damages sustained by the government.[44] The FCA damages provisions can add up to staggering amounts, even for modest violations.

---

[36] 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.

[37] 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.

[38] 84 Fed. Reg. at 55698.

[39] 42 U.S.C. § 1320a-7b(b)(1) (emphasis added); *see also id.* § 1320a-7a(7).

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

[41] 31 U.S.C. § 3729(a)(1)(B).

[42] 42 U.S.C. § 1320a-7b(b).

[43] Id. § 1320a-7a(a).

[44] 31 U.S.C. § 3729(a)(1); 28 C.F.R. § 85.5 (increasing the per-claim penalties to $11,181-$22,363 for violations that occurred after Jan. 29, 2018).

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. HHS Deputy Secretary Hargan recognized the seriousness of the issue 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."[45] This is precisely why it is so critical for OIG to finalize the proposed safe harbors to the AKS as soon as possible.

## III. OIG Should Finalize the Newly Proposed Safe Harbors and Revisions to Existing Safe Harbors to Protect Independent Specialty Practices that Seek to Deliver High Quality, Coordinated Care in a Value-Based Payment System.

We agree with OIG that the newly proposed safe harbors and revisions to existing safe harbors would provide pathways for protection for most beneficial care coordination and value-based care and payment arrangements. We focus in Part III on the proposals that we believe will have the most significant impact in unlocking the ability of independent specialty practices to develop and operationalize value-based arrangements for the benefit of their patients.

### A. LUGPA Supports the Proposed Definitions that Serve as the Foundation for the Newly Proposed Safe Harbors.

LUGPA appreciates that OIG and CMS have coordinated with one another to agree upon definitions of key terms that serve as the foundation for the proposed changes to the AKS and Stark law. The Administration can only achieve its aim of removing barriers to coordinated care if the agencies charged with enforcing the AKS and Stark law coordinate their efforts to modernize the country's fraud and abuse laws. In finalizing the AKS and Stark proposed rules, we urge OIG and CMS to continue their efforts to develop a single lexicon that will be used to protect value-based care delivery and payment models.

We offer the following comments in response to OIG's solicitation of input on the proposed value-based terminology:[46]

1. We agree with OIG's approach to use the term "value-based" in a non-technical way to signal value produced through improved care coordination, improved health outcomes, lower costs or reduced growth of costs for patients and payors, and improved efficiencies in the delivery of care.[47] LUGPA believes it is critical for OIG and CMS to provide as much flexibility as possible in how they define the key terms that form the foundation for our value-based care and payment delivery system. Accordingly, we believe it would be too limiting for OIG, as suggested in the Proposed Rule, to define "value" in the final rule with reference to financial arrangements under Advanced APMs.[48] As OIG noted, value-based enterprises ("VBEs") "may take many different forms, and we intend for the definition of 'VBE' to be flexible."[49] It is for that very

[45] 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).
[46] 84 Fed. Reg. at 55700-08.
[47] Id. at 55700.
[48] See id.
[49] Id. at 55701.

reason that the most fundamental term in this regulatory lexicon—"value"—should be defined with maximum flexibility and not limited through reference to Advanced APMs, which represent only one form of value-based arrangement ("VBA").

2. We support OIG's proposed definition of VBE, including the requirement that the VBE have an accountable body or accountable person responsible for financial and operational oversight of the VBE.[50] Although we agree that it is appropriate for the accountable body or person to be in position to identify program integrity issues and to initiate action to address those issues, we do not believe that the VBE or its participants should be required to have a distinct compliance program covering those VBAs for which safe harbor protection is sought.[51] As OIG noted, VBEs might be quite small—limited to two physicians in separate practices or a single physician and a separate medical practice. In such instances, the creation of distinct compliance programs—separate from the physicians' and providers' existing compliance programs—would impose unnecessary costs and administrative burdens on these providers.

3. We believe that OIG's proposed definition for the term VBA—an arrangement for the provision of at least one value-based activity for a target population between or among a VBE and one or more of the VBE's participants or VBE participants in the same VBE—will provide maximum flexibility for those seeking to develop VBAs.[52] Importantly, the proposed definition recognizes that VBAs might be quite small with value-based participants being individual physicians and/or small, independent medical practices.

