1100 East Woodfield Road
Suite 350
Schaumberg, IL 60613
www.lugpa.org

August 24, 2018

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

RE: Comments to CMS-1720-NC

Dear Administrator Verma:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Program Request for Information ("RFI") Regarding the Physician Self-Referral ("Stark") Law.[1] We appreciate the seriousness with which the U.S. Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS") are responding to the need to modernize the Stark law. We agree that HHS will not be able to achieve its goal of "transform[ing] the healthcare system into one that pays for value,"[2] unless the statutory and regulatory requirements and prohibitions that act as barriers to coordinated care are addressed. In fact, we testified on this exact issue last month before the House Ways & Means Subcommittee on Health, noting the critical importance of modernizing the Stark law to promote the transition from fee-for-service to value-based care in the Medicare program and in our healthcare system more broadly.[3]

As we explain in this comment letter, we do not advocate for wholesale repeal of the Stark law. Nevertheless, there are targeted modifications to the Stark law that must be made, without delay, to allow for the creation and operation of innovative care delivery systems—across medical specialties and sites of service—that will improve outcomes and decrease cost. And while certain of the changes to the Stark law will need to occur through legislation such as the bipartisan Medicare Care Coordination Improvement Act of 2017,[4] we believe that CMS can make

[1] 83 Fed. Reg. 29524 (June 25, 2018).
[2] Id.
[3] Testimony of Dr. Gary Kirsh, LUGPA Immediate Past President & Chair of LUGPA Alternative Payment Model Task Force, Hearing before the U.S. House of Representatives Ways and Means Subcommittee on Health, "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program" (July 17, 2018) ("LUGPA Cong. Testimony").
[4] S. 2051 & H.R. 4206, 115th Congress (2017-2018).

meaningful modifications to the Stark law through the Agency's existing regulatory authority.

We agree with CMS that an analysis of whether (and how) to modify the Stark law should begin with an examination of specific care delivery models that are adversely impacted by the law. Accordingly, in Part I, we provide concrete examples of alternative payment models ("APMs") and other novel financial arrangements that LUGPA member practices have developed and wish to develop in the future. We believe that these examples are the types of value-based arrangements that Congress envisioned when it passed the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), but that have hit a roadblock in the form of the Stark law. In Part II, we discuss the targeted changes to the Stark law that are needed to ensure that independent, integrated specialty practices can continue delivering high quality, coordinated care in the post-fee-for-service era.

As we present in more detail below, LUGPA recommends that CMS take the following steps to modernize the Stark law:

- Clarify, through regulation, that a group practice's distribution of a productivity bonus or profit share on the basis of a physician's MIPS composite score (or a component thereof) or in support of APM goals is not deemed to take into account the volume or value of referrals;
- Create a single, comprehensive waiver of the Stark law for participants in any bona fide APM;
- Exercise the Agency's general authority to develop regulatory exceptions to extend the protections of the ACO waivers to physicians and designated health services ("DHS") entities that participate in Other Payer APMs;
- Amend the definition of "entity" or use the Agency's exception authority to clarify that bona fide "under arrangement" relationships designed to achieve MIPS quality metric, CPIA or APM goals are permitted under the Stark law;
- Support passage of—and provide technical assistance in connection with—the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for making those changes to the Stark law that cannot be achieved through regulation; and
- In the course of efforts to modernize the Stark law, refrain from regulatory changes that would limit the ability of physicians to utilize the in-office ancillary service exception ("IOASE") to incorporate DHS into their practices.

CMS Administrator Verma said it perfectly in remarks this past Spring, when she noted that modifications to the Stark law must "leave in place the law's important protections for our beneficiaries—and for the trust fund—while not penalizing providers who are taking brave steps away from fee-for-service."[5] LUGPA member practices are taking those steps and look forward to working with CMS, HHS, and Congress to help develop responsible reforms to the Stark law that will remove roadblocks to the development of value-based care models.

I. LUGPA

In 2008, when physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the

[5] 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.

purpose of enhancing communication between large urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 145 urology group practices in the United States, with more than 2,100 physicians who, collectively, provide approximately 35% of the nation's urology services.[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 men with prostate, kidney and bladder cancer, in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, regulatory agencies, and legislative bodies.

