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September 8, 2015

BY ELECTRONIC SUBMISSION

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

RE: Comments on CMS-1631-P

Dear Acting Administrator Slavitt:

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016 Proposed Rule (CMS-1631-P), published in the July 15, 2015 Federal Register (the "Proposed Rule").[1] These comments principally address two issues of great concern to LUGPA's member medical practices and, more broadly, to the sustainability of independent physician specialty practices as a high quality, low cost option for delivery of health care services.

First, LUGPA comments on the proposed change in Medicare policy with regard to the coding and billing of radiation oncology services. We strongly disagree with (1) CMS's proposals to classify intensity-modulated radiation therapy ("IMRT") for breast and prostate cancer under a new "simple" code (CPT Code 77385) that functions as a massive reimbursement cut for these services, in apparent violation of CMS's obligations under relevant statutes; (2) CMS's application of an equipment utilization rate for IMRT that is unjustifiably high and not consistent with available data; and (3) CMS's inappropriate exclusion of on-board imaging from the direct practice expense component ("PE") of radiation therapy work relative value units ("wRVUs"). Finally, we ask CMS to carefully consider the cumulative impact of cuts like these on the overall market structure of healthcare delivery. In the face of significant and rapid healthcare consolidation, CMS should ensure that reimbursement policy does not have the unintended consequence of shifting critical health care services, including cancer care, into higher cost centers.

Second, LUGPA responds to CMS's request for comments "regarding the impact of the physician self-referral law on health care delivery and

[1] 80 Fed. Reg. 41686 (July 15, 2015).

payment reform."[2] LUGPA believes the federal physician self-referral law—commonly referred to as the Stark law—is long overdue for significant revisions to protect a wide range of practice models as CMS aggressively transitions from fee-for-service to value-based care. In particular, we propose that CMS should extend protections similar to those found in its existing waivers for Accountable Care Organizations to all physicians and entities complying or working to comply with the value-based payment models created under the Medicare Access and CHIP Reauthorization Act.

We also believe CMS has erroneously—and possibly unintentionally—understated the wRVUs for laparoscopic radical prostatectomy (CPT Code 55866) in Addendum B to the Proposed Rule. Without explanation, Addendum B lists wRVUs of 21.36—nearly one-third lower than the wRVUs currently in place for CY 2015 (32.06). We request that CMS restore the wRVUs for CPT Code 55866 to the current level of 32.06 and not finalize any reduction without providing stakeholders with the opportunity to comment in the proposed MPFS for CY 2017.

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 groups, allowing for benchmarking of operations, promoting quality clinical outcomes, developing new business opportunities, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 118 urology group practices in the United States, with more than 2,000 physicians who collectively provide approximately 30% of the nation's Urology services.[3]

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, as well as better meet the economic and administrative obstacles to successful practice. LUGPA's mission is to provide urological surgeons committed to providing integrated, comprehensive care the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system, including men with prostate cancer, in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, and regulatory agencies and legislative bodies.

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[2] Id. at 41929.

[3] 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.

Over the past several years, LUGPA has taken an active role in providing CMS and other governmental agencies, including the Medicare Payment Advisory Commission (MedPAC) and the Government Accountability Office (GAO), critical data and other information regarding diagnostic and therapeutic modalities used in providing prostate cancer care to Medicare beneficiaries. On numerous occasions, LUGPA representatives have met with senior leaders in all of these agencies, as well as with members of Congress, to discuss peer-reviewed and other empirical studies of the utilization of various modalities for diagnosing and treating prostate cancer in Medicare beneficiaries. In addition, LUGPA has provided comments to CMS on the Medicare Shared Savings Program/Accountable Care Organizations proposed rule and continues to take a leadership role with respect to proposed bundled payment systems for prostate biopsy services.

We hope to continue the relationship we have established with CMS, MedPAC, GAO, and others by providing meaningful commentary to agency reports, inquiries, and proposals. Thus, we respectfully provide the following comments on CMS-1631-P.

II. CMS Should Not Finalize Its Proposed Changes in Payment Policy for IMRT for Treatment of Prostate Cancer and Should Maintain CY 2015 Payment Levels Pending Further Study.

A. CMS's Valuation of "Simple" IMRT Procedures is Flawed.

In the CY 2016 Proposed Rule, CMS continues its initiative to reconsider "potentially misvalued codes" by proposing new wRVU and PE components for radiation treatment and related imaging guidance services.[4] In the case of "simple" IMRT—including all IMRT treatments of the prostate and breast—this amounts to a cut in payments of **over 30 percent** in the daily treatment code with absolutely no clinical or policy justification on CMS's part for such a dramatic change in reimbursement.[5] LUGPA strongly believes that the inclusion of IMRT services on CMS's list of misvalued codes is unjustified, and that this significant cut to vital cancer treatment is inappropriate.

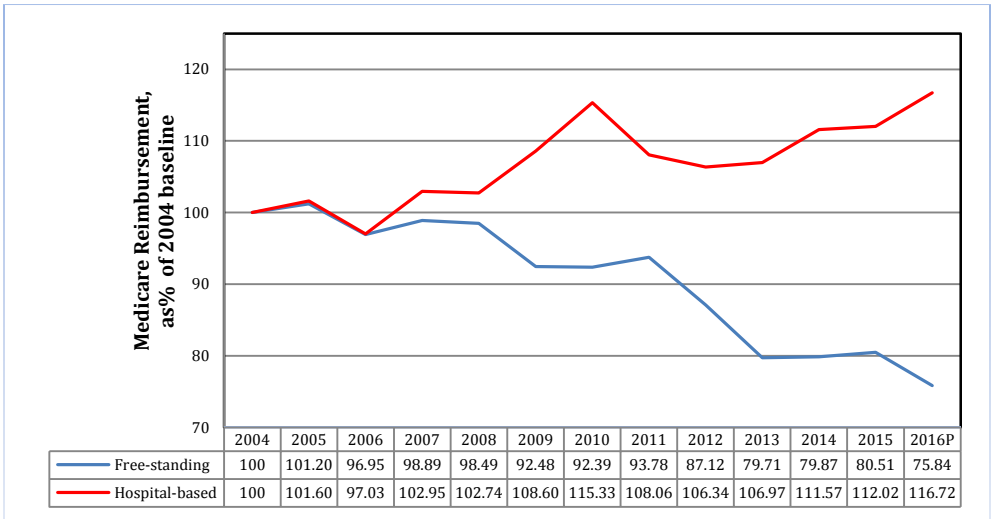
1. Changes to IMRT Reimbursement.

In the CY 2015 Proposed Rule, CMS identified certain radiation therapy services as potentially misvalued.[6] As a result, CMS proposed significant changes to the entire radiation therapy code set, including IMRT, in the CY 2015 Final Rule.[7] This year, CMS proposes to create two new IMRT codes: simple (CPT Code 77385) and complex (CPT Code 77386).[8] This reclassification translates to an effective cut of over 30% for each "simple" IMRT procedure (comparing current CPT Code 77418 to new CPT Code

[4] 80 Fed. Reg. 41686, 41769; see also 79 Fed. Reg. 67548, 67666-67.
[5] Centers for Medicare and Medicaid Services, Addendum B – Relative Value Units and Related Information Used in CY 2016 Proposed Rule, available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2016-PFS-NPRM-Addenda.zip. The 30% difference is based on a comparison of the current CPT Code 77418 to new CPT Code 77385.
[6] 79 Fed. Reg. 40318, 40337.
[7] 79 Fed. Reg. 67548, 67666.
[8] IMRT services are currently reimbursed under a transitional G code. See id. at 67667.