4. We agree with the proposed definition of "target patient population," but are concerned by OIG's statement in the Proposed Rule that it is considering for the final rule a significant narrowing of that definition to include only patients with chronic conditions.[53] Although it would be less limiting, we do not believe it is adequate for OIG to expand the universe of "target patient populations" to also include "patients with a shared disease state who would benefit from care coordination."[54] Meaningful value-based arrangements are being developed and contemplated by LUGPA member practices that would be for the benefit of patients who neither have a disease nor suffer from a chronic condition. We urge OIG (and CMS) to finalize the definition of "target patient population" as proposed and without modification. Any identified patient population selected by the VBE or its VBE participants that is selected using legitimate and verifiable criteria that are set out in writing in advance of the commencement of the VBA and further the VBE's value-based purpose should qualify as a target patient population. For example, coordinated care efforts that create risk mitigation or harm reduction programs would be excluded if the definition was limited as proposed. Indeed, it can be argued that creating coordinated efforts between physicians and affiliated professionals (such as social workers or nutritionists, to name but two) to prevent disease

[50] Id.
[51] See id.
[52] Id. at 55702.
[53] Id.
[54] Id.

(such as obesity) would be equally, if not more, valuable than the narrow definition proposed.

5. OIG should finalize its proposed definition of "value-based activity" with one modification. On the one hand, OIG states that a value-based activity "does not include the making of a referral"; yet, OIG then goes on to state that "[u]nder no circumstances would *simply* making a referral constitute a 'value-based activity.'"[55] We agree with the second statement—i.e., a referral, standing alone, should not constitute a value-based activity, but it is important to recognize that a value-based activity could very well encompass a referral as part of that activity. Care coordination efforts between physicians in two separate medical practices could require referrals of patients for the delivery of health care services and such referrals should not prevent that care coordination effort from being deemed a "value-based activity."

6. We generally support the broad definition of "value-based purpose," but we do not agree with the modification that OIG is considering to the third of the four proposed value-based purposes. As proposed, "value-based purposes" include "appropriately reducing the costs to, or growth in expenditures of, payors *without reducing the quality of care* for a target patient population."[56] This is a valid and valuable purpose—maintaining quality care while reducing the cost of that care. Conversely, we think it is overly restrictive to limit the definition of "value-based purpose"—as OIG is contemplating—to those instances in which costs are reduced when there is an *improvement* in patient quality care or the parties are maintaining an *improved* level of care.[57] To be clear, LUGPA member practices strive in their development of, and participation in, VBAs to improve the quality of patient care while simultaneously reducing the costs of that care, but safe harbor protection should not be triggered only once an improved level of care has been established. The definition of "value-based purpose" should be finalized as proposed and without modification.

**B. OIG Should Finalize the Three Newly-Proposed Safe Harbors Applicable to Participants in Value-Based Arrangements with Limited Modifications.**

1. Care Coordination Safe Harbor

We agree with OIG that it is important to create a safe harbor for VBAs that do not involve the assumption of financial risk, but are designed to and, in fact, improve quality, health outcomes, and efficiency in care delivery. HHS cannot accomplish its Regulatory Sprint to Coordinated Care without adding such a safe harbor to the AKS.[58] We comment here on those aspects of the Care Coordination Safe Harbor that we believe are critical to finalize as written or with modification.

We support OIG's proposal that the Care Coordination Safe Harbor require the establishment of at least one evidence-based, valid outcome measure against which the recipient of remuneration will be

[55] Id. at 55703 (emphasis added).
[56] Id. at 55706 (emphasis added).
[57] Id. at 55707.
[58] We do not believe that OIG's alternative proposal—to forgo the creation of a Care Coordination Safe Harbor and to rely instead on a tiered set of protections under the revised personal services and management contracts safe harbor (id. at 55716)—would provide as clear a mechanism for obtaining safe harbor protection from AKS liability and would create operational challenges for parties in determining fair market value for VBAs.

measured. It is particularly important that OIG has proposed to grant parties to a VBA the flexibility to ground the evidence-based outcome measure in information internal to one or more of the VBE participants.[59] We believe that internal metrics that illustrate patient satisfaction and efficiency of care should be included as parameters of value-based care. Creating systems that prevent visits to the emergency room (for example, rapid access to outpatient testing and evaluation services for patients with renal colic) would improve outcomes and reduce cost. In addition, patients who are satisfied are more likely to keep follow-up appointments and be compliant with care; these parameters are innately valuable and should be recognized as contributing to value-based care.