LUGPA and its member practices were early proponents of the shift from fee-for-service to value-based payment models and, since passage of MACRA, we have been advocating for targeted reforms of the Stark law 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 Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206), which has been endorsed by 25 physician organizations representing 500,000 doctors;[8] and (iii) testified in Congress on the subject of modernizing the Stark law to support value-based care delivery models.[9] In short, we have been highly engaged on the important issues on which CMS has sought comment in the RFI.

---

[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.

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

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

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

As the Stark law statute has not been fundamentally revisited or amended since 1993, it has not kept pace with the evolution of care delivery models and payment paradigms established since passage of MACRA more than three years ago. The archaic nature of the Stark law has been particularly harmful to independent specialty practices and the patients we serve. The need for reform is evident as studies are confirming that independent practices are commonly the highest value site-of-service. In this Part I, we briefly summarize why it is so important for CMS to promote the role of independent practices in value-based care delivery and then set forth specific examples of APMs and other novel financial arrangements that LUGPA member practices are developing for the benefit of our patients and the Medicare program.

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

Protecting the independent practice model is critical to the continued viability of our healthcare system, generally, and the Medicare program, in particular, as this provides an important competitive model 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]

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 Accountable Care Organizations ("ACOs") and other integrated care systems lagging in their inclusion of physician specialists.[13] This is not surprising given the fact that waivers of the Stark law prohibitions 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-

[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).

[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/.

employed physicians increased by 50 percent.[14] Without modernizing the Stark law, the trend of physicians being driven out of independent practice and into the higher-cost hospital setting will continue and, almost certainly, worsen.

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

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

For the benefit of our patients, LUGPA's member practices are eager to move from the theoretical to the practical. Doing so is exactly what the architects of MACRA expected of us and, yet, we remain thwarted by a Stark law that simply has not caught up with 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 with respect to APMs and other novel financial arrangements will benefit Medicare beneficiaries (and other patients).

1. A LUGPA practice in the Northeast was unable to develop an episode of care that would reduce infectious complications from prostate biopsies.

The diagnosis of prostate cancer is contingent upon the performance of a prostate biopsy; the most common method of doing so is via a trans-rectal approach with a variety of different guidance mechanisms. Episodes of care surrounding prostate biopsy would be an excellent opportunity for APM development because significant savings and improved patient care can be achieved by minimizing infections, which are all too common. This episode could include professional services, facility fees, anatomic pathology services, and imaging services. 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.[15]

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

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

[15] 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[16] to as high as $94,737 per episode in patients who had prior antibiotic exposure in the prior 90 days.[17] The rate of infection after prostate biopsy is reported to be as high as 4.1%,[18] and the most recent Medicare data shows that urologists performed 111,905 prostate biopsies in 2016.[19] Given this data, Medicare expenditures to manage this complication could exceed $250 million annually.[20]

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 DHS (pathology, 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 Anti-Kickback Statute. 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 the same terms, as the organization. After legal review, attempts to create this care model were abandoned as impermissible.

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

About two-thirds of all cancer patients undergo radiation therapy at some point during the course of their disease.[21] Data suggests that, nationally, there is broad variation in the administration of radiation therapy; factors unrelated to the individual patient account for the majority of such variations in the cost of radiation therapy, indicating potential inefficiency in health care expenditure.[22] Given this, communities would be better served through consolidation and elimination of unnecessary, expensive services. Part of this strategy ideally involves a variety of stakeholders, each of which could participate in such a model in a value-based ecosystem.

With the intent of preventing oversaturation of services, the practice entered good faith negotiations with a regional hospital system; however, the fair market value portion of the deal could not navigate around

[16] 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.
[17] 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.
[18] 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.
[19] 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
[20] 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.
[21] Yamada Y. Cancer Rehabilitation: Principles and Practice 2009 New York, NY Demos Medical Publishing.
[22] Paravati AJ, Boero IJ, Triplett DP, et al. Variation in the Cost of Radiation Therapy Among Medicare Patients With Cancer. J Oncol Pract. 2015 Sep;11(5):403-9.

the "hourly" rule. Physicians could only be paid an hourly rate which had to be recorded. This radiation joint venture would have created clinical pathways, outcome measures and management relationships that would have lowered overall costs for radiation, yet existing Stark law prohibitions created a roadblock as the hospital system could not remunerate the practice for those efforts or risk sharing without assigning and tracking an hourly physician unit of work. Although both parties would have been comfortable with assigning a fixed dollar amount to those activities the fair market hourly rate for physicians simply did not allow for the appropriate distribution of shared savings. Despite the opportunity to achieve better outcomes, improve adherence to clinical pathways and lower cost, the project was abandoned out of concern for running afoul of the Stark law.

