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December 31, 2019

BY ELECTRONIC SUBMISSION

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

RE: Comments to CMS-1720-P

Dear Administrator Verma:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Program's Proposed Rule to Modernize and Clarify the Physician Self-Referral Regulations ("Stark Proposed Rule").[1] We appreciate the bold steps that HHS and CMS are taking to modernize our country's health care fraud and abuse laws. LUGPA agrees that in order "to help accelerate the "transformation of the health care system into one that better pays for value and promotes care coordination,"[2] we need to confront the provisions within the Stark law that act as barriers to our achieving these goals.

LUGPA and its member practices have been championing statutory and regulatory reform of the Stark law and Anti-Kickback Statute ("AKS") to support 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").[3] In addition to submitting comments in response to CMS's and OIG's respective Requests for Information regarding the Stark law and AKS, 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 transition to value-based care in the Medicare program and in our health care system more broadly.[4]

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[1] 84 Fed. Reg. 55766 (Oct. 17, 2019).
[2] Id. at 55768.
[3] Pub. L. 114-10, enacted April 16, 2015.
[4] 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").

LUGPA appreciates how closely CMS and OIG worked with one another in developing the complementary proposed rules designed to modernize the Stark law and AKS. 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 OIG in response to the AKS Proposed Rule at the same time we are submitting these comments in response to the Stark Proposed Rule.

We strongly support CMS's proposal to create permanent exceptions to the Stark law for value-based arrangements ("VBAs") that will apply to care delivery for all patients, not just Medicare beneficiaries. These exceptions will 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.

We were particularly grateful to see that the Stark Proposed Rule (much like the AKS Proposed Rule) contemplates new value-based enterprises ("VBEs") under which both small and large providers will be able to collaborate in furtherance of value-based purposes that benefit patients. It is especially important that the Stark and AKS Proposed Rules provide opportunities for the creation of VBAs with varying degrees of risk-sharing without presuming that a one-size-fits-all approach can work for different specialties, regions, or size of practices. We appreciate the lengths to which CMS has gone to ensure that independent medical practices are given an equal opportunity to design and implement innovative care delivery and payment models for the benefit of Medicare beneficiaries and all patients.

We cannot overstate the importance of finalizing the proposals as early in 2020 as possible. CMS rightly acknowledged the "chilling effect" that the threat of penalties and liability under the Stark law and False Claims Act is having "on models and arrangements designed to 'bend the cost curve and improve quality of care to patients.'"[5] Until the proposals are finalized and take effect, the Stark law will continue operating as a barrier to the types of clinical and financial integration—and "behavior shaping"—designed to improve health care outcomes while reducing costs contemplated by MACRA.

In short, CMS's proposals for modernizing the Stark law are good for patients and good for our health care system as a whole. In Part II, we provide CMS 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 Stark exceptions for VBAs and revisions to existing Stark regulations are needed. We believe that these examples are the types of VBAs that Congress envisioned when it passed MACRA, but the potential arrangements have hit a roadblock in the form of outdated aspects of the Stark law (under CMS's jurisdiction) and the AKS (under OIG's jurisdiction). In Part III, we provide comments on certain of the proposed definitions of key terms that are at the heart of the newly proposed Stark exceptions and AKS safe harbors and also comment on the three proposed exceptions for VBAs in which participants take on different levels of risk. In Part IV, we comment on the equally important proposals with respect to the definition of "commercial reasonableness," the "volume or value" and "other business generated" standards, and the definition of "fair market value." We believe that CMS should finalize each of its proposals with limited modifications. Finally, in Part V, we urge CMS to refrain from regulatory changes limiting the Stark Law's In-Office Ancillary Services Exception

[5] 84 Fed. Reg. at 55777.

("IOASE") and raise concerns with certain proposed clarifying changes that could have the inadvertent effect of undermining protection under the IOASE.

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.[6]

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;[7] (ii) spearheaded support in the medical community for the bipartisan Medicare Care Coordination Improvement Act of 2019 (S. 966 & H.R. 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;[8] and (iv) submitted comments in response to CMS's and OIG's

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[6] 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 Dec. 12, 2019).

[7] 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.

[8] LUGPA Cong. Testimony, supra n.4.

respective Requests for Information regarding the Stark law and AKS.[9] In short, we have been highly engaged on the important issues on which CMS 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 Stark Law Are Needed.

The Stark law 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 Stark (and the AKS) 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 CMS, when finalizing the Proposed Rule, to ensure that the new exceptions and revisions to key terminology in the Stark regulations 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 Stark law (and AKS) are so critical.

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

It is critical that CMS's changes to the Stark regulations 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,[10] as evidenced by data demonstrating that healthcare costs increase significantly when physician groups are acquired by hospitals and even more dramatically when physician groups are acquired by hospital systems.[11] 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.[12]

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[9] 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); 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).