77385), which includes all use of IMRT to treat prostate and breast cancer regardless of the complexity of the given case. A recent analysis from Avalere Health suggests this also represents a large cut to the overall payment for an episode of care for prostate or breast cancer performed in a physician office or freestanding clinic using IMRT—reflecting drops of nearly 25% and 20%, respectively.[9]

These proposed cuts come on the heels of a decade of cuts in reimbursements for IMRT in the physician office and freestanding radiation center setting as contrasted with IMRT delivered in the hospital setting, as reflected in the following graph:[10]



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016P
Free-standing	100	101.20	96.95	98.89	98.49	92.48	92.39	93.78	87.12	79.71	79.87	80.51	75.84
Hospital-based	100	101.60	97.03	102.95	102.74	108.60	115.33	108.06	106.34	106.97	111.57	112.02	116.72

Figure 1: Medicare PFS Reimbursement 2004–2016 (Proposed), Freestanding vs. Hospital-Based

The widening payment disparity reflected in Figure 1 runs directly counter to the concern articulated by MedPAC (and cited by CMS in the CY 2015 Proposed Rule) that inappropriate valuation of codes could "distort the price signals for physicians' services as well as for other health care services that physicians order, such as hospital services."[11]

Unfortunately, CMS's reorganization of IMRT codes risks causing exactly this kind of distortion by driving breast and prostate IMRT services out of the lower cost physician office setting and into the higher-cost hospital setting. This would only exacerbate the payment differential between IMRT furnished in hospital-based versus freestanding settings—**with hospital-based reimbursement for IMRT having grown almost 17% over the last decade while reimbursement for the identical service in physician offices and freestanding radiation centers have declined nearly 25 percent**.[12]

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[9] See Public Comment Letter from Christopher M. Rose, M.D., FASTRO, Chair, Policy Committee, Radiation Therapy Alliance, to Acting Administrator Andrew Slavitt, CMS, Comments on CMS-1631-P (September 8, 2015) ("RTA Comment Letter to CMS-1631-P").

[10] Id.

[11] 79 Fed. Reg. 40318, 40335.

[12] See Public Comment Letter from James Welsh, M.D., FACRO, President, and Sheila Rege, M.D., FACRO, Chair, Economics Committee, American College of Radiation Oncologists, to Acting

2. The Inclusion of IMRT in the Misvalued Code Initiative is Based on Outdated Information and Risks Shifting Services to More Expensive Facilities.

We are concerned that CMS's proposed, sweeping cuts in reimbursement for IMRT treatment for prostate cancer do not reflect actual utilization and cost data for this service in the physician office setting. The GAO's examination of this issue found that although total utilization of IMRT to treat prostate cancer from 2007-10 remained flat, there was a shift in services away from the hospital towards the more cost-effective physician office site of service.[13] As seen in Figure 2 below, despite the migration of patients away from hospitals to physicians' offices, prostate cancer-related IMRT costs in physicians' offices decreased by $28 million. Simultaneously, although the number of services provided by hospitals declined substantially, hospital prostate IMRT expenditures increased by $8 million. The GAO explains this paradox in its IMRT report, stating, "reimbursement rates for IMRT services have been increasing for services performed in hospital outpatient departments and declining for those performed in physician offices."[14]

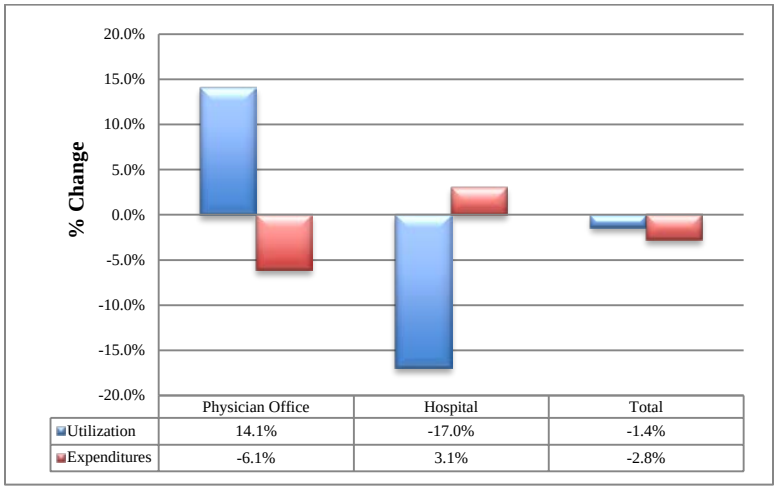


Figure 2: IMRT Utilization and Expenditures by Site of Service, 2007-10[15]

As depicted in Figure 3, this result has been confirmed by more recent data showing that overall IMRT utilization has been flat since 2011 and that hospital outpatient departments ("HOPDs"), not physician offices and freestanding radiation centers, are the drivers of utilization and cost of IMRT. [16]

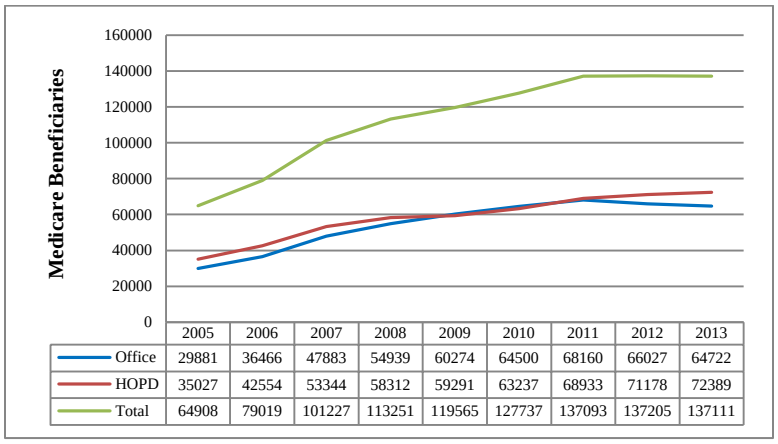
Administrator Andrew Slavitt, CMS, Comments on CMS-1631-P (September 8, 2015) ("ACRO Comment Letter to CMS-1631-P")

[13] GAO-13-525 pp. 11 & 36 Figure 4 (July 2013).

[14] Id. p. 36.

[15] Percentage changes based on utilization and expenditure data presented in GAO's July 2013 Report. See id. p. 37 Figure 5.

[16] Milliman analysis of certain Medicare ancillary services, commissioned by LUGPA, 2015, using Medicare Advantage enrollment data from the Kaiser Family Foundation. ("LUGPA Milliman Analysis").

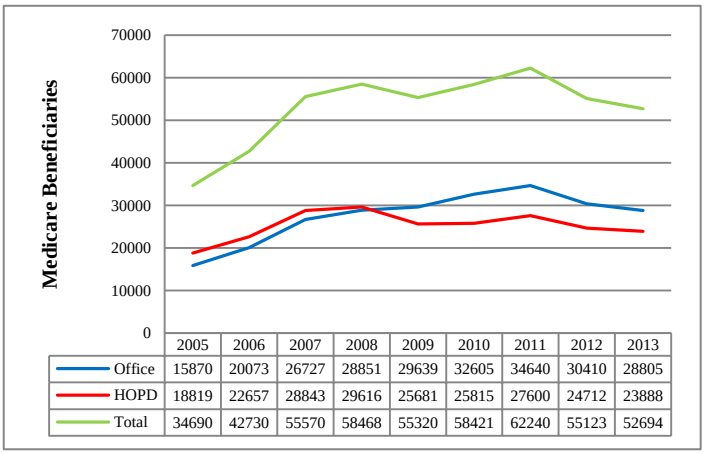


	2005	2006	2007	2008	2009	2010	2011	2012	2013
Office	29881	36466	47883	54939	60274	64500	68160	66027	64722
HOPD	35027	42554	53344	58312	59291	63237	68933	71178	72389
Total	64908	79019	101227	113251	119565	127737	137093	137205	137111