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

There is ample data supporting the notion that vertical integration of physicians and hospitals increase cost without any commensurate increase in quality.[23] 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."[24] 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).[25] 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.

[23] 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.
[24] 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.
[25] 82 Fed. Reg. at 30027-34.

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

Data illustrating the trend towards increased acquisition of physician practices by hospitals[26] belie statistics suggesting that hospitals lose an average of $128,000 per employed physician.[27] 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."[28] 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.[29]

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 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.

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

There exists substantial price disparities between ambulatory surgical centers (ASCs) and both inpatient and outpatient hospital departments.[30] This has led to an increased number of ASCs and a concomitant increase in the number of procedures performed at this site of service,[31] a trend observed as well in the

[26] Physicians Advocacy Institute. Op. Cit. p 8.
[27] MGMA Cost Survey: 2016 Report Based on 2015 Data. Accessed at: https://www.mgma.com/resources/products/mgma-2016-practice-operations-report.
[28] 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.
[29] 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.
[30] 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.
[31] 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.

urology space.[32] An unintended consequence of this trend is the adverse financial effect on hospitals that can result from this migration of services out of the hospital environment.[33]

A LUGPA practice with close ties to a local community hospital sought a compromise solution that would lower costs and not contribute to oversupply of healthcare resources in the region. Utilizing their specialty-specific expertise, this group worked with the hospital 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 Anti-Kickback Statute.

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

As CMS Administrator Verma recently noted, 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."[34] 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 nearly 30 years ago to respond to the risk of overutilization of health care services in a fee-for-service world, 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 described in Part I(B) above.

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."[35] Three years later, those barriers are proving to be even more onerous than originally perceived, and the vision of MACRA and value-based care delivery is in jeopardy.

According to CMS, currently only five percent of physicians are even participating in an APM. More troubling, there are almost no APMs in the pipeline. In the two and a half years that the Physician-Focused Payment Model Technical Advisory Committee ("PTAC") has been operational, only 26 APMs have been submitted for review. Of these 26 submissions, only four have been recommended for implementation and six for limited scale testing. Moreover, not a single PTAC-recommended APM has

[32] 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.

[33] Carey K, Burgess JF Jr, Young GJ. Hospital competition and financial performance: the effects of ambulatory surgery centers. Health Econ. 2011 May; 20(5):571-81.

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

[35] 81 Fed. Reg. 28162, 28180 (July 2015).

been enacted by CMS. Earlier this summer, PTAC cancelled its meeting for lack of submitted APM proposals. And while there are many factors contributing to the lack of APM submissions and approvals, there can be little doubt that the barriers posed by the Stark law are inhibiting innovation.

Fortunately, there are a discrete set of changes that can be made to the Stark law—some by regulation through CMS's existing regulatory authority and others through Congressional action—that will enable us to realize MACRA's goal of shifting our healthcare system from fee-for-service to value-based care delivery. These discrete modifications to the Stark law, 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 would enable distribution of shared savings presently prohibited under volume or value restrictions. For those practices that have incorporated ancillary services into their practices, modification of the Stark law would enable them to reward compliance with pathways that encourage surveillance for appropriate patients. Current Stark law provisions 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 utilization of ancillary services.

In Part II(A), we focus on those steps that CMS can take, using its existing regulatory authority, to eliminate barriers to provider alignment and collaboration in the Stark law. In Part II(B), we examine those aspects of the Stark law for which Congressional action—with support and assistance from HHS and CMS—will likely be needed.

A. CMS Should Exercise its Existing Statutory Authority to Modernize the Stark Law to Protect Financial Arrangements that Involve Integrating and Coordinating Care within a Single Medical Group Practice and between Distinct DHS Entities.