[10] 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.

[11] 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.

[12] 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).

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.[13] 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.[14] Without targeted changes to the Stark law and AKS 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. CMS Finalizing the Newly Proposed Stark Exceptions and Revisions to Key Terminology in the Stark Regulations Will Enable Medicare Beneficiaries and the Healthcare System to Benefit from the Value-Based Arrangements Being Developed by Independent Urology Practices.

As CMS Administrator Verma noted last year, an "important step in moving to a value-based system, is removing barriers that prevent providers from participating in value based models [, and] CMS's enforcement of the Stark Law is one example."[15] It is not surprising that the Stark law is in need of modification given the fundamental changes to healthcare delivery and payment systems since enactment of the statute in 1989. In certain respects, the Stark law is an anachronism. Developed 30 years ago to respond to the risk of overutilization of health care services in a fee-for-service payment system, the Stark law now serves as a barrier to the types of clinical and financial integration contemplated by MACRA and being developed by LUGPA member practices as we describe in this section.

CMS recognized as far back as the MPFS Proposed Rule for CY 2016—issued months after passage of MACRA—the "barriers to achieving clinical and financial integration posed by the physician self-referral [Stark] law."[16] More than four years later, those barriers are proving to be even more onerous than originally perceived, and the vision of MACRA and the transition to value-based care delivery is in jeopardy. CMS rightly noted in its announcement of the Proposed Rule that "[t]he Stark Law has not evolved to keep pace with this transition."[17]

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[13] 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).

[14] 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).

[15] 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 (last accessed Dec. 12, 2019); see also Interview of CMS Administrator Seema Verma, AHA/CMS Regulatory Relief Town Hall Webcast: Stark Law, *available at* https://www.youtube.com/watch?v=vrtey7QPAYg&feature=youtu.be ("Stark was developed a long time ago…and the payment systems and how we are operating is different now and we need to bring along some of those [Stark] regulations") (last accessed Dec. 12, 2019).

[16] 81 Fed. Reg. 28162, 28180 (July 2015).

[17] CMS Fact Sheet, "Modernizing and Clarifying the Physician Self-Referral Regulations Proposed Rule," *available at* https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-proposed-rule (last accessed Dec. 12, 2019).

We cannot overstate the need for CMS to finalize its proposed changes to the Stark regulations 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 CMS finalizes the proposed changes to the Stark regulations (and OIG finalizes the proposed changes to the AKS). 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 CMS (and by OIG with respect to the AKS) 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 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."[18] 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."[19]

That is why CMS's and OIG's approaches in the Stark and AKS 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 Stark exceptions and AKS safe harbors.

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 crushing financial penalties under the Stark law (and criminal liability 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 Stark law and AKS with respect to value-based arrangements will benefit Medicare beneficiaries (and other patients) and underscore the need for CMS to finalize its proposed changes to the Stark regulations as soon as possible. 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.

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[18] 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).

[19] Id.

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 VBAs because significant savings and improved patient care can be achieved by minimizing infections, which are all too common. This VBA could include professional services, facility fees, anatomic pathology services, and imaging services across multiple sites of service. In addition, expanding a 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.[20]

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[21] to as high as $94,737 per episode in patients who had prior antibiotic exposure in the prior 90 days.[22] The rate of infection after prostate biopsy is reported to be as high as 4.1%,[23] and recent Medicare data shows that urologists performed 111,905 prostate biopsies in 2016.[24] Given this data, Medicare expenditures to manage this complication could exceed $250 million annually.[25]

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 under the Stark law to distribute shared savings from this model in a logical—and compliant—fashion. In particular, the distribution of such savings was complicated, given that a prostate biopsy episode of care would include designated health services (“DHS”), namely pathology and advanced imaging. As such, the practice would be unable to account for differences in volume of services performed or for compliance with clinical protocols in compensating its member providers. When factoring in insurance considerations and technology requirements, this prostate biopsy episode of care included free-standing pathology labs and imaging facilities. Sharing revenue across these service lines raises additional concerns under the Stark law and AKS. Moreover, such a bundle, by necessity, would range across different sites of service (physician office, outpatient facility, inpatient facility), yet current Stark regulations provide that the physician owners of the practice “stand in the shoes” of the organization, and are deemed to have the same compensation arrangements, with the same parties and on

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[20] 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.

[21] 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.

[22] 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.

[23] 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.

[24] Medicare Provider Utilization and Payment Data: Physician and Other Supplier PUF CY2016, *available at* https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/utc4-f9xp (last accessed Dec. 14, 2019).