Figure 3: Medicare IMRT Utilization, All Disease Adjusted for Medicare Advantage

This change in IMRT use for prostate cancer is partly due to greater acceptance of active surveillance among the Medicare population—a recent study published in JAMA found that 3 out of 4 men over age 75 with low-risk prostate cancer opted for active surveillance; up more than three-fold from just 22% for the same cohort in 2000-2004.[17] In fact, active surveillance has now increased for all ages, with about 40% of men choosing to be placed on active surveillance as an alternative to affirmative treatment.[18]

CMS's proposed cut to reimbursement of IMRT for prostate cancer in the physician office setting is particularly curious, given that utilization of IMRT to treat prostate cancer is declining *more rapidly* in the office setting than in HOPDs:[19]



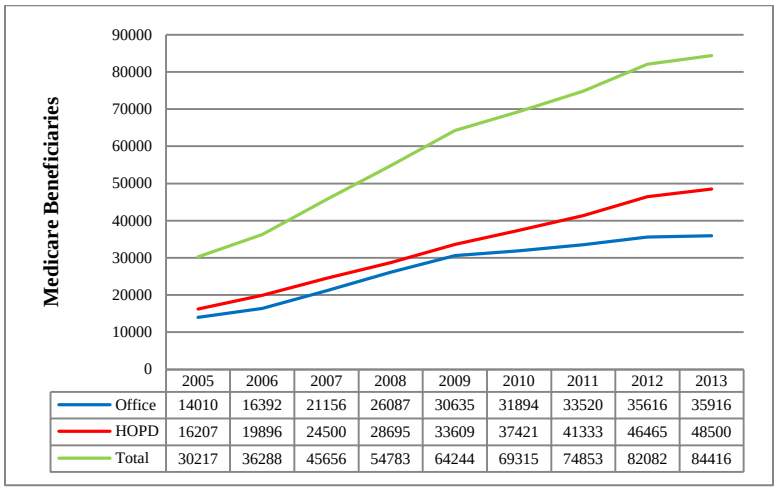
	2005	2006	2007	2008	2009	2010	2011	2012	2013
Office	15870	20073	26727	28851	29639	32605	34640	30410	28805
HOPD	18819	22657	28843	29616	25681	25815	27600	24712	23888
Total	34690	42730	55570	58468	55320	58421	62240	55123	52694

Figure 4: Decline In Utilization of IMRT to Treat Prostate Cancer, 2011-13	
Physician Office	**-16.80%**
HOPD	-13.40%
Total	-15.30%

In marked contrast to IMRT utilization for prostate cancer, IMRT use for non-prostate cancer purposes (which predominantly fall within the newly created "complex" code) is

[17] Cooperberg, MR Carroll PR. "Trends in Management for Patients With Localized Prostate Cancer, 1990-2013." JAMA 2015 314(1), 80-82.
[18] Id.
[19] LUGPA Milliman Analysis.

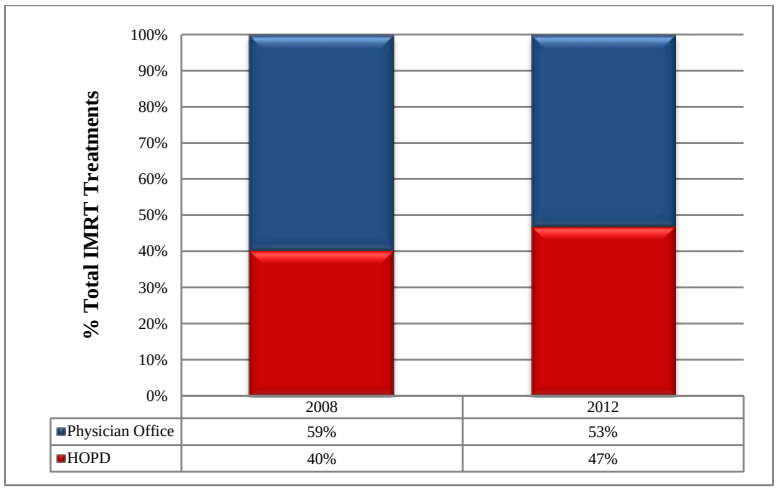
steadily increasing. And here again, utilization is increasing faster in HOPDs than in the physician office setting:[20]



	2005	2006	2007	2008	2009	2010	2011	2012	2013
Office	14010	16392	21156	26087	30635	31894	33520	35616	35916
HOPD	16207	19896	24500	28695	33609	37421	41333	46465	48500
Total	30217	36288	45656	54783	64244	69315	74853	82082	84416

Figure 5: Medicare IMRT Utilization, non-Prostate Cancer 2005-13, Adjusted for Medicare Advantage

Multiple data analyses have found a similar change in *where* Medicare beneficiaries are receiving IMRT for treatment of cancer. For example, an analysis of Medicare data commissioned last year by the American Medical Association showed that an increasing percentage of Medicare beneficiaries receiving IMRT are shifting into the higher cost hospital outpatient setting.[21]



	2008	2012
Physician Office	59%	53%
HOPD	40%	47%

Figure 6: Distribution of IMRT Treatments by Site of Service 2008 vs. 2012

We have previously described how the payment disparity between the physician office and HOPD site of service impacts overall Medicare costs for prostate cancer-related

[20] LUGPA Milliman Analysis.

[21] Milliman analysis of certain Medicare ancillary services, commissioned by the AMA, October 2014. Available at: http://www.ama-assn.org/ama/pub/advocacy/topics/in-office-ancillary-services-exception.page

IMRT treatments. When combined with changing utilization patterns for other disease states in which IMRT treatments are used, these payment disparities result in substantial cost differentials: from 2008 to 2012, while overall IMRT use in the physicians' office increased by 4.9%, costs increased by just 0.6%; conversely, the 3.5% increase in use of IMRT in the HOPD setting was associated with a 7.3% increase in costs.[22]

LUGPA has an even more fundamental concern about CMS's proposed division of IMRT treatment into "simple" and "complex" codes that extends beyond the fact that we do not believe the proposed division is justified in light of the most recent utilization and cost data. CMS's creation of the simple/complex dichotomy in CPT Codes 77385 and 77386 has a profound impact on the level of reimbursement for IMRT treatment in physician offices and freestanding radiation centers. And, yet, CMS has proposed no such payment differential between supposedly "simple" and "complex" IMRT furnished in the HOPD setting—where CPT Codes 77385 and 77386 are both classified under Ambulatory Payment Classification (APC) 5623.[23] In grouping CPT Codes 77385 (IMRT "simple") and 77386 (IMRT "complex") under the same APC for purposes of the Hospital Outpatient Prospective Payment System (HOPPS), CMS is acknowledging that these services are "comparable clinically and with regard to the use of resources."[24] LUGPA agrees and believes that CMS's decision to group these two codes under a single APC highlights the fact that, in the physician office setting, CMS is creating an artificial distinction between the use of IMRT to treat different types of cancer.

This is a distinction that LUGPA believes will have profound—and unintended—consequences on the Medicare program. CMS proposes to cut reimbursement drastically for "simple" use of IMRT to treat prostate cancer. These services are primarily performed in the less-expensive physician office setting and are declining in volume as active surveillance becomes more common. At the same time, the Agency proposes to increase payment for "complex" IMRT services for other types of cancer that are becoming *more* common and are more likely to be performed in the costlier HOPD setting. The net effect of CMS's proposal—if finalized—will be to increase reimbursement for procedures with increasing utilization at the highest cost site of service while simultaneously reducing reimbursement for procedures with declining utilization at the lowest cost site of service. Thus, **in its effort to address a "misvalued" code, CMS risks significantly increasing the Medicare program's payments for total IMRT services.**

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[22] Id.