We agree with the flexibility OIG created by proposing that safe harbor protection will be triggered when the remuneration provided by, or shared among, VBE participants "be used primarily to engage in value-based activities that are directly connected to the coordination and management of care of the target population."[60] OIG was right not to mandate that the remuneration be used *exclusively* for the benefit of the target population. As OIG recognized, "in-kind remuneration exchanged for value-based activities may indirectly benefit patients outside of the scope of the VBA" and parties to the VBA "may find it difficult to anticipate or project the scope or extent of such 'spillover' benefits."[61] It is because of the need—as OIG identified—"to provide parties with sufficient flexibility" that OIG should not finalize the alternative approach it laid out in the Proposed Rule that would require the remuneration exchanged to be limited to VBAs "that *only* benefit the target patient population."[62] We are concerned that this change would jeopardize the practical value of the Care Coordination Safe Harbor, because value-based participants would be loath to risk criminal liability under the AKS triggered by the potential spillover benefits received by patients who are not part of the target patient population. Indeed, preventing other patient populations from benefitting from initiatives developed for "target" populations seems fundamentally counterintuitive to the concept of promoting care coordination and value-based care.

OIG struck the right balance in how it framed its proposal for limiting the extent to which the offeror of remuneration may take into account the volume or value of referrals or business generated in setting aggregate compensation. As proposed, the offeror cannot take into account the volume or value of, or condition an offer of remuneration, on (i) referrals of patients that are not part of the VBA's target patient population, or (ii) business not covered under the VBA.[63] The alternative approach for which OIG seeks comment is deeply troubling. Under that approach,[64] safe harbor protection would not be available if aggregate compensation paid by the offeror is determined in a manner that takes into account the volume or value of referrals or business generated between the parties for which payment may be made by a Federal health program. Adopting such a limitation would gut the very purpose of the Care Coordination Safe Harbor and, we fear, the AKS proposed rule as a whole. As OIG has made clear, "the goal of this proposed rulemaking is to remove barriers to improved care coordination and to promote value-driven care";[65] yet, the alternative approach being contemplated would eliminate one of the most important elements of the proposed regulatory changes—the ability of value-based participants to take into account the value of care delivered in a value-based care and payment delivery structure where payment is made by a Federal health program. For example, it has been clearly demonstrated that radiation therapy for

[59] Id. at 55708.
[60] Id. at 55710.
[61] Id.
[62] Id.
[63] Id. at 55711.
[64] Id. at 55711, 55714.
[65] Id. at 55711.

prostate cancer delivered in the physician office setting is substantially less expensive than when delivered in the hospital outpatient department ("HOPD") setting.[66] Developing care coordination pathways between providers that produce equivalent outcomes may be related to the value of services provided, but clearly produce equivalent outcomes, improved convenience and lower Medicare program and beneficiary costs. Such initiatives should be supported, not restricted.

We agree with OIG that, in most instances, it is appropriate to include a recipient contribution requirement as a safeguard to help ensure that the use of remuneration exchanged pursuant to the Care Coordination Safe Harbor be used for the coordination and management of care.[67] With that said, we are concerned about the administrative burden that would be placed on recipients of in-kind remuneration if a contribution requirement were to exist in perpetuity during the life of a VBA. We also do not believe that the one-size-fits-all proposal of a 15% contribution by the recipient of the offer's cost for the in-kind remuneration is appropriate given the wide range of size and financial resources of value-based participants ranging from large ACOs and health systems, on the one hand, to individual physicians and small practices, on the other hand. A better approach—which OIG stated it is considering—is to exempt certain classes of recipients (e.g., rural providers, small providers, Tribal providers) from the contribution requirement altogether. We also believe it would be appropriate, given OIG's commitment to supporting cybersecurity, for OIG to make explicit in the Care Coordination Safe Harbor that in-kind remuneration of cybersecurity and related technology would not require a recipient contribution. Finally, we agree with OIG's alternative proposal of establishing a contribution requirement for the initial provision of remuneration but not with respect to updates, upgrades or patches of remuneration provided over the course of a VBA.[68]