1. <u>CMS Should Use Its Regulatory Authority to Ensure that Group Practices Can Distribute Resources on the Basis of Activities Designed to Achieve the Goals of the MIPS.</u>

CMS should modify its Stark regulations to protect physician group practices that seek to implement innovative compensation strategies that incentivize achievement of the MIPS goals of improved quality outcomes (and reporting thereof), more efficient resource use, adoption of electronic health record ("EHR") technology, and engagement in Clinical Practice Improvement Activities ("CPIAs").[36] At present, the CMS group practice regulation requires that "no physician who is a member of the group practice directly or indirectly receives compensation based on the volume or value of his or her referrals," unless such compensation fits one of the "special rules for productivity bonuses or profit shares."[37]

Congress included general references to special rules for productivity bonuses and profit shares in the Stark statute:[38]

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

[36] 42 U.S.C. § 1395w-4(q)(2)(A).
[37] 42 C.F.R. § 411.352(g).
[38] 42 U.S.C. § 1395nn(h)(4)(B).

CMS has used its regulatory authority to flesh out in much greater detail what is meant by the "productivity bonus and profit share" provision. Through rulemaking, CMS established that certain types of bonuses or profit shares would be deemed not to take into account the "volume or value of referrals."[39] These deeming provisions, however, almost uniformly relate to volume-based (as opposed to value-based) measures. For example, CMS established that a profit share will be deemed not to take into account the volume or value of referrals if payment is: 1) distributed equally on a per-capita basis; 2) distributed on the basis of revenues attributed to non-DHS services; and 3) revenues from DHS are a *de minimis* part of the group's total revenues and of each physician's compensation.[40] Similarly, a productivity bonus will be protected if: 1) it is based on the physician's total patient encounters or relative value units ("RVUs"); 2) it is based on the allocation of the physician's compensation attributable to services that are not DHS; and 3) revenues from DHS are a *de minimis* part of the group's total revenues and of each physician's compensation.[41]

The existing regulations create a quandary for independent physician practices under MACRA. On the one hand, CMS explicitly protects the distribution of profit shares and productivity bonuses by a group practice on the basis of certain measures of volume (either proportionately to non-DHS revenue or on the basis of RVUs). On the other hand, under the MIPS, the amount of reimbursement for each physician is adjusted due to services provided wholly outside the physician practice because each group's resource use and performance on certain quality metrics depends in part on the overall experience of attributed patients who may receive care from many providers *outside* a given group. The result is that group practices are held accountable for the collective performance of all professionals who bill through their Tax Identification Number ("TIN") for the MIPS.[42] As a result, group practices are more accountable for the management of the total performance of physicians who bill through the group's TIN than ever before—including the referral patterns of physicians to hospitals or other providers outside the group. Yet the Stark regulations, if left unchanged, do not permit a group practice to incentivize its physicians to comply individually with these new treatment protocols. These protocols may engender obligations for individual practitioners to modify behaviors relative to treatment decisions and collaboration across sites of service.

The problem is that CMS's "deeming" rules predate—and are therefore silent on—incentives for improved care coordination, partnership with high-quality physicians, and other mechanisms to improve quality, resource use, and CPIAs. And yet, more than ever, a group practice's performance depends upon better management of a physician's referral patterns, utilization of ancillary services, and collaboration with high-quality or cost-efficient partners. These activities are inherently different from measures of personal productivity (such as RVUs). As a result, the conflicting requirements of MACRA and the Stark law inhibit group practices from structuring incentives that extend beyond a physician's personally performed services and take into consideration compliance with the group's population management objectives.

In crafting the "deeming" provisions, CMS noted that it had the ability to define other financial relationships as being outside the "volume or value" prohibition of the special rules. For example, the Agency noted (without implementing through regulation) that capitation arrangements would also be

[39] 66 Fed. Reg. 856, 908-10.
[40] 42 C.F.R. § 411.352(i)(1) & (2).
[41] Id. § 411.352(i)(3).
[42] 81 Fed. Reg. at 28178-9.

deemed as not taking into account the volume or value of referrals.[43] CMS should now revisit its more than15-year-old regulation deeming certain forms of group practice compensation as not taking into account the "volume or value" of referrals to ensure that group practices may properly compensate physicians on the basis of meeting clinical benchmarks, referrals to high-quality or cost-efficient providers, and other measures relevant to the MIPS.