[23] Centers for Medicare and Medicaid Services, "Addendum B.-Proposed OPPS Payment by HCPCS Code for CY 2016," available at: https://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1633-P-OPPS-Addenda.zip.

[24] 79 Fed. Reg. 40916, 40980.

B. The Proposed Cut in Reimbursement for IMRT Services for Treatment of Prostate Cancer Violates CMS's Statutory Mandate Under the Protecting Access to Medicare Act and the Achieving a Better Life Experience Act.

Beginning with the development of the Medicare Physician Fee Schedule for CY 2016, federal law now places limitations on the extent to which CMS can cut reimbursement for services from one fee schedule to the next. The Protecting Access to Medicare Act ("PAMA"), as amended by the Achieving a Better Life Experience Act ("ABLE"), provides, in relevant part, as follows:

> "'[F]or services that are not new or revised codes, if the total relative value units for a service for a year would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total relative value units for the previous year, the applicable adjustments in work, practice expense, and malpractice relative value units shall be phased-in over a 2-year period.'"[25]

CMS's proposed cut in reimbursement to IMRT for treatment of prostate cancer—estimated at a 25% to 30% reduction—runs afoul of the letter and spirit of this statutory limitation on the Agency's authority. And, we do not believe that the proposals CMS makes for ensuring compliance with PAMA and ABLE remedy this statutory violation.

On the face of PAMA, Congress's clear statutory intent was to protect "services that are not new or revised codes." The *service* provided under the new "simple" IMRT code (CPT Code 77385) is not new. CMS did not base its decision to create this code on any clinical or technological changes in the delivery of IMRT for prostate cancer. Rather, the shifting of IMRT services for treatment of prostate and breast cancers into a "simple" category is directly based on the family of radiation oncology codes having been "potentially misvalued." Thus, CMS's reason for shifting IMRT for prostate cancer into a "simple" code was based purely on cost rather than on clinical distinctions. But the slashing of reimbursement by 25% or more for delivery of IMRT for prostate cancer is precisely the kind of sharp payment reduction that Congress intended to limit under PAMA and ABLE. And, we do not believe it is reasonable to believe that Congress intended that the 20% limitation on reductions in reimbursement for existing be waived by shifting such services into brand new codes—as occurred with the shift of IMRT for prostate and breast cancer from CPT Code 77418 to the new CPT Code 77385.

We also do not believe that CMS should be permitted to avoid the new statutory limitation by offsetting the reductions in reimbursement for IMRT for prostate cancer by the increases in reimbursement for IMRT for cancers designated as "complex" and placed in the new CPT Code 77386. Nevertheless, CMS takes the following position in the Proposed Rule:

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[25] Section 220(e) of the Protecting Access to Medicare Act of 2014, Pub. L. 113-93, enacted April 1, 2014), as amended by Section 202 of the Achieving a Better Life Experience Act of 2014 (Division B of Pub. L. 113-295, enacted December 19, 2014)). See also 80 Fed. Reg. 41686, 41714.

> "A service that is described by a single code in a given year, like [IMRT] could be addressed as a misvalued service in a subsequent year through a coding revision that splits the service into two codes, 'simple' and 'complex.' If we counted only the reductions in RVUs, we would count only the change in value between the single code and the new code that describes the 'simple' treatment delivery code. In this scenario, the change in value from the single code to the new 'complex' treatment delivery code would be ignored, so that even if there were an increase in the payment for IMRT treatment delivery service(s) overall, the mere change in coding would contribute inappropriately to a 'net reduction in expenditures.' Therefore, *we are proposing to net the increases and decreases in values for services, including those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes*."[26]

We believe that this proposal—netting the increase in reimbursement for "complex" IMRT procedures against the decrease in reimbursement for "simple" IMRT procedures, when CPT Codes 77385 and 77386 are compared against the current CPT Code 77418—violates PAMA and ABLE. The reality is that CMS is proposing a 25% to 30% cut in reimbursement for IMRT used to treat men with prostate cancer. With this action, CMS runs afoul of the limitations Congress placed on its authority by "netting" those draconian cuts against increases in reimbursement for IMRT used for other disease states so as to avoid having to comply with the dictates of federal law.

Nor do we believe that CMS has the authority to rectify this error—at this stage of the rulemaking process—by phasing in the 25% to 30% cut over a two-year period. The requirements of CMS's new transparency obligations, which take effect with the CY 2016 MPFS, do not, in our view, permit CMS in the Final Rule for CY 2016 to present a new approach for reimbursing IMRT for prostate cancer different from levels established for the current CY 2015.

C. CMS Has Overestimated the Equipment Utilization Rate for LINAC.

In the Proposed Rule, CMS proposes that the equipment utilization rate for linear accelerator ("LINAC") machines be increased from 50% to 70% over a period of two years.[27] This increase in projected utilization rate would have the effect of reducing the practice expense relative value units ("PE RVU") for procedures using the LINAC. CMS based this decision on its understanding that new radiation treatment CPT Codes recommended by the American Medical Association's Relative Value Scale Update Committee ("RUC") meant that a single type of LINAC machine was used to furnish all levels and types of external beam radiation treatment services.[28] CMS thought it "illogical to continue to assume that the equipment is only used for 25 out of a possible 50 hours per week," and therefore estimated a 70% utilization rate by projecting that utilization of this kind of LINAC would change from the 44.8 million minutes of external

[26] 80 Fed. Reg. at 41713 (emphasis added).
[27] Id. at 41771-41772.
[28] Id.

beam treatments furnished to patients last year to the full 65 million minutes of *all* external beam treatments last year.[29] Yet, CMS acknowledged that this estimate "was not itself rooted on empirical data," and further noted that shifting to a 70% utilization rate assumption could be an overestimate if practices have added additional machines rather than increased their utilization of existing machines.[30]

There are numerous reasons why CMS's assumptions regarding the equipment utilization rate are inaccurate. As detailed in separate comment from the American College of Radiation Oncology, these include transition time between simple and complex treatments; the necessity for multiple machines optimized to treat specific types of cancer or to ensure a backup to ensure strict compliance with patient treatment plans; unused patient slots due to scheduling conflicts or patient unavailability due to disease symptoms or co-morbidities; warm-up, maintenance, testing, and quality assurance tasks—many of which are required by national accrediting bodies; and the use of the radiation treatment vault for therapies that do not involve the LINAC.[31] As such, CMS should not assume that the consolidation of delivery of radiation therapy to a single *type* of LINAC necessarily means that each LINAC *device* is now utilized more frequently.

Indeed, LUGPA has worked with the Radiation Therapy Alliance to develop empirical data to assist CMS in the proper assessment of the equipment utilization rate for LINAC. RTA surveyed its member practices and US Oncology practices in August 2015, receiving 242 replies. The RTA survey collected detailed data on each facility's location, number of LINACs, number of treatments per LINAC, the maximum number of patients that can be scheduled per hour per LINAC, the amount of time the LINAC is idle, and other pertinent information. RTA then calculated equipment utilization through the first six months of 2015, dividing the average number of patients treated per week by: (i) CMS's estimate of 50 hours per week, and (ii) the actual hours that each facility provides radiation therapy services (typically less than 50 hours per week). **The survey yielded an estimated equipment utilization rate of just 46.7% using CMS's estimate of 50 hours per week, and 56% using the actual operating hours of surveyed facilities.** On average, practices provided 20.3 treatments per LINAC per day. The range of utilization was also extremely wide, from 12.7 at the 25th percentile to 26.7 at the 75th percentile. [32]

This data strongly suggests that CMS should not move forward with its proposed change to the equipment utilization rate. While certain extremely high-volume practices may utilize each LINAC machine for 70% of the potential usable time, **the data clearly shows the normal utilization pattern is to use each machine at or *under* 50%** of the potentially usable time. In fact, the RTA survey found that two-thirds of all LINACs have an equipment utilization rate lower than 50%. Over one-quarter of the LINACs covered in the RTA survey had equipment utilization rates less than or equal to 35%, while only 3% had utilization rates at or above CMS's proposed 70 percent rate.