[25] 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.

the same terms, as the organization. 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.[26] 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."[27] 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 MIPS reporting (recall that LUGPA commended CMS for its proposals establishing requirements for MIPS participation at the virtual group level).[28] And while the Agency exercised its discretion to create as much flexibility as possible to encourage formation of virtual groups, including among individual physician specialists and specialty group practices, these provisions did not allow 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. Absent the opportunity for shared savings that would result from higher level of care coordination, 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[29] belie statistics suggesting that hospitals lose an average of $128,000 per employed physician.[30] 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."[31] This ability to cost shift physician compensation affords hospitals an often insurmountable competitive advantage in recruiting physicians which can lead to

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[26] 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.

[27] 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.

[28] 82 Fed. Reg. at 30027-34.

[29] Physicians Advocacy Institute. Op. Cit. p 8.

[30] MGMA Cost Survey: 2016 Report Based on 2015 Data.

[31] Goldsmith J, Hunter A, Strauss, A. Do Most Hospitals Benefit from Directly Employing Physicians? Harvard Business Review; May 29, 2018, *available at* https://hbr.org/2018/05/do-most-hospitals-benefit-from-directly-employing-physicians (last accessed Dec. 14, 2019).

virtual monopolies in healthcare services. Measurement of the Herfindahl-Hirschman Index data suggests that this market share domination can vary widely by specialty.[32]

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 develop 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 current Stark law. After six months of expensive legal research, which did not result in a viable proposal, the breast surgeons commenced soliciting offers from hospitals.

4. <u>A Western LUGPA practice cannot create practice efficiencies in a hospital outpatient surgical department.</u>

There exists substantial price disparities between ambulatory surgical centers ("ASCs") and both inpatient and outpatient hospital departments.[33] This has led to an increased number of ASCs and a concomitant increase in the number of procedures performed at this site of service,[34] a trend observed as well in urology.[35]

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 Stark law and AKS.

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[32] 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.

[33] Commercial Insurance Cost Savings in Ambulatory Surgery Centers. Prepared by Healthcare Bluebook for the Ambulatory Surgical Center Association, *available at* https://www.ascassociation.org/asca/communities/community-home/librarydocuments/viewdocument?DocumentKey=61197e80-d852-4004-860a-2424968b005b (last accessed Dec. 12, 2019).

[34] Dyrda L. 16 financial and operational trends for ASCs. Becker's ASC Review, May 2, 2017, *available at* https://www.beckersasc.com/asc-turnarounds-ideas-to-improve-performance/16-financial-and-operational-trends-for-ascs.html (last accessed Dec. 12, 2019).

[35] 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.

III. CMS Should Finalize the Newly Proposed Exceptions and Revisions to Key Terminology in the Stark Regulations to Protect Independent Specialty Practices that Seek to Deliver High Quality, Coordinated Care in a Value-Based Payment System.

LUGPA believes that the bold changes CMS is proposing to the Stark regulations will enable us to realize MACRA's goal of shifting our healthcare system from fee-for-service to value-based care delivery. These modifications to the Stark regulations, when combined with the Stark law's existing in-office ancillary services exception that is critical to the success of value-based payment models that deliver integrated, comprehensive care, will allow for the development of arrangements between providers to create referral pathways that will incentivize care coordination across sites of service and enable distribution of shared savings presently prohibited under volume or value restrictions. For those practices that have incorporated ancillary services into their practices, CMS's proposed modifications to the Stark regulations, once finalized, will enable them to reward compliance with pathways that encourage surveillance for appropriate patients—critical "behavior shaping" that will improve health care outcomes while reducing costs to Medicare beneficiaries and the Medicare program as a whole. Current Stark regulations prevent the type of gainsharing arrangements that would be required for non-employed physicians to create arrangements with hospitals that would enable care coordination and distribution of shared savings that result from modification of how ancillary services are utilized.

We focus in this Part III on those proposals that we believe will have the most significant impact in unlocking the ability of independent urology (and other specialty) practices to develop and operationalize value-based arrangements for the benefit of their patients. With limited modifications we describe below, CMS should finalize its proposed regulations as early in 2020 as possible.

A. LUGPA Supports the Proposed Definitions that Serve as the Foundation for the Newly Proposed Stark Exceptions.

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

We offer the following comments in response to CMS's solicitation of input on the proposed value-based terminology:[36]

1. We agree with the flexible approach that CMS has taken in defining the term "value-based activity" to include "the provision of an item, the provision of a service, the taking of an action, or the refraining from taking an action provided that the value-based activity is reasonably designed to achieve at least one value-based purpose of the value-based enterprise of which the parties are participants."[37] CMS should finalize the proposed definition with one modification. CMS states that "the act of referring patients for designated health services is itself not a value-based activity."[38]

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[36] 84 Fed. Reg. at 55773-76.
[37] Id. at 55773.
[38] Id. at 55773.