We believe OIG should modify its proposal with respect to termination of VBAs. As proposed, the parties to a VBA would be required to terminate the VBA within 60 days of determining that the VBA is unlikely to further coordination and management of care for the target patient population, has resulted in material deficiencies in quality of care, or is unlikely to achieve the evidence-based, valid outcome measures.[69] In light of OIG's goal of promoting efficient, value-driven care, the Care Coordination Safe Harbor should include a reasonable timeframe of 120 days for remediation before parties are forced to terminate the VBA or lose safe harbor protection. We are concerned that the criminal liability and financial penalties that attach to violations of the AKS would chill the development of and participation in value-based care models if a reasonable period of time were not given to parties to remediate deficiencies in their VBAs.

OIG has carefully designed the Proposed Rule in a manner that is consistent with HHS's goal of reducing administrative burden while safeguarding value-based care delivery models. LUGPA believes that it would be inconsistent with that worthy goal for OIG to modify the Proposed Rule (as is being contemplated) to require VBEs to submit data to HHS identifying the VBE, VBE participants, and VBAs in order to receive protection under the Care Coordination Safe Harbor.[70] One of the most important aspects of the AKS and Stark Proposed Rules is that the proposed AKS safe harbors and proposed Stark exceptions (much like current safe harbors and exceptions) are self-executing—i.e., providers are

[66] Kapoor DA, Holton M, Albala D. Trends in Prostate Cancer Therapy. Rev Urol (in press).
[67] 84 Fed. Reg. at 55700-08.
[68] Id. at 55712.
[69] Id. at 55713.
[70] Id.

protected by satisfying the elements of the particular AKS safe harbor or Stark exception without the added administrative burden of submitting data to a government agency or obtaining agency approval. We do not believe that OIG (or CMS with respect to the Stark law) should impose a layer of administrative burden on participants in VBAs that does not exist with respect to AKS (or Stark) in the fee-for-service payment system.

2. Substantial Downside Financial Risk Safe Harbor

LUGPA generally supports OIG's proposed safe harbor to protect VBAs in which participants take on substantial downside risk.[71] Like OIG, we believe that it is important to include a safe harbor that covers both in-kind and monetary remuneration, thereby providing greater flexibility than the Care Coordination Safe Harbor that is limited to protecting in-kind remuneration, while stopping short of requiring a VBE to take on full financial risk. To be sure, we expect that full financial risk models will become more common over time, but in what are still the early days of our health care system's transition from fee-for-service to value-based care and payment delivery systems, it is particularly important for independent urology (and other specialty) practices to be given the flexibility to participate in VBAs that do not require the taking on of full financial risk.

It is critical that OIG build into the Substantial Downside Financial Risk Safe Harbor protection for a substantial period of time prior to the date by which the VBE must assume substantial financial risk. We are concerned, however, that while the proposed six-month period might be sufficient for larger VBEs and VBE participants such as ACOs and large health systems,[72] we believe that the development of VBAs amongst smaller health care providers such as independent medical practices and, potentially, individual physicians will take longer to develop and would benefit from a full 12-month window in which safe harbor protection will be available prior to the VBE having to assume substantial financial risk. These are nascent and potentially complex projects; development of auditing and reporting metrics will be challenging and refinement of these metrics can potentially take months. An exemption period that is too short could chill innovators from entering into risk-sharing models.

In a similar vein, OIG appropriately recognized that it will likely prove more challenging for new or smaller VBEs to establish baselines against which to measure losses or payments that will serve as the basis for calculating the repayment obligations required to meet the Substantial Downside Financial Risk Safe Harbor.[73] We fully endorse the proposal OIG is considering which would permit new or small VBEs—defined to include those VBEs created by or amongst independent medical practices—a period of one year from the start of operations to establish the necessary baselines against which performance is measured.

As a final point with respect to the Substantial Downside Financial Risk Safe Harbor, we were concerned with the difference in terminology between OIG's proposed safe harbor that will protect VBEs that take on "substantial" downside risk and CMS's proposed exception to the Stark law for physicians who take on "meaningful" downside financial risk.[74] Ultimately, though, we believe OIG struck the right balance by making clear that when a VBE participant is a physician, a payment that meets the requirements of the Stark law's exception for VBAs that take on "meaningful" downside financial risk will also be protected

[71] Id. at 55716-18.
[72] 84 Fed. Reg. at 55717.
[73] Id.
[74] Stark Proposed Rule, 84 Fed. Reg. at 55782.

under the Substantial Downside Risk Safe Harbor.[75] We comment to underscore the importance of OIG and CMS remaining aligned in their respective final rules as to the level of financial risk that physicians will need to take on in order to benefit from the protections of the AKS safe harbor and Stark exception.