Specifically, CMS should clarify, through regulation, that the distribution of a productivity bonus or profit share on the basis of a physician's MIPS composite score (or a component thereof) or in support of APM goals is not deemed to take into account the volume or value of referrals.

2. CMS Should Establish a Single, Comprehensive Waiver of the Stark Law for Participants in APMs that Adopts the Same Flexible Approach Used in the ACO Waivers.

MACRA requires CMS to move its existing care coordination programs away from a voluntary, incentive-based model to a truly universal non-fee-for-service ("FFS") payment system. As CMS recognizes, this transition necessitates modifications to the fraud and abuse laws. A healthcare marketplace in which all or most physicians are effectively *required* to accept risk and closely collaborate with hospitals and other DHS entities will be difficult to sustain under existing Stark law exceptions. It is inappropriate for physician specialists caring for Medicare beneficiaries in independent medical practices to face burdens in this new post-FFS payment system that CMS has eliminated—through the grant of broad waivers and other regulatory flexibility—for primary care physicians and hospitals.

Currently, the most common Medicare APMs are ACOs. However, existing ACO models are effectively closed to physician specialists because these models require participants to manage a patient population's full spectrum of care in a manner that is fundamentally inconsistent with specialty practice. Consequently, only 30 percent of ACOs are physician-only and, of these, almost all are primary care.[44] As we showed in Part I(B) above, LUGPA and its member practices have been developing potential APM models and other novel financial arrangements that would provide meaningful opportunities for urologists and other physicians to collaborate across sites of service in order to improve care delivery and reduce expenditures.

CMS's most comprehensive effort to address the problematic nature of the Stark exceptions is the set of waivers produced for ACOs.[45] These waivers, adopted in 2011 and recently extended, represent a significant departure from the exacting provisions of the existing Stark exceptions. Simply stated, the waivers provide broad protection to physicians and entities who are participating (or intend to participate) in the Medicare Shared Savings Program ("MSSP") or certain initiatives proposed by the Center for Medicare and Medicaid Innovation ("CMMI"). CMS proposed a set of flexible waivers covering ACOs' operations (the "participation" waiver) *and* the activities of the physicians and entities preparing to join or create an ACO (the "pre-participation" waiver).[46] CMS also believed it was necessary to waive each ACO's distribution of shared savings to entities inside and outside the ACO (as long as they are used for activities reasonably related to the purposes of the ACO).[47]

---

[43] 66 Fed. Reg. at 910.
[44] 2018 Medicare Shared Savings Program Fast Facts. Accessed at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf.
[45] 76 Fed. Reg. 67992 and 79 Fed. Reg. 62356.
[46] Id. at 68000.
[47] Id. at 68001.

Existing waivers, however, are of limited utility to integrated physician specialty practices because the MSSP is heavily weighted towards primary care. For example, beneficiary assignment to an MSSP ACO is determined based on where the beneficiary receives a plurality of his or her primary care services, with a preference for "primary care physicians" defined as internal medicine, general practice, family practice, and geriatric medicine.[48] Other specialties are considered only where a beneficiary has *no* primary care services furnished by any other primary care physician—whether inside or outside the ACO.[49] In addition, the set of quality metrics identified for MSSP ACOs is heavily weighted toward primary care case management.[50] Moreover, a specialty practice that *does* serve as the basis for beneficiary assignment is forbidden from participating in another ACO.[51] Although CMS attempted to solve the latter problem in revised MSSP regulations, the solution it applied was to exclude certain specialties entirely from involvement in beneficiary assignment.[52] As a result, most independent specialty practices are unable to take full advantage of the ACO waivers authorized under the MSSP statutory authority at 42 U.SC. § 1395jjj(f).

At the time CMS finalized its set of Stark law ACO waivers in 2011, the Agency noted that it would engage in extensive monitoring and consider additional program safeguards.[53] Since then, with the continued growth of ACOs, CMS has extended these waivers, solicited additional comment, and suggested that it would engage in further rulemaking.[54] In the seven years following the finalizing of the ACO waivers, these important policy changes have become fundamental parts of the healthcare payment system and represent a significant departure from the Stark law exceptions.