For its part, OIG, in the AKS Proposed Rule, notes that "[u]nder no circumstances would *simply* making a referral constitute a 'value-based activity.'"[39] 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, including DHS; such referrals should not prevent that care coordination effort from being deemed a "value-based activity."

2. We believe that CMS'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.[40] Importantly, the proposed definition recognizes that VBAs might be quite small with value-based participants being individual physicians and/or small, independent medical practices. CMS should not narrow the definition of VBA, as it is considering doing, by requiring care coordination and management in order to qualify as a VBA.[41] To be sure, we expect that a significant percentage—perhaps a great majority—of VBAs will involve activities that coordinate and manage the care of a target population, but we are too early in the development of a value-based health care delivery system to limit VBAs in such fashion.

3. It is particularly important that, in defining the term VBE, CMS explained that "it is not our intention to dictate or limit the appropriate legal structures for qualifying as a value-based enterprise."[42] Although we fully expect that VBEs will include ACOs and other mega-health care entities, we know that our LUGPA member practices—distinct, independent group practices—will also seek to collaborate with one another to develop and operate VBAs in furtherance of the goals of a value-based health care system.

4. We generally support the broad definition of "value-based purpose," but we do not agree with the modification that CMS 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."[43] 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 CMS 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.[44] To be clear, LUGPA member practices strive in their development of, and participation in, VBAs to improve the quality of patient care while

[39] AKS Proposed Rule, 84 Fed. Reg. at 55703 (emphasis added).
[40] Stark Proposed Rule, 84 Fed. Reg. at 55773-74.
[41] Id. at 55774.
[42] Id.
[43] Id. (emphasis added).
[44] Id. at 55774-75.

simultaneously reducing the costs of that care, but protection under the new Stark exceptions 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.

5. We agree with the proposed definition of "target patient population" to mean that "the identified patient population selected by a value-based enterprise or its VBE participants us[es] legitimate and verifiable criteria that are set out in writing in advance of the commencement of the value-based arrangement and further the value-based enterprise's value-based purpose(s)."[45] We were pleased to see that CMS apparently is not considering a narrowing of the definition of "target patient population" along the lines of what OIG articulated in the AKS Proposed Rule. For its part, OIG stated that it is considering for the AKS Final Rule a significant narrowing of the definition to include only patients with chronic conditions and/or those with a shared disease state who would benefit from care coordination.[46] 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 CMS and OIG to finalize the definition of "target patient population" as proposed in the Stark and AKS Proposed Rules and without the modification OIG is contemplating. 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 OIG is contemplating. 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 (such as obesity) would be equally, if not more, valuable than the narrow definition proposed.

6. Consistent with the flexibility that is the hallmark of CMS's proposed definitions to key "value-based" terminology, we do not believe it is desirable or necessary for CMS to define in regulation what is meant by "coordinating and managing care."[47] As CMS recognizes, creating a definition for the phrase "coordinating and managing care" would open up a series of additional questions regarding how to determine (i) whether quality of care has improved, (ii) whether costs are reduced or expenditure growth has been stopped, and (iii) what parties must do to show they are transitioning from free-for-service to value-based health care delivery and payment mechanisms.[48] The fact that OIG is proposing to define the term "coordinating and managing care" in the context of the AKS should not lead CMS, in finalizing its own proposed regulations, to create such limits within the Stark law.

[45] Id. at 55776.
[46] AKS Proposed Rule, 84 Fed. Reg. at 55702.
[47] Stark Proposed Rule, 84 Fed. Reg. at 55775.
[48] Id.

B. CMS Should Finalize, with Limited Modifications, the Three Proposed Stark Exceptions Applicable to Value-Based Arrangements.

LUGPA strongly endorses, with limited modifications described below, the three newly proposed exceptions for compensation arrangements—(i) the full financial risk exception, (ii) the meaningful downside financial risk exception, and (iii) the exception for VBAs that applies regardless of the level of financial risk taken. Before discussing each exception, we wish to comment on what we believe is the single most important aspect of these exceptions—CMS's decision not to subject the new exceptions to the requirements applicable to existing Stark exceptions that compensation be set in advance, at fair market value, and not take into account the volume or value of a physician's referrals or other business generated between the parties to a VBA.

It is not merely that these requirements "may be difficult to satisfy" for VBAs designed to foster the "behavior shaping" necessary for the provision of high-quality patient care that is not reimbursed on a traditional fee-for-service basis;[49] the requirements are antithetical to—and conflict with—CMS's goal of addressing regulatory barriers to value-based care transformation. If applied to VBAs, these requirements would "inhibit the innovation necessary to achieve well-coordinated care that results in better health outcomes and reduced expenditures (or reduced growth in expenditures)."[50] Although compensation *methodologies* can be set in advance of operationalizing a VBA, the amount of the compensation cannot be. More fundamentally, the alignment of clinical and financial interests that is key to the behavior shaping necessary to succeed in a value-based payment system will, by definition, take into account the volume or value of physician referrals and/or other business generated between parties to a VBA. CMS should not lose sight of this critically important fact as it finalizes the new Stark exceptions.