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[29] Id.
[30] Id.
[31] ACRO Comment Letter to CMS-1631-P.
[32] RTA Comment Letter to CMS-1631-P.

An alternative estimate developed by the Association of Freestanding Radiation Oncology Clinics reached a similar conclusion.[33] This estimate used CMS's own 2014 claims data for radiation therapy delivery codes, the CMS crosswalk to proposed codes and volumes, and the 2015 proposed treatment times for each code to estimate the total number of treatment minutes for Medicare fee-for-service beneficiaries in the freestanding setting (64.5 million). This number was then divided by the share of all patients that are Medicare fee-for-service (0.5), an estimated number of linear accelerators in the freestanding setting (1,830), and the total number of available minutes per year (150,000). **This estimate—based on data provided by CMS to the public—yields an equipment utilization rate of 47 percent.** AFROC ran several models, varying the estimated number of LINACs in use and the share of treatments covered by Medicare fee-for-service and, in each instance, the models yielded an estimated utilization rate **between 45 and 52 percent**.

CMS should respect this empirical data and maintain the current 50% equipment utilization rate for LINAC. Any upward change in the equipment utilization rate should be based on verifiable changes in the clinical use of equipment. Alternatively, CMS should work to obtain empirical data like the RTA survey to ensure that any changes in the equipment utilization rate are based on actual data.

Lastly, the proposed increase in equipment utilization rate is at odds with recent data showing decreases in diagnoses of—and, correspondingly, treatment of—prostate cancer. Specifically, **in recent years, screening and treatment recommendations for prostate cancer have undergone significant change—particularly for older men who are served by Medicare.** For example, recent analyses have shown a significant decline in screening rates for older Americans following the United States Preventive Services Task Force's recommendation against routine prostate-specific antigen ("PSA") screening. One recent analysis found that monthly prostate cancer diagnoses dropped by over 1,300 cases (or over 12%) in the month after the USPSTF recommendation, and continued to reduce by 164 cases per month relative to baseline.[34] In the first year after the USPSTF recommendation, diagnoses of new prostate cancers dropped nearly 30 percent.[35] At the same time, there has been an increase in the use of active surveillance, particularly in more elderly patients,[36] leading to less-frequent use of IMRT.[37]

D. CMS Inappropriately Excludes the Cost of On-Board Imaging Equipment From the Practice Expense Calculation.

In the Proposed Rule, CMS proposes to exclude the cost of on-board imaging from the direct practice expense input of radiation therapy codes.[38] Imaging guidance is an

[33] Id.
[34] Barocas DA, Mallin K, Graves AJ, et al. "The effect of the United States Preventive Services Task Force grade D recommendation against screening for prostate cancer on incident prostate cancer diagnoses in the US." J Urol (2015). DOI: 10.1016/j.juro.2015.06.075.
[35] Id.
[36] Shelton J, Buffington P, Koo A, et al. "Contemporary Active Surveillance Rates for Newly Diagnosed Prostate Cancer Patients in Community Urology Practices." J Urol (2015) 193(4) e27-e28.
[37] Op. cit. Cooperberg.
[38] 80 Fed. Reg. at 41770.

extremely important aspect of IMRT therapy because IMRT creates a complex treatment field that must be precisely applied to diseased tissue without endangering sensitive nearby organs. However, imaging guidance may not be needed with lower-dose radiation therapies (such as those captured in CPT Codes 77402, 77407, and 77412). The technical component of image-guided radiation therapy ("IGRT") is therefore separately billable for these codes (as CPT Code 77387). In this case, the RUC's recommendation appears to assume that a single LINAC informs the capital costs for all of these treatments, because older, lower-dose external beam radiation machines are no longer manufactured.[39]

Unfortunately, CMS also understood the RUC to state that "image guidance technology is integrated into the single kind of LINAC used for all the radiation treatment services." This led CMS to exclude on-board imaging from the direct PE inputs for certain important services—including IMRT and IGRT. But, CMS's proposal directly contradicts the RUC's recommendation and has a profound practical effect—a $60 million aggregate reduction in payments. CMS claims this is appropriate "because the invoices used to price the capital equipment included on-board imaging." As part of this comment process, we are aware that manufacturers have submitted new invoice data clearly demonstrating that on-board imaging, in fact, represents a significant additional capital cost. We urge CMS to consider this additional detailed invoice data as it finalizes the MPFS for CY 2016.

E. CMS's Reimbursement Policy with Respect to Delivery of IMRT has the Effect of Creating "Winners" and "Losers" in the Healthcare Market.

As detailed above, the cumulative effect of the changes in the Proposed Rule would be substantial reimbursement cuts in the physician office setting coupled with increased reimbursement for HOPDs. Unfortunately, this change would exacerbate a variety of serious threats to independent medical practice.

CMS has an obligation to consider wider healthcare market trends as it implements policies such as its "misvalued code" initiative. A significant trend in the current healthcare market is the number of physicians abandoning independent practice in favor of hospital employment. A recent Accenture analysis found that from 2000-2013, the portion of physicians in private practice dropped from 57% to just 37%, projecting that, by next year, only one-third of physicians will remain independent. [40] In this study, **reimbursement pressure was the most common reason cited by physicians for abandoning independent practices**.

This analysis underscores the profound impact that CMS's reimbursement policy decisions can have on the decisions of individual physicians. Indeed, CMS has direct experience with the potential industry-changing consequences of its reimbursement decisions. For example, reimbursement changes have resulted in the virtual elimination

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[39] Id.

[40] Kristin Ficery and Kimberly Kushner, *The (Independent) Doctor Will Not See You Now*, Accenture, available at: https://www.accenture.com/us-en/insight-clinical-care-independent-doctor-will-not-see-you-now.

of independent cardiology practices—in under a decade, this specialty has become almost entirely hospital-based.[41]

CMS's proposed changes in reimbursement for IMRT for prostate and breast cancer—which will only serve to widen the gap between the reimbursement of these services in hospital and non-hospital settings—are especially confounding and are likely to have (what we assume to be) an unintended consequence of driving additional physicians out of independent practice and into the more expensive hospital setting. Unfortunately, this kind of payment disparity sends a market signal that CMS wishes to incentivize IMRT services in HOPDs rather than in independent physician practices or other freestanding settings. **This kind of preferential treatment between two clinically equivalent sites of service is an inappropriate use of CMS's reimbursement policy.**

III. The Stark Law Requires Significant Change to Protect Independent, Integrated Specialty Practices in the Post-Fee-for-Service Era.

LUGPA appreciates CMS's solicitation of comments "regarding the impact of the physician self-referral law on health care delivery and payment reform."[42] We are hopeful that the Agency's willingness to obtain input from stakeholders reflects a recognition that the federal physician self-referral law (commonly known as the Stark law) is in need of substantial overhaul given the fundamental changes to healthcare delivery and payment systems since the Stark law's enactment in 1989.

Respectfully, the Stark law is an anachronism. Developed more than 25 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 the Affordable Care Act. More significantly, the barriers to innovation posed by Stark fall squarely on those physician specialists who have chosen to continue caring for patients in the high quality, cost-efficient independent practice setting. Without fundamental changes to 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. We applaud CMS' apparent willingness to consider reform of the Stark law to keep pace with health care delivery and payment reform.