3. Full Financial Risk Safe Harbor

In time, we believe that the Full Financial Risk Safe Harbor will be the most important of the safe harbors being proposed, because—like OIG—we view this safe harbor as offering VBEs the "greatest ability to innovate with respect to coordinated care arrangements" in light of VBEs assumption of the highest level of risk contemplated in the Proposed Rule.[76] We agree with OIG's proposal that a VBE should be deemed to have taken on full financial risk if it receives a prospective, capitated payment for all items and services covered by Medicare Part A and B for a target population and, at the same time, it is critical that safe harbor protection be available even if the VBE obtains global risk adjustments, reinsurance or stop loss agreements to protect against catastrophic loss. OIG was right to propose this protection and should include it in the Final Rule; otherwise, we are concerned that VBA participants—particularly physicians and independent medical practices—will be reluctant to pursue full financial risk models.

For the same reasons we noted above with respect to the Substantial Downside Financial Risk Safe Harbor, we are concerned that VBEs designed between smaller providers such as independent medical practices and individual physicians will need more than the 6-month period being proposed for safe harbor protection to develop and implement arrangements in anticipation of taking on full financial risk.[77] Although the proposed six-month period might be sufficient for larger VBEs and VBE participants such as ACOs and large health systems,[78] we believe that the development of VBEs amongst smaller health care providers will take longer to develop and would benefit from a full 12-month window in which safe harbor protection will be available prior to the VBE having to assume full financial risk.

The most important modification that we believe needs to be made is the one that OIG identified at the end of its discussion of the Full Financial Risk Safe Harbor—protection for remuneration that passes from a VBE participant to a downstream contractor.[79] The Full Financial Risk Safe Harbor is designed to provide the greatest flexibility in order to maximize innovation in the development of value-based care delivery models, and we fully expect that such models will look to coordinate care with downstream contractors that may or may not assume financial risk. Without building in protection for downstream contractors (whether they be VBE participants or not), OIG will limit care coordination opportunities. In Part III(C) below, we provide examples of how encouraging relationships with downstream contractors could promote value based purposes for VBE participants.

[75] OIG Proposed Rule, 84 Fed. Reg. at 55718 (proposing that a "VBE participant 'meaningfully shares' in th VBE entity's substantial downside financial risk if . . . in the case of a VBE participant that is a physician, a payment [] meets the requirements of the physician self-referral law's regulatory exception for value-based arrangements with meaningful downside financial risk at section 411.357(aa)(2)).
[76] Id. at 55719.
[77] Id. at 55720.
[78] Id.
[79] Id. at 55721.

### C. OIG Should Finalize the Proposed Patient Engagement and Support Safe Harbor with Limited Modifications.

OIG has properly recognized that it is not sufficient to modify the AKS by creating protections for value-based care delivery and financial arrangements between and among providers. Ultimately, the purpose of the Administration's Regulatory Sprint to Coordinated Care is to obtain better health care outcomes for patients through enhanced care coordination. Such coordination must include the patient, which is why it is so important that the new safe harbors include protection for providers who seek to offer patients tools and supports to improve quality, health outcomes, and efficiency by promoting engagement with their care and adherence to care protocols. LUGPA endorses OIG's proposal to exclude from the definition of "remuneration" under the AKS in-kind patient engagement tools or supports furnished to patients in a target population that are "directly connected to the coordination and management of care."[80]

We do not believe, however, that such protection should be available only to VBE participants but, rather, as OIG is considering, should be offered to hospitals or physician group practices that seek to provide patient engagement tools and supports that would advance coordination and management of care for a patient.[81] If such tools and supports are directly connected to the "coordination and management of care"—as that term is defined in the Proposed Rule—and as long as a monetary cap is applied to the value of the tools and supports provided, then OIG should offer safe harbor protection regardless of whether the hospital or physician group practice is a VBE participant.[82]