1. <u>Full Financial Risk Exception</u>

In time, we believe that the Full Financial Risk Exception will be become a more commonly relied upon exception by independent medical practices. We appreciate that CMS has not purported to prescribe a specific manner for the assumption of full financial risk apart from offering examples such as capitation payments and global budget payments from payors that compensate VBEs for providing all patient care items and services for a target population for a predetermined period of time.[51] Our comments focus on ensuring that the Full Financial Risk Exception, when finalized, will provide maximum flexibility to VBE participants across sites of service, including independent urology (and other specialty) practices.

It is critical that CMS build into the Full Financial Risk Exception protection for a substantial period of time prior to the date by which the VBE must assume full 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,[52] the development of VBAs amongst smaller health care providers such as independent medical practices will take longer to develop and would benefit from a full 12-month window in which protection will be available prior to the VBE having to assume full financial risk.

The Full Financial Risk Exception is designed to provide the greatest flexibility in order to maximize innovation in the development of value-based care delivery models. As such, and in order to encourage

[49] <u>Id</u>. at 55777.
[50] <u>Id</u>. at 55776-77.
[51] <u>Id</u>. at 55779.
[52] <u>Id</u>. at 55780.

the development of such models by independent medical practices, we support the proposal CMS is considering of VBEs being deemed to be at full financial risk even when the VBE is responsible only for a defined set of patient care services for a target population (as opposed to being at risk for all patient care items and services) for the target population.[53] And while we believe it is appropriate for a VBE to be at full financial risk for a predetermined period of time, we do not believe that a minimum period of time need be prescribed by regulation (as CMS suggested it was considering by creating a 1-year minimum period for the VBE to be at full financial risk).[54]

2. Exception for Meaningful Downside Financial Risk to the Physician

LUGPA generally supports CMS's proposed exception to protect VBAs in which physicians take on meaningful downside financial risk.[55] Like CMS, we believe that it is important to include an exception that covers both in-kind and monetary 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.

For the same reasons we noted above with respect to the Full Financial Risk Exception, we are concerned that VBEs designed amongst smaller providers such as independent medical practices and individual physicians will need more than the 6-month period being proposed for protection to develop and implement arrangements in anticipation of physicians taking on meaningful downside financial risk.[56] Although the proposed six-month period might be sufficient for larger VBEs and VBE participants such as ACOs and large health systems,[57] 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 protection will be available prior to the physician having to assume meaningful downside financial risk.

3. General Exception for Value-Based Arrangements

We agree with CMS that it is important to create an exception for VBAs that does not require the assumption of financial risk, but is designed to and, in fact, improves quality, health outcomes, and efficiency in care delivery.[58] HHS cannot accomplish its Regulatory Sprint to Coordinated Care without adding such an exception to the Stark law. This exception is particularly important for physicians and independent group practices, especially smaller practices that are not as likely to be used to sharing risk or to absorbing downside financial risk. CMS is right that the inclusion of a broad-based exception for VBAs will "encourage more physicians to participate in care coordination activities now while they continue to build towards being able to enter into two-sided risk-sharing arrangements."[59] We comment here on those aspects of the exception for VBAs that we believe are critical to finalize as written or with modification.

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[53] Id. at 55779.
[54] Id.
[55] Id. at 55781-83.
[56] Id. at 55782.
[57] Id.
[58] Id. at 55783-86.
[59] Id. at 55783.

We do not believe that CMS should narrow the proposed exception to permit only nonmonetary remuneration. CMS need not look any further than the example it offered in the Proposed Rule in which a hospital revises its care protocol for screening for a certain type of cancer to incorporate newly issued guidelines from a nationally recognized organization recommending screening by combining two modalities to achieve more accurate results.[60] The hospital's offer to pay physicians $10 for each instance that they order dual-modality screening—a clear effort at "behavior shaping" aimed at detecting more cancers and avoiding potentially unnecessary overtreatment of false positive results—is monetary remuneration that should be protected under the exception for VBAs. CMS should finalize this aspect of the proposed exception, as written, to create greater flexibility with respect to the form of remuneration protected under the VBA exception.