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. First, physicians in LUGPA's member practices and other physician specialty practices provide high-quality, cost-efficient care to a wide range of patients, including in underserved and rural communities. Second, independent practices such as LUGPA member groups reduce healthcare costs and represent competition to increasingly-consolidated hospital

[41] See e.g., Anna Wilde Mathews, Same Doctor Visit, Double the Cost: Insurers Say Rates Can Surge After Hospitals Buy Private Physician Practices; Medicare Spending Rises, Too, Wall Street Journal, August 27,2012, available at:http://www.wsj.com/articles/SB10000872396390443713704577601113671007448.

[42] 80 Fed. Reg. 41686, 41929.

systems,[43] 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.[44] Third, and perhaps most relevant to future payment paradigms, independent physician groups have been shown to provide higher quality and lower cost in Medicare risk sharing arrangements.[45]

In an era where cost savings and value-based care are increasingly vital considerations, one might predict that 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.[46]

B. The Stark Law Currently Limits Clinical and Financial Integration.

Unfortunately, the Stark law as presently written exacerbates the competitive disadvantage at which physician specialists in independent practice find themselves. The Stark law's rigid, strict liability prohibition and complex set of exceptions is tailored to a fee-for-service system that is becoming increasingly outdated. Furthermore, aspects of this legal structure create enormous problems for integrated physician groups, while simultaneously allowing hospitals far more flexibility.

For example, integrated physician specialty groups are typically composed of a group of physician owners who provide care through their group practice. The group practice rules are complex and place a number of limitations on physician owners' ability to distribute profits or pay productivity bonuses to "physicians in the group practice," including employees or contractors.[47] By comparison, hospitals are not required to qualify as a "group practice." As a result, physicians who move to hospital-based employment can be freely paid under the broad compensation exception for bona fide employment relationships.[48] Under the terms of this exception, an employed physician may be paid a performance bonus and the hospital may condition the physician's employment on referrals within its clinical network,[49] creating *de facto* compensation for DHS referrals.

The Stark law also poses a number of serious challenges for independent specialty medical practices that wish to enter into integrated relationships with hospitals or other entities providing "designated health services." As CMS acknowledged, a waiver under

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[43] 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.

[44] 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.

[45] 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.

[46] 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/.

[47] 42 C.F.R. 411.352(i).

[48] 42 C.F.R. 411.357(c).

[49] Id. and 42 C.F.R. 411.354(d).

the Medicare Shared Savings Program's ("MSSP") statutory authority was necessary to distribute shared savings within or outside an ACO.[50] This is important because the "volume or value" standard present in many of the compensation exceptions could be interpreted to prohibit physician compensation arrangements that incentivize physicians to *reduce* utilization or the overall cost of care. Because most hospital relationships are with employed physicians, they have significantly more flexibility to classify such incentive plans as "productivity bonuses."[51]

The Stark law may prevent physicians and hospitals from collaborating to offer necessary services. This is most seriously felt in the "under arrangements" context, where a physician-owned entity enters into an arrangement (including a joint venture) with a hospital to provide medically necessary services to patients. CMS's revised definition of the term "entity" required physicians to meet a Stark law ownership exception (which are extremely narrow) to continue to provide such services.[52] Although "under arrangements" relationships have not traditionally been analyzed under the rubric of coordinated care, 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. This is particularly true 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.

Unfortunately, the Stark law also impedes care coordination *outside* of Medicare and Medicaid due to the "other business generated" requirement of several compensation exceptions.[53] To its credit, CMS recognizes that much of the activity on innovative payment models is occurring in the private sector through programs like the Blue Cross and Blue Shield Alternative Quality Contract.[54] Unfortunately, payment based on the volume or value of "other business generated" frequently causes a compensation relationship to fall out of compliance with a Stark law compensation exception. This means that a *private plan's* program to provide incentive payments to a hospital or physician practice for cooperating to achieve quality goals or cost reductions could taint all of the practice's referrals to the hospital—even if the hospital and practice's *Medicare* payments are under traditional fee-for-service.

Finally, note that the Stark law's structure is inherently tied to features of the fee-for-service payment system. The concerns regarding the "volume or value" of referrals or other business generated stem from a belief that a physician's sole incentive is to increase volume. The public policy concerns of overutilization supporting the Stark law will

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[50] 76 Fed. Reg. 67992, 67999.
[51] 42 C.F.R. § 411.357(c)(4).
[52] "Entity," 42 C.F.R. § 411.351. See also 73 Fed. Reg. 48434, 48721.
[53] See e.g., the lease exceptions at 42 C.F.R. §§ 411.357(a) & (b), the personal services exception at 42 C.F.R. § 411.357(d), the non-monetary compensation exception at 42 C.F.R. § 411.357(k), and the fair market value compensation exception at 42 C.F.R. § 411.357(l).
[54] 80 Fed. Reg. at 41928.

necessarily become less relevant as bundled payment and other value-based payment models become more common.

C. Existing Flexibilities are Incomplete.

For all of the foregoing reasons, CMS has recognized that the structure of the current exceptions does not account for the new imperative for hospitals and physician practices to collaborate and coordinate patient care. Efforts to date, unfortunately, have been piecemeal and generally exclude independent specialty practices.

CMS's most comprehensive effort to address the problematic nature of the Stark exceptions is the set of waivers produced for Accountable Care Organizations.[55] These waivers, finalized in 2011 and extended just last year, 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 MSSP or certain initiatives proposed by the Center for Medicare and Medicaid Innovation. 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).[56] 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).[57]

The waivers, however, are of limited utility to integrated physician specialty practices because **the MSSP is heavily weighted towards primary care.** For example, beneficiary assignment to an MSSP ACO is determined based on where the beneficiary receives a plurality of his or her primary care services, with a preference for "primary care physicians" defined as internal medicine, general practice, family practice, and geriatric medicine.[58] Other specialties are considered only where a beneficiary has *no* primary care services furnished by any other primary care physician—whether inside or outside the ACO.[59] In addition, the set of thirty-three quality metrics identified for MSSP ACOs is heavily weighted toward primary care case management.[60] Moreover, a specialty practice that *does* serve as the basis for beneficiary assignment is forbidden from participating in another ACO.[61] Although CMS attempted to solve the latter problem in this year's revised MSSP regulations, the solution it applied was to exclude certain specialties entirely from involvement in beneficiary assignment.[62]

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[55] 76 Fed. Reg. 67992 and 79 Fed. Reg. 62356.
[56] 76 Fed. Reg. 67992, 68000.
[57] Id. at 68001.
[58] See 42 C.F.R. § 425.402 and definition of "primary care physician" and "primary care services" at 42 C.F.R. § 425.20.
[59] Id.
[60] Centers for Medicare and Medicaid Services, "ACO Quality Metrics," available at: https://www.cms.gov /Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads /ACO-Shared-Savings-Program-Quality-Measures.pdf.
[61] See 42 C.F.R. §§ 425.402 and 425.306(b) and associated discussion in 80 Fed. Reg. 32692, 32750-32755.
[62] Id.

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). CMS is also statutorily empowered to create Stark law exceptions that protect any financial relationship that the agency determines "does not pose a risk of program or patient abuse."[63]

Unfortunately, CMS has been unable to use this statutory authority to protect innovative payment arrangements. CMS attempted to exercise this authority to propose a gainsharing exception in the 2009 MPFS Rule.[64] However, this attempt was hampered by the need to use the extremely rigid and precise structure of other Stark exceptions. The proposed gainsharing exception only protected incentive payments and shared savings programs offered by hospitals, only cash (or cash equivalent) payments, and only those payments to physicians who directly achieved savings (rather than to their groups), and were on the hospital's medical staff, and even then only in "pools" of five or more.[65] The proposed rule also included requirements for an applicable gainsharing program's quality metrics, performance goals, prior review by CMS or an accrediting body (and annual reviews thereafter), and other complex administrative requirements.[66] Despite enormous interest and active public comment, CMS never finalized this exception.[67] As CMS stated at the time, **"the majority of commenters urged [the agency] to finalize such an exception or exceptions only if substantial modifications were made to the conditions proposed."**[68] The commenters' reaction underscores the fact that the extremely technical and directive approach characteristic of traditional Stark law exceptions is inappropriate in the world of innovative, coordinated care models.