We recognize that the ACO waivers were created under statutory authority, which is limited to the MSSP and initiatives under the CMMI. However, CMS has previously exercised its authority under 42 U.S.C. § 1395nn(b)(4) to propose new exceptions that pose "no risk" of patient or program abuse. We believe the long tenure of the ACO waivers, their increasing incorporation into the daily practices of ACOs across the country, and the widespread familiarity they have achieved in the provider community are powerful arguments in their favor.

Moreover, despite HHS's warnings of increased monitoring, additional safeguards, and potential narrowing of the waivers, we are not aware of any significant patient or program abuse arising out of their use. Finally, we see no reason why CMS could not create the kind of tight integration between substantive program requirements and program integrity protections it achieved under the MSSP. If CMS is capable of crafting a set of policies that holistically support the full range of primary care-focused ACO business models, it should be able to expand this set of policies to facilitate the kind of far-reaching, change contemplated by Congress in MACRA applicable to all physicians, regardless of specialty or site of service.

Advanced APM rules create objective, stringent standards to ensure that participants in an Advanced APM are truly accepting the "downside risk" of failing to meet specified metrics.[55] Managing downside

---

[48] See 42 C.F.R. § 425.402 and definition of "primary care physician" and "primary care services" at 42 C.F.R. § 425.20.
[49] Id.
[50] Centers for Medicare and Medicaid Services, "ACO Quality Metrics," available at: https://www.cms.gov /Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads /ACO-Shared-Savings-Program-Quality-Measures.pdf.
[51] See 42 C.F.R. §§ 425.402 and 425.306(b) and associated discussion in 80 Fed. Reg. 32692, 32750-32755.
[52] Id.
[53] 76 Fed. Reg. 67992, 68008.
[54] 79 Fed. Reg. 62357.
[55] Id. at 28304-9.

risk inherently requires tremendous coordination between physicians operating within a practice and, at times, across different practices and sites of service—coordination that is fundamentally hindered by the current application of the Stark law. The *ad hoc* approach reflected in CMS's current waiver policy is no longer appropriate given the integral nature of Advanced APMs to successful MACRA implementation. CMS now has extensive experience crafting waivers for ACOs and other arrangements, particularly for Advanced APMs. These waivers have certain features in common:

1) at a minimum, they protect relationships between participants when distributing shared savings (and may also waive "pre-participation" relationships undertaken in contemplation of entering a model);

2) they require bona fide participation in an APM as evidenced by a participation agreement, under which the ACO or other responsible entity remains in good standing; and

3) they require documentation of a bona fide determination by an ACO or other responsible entity's governing body that the arrangement is reasonably related to program goals.

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

Accordingly, we ask CMS to create a single, comprehensive waiver of the Stark law as a rule published in the Code of Federal Regulations for participants in any bona fide APM.

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

Under MACRA, Congress clearly meant to transform healthcare beyond just the Medicare program. This is why participants in APMs will be able to satisfy the QP eligibility standards by using an all-payer metric that reflects participation in non-Medicare APMs.[56] But participation in non-Medicare models raises its own set of concerns under the Stark law, because payments under these models may be treated as "financial relationships" under the law. As a result, the distribution of shared savings, incentive payments, and the provision of infrastructure necessary to earn *non-Medicare* bonuses also raise concerns under the Stark law. Moreover, many of the Stark law exceptions prohibit remuneration that reflects "other business generated" between a DHS entity and a physician, which may include private pay or Medicaid business.[57]

CMS only possesses the authority to waive the Stark law for the MSSP and CMMI models, which arguably do not reach innovative payment arrangements developed entirely outside Medicare.[58] However, CMS possesses general regulatory authority to craft new exceptions, as long as they pose "no risk of program or patient abuse."[59] The Agency has previously exercised this authority to create some of

[56] 42 U.S.C. § 1395L(z)(2)(B).

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

[58] 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1).

[59] 42 U.S.C. § 1395nn(b)(4).

the most important Stark law exceptions, including the general exception for "fair market value" arrangements.[60] And, since passage of the Affordable Care Act, CMS has gained substantial experience with developing a meaningful fraud and abuse framework for the distribution of shared savings through the waiver models. That experience should give CMS the confidence that it can develop a workable exception posing "no risk of program or patient abuse."