We agree with CMS 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 in furtherance of a VBA be used for the coordination and management of care.[61] 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 VBA 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 CMS stated it is considering—is to exempt certain classes of recipients (e.g., small and rural providers) from the contribution requirement altogether.[62] Finally, we urge CMS to adopt an alternative proposal that OIG is considering in connection with the Care Coordination Safe Harbor in the AKS Proposed Rule 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.[63]

Although we agree that one or both parties must monitor the compliance of their VBE with an applicable exception, we do not believe CMS should modify the VBA exception—as it is considering doing—to require a physician to cease referring DHS to the VBE immediately upon determining that the value-based purpose(s) will not be achieved through the value-based activities.[64] Some meaningful period of time—and we recommend 120 days—should be provided to the VBE to address ways in which the value-based activities are not meeting the value-based purpose(s). We are concerned that the Stark law's strict liability structure combined with the risk of financial penalties under the Stark law and potential liability under the False Claims Act would chill the development of, and participation in, value-based care models if a reasonable period of time were not given to VBA participants to remediate deficiencies in their VBAs before losing protection under the VBA exception.

IV. CMS's Proposals Clarifying the Meaning of "Commercial Reasonableness," the "Volume or Value" and "Other Business Generated" Standards, and the Definition of "Fair Market Value" Are Critical to Reducing the Burden Imposed by the Stark Law.

LUGPA commends CMS for the bold steps the Agency is taking to unlock innovation in a value-based care delivery and payment system. Every bit as important as the new exceptions discussed in Part III(B)

[60] Id. at 55784-85.
[61] Id. at 55785-86.
[62] Id. at 55786.
[63] AKS Proposed Rule, 84 Fed. Reg. at 55712.
[64] Stark Proposed Rule, 84 Fed. Reg. at 55785.

above are the clarifications and changes that CMS has proposed to fundamental terminology in the Stark regulations that, unless finalized, will continue to block providers across health care settings—particularly in independent medical practices—from developing and operationalizing VBAs and otherwise maintaining compliance with the Stark law.

A. Definition of "Commercially Reasonable" Compensation Arrangements

A formal definition for the term "commercially reasonable" is long overdue, and we thank CMS for proposing options for a regulatory definition.[65] We believe that the first of the two options CMS presented in the Proposed Rule is more straightforward and, with a modification described below, should be adopted. As proposed, the term "commercially reasonable" would mean that "the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements."[66] Our one concern about the definition is that it requires commercial reasonableness to be assessed, in part, by comparing the terms and conditions of the arrangement to the terms and conditions of "like" arrangements. At a moment when HHS is encouraging innovation, including the development of novel value-based care delivery and payment models, we are concerned that assessing commercial reasonableness by comparison to "like" arrangements will prove challenging. If CMS's aim is for an arrangement to be deemed "commercially reasonable" when the arrangement "makes sense as a means to accomplish the parties' goals,"[67] then it would be more appropriate to keep the formal definition equally simple and to require only that the arrangement "furthers a legitimate business purpose of the parties."[68]

B. The "Volume or Value" and "Other Business Generated" Standards

As we noted in Part III(B) above, we strongly support CMS's proposal not to include the "volume or value" and "other business generated" standards as requirements for remuneration between parties to a VBA. Physicians cannot meaningfully participate in the development and operation of VBAs without eliminating these requirements as applied to value-based payment systems. It is equally true, however, that even outside the context of VBAs, the "volume or value" and "other business generated" standards applicable to compensation arrangements between health care entities and physicians have needed to be clarified and simplified for decades. We applaud CMS for taking such steps in the Proposed Rule.

LUGPA supports CMS's proposal to create an objective test for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician.[69] Physicians and health care entities have long-needed such a bright line rule. We agree with the proposal insofar as it limits the prohibition on taking into account the volume or value of referrals or the volume or value of other business generated to instances in which "the mathematical formula used to calculate compensation includes as a variable referrals or other business generated, and the amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity."[70] If the formula used to calculate compensation from an entity to a physician (or from a physician to an entity) does not include the physician's referrals as a variable, then physicians and health care entities will know that they have not run afoul of the Stark law's

[65] Id. at 55790-91.
[66] Id. at 55790.
[67] Id.
[68] We note that such a definition of the term "commercially reasonable" would be consistent with CMS's aim of making clear that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties. Id.
[69] Id. at 55791-95.
[70] Id. at 55793.

prohibition of compensation being paid in a manner that takes into account the volume or value of the physician's referrals to the entity or the physician's generation of other business for the entity.

C. Definition of "Fair Market Value"

We comment to emphasize one important aspect of CMS's proposed revision to the definition of "fair market value" compensation. Ever since CMS issued its Phase II regulations, the definition of "fair market value" has been inappropriately (and unnecessarily) encumbered by the Agency having layered into the definition that price or compensation cannot be determined in any manner that takes into account the volume or value of anticipated or actual referrals. The "volume or value" standard is an independent requirement in the Stark law, and we have long believed that it is a mistake to define fair market value, even in part, in terms of the volume or value standard. As noted in Part IV(B) above, we support CMS's simplification of the volume or value standard; we likewise support the Agency's proposed revision to the definition of "fair market value" to eliminate the connection to the volume or value standard.