D. Congress and CMS' Aggressive Timeline to Shift Away from Fee-For-Service Payment Structures Needs to be Supported by Reform to the Stark Regulations.

In the half-decade since passage of the Affordable Care Act, the healthcare payment landscape has undergone enormous, transformative change. From an experimental beginning in 2011, ACOs have grown to the point that over 420 Medicare ACOs have been established, and Medicare ACOs now serve 7.8 million Americans.[69] The growth in the private and Medicaid market has also been strong, to the point that nearly 750 ACOs now serve nearly 30 million Americans.[70] CMS has openly committed to the total transformation of the healthcare payment system, with bold goals of moving 50% of its payments to alternative models by 2018, and by incorporating value-based metrics into

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[63] 42 U.S.C. § 1395nn(b)(4).
[64] 73 Fed. Reg. 38502, 38548.
[65] Id. at 38552-38558.
[66] Id.
[67] 73 Fed. Reg. 69726, 69793.
[68] Id.
[69] David Muhlestein, Growth And Dispersion Of Accountable Care Organizations In 2015, Health Affairs Blog (March 31, 2015) available at: http://healthaffairs.org/blog/2015/03/31/growth-and-dispersion-of-accountable-care-organizations-in-2015-2/
[70] Id.

90% of its payments by 2018.[71] **In other words, CMS has committed to ending the fee-for-service system that originally triggered passage of the Stark law.**

This year, Congress signaled powerful support of this goal. The Medicare Access and CHIP Reauthorization Act ("MACRA") included a set of reforms to reauthorize and streamline Medicare's payment system to focus on value-based care. Providers will have to choose between remaining in largely fee-for-service payments and moving towards increased compensation via Alternative Payment Models ("APMs"). There is strong incentive to choose the latter: providers choosing the former will be subject to consolidation of existing value-based payment initiatives into the Merit-Based Incentive Payment System ("MIPS") and failure to meet these measures will result in substantial penalties. Conversely, those providers choosing to accept a higher degree of risk-based compensation under APMs may be able to increase compensation through a variety of shared savings mechanisms and payment enhancements. Notably, this approach is much broader than the primary care focus of ACOs, and potentially applies to all physicians regardless of specialty.

Specifically, under MACRA, the Medicare sustainable growth rate ("SGR") has been repealed and replaced with a payment system **explicitly based on value-based care**. Beginning in 2019, payment updates to all physicians will be tied to participation in the MIPS or APM.[72] Providers paid under the MIPS will receive certain annual incentive payments based on their attainment of specific quality goals.[73] Providers under APMs will receive a lump sum yearly incentive payment equal to 5% of their estimated aggregate payments.[74] HHS has discretion to create and administer APM's, but an APM must include quality measures, the use of electronic health record technology, and either a risk-bearing entity or a medical home.[75] An APM may include a model under the Center for Medicare & Medicaid Innovation, the Medicare Shared Savings Program, the Healthcare Quality Demonstration Program, or another demonstration required by Federal law.[76]

Unfortunately, CMS' fraud and abuse rules do not adequately support these new initiatives. The current set of waivers, exceptions, and flexibilities have carved out support for primary care physicians and hospitals, but leave independent specialty practices unprotected. This lack of protection for physicians in specialty practices becomes increasingly troubling as we transition into an era in which value-based, coordinated care is no longer an experiment, but rather the dominant form of payment.

We also note that MACRA's requirement that APM's must take on risk appears to be more stringent than even certain ACO agreements under the Medicare Shared Savings

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[71] Centers for Medicare and Medicaid Services, Fact Sheet: Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume (January 26, 2015), available at: https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html.
[72] 42 U.S.C. § 1395L(z) and 42 U.S.C.§ 1395w-4(q) .
[73] 42 U.S.C. § 1395w-4(q).
[74] 42 U.S.C. § 1395L(z).
[75] 42 U.S.C. § 1395L(z)(2)(B)(iii).
[76] 42 U.S.C. § 1395L(z)(3)(C).

Program. This has led at least one national body representing ACO's to opine that even Track One ACOs (which share savings without taking on "downside" risk) would not qualify as APMs.[77] **However, these entities would still benefit from waivers of the Stark law under the MSSP waivers**. CMS must therefore consider how to broaden its existing set of waivers to provide truly universal protection for innovative arrangements.

MACRA requires CMS to move its existing care coordination programs away from a voluntary, incentive-based model to a truly universal non-FFS payment system. We eagerly await HHS's additional regulations implementing this change. However, this transition will require support from 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—to primary care physicians and hospitals.

E. CMS Should Extend the Protections of the ACO Waivers to Any Physician Participating in an Alternative Payment Model.

CMS finalized its set of Stark law ACO waivers in 2011. At the time, CMS warned that it would engage in extensive monitoring and consider additional program safeguards.[78] Since then, with the continued growth of ACOs, CMS has extended the deadline for these waivers, solicited additional comment, and suggested that it would engage in further rulemaking.[79] As a result, in the four 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.

CMS chose to preserve flexibility by integrating the provisions of the waivers with the substance of the MSSP final regulations.[80] As CMS stated in its interim final rule, "these waivers incorporate conditions that, in combination with additional safeguards in the Shared Savings Program final rule, are intended to protect Medicare beneficiaries and the Medicare program from fraud and abuse while furthering the quality, economy, and efficiency goals of the Shared Savings Program."[81] **We believe CMS should propose a new exception for participants or prospective participants in APMs that adopts the same flexible approach used in the ACO waivers.**

We recognize that the ACO waivers were created under statutory authority, which is limited to the MSSP and initiatives under the Center for Medicare & Medicaid Innovation. 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. In fact, the Agency has done so again in the CY 2016 Proposed Rule, with newly

[77] National Association of ACOS, Summary of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (May 4,2015), available at: https://www.naacos.com/pdf/MACRASummary050415.pdf.
[78] 76 Fed. Reg. 67992, 68008.
[79] 79 Fed. Reg. 62357.
[80] 76 Fed. Reg. 67992, 67992-67993.
[81] Id.

proposed exceptions for timeshares and recruitment of non-physician professionals.[82] 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. **As such, we ask CMS to include in any future rulemaking new Stark law exceptions necessary to implement APMs and other similar value-based payment models for all physicians.**

IV. CMS Has Drastically Reduced the wRVUs for Laparoscopic Radical Prostatectomy.

A. Laparoscopic Radical Prostatectomy Has Replaced Open Radical Prostatectomy in Medicare Beneficiaries.

Radical prostatectomy has been considered the surgical "gold standard" for treatment of localized prostate cancer since 1905. Widespread use of open radical prostatectomy ("ORP") increased in the 1980s, after modification in surgical technique rendered the procedure vastly safer.[83] Although the first laparoscopic prostatectomy ("LRP") was carried out in the United States in 1991,[84] it was not until a decade later that the feasibility of the approach was demonstrated.[85] Around the same time as the first large series on LRP was being published, the first robot-assisted LRPs were being performed ("RALRP"). The Medicare data demonstrates that there is a clear trend towards this minimally invasive approach:[86]

[82] 80 Fed. Reg. 41686, 41910, 41920.
[83] Reiner, W., Walsh, PC. Anatomical surgical approach to the management of the dorsal vein complex during radical retropubic surgery. J. Urol. 1979; 121:198-200
[84] Schuessler WW, Schulam PG, Clayman RV, et al. Laparoscopic radical prostatectomy: initial short-term experience. Urology; 1997 Dec; 50(6):854-7
[85] Guillonneau B, Cathelineau X, Doublet JD, et al. Laparoscopic radical prostatectomy: the lessons learned J. Endourol. 2001 May; 15(4):441-5; discussion 447-8
[86] LUGPA Milliman Data.