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

4. CMS Should Reconsider Rules for Services Provided "Under Arrangement" to Facilitate Coordinated Care.

MACRA's overall focus on management of the total cost of care (without regard to the site of service) creates enormous pressure for entities across various sites of service to collaborate with one another. However, regulatory changes to the Stark law in recent years have made it more difficult for entities—particularly independent physician practices and hospitals—to offer services jointly that are not feasible for a single entity to operate. Most importantly, CMS's changes to the definition of a "DHS entity" in 2008 either prohibited or greatly complicated "under arrangement" relationships in which a hospital and physician group jointly operate a service that neither could provide on its own. Following the rulemaking, physicians and hospitals were forced either to unwind many of these relationships, including services that may, otherwise, not have been available, or to restructure these arrangements so as to comply with the new regulations. Compliance with the regulations generally restricts the degree of potential coordination that may be achieved (for example, by severely limiting the services provided by a joint-ventured entity so that it does not "perform" the DHS). This restriction is at odds with MACRA and this Administration's commitment to enhancing care coordination.

In the "under arrangement" context, a physician-owned entity enters into an arrangement (including a joint venture) with a hospital to provide medically necessary services to patients. CMS's revised definition of the term "entity" required physicians to meet a Stark law ownership exception (which are extremely narrow) to continue providing such services.[61] The ability to provide a full spectrum of services to patients is a core part of achieving the "triple aim" of enhanced population health, improved patient experience, and reduced per capita cost, particularly where a physician group is providing capital to support core services for a safety net system. Reasonable collaboration between a hospital and physician group should be encouraged if such collaboration serves to (a) ensure necessary services are available to avoid readmissions; (b) increase quality; (c) ease transitions between sites-of-service; or (d) provide more integrated care.

"Under arrangement" models can play an essential role in achieving the kind of close collaboration incentivized by MACRA. These models allow hospitals and physicians to negotiate clear, written rules surrounding the joint operation of a medically necessary service that would otherwise be impractical for either to offer on its own. In this way, a properly constructed, arms-length "under arrangements" model is *more* consistent with the policy rationale of the Stark law than the kinds of vertically integrated hospital models that have flourished (often at the expense of independent specialty care models) since CMS revised the definition of "entity." For example, under the terms of the *bona fide* employment exception to the Stark law, hospitals may pay employed physicians a bonus based on their productivity

[60] 42 C.F.R. § 411.357(l).
[61] "Entity," 42 C.F.R. § 411.351; see also 73 Fed. Reg. 48434, 48721.

and may condition the physician's employment on referrals within the hospital's clinical network,[62] creating *de facto* compensation for DHS referrals.

Enhancing the ability for physician groups to create APMs in collaboration with hospitals will allow them to remain independent of the hospital—a critical component of maintaining the viability of our healthcare system, generally, and the Medicare program, in particular.[63]

Accordingly, CMS should either amend the definition of "entity" or use its exception authority to clarify that bona fide "under arrangement" relationships designed to achieve MIPS quality metric, CPIA or APM goals are permitted under the Stark law.

5. 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 on certain services may use the opportunity to encourage CMS to restrict or revise the in-office ancillary services exception ("IOASE") to the Stark law's referral prohibitions.[64] 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. These efforts could be stymied by language in the President's budget suggesting that prior authorizations should be considered for certain in-office ancillary services.[65] It would be fundamentally antithetical to modernizing the Stark law to suggest that it should be made even more burdensome and less congruent with integrated health 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 of 2015, two different studies by Milliman Inc. - commissioned by the American Medical Association and the Digestive Health Physicians Association -showed 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.[66,67]

[62] 42 C.F.R. § 411.357(c) and 42 C.F.R. § 411.354(d).
[63] See Part I(A), supra.
[64] 42 U.S.C. §13955nn(b)(2).
[65] 2019 Presidents Budget, 2019 Major Savings and Reforms (Feb. 12, 2018) pg 153. Accessed at: https://www.whitehouse.gov/wp-content/uploads/2018/02/msar-fy2019.pdf.
[66] American Medical Association, Milliman Study, March 2015. Accessed at: http://www.ama-assn.org/ama/pub/advocacy/topics/in-office-ancillary-services-exception.page. http://cqrcengage.com/dhpa/file/Mqq6fLiKQM1/03-2009-2013%20Medicare%20Utilization%20Analysis.pdf
[67] Digestive Health Physicians Association, Milliman Study, February 2015. Accessed at: http://cqrcengage.com/dhpa/file/Mqq6fLiKQM1/03-2009-2013 Medicare Utilization Analysis.pdf.