V. CMS Should Refrain from Regulatory Changes Limiting the Stark Law's In-Office Ancillary Services Exception.

While we applaud efforts to modernize the Stark law, we are concerned that those who had historical monopolies over certain services may use the opportunity to encourage CMS to restrict or revise, through regulation, the protections afforded by the in-office ancillary services exception ("IOASE") to the Stark law's self-referral prohibitions.[71] The IOASE provision is critical to the efficient delivery of health care services and to independent practices' ability to integrate care and successfully compete with mega-hospital systems. Yet, providers with historic monopolies over certain designated health services ("DHS") seek to undermine the ability of physicians in other specialties and sites of service to furnish comprehensive, integrated care by seeking a narrowing of IOASE protection or elimination of the provision entirely.

It would be fundamentally antithetical to modernizing the Stark law to suggest that the law (either through statutory or regulatory change) be made even more burdensome and less congruent with integrated health care delivery by narrowing or repealing the IOASE. That provision has enabled our practices to provide convenient, integrated and less expensive high-quality care. As the House GOP Doctors Caucus pointed out in a letter in June 2015, two different studies by Milliman—commissioned by the American Medical Association and the Digestive Health Physicians Association—showed that utilization of ancillary services in physician practices is a small percentage of total spending on ancillary services and is declining or growing more slowly than in hospital settings.[72]

In light of the importance of the IOASE in furthering coordinated care models, we are concerned that certain purported clarifications in the Proposed Rule could undermine the effectiveness of the IOASE. We are particularly troubled by the proposed revision to § 411.352(i)(1)(ii) insofar as it includes the words "all the" before the term "designated health services."[73] As revised, "'the profits derived from all the designated health services' in proposed §411.352(i)(1)(ii) would mean that the profits from all the designated health services of the practice (or a component of at least five physicians in the practice) must

[71] 42 U.S.C. §13955nn(b)(2).

[72] Letter from House GOP Doctors Caucus to Speaker John Boehner and Leader Kevin McCarthy, *available at* https://dhpassociation.org/wordpress/wp-content/uploads/2015/12/GOP-Docs-to-Leaders-IOASE.pdf (last accessed Dec. 13, 2019).

[73] 84 Fed. Reg. at 55801.

be aggregated and distributed, with profit shares not determined in any manner that directly takes into account (that is, in any manner that is directly related to) the volume or value of a physician's referrals."[74]

This proposed revision is at odds with CMS's stated goals of reducing regulatory burden and providing physician practices with the flexibility to offer comprehensive services as a competitive counterbalance to higher-cost hospitals and health systems. Forcing all DHS into a single pool and eliminating the ability of a group practice to create distinct pools for different DHS will create challenges for those independent practices that operate across multiple geographies and, particularly, across states. For those practices, disparate state certificate of need and/or self-referral laws as well as differing payor contracts could result in a patchwork of permitted and prohibited DHS within different segments of the same group practice. Furthermore, multispecialty practices may offer certain DHS in which all physicians do not participate (e.g., radiation oncology services for treatment of prostate cancer in which the group practice's pathologists do not participate). As long as a group practice meets the other requirements of the IOASE, CMS should provide flexibility for the group practice to distribute DHS without having to combine all DHS into a single profit pool. As noted above, providing group practices with such flexibility is consistent with CMS's broader aim of protecting independent practices as a competitive counterbalance to more expensive and less convenient care furnished in the hospital setting.[75]

In that regard, as CMS modernizes the Stark law to create a level playing field for physicians caring for patients across sites of service, it is imperative that Stark law obligations apply with equal force whether physicians work in the independent practice or hospital setting. We continue to be troubled by hospitals' and health systems' use of "narrow networks" through which physicians are employed and then compelled to funnel patients to more expensive and, typically, less convenient DHS and other health care services in the hospital setting that not only limit patient choice and drive system and beneficiary costs but further fuels the inflation of physician salaries in the hospital setting over fair market value. LUGPA believes in a level playing field such that patients are treated at the site of service that 1) is most convenient; 2) is most cost effective; and 3) produces the best outcomes. Protecting patient choice and access to high quality, convenient care, including in the independent practice setting, should be of paramount concern to CMS as it finalizes changes to the Stark regulations. At the very least, a hospital-employed physician referring patients into a narrow network for DHS should be compelled to disclose the limited nature of those options and offer alternative locations, outside the hospital setting, for delivery of those services. As the Agency contemplates implementing the special rules on compensation in § 411.354(d), it is imperative that these rules are not used to exacerbate hospitals' competitive advantage in compensating physicians; competitive advantages that may be derived from inequities in differential payments based on site of service.