In that same vein, we agree with OIG that the safe harbor protection should not be limited to Federal health care program beneficiaries, given that the target population might very well be defined without regard to payor type. In fact, we believe OIG should go a step further—as it is contemplating doing—by affording safe harbor protection for tools and supports VBE participants furnish to any patient as long as those tools and supports predominantly address needs of the target population and the tools and supports have a direct connection to the coordination and management of care for the patient.[83] For example, patients have been responsive to personal devices that use technology to maximize desired behavior (such as watches that promote target "steps" or distance walked in a day or track blood sugar). Two examples of harnessing this technology in urology would be to 1) provide patients with stone disease a software tool that would track intake of foods demonstrated to either promote or inhibit stone formation as well as to encourage hydration; or 2) encourage patients with urinary incontinence to perform pelvic floor exercises, which has been demonstrated to reduce the need for medications and surgery to treat this condition. Of concern is that development of such devices and the software needed to operate them would certainly cost more than $500 to develop as well as expertise likely not resident within VBE participants; encouraging downstream collaborative relationships would do much to promote innovation in this space.

### D. LUGPA Supports OIG Finalizing its New Safe Harbor for Participants in CMS-Sponsored Models.

LUGPA appreciates the steps OIG is taking to simplify application of the AKS, and we believe that the newly proposed safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient

[80] Id. at 55722.
[81] Id.
[82] Id.
[83] Id. at 55723.

incentives is a positive step in that direction.[84] With that said, it has not been the lack of such a safe harbor that has impeded the development and operation of CMS-sponsored model arrangements but, rather, as we discussed in Part II(B) above, the dearth of models or other initiatives the Innovation Center has been willing to approve. The new safe harbor will be of little value if the Innovation Center does not signal a greater willingness than it has shown over the last several years to approve the testing of innovative care delivery and payment models. It is the lack of approvals from the Innovation Center that makes it so critical for OIG to finalize the other proposed safe harbors in a timely fashion.

### E. OIG Should Finalize its Proposed Modifications to the Existing Safe Harbor for Personal Services and Management Contracts.

OIG's proposed changes to the existing safe harbor for personal services and management contracts are as important to enhancing care coordination and encouraging the development of VBAs as the new safe harbors being proposed.[85] The changes are particularly valuable because they provide enhanced flexibility to independent medical groups and other providers seeking to develop innovative care delivery models. The most important change being proposed is the one that would eliminate the requirement that an arrangement's aggregate compensation be set in advance and replace it with a requirement that an arrangement's compensation *methodology* be set in advance of the initial payment under the arrangement.[86] In fact, we do not believe that this safe harbor will be of any practical utility in a value-based care delivery system without this modification because—almost by definition—VBAs will not be able to set aggregate compensation in advance of the arrangement beginning operations.

It is equally critical for OIG to offer express protection for outcomes-based payment arrangements under this safe harbor. In keeping with the flexibility OIG is offering through the proposed modifications to this safe harbor, we believe it is most appropriate for OIG to define "outcomes-based payment" as proposed—i.e., as payments from a principal to an agent that (i) reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across settings or (ii) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved quality of care for patients.[87] We do not believe OIG should revise the proposed definition to reference specific types of payments as is being considered.[88] Such a modification would be unnecessarily limiting at a time when OIG is seeking to encourage innovation and development of new value-based care and payment models.

Although we generally support the proposed changes to the Personal Services and Management Contracts Safe Harbor, we believe the continued use of a fair market value requirement poses a significant impediment to this safe harbor being of practical utility in a value-based care system. As OIG acknowledges, its fair market value requirement will pose challenges because there simply are not industry standards yet developed to determine fair market value for outcomes-based payment arrangements. Worse yet, the notion of a "fair market value" will often be a non sequitur because, as OIG notes, some of the outcomes-based payment arrangements it proposes to protect "do not correlate payments with actual services performed." That complication is magnified when outcome-based

[84] Id. at 55730-33.
[85] Id. at 55744-50.
[86] Id. at 55744.
[87] Id. at 55745.
[88] Id.

payment arrangements reward *not* performing services.[89] Because a fair market value requirement does not align with OIG's and the Administration's goals in developing a value-based care delivery system, we believe OIG needs to adopt a different approach by substituting the fair market value requirement with a different safeguard that still ensures that payments are for legitimate participation in arrangements that drive value-based care. LUGPA is of the strong opinion that if 1) a VBE is engaged in a value based activity that meets the criteria for a value based purpose; and 2) meaningful clinical metrics are in place to ensure that outcomes are preserved or enhanced, then the internal compensation arrangements are largely irrelevant and should be left to the discretion of VBE participants.