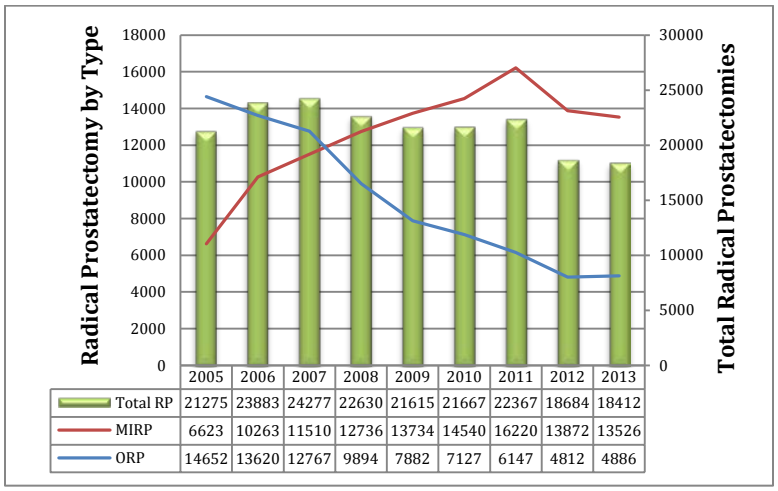


Figure 7: Minimally Invasive vs. Open Radical Prostatectomies, Medicare Beneficiaries 2005-2013

Figure 7 demonstrates that while the total number of radical prostatectomies ("RP") received by Medicare beneficiaries between 2005-10 varied only slightly (note: plotted on secondary axis), within that population, the likelihood of receiving minimally invasive radical prostatectomy ("MIRP") vs. ORP substantially increased, such that by 2013, 73.4% of patients having RP had it done via a minimally invasive approach, extending trends noted in earlier reports.[87] Interestingly, while the number of radical prostatectomies remained constant from 2005-10, more recently, the number of radical prostatectomies has declined by 16.5%, mirroring the changes noted earlier in utilization of IMRT, again likely due to increased use of active surveillance in newly diagnosed patients with prostate cancer.[88]

B. CMS Did Not Provide a Rationale for the Substantial Cut in wRVU for Laparoscopic Radical Prostatectomy and Such Cut Should Not Be Implemented in the Final Rule.

In Addendum B of the Proposed Rule, CMS lists the PFS components for each CPT code. As noted in Figure 8 below, in the case of laparoscopic radical prostatectomy, Addendum B lists a wRVU amount significantly lower than the current value.

Year	Work	Office PE	Malpractice	Global
2016p	21.36	0	3.5	24.86
2015	32.06	0	3.18	35.24
Δ	-33.4%	0.0%	10.1%	-29.5%

Figure 8: RVU Changes for CPT 55866, 2015-2016(p)

[87] Dinan MA, Robinson TJ, Zagar TM, et al. Changes in initial treatment for prostate cancer among Medicare beneficiaries, 1999-2007. Int J Radiat Oncol Biol Phys. 2012 Apr 1;82(5):e781-6.

[88] Op. cit. Cooperberg.

Under the CY 2015 MPFS, the global RVU associated with CPT Code 55866 is 35.24.[89] With no explanation whatsoever, Addendum B reduces this to 24.86, and the increase in malpractice RVUs does little to offset the dramatic reduction in wRVUs. CMS does not analyze or otherwise justify this significant reduction in the body of the Proposed Rule.

LUGPA believes that the proposed wRVUs for CPT 55866 substantially undervalue the procedure and should be reversed. Moreover, in the light of CMS's commitment to greater transparency in the development of the MPFS, we believe it is very important for CMS to avoid imposing such significant reductions in reimbursement levels without first explaining its rationale for such changes and providing stakeholders with the opportunity to provide meaningful comment in response. LUGPA requests that CMS restore the wRVUs for CPT Code 55866 to the current level of 32.06 and not finalize changes—if any are warranted—until the notice and comment rulemaking process for CY 2017.

V. Request for CMS Action

Consistent with our comments above, LUGPA respectfully requests that CMS take the following action in finalizing the MPFS for CY 2016.

With respect to reimbursement of IMRT for treatment of prostate cancer:

- CMS should reconsider its inclusion of IMRT in its misvalued code initiative in light of the clear evidence that utilization trends for prostate and breast IMRT are flat or falling and given the fact that the physician office setting is the lower cost option for the delivery of these services as compared to identical services furnished in the HOPD setting. Moreover, the degree to which CMS is proposing to cut reimbursement for IMRT for prostate cancer contravenes the letter and spirit of recent statutory limitations that PAMA and ABLE placed on CMS's authority.

- It seems contradictory that CMS has placed "simple" and "complex" IMRT codes in the same OPPS APC while substantially differentiating resource utilization for these same codes in the physician office setting. If CMS continues to believe that distinct "simple" and "complex" IMRT codes are clinically warranted, then CMS should not create disparate reimbursement levels for these codes between the physician office and HOPD settings until a more nuanced analysis of the clinical consequences of such a change can be performed.

- CMS should acknowledge the substantial invoice information provided by equipment manufacturers and include the cost of on-board imaging in the PE components of the IMRT and IGRT codes.

[89] Centers for Medicare and Medicaid Services, *Addendum B – CY 2015 Relative Value Unites (RVUs) and Related Information Used in Determining Final Medicare Payments*, available at: https://www.cms.gov/ Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/ Downloads /CY2015-PFS-FR-Addenda.zip.

- CMS should retain the existing equipment utilization rate of 50% for LINAC. Empirical data collected by RTA, as well as an analysis of CMS's own data, shows an actual equipment utilization rate equal to or less than 50 percent. CMS's analysis does not incorporate this empirical data, nor does it acknowledge important clinical changes in the treatment and monitoring of prostate cancer that would naturally lead to lower equipment utilization—such as the rapid growth of active surveillance and the effect that the USPSTF downgrading of PSA testing has had on the number of newly diagnosed prostate cancer cases and corresponding treatment of the disease.

With respect to CMS's request for comment regarding the impact of the physician self-referral law on health care delivery and payment reform:

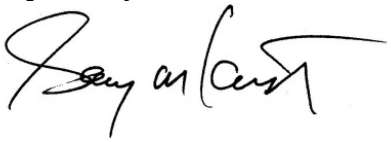
- CMS should acknowledge that the Stark law in its current form obstructs innovative payment arrangements in the context of CMS's overall, historic move towards value-based payment. As such, CMS should use its statutory authority to create one or more new Stark law exceptions to extend the provisions of its existing ACO waivers to any physician or entity that is complying or working to comply with future value-based payment initiatives.

With respect to CPT Code 55866:

- We do not believe there is any support for CMS's dramatic cut in wRVUs—from 32.06 to 21.36—associated with laparoscopic radical prostatectomy services (CPT Code 55866). The nearly one-third cut appears in Addendum B of the Proposed Rule without explanation, which makes it impossible for LUGPA to offer meaningful comment on the rationale for the reduction. CMS should restore the wRVUs for CPT Code 55866 to the current level of 32.06 and not finalize any changes—if any are warranted—until the rulemaking process associated with the MPFS for CY 2017.

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@kattenlaw.com, if you have any questions or if LUGPA can provide additional information to assist CMS as it considers these issues.

Respectfully submitted,



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