VI. Request for Action

We thank CMS for the bold efforts it has proposed to address the impact and burden of the Stark law, including the ways in which Stark regulations inhibit—and, in many instances, prohibit—improved care coordination as well as the development and operation of value-driven care delivery models. Simply put, there are certain aspects of the Stark law (and AKS under the jurisdiction of OIG) that are anathema to the types of care delivery and payment models that Congress sought to unlock through MACRA. As a

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[74] Id.

[75] As one further point of clarification, we believe it is important for CMS to clarify that when referring to "the profits derived from *all* the designated health services," CMS does not mean to include services that are performed directly by a physician or incident to physician services. Although Stark is not implicated in such a situation, given that there is no referral involved, it would be useful for CMS to make clear that "all" DHS only means DHS referred by a physician.

result, we can expect that physicians and independent medical practices will continue to be "discouraged from entering into innovative arrangements that would improve quality outcomes, produce health system efficiencies, and lower costs (or slow their rate of growth)"[76] until CMS and OIG finalize the Stark and AKS Proposed Rules.

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

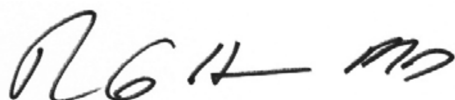
- Coordinate with OIG to finalize a single set of definitions to govern the lexicon of value-based terminology for the Stark law and AKS, including:
    - Clarifying that although a referral, standing alone, will not constitute a "value-based activity," a value-based activity can encompass a referral as part of a care coordination effort;
    - Finalizing the definition of "value-based arrangement" without narrowing it to require care coordination and management in order to qualify as a VBA;
    - 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;
    - Finalizing the definition of "target patient population" as proposed and without modification being considered by OIG that would narrow the definition to include only those patients with chronic conditions or a shared disease state;
    - Maintaining flexibility in the "value-based" terminology by not defining—and thereby limiting—what is meant by "coordinating and managing care";
- With respect to the three newly-proposed exceptions applicable to VBAs:
    - Finalize all three exceptions without subjecting them to the requirements applicable to existing Stark exceptions that compensation be set in advance, at fair market value, and not take into account the volume or value of a physician's referrals or the other business generated between the parties to a VBA;
    - Finalize the Full Financial Risk Exception with limited modifications to (i) provide a full 12-month period in which protection under the exception will be available prior to the VBE having to assume full financial risk, and (ii) extend protection under the exception even when the VBE is responsible only for a defined set of patient care services for a target population.
    - Finalize the Meaningful Downside Financial Risk Exception with a limited modification to provide a full 12-month period in which protection under the exception will be available prior to the physician having to assume meaningful downside financial risk;
    - Finalize the exception for VBAs that does not require the assumption of financial risk without narrowing the exception to permit only nonmonetary remuneration and with limited modifications to (i) exempt small and rural providers from any contribution requirement, (ii) impose a contribution requirement only for the initial provision of remuneration but not with respect to updates, upgrades or patches of remuneration provided over the course of the VBA, and (iii) permit the VBE a period of 120 days to address ways in which the value-based activities of the VBE are not meeting the value-based purpose(s) before protection under the VBA exception is lost.

[76] Stark Proposed Rule, 84 Fed. Reg. at 55768.

- Modify the proposed definition of what constitutes a "commercially reasonable" arrangement to mean that the arrangement "furthers a legitimate business purpose of the parties";
- Finalize the proposed, objective test for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician such that, if the formula used to calculate compensation from an entity to a physician (or from a physician to an entity) does not include the physician's referrals as a variable, then physicians and health care entities will know that they have not run afoul of the Stark law's prohibition of compensation being paid in a manner that takes into account the volume or value of the physician's referrals to the entity or the physician's generation of other business for the entity;
- Finalize the revision to the definition of "fair market value" to eliminate the connection to the volume or value standard;
- Refrain from proposing regulatory limitations to the Stark law's in-office ancillary services exception or to the related distribution of DHS that would place independent practices at a competitive disadvantage to physicians furnishing care in the higher-cost hospital setting; and
- Support the continued viability of the high quality, lower-cost independent practice model by forbidding the use of downstream revenue to support the salaries of hospital-employed physicians as a mechanism for leveraging payment advantages to keep care in the high-cost hospital setting.

On behalf of LUGPA, we would like to thank CMS for providing us with this opportunity to comment on the Proposed Rule. Please feel free to contact Dr. Kapoor at (516) 342-8170 or dkapoor@impplc.com, 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 CMS as it considers these issues.

Respectfully submitted,



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