B. The Medicare Care Coordination Improvement Act of 2017 is a Critical Component of the Effort to Modernize the Stark Law and Is Worthy of CMS's Support.

Modernizing the Stark law in support of APMs and other novel financial arrangements is also going to require action by Congress. We recognize that CMS has certain statutory limits to its regulatory authority to modify Stark and that is why 25 diverse physician organizations—across specialties and sites of service—have endorsed the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206).[68]

We appreciate CMS's commitment to working with Congress on this legislation. Legislators across both sides of the aisle recognize—as does CMS—that physicians are unable to participate in APMs because of the barriers posed by the Stark law.[69] As Principal Deputy Administrator Kouzoukas noted during a Congressional hearing this past spring, the concepts for Stark reform described by the lead sponsors of the Medicare Care Coordination Improvement Act are in line with similar concepts included in President Trump's FY 2019 budget.[70]

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

- Establishes that the Secretary's waiver authority under the Civil Monetary Penalties Law and Anti-Kickback Statute "shall apply with respect to covered APM entities to the same extent and in the same manner as such provisions apply with respect to accountable care organizations";[71]
- Creates a new exception to the Stark law's physician ownership and compensation arrangement prohibitions designed to facilitate the development and operation of APMs so that physicians can test a proposed APM when it is submitted in writing and approved by the Secretary;[72]
- Expands CMS's authority to create additional exceptions to the Stark law's physician ownership and compensation arrangement prohibitions when the Secretary determines that the financial relationship does not pose a "significant risk of program or patient abuse, including those that would promote care coordination, quality improvement and resource conservation by physician practices";[73]

We believe that the Medicare Care Coordination Improvement Act is critical to the Administration's goal of "transform[ing] the healthcare system into one that pays for value."[74] The Secretary cannot modify the scope of his own statutorily-created waiver authority; nor can CMS change the parameters—created by Congress—that permit CMS to add new exceptions to the Stark law. Such changes require Congressional action in the form of S. 2051 and H.R. 4206. Beyond that, however, CMS already has the

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

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

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

[71] See H.R. 4206, Section 2(a); S. 2051, Section 2(a).

[72] See H.R. 4206, Section 2(c); S. 2051, Section 2(c).

[73] See H.R. 4206, Section 2(b); S. 2051, Section 2(b).

[74] 83 Fed. Reg. at 29524.

authority to modify the Stark law along the lines detailed in Part II(A) above to facilitate care coordination and support physicians' efforts to deliver better value and care to their patients.

IV. Request for Action

We thank CMS for the efforts it is making to address the impact and burden of the Stark law, including the ways in which the law inhibits—and, in certain instances prohibits—care coordination. The Stark law does not need to be eliminated for our healthcare system to transition successfully from a fee-for-service to a value-based payment system. However, there are certain aspects of the Stark law that are anathema to the types of care delivery and financial models that Congress sought to unlock through MACRA. Although certain reform efforts will need to be achieved through legislation such as the bipartisan Medicare Care Coordination Act of 2017 (S. 2051/H.R. 4206), there are valuable steps that CMS can take, pursuant to its existing regulatory authority, to eliminate barriers to coordinated care.

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

- Clarify, through regulation, that a group practice's distribution of a productivity bonus or profit share on the basis of a physician's MIPS composite score (or a component thereof) or in support of APM goals is not deemed to take into account the volume or value of referrals;
- Create a single, comprehensive waiver of the Stark law for participants in any bona fide APM that adopts the same flexible approach used in the ACO waivers;
- Exercise the Agency's general authority to develop regulatory exceptions to extend the protections of the ACO waivers to physicians and DHS entities that participate in Other Payer APMs;
- Amend the definition of "entity" or use the Agency's exception authority to clarify that bona fide "under arrangement" relationships designed to achieve MIPS quality metric, CPIA or APM goals are permitted under the Stark law;
- Support passage of—and provide technical assistance in connection with—the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for making those changes to the Stark law that cannot be achieved through regulation; and
- Refrain from proposing regulatory limitations to the Stark law's in-office ancillary services exception.

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

Respectfully submitted,

Neal D. Shore, 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