## 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 many instances, prohibits—improved care coordination as well as the development and operation of value-driven care delivery models. Simply put, there are certain aspects of the AKS and Stark law that are anathema to the types of care delivery and payment models that Congress sought to unlock through MACRA. As a result, we can expect that the innovation the Administration is so committed to unlocking will remain stymied until OIG (and CMS) finalize the AKS (and Stark) Proposed Rules.

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

- Coordinate with CMS to finalize a single set of definitions to govern the lexicon of value-based terminology for the AKS and Stark law, including:
    - Defining the term "value-based," as proposed, in a non-technical way, and without reference to Advanced APMs;
    - Not imposing an obligation on VBEs—which could be comprised of small independent medical practices—to construct compliance programs for the VBEs separate and apart from the medical practices' existing compliance programs;
    - Finalizing the definition of "target patient population" as proposed and without modification that would narrow the definition to include only those patients with chronic conditions or a shared disease state;
    - Clarifying that although a referral, standing alone, will not constitute a "value-based activity," a value-based activity can encompass a referral as part of a care coordination effort;
    - Finalizing the definition of "value-based purpose" as proposed and without modification that would require an *improvement* in patient quality care rather than the current proposal of ensuring that there is *no reduction* in the quality of care for a target population while reducing costs to, or growth in expenditures, of payors;
- With respect to the three newly-proposed safe harbors applicable to participants in VBAs:
    - Finalize the Care Coordination Safe Harbor, as proposed, and (i) not require that remuneration exchanged be used *exclusively* for the benefit of the target population without any spillover benefit for other patients, (ii) not modify the proposal to prohibit taking into account the volume or value of referrals or business generated between parties for which payment may be made by a Federal

[89] Id. at 55747.

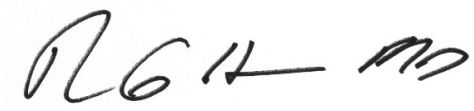
health program, (iii) not impose an administrative burden of submitting data to HHS identifying the VBE, VBE participants, and VBAs in order to receive protection under the safe harbor, and (iv) not force parties to terminate a VBA without providing a reasonable timeframe of 120 days to remediate deficiencies in quality of care or an inability to meet evidence-based, valid outcome measures.

  - Finalize the Substantial Downside Financial Risk Safe Harbor with limited modifications to (i) provide a full 12-month window in which safe harbor protection will be available prior to the VBE having to assume substantial financial risk, and (ii) permit new or small VBEs defined to include those created by or amongst independent medical practices a period of one year from the start of operations to establish the necessary baselines against which to measure losses or payments that will serve as the basis for calculating the repayment obligations to satisfy the safe harbor;
  - Finalize the Full Financial Risk Safe Harbor with limited modifications to (i) provide a full 12-month period in which safe harbor protection will be available prior to the VBE having to assume full financial risk, and (ii) protect remuneration that passes from a VBE participant to a downstream contractor;

- Finalize the proposed Patient Engagement and Support Safe Harbor with limited modifications to (i) make the safe harbor protection available regardless of whether the provider offering the tool or support is a VBE participant, and (ii) afford safe harbor protection for tools and supports VBE participants furnish to any patient and not just Federal health care program beneficiaries;
- Finalize the proposed modifications to the existing Personal Services and Management Contracts Safe Harbor, including eliminating the requirement that an arrangement's aggregate compensation be set in advance and replacing it with a requirement that an arrangement's compensation *methodology* be set in advance of the initial payment under the arrangement, but remove the safe harbor's fair market value requirement and replace it with a different safeguard that still ensures that payments are for legitimate participation in arrangements that drive value-based care.

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

Respectfully submitted,



Richard G. Harris, M.D.
President

Deepak A. Kapoor, M.D.
Chairman, Health Policy

cc: Celeste Kirschner, Chief Executive Officer, LUGPA
Howard Rubin, Esq., Katten Muchin Rosenman LLP