September 16, 2019

BY ELECTRONIC SUBMISSION

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

RE: Comments to CMS-5527-P

On behalf of LUGPA, we thank you for the opportunity to comment on the Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures Proposed Rule (the "Proposed Rule").[1] As the voice of integrated urology groups that bring together urologists, radiation oncologists and pathologists in a team approach to diagnose and treat patients with prostate cancer, we write to comment on CMS's proposed, mandatory Medicare payment model for delivery of radiation oncology services (the "RO Model").

LUGPA was an early proponent of developing alternative payment models and other value-based payment structures for use in treating patients with cancer, and we are highly appreciative of the efforts CMS has made to design an RO Model. Indeed, the APM submitted by LUGPA for treating newly diagnosed patients with prostate cancer included global payments for radiation therapy.[2] We are in favor of CMS testing a value-based care delivery model for the purpose of enhancing the quality of cancer care, reducing overall Medicare expenditures, and reducing administrative burdens placed on providers, but we cannot support the RO Model as currently proposed.

CMS states that it "is committed to promoting higher quality of care and improving outcomes for Medicare beneficiaries while reducing costs."[3] We share that commitment; yet, we must oppose implementation of the RO Model as formulated, because it threatens to undermine the quality of care furnished to Medicare beneficiaries with prostate cancer, particularly African-American men for whom access to advanced treatment technologies is already limited—a serious problem that will only be

[1] 84 Fed. Reg. 34478 (July 18, 2019).
[2] LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer submitted to Physician-Focused Payment Model Technical Advisory Committee (July 5, 2017), *available at* https://aspe.hhs.gov/system/files/pdf/255906/LUGPAAPM.pdf (last accessed Sept. 13, 2019).
[3] 84 Fed. Reg. at 34490.

exacerbated if the RO Model is finalized as proposed. Moreover, the Medicare utilization and cost data we present below make clear that hospital outpatient departments ("HOPDs")—not freestanding radiation centers or physician group practices—are driving Medicare program expenditures for RT services and, therefore, the RO Model (with its site-neutral payment structure) need not be mandatory other than in the HOPD setting.

In summary form, we offer the following comments on the proposed RO Model:

- **We are deeply concerned that the RO Model—particularly as applied to prostate cancer treatment—exceeds the body of clinical data as the Model is based on the incorrect assumption that hypofractionation is clinically equivalent to conventional length treatment for men with newly diagnosed prostate cancer**.[4] Although there is data to suggest that for certain patients, hypofractionation may be a viable alternative to conventional treatment regimens, there is no consensus yet on what constitutes an optimal hypofractionation schedule. A cursory literature review revealed 279 peer-reviewed publications in the last five years with more than 100 such publications in the last 12 months alone with multiple different treatment protocols.[5] Even the studies on which CMS relies make clear that it is premature to base a care delivery system on a protocol with uncertain treatment outcomes, and those studies were based on patients with low- to intermediate-risk disease. Extrapolating those findings to all potential candidates for radiotherapy is premature and dangerous.

- **We are alarmed by the impact that the RO Model will have on underserved populations that do not have access to advanced treatment technologies.**[6] As we demonstrate in Part II(B) below, treatment decisions are often impacted by patient demographics that vary widely in urban versus rural settings and in different regions of the country. For this reason, we believe that using CBSAs in the "comparison" group to benchmark adjustments for groups in the "participant" arm after the first year may substantially disadvantage providers who treat higher-risk patients and compromise therapy to vulnerable populations such as African-American men newly diagnosed with prostate cancer. CMS must study this issue further before finalizing an RO Model that could have such serious implications for cancer treatment in racially diverse and underserved regions of the country.

- **We believe that mandatory participation is not warranted in the freestanding radiation center and physician group practice settings (collectively, the "Office setting")**. CMS seeks to reduce Medicare program costs by mandating participation across all sites of service, yet LUGPA's analysis of Medicare utilization and cost data presented in Part II(C) below shows that from 2015 through 2017, utilization and cost of RT services continued to skyrocket in the HOPD setting for treatment of non-prostate disease, while

[4] Id. at 34991.
[5] PubMed, US National Library of Medicine National Institutes of Health, *available at* https://www.ncbi.nlm.nih.gov/pubmed/?term=hypofractionation+prostate+cancer+radiotherapy (last accessed Sept. 13, 2019).
[6] 84 Fed. Reg. at 34503.

utilization and cost have remained stable in the Office setting for non-prostate disease and decreased in the Office setting for treatment of prostate cancer.

- **We oppose CMS's proposal to make participation in the RO Model mandatory for all RT providers and suppliers within selected geographic areas.**[7] At a minimum, participation in the RO Model should be voluntary in the Office setting during the first three performance years before a possible transition to a mandatory model across all sites of service for the fourth and fifth performance periods.

- **We oppose CMS's proposed start dates of January 1 and April 1, 2020.**[8] CMS has underestimated the practical challenges that physician group practices and other RO participants are going to face readying for and operationalizing the RO Model and neither of the proposed dates will provide RO participants with enough time to prepare. **We ask that CMS delay implementation until July 1, 2020, which would result in a six-month, initial performance period.**

- **We support CMS's application of site-neutral payment in the RO Model**.[9] In light of CMS's well-founded concern that the payment differential that exists under the OPPS and PFS is "incentivizing Medicare providers and suppliers to deliver RT services in one setting over another,"[10] we believe that site-neutral payments should be applied to all providers, not only those in the 40% of Core Based Statistical Areas ("CBSAs") required to participate in the RO Model.

- **We support CMS's inclusion of proton beam therapy ("PBT") as one of the RT modalities in the RO Model.**[11] The value of the RO Model will be undercut significantly if CMS excludes one of the most expensive RT modalities, particularly given the "debate regarding the benefits of proton beam relative to other, less expensive modalities."[12]

- **Providers required to participate in the RO Model should receive the national base rates without application of a "discount rate" adjustment.** It is patently unfair for CMS to impose special payment reductions on providers that are arbitrarily selected and forced to participate in the RO Model; on the other hand, we do not object to CMS considering a discount for those providers that voluntarily choose to participate in the Model.

In short, the proposed RO Model—particularly as applied to treatment of prostate cancer—fails to deliver on the Innovation Center's statutory charge of testing innovative payment and service delivery models for the purpose of decreasing Medicare program expenditures, but to do so "while preserving or enhancing the quality of care furnished" to Medicare beneficiaries.[13] CMS should not subject the entire country to a mandatory, untested demonstration project that threatens to undertreat men with prostate cancer, especially

[7] 84 Fed. Reg. at 34480, 34490, 34494.
[8] Id. at 34493.
[9] Id. at 34490; id. at 34524 (stating that "the calculation of how much each RO participant would be paid for the PC and TC of the episode is designed to be as similar as possible, irrespective of whether the RO participant is an HOPD or a freestanding radiation therapy center").
[10] Id. at 34491.
[11] Id. at 34503.
[12] Id.
[13] 42 U.S.C. § 1315a(1); id. § 1315(b)(2)(A).

racially diverse populations, and deprive beneficiaries of choice of where they receive RT services, when the driver of utilization and cost is confined to the HOPD setting.

I. LUGPA

LUGPA's mission is to provide urological surgeons committed to furnishing 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. Established more than a decade ago, LUGPA represents 154 urology group practices in the United States, with approximately 2,200 physicians who, collectively, provide nearly 40% of the nation's urology services.[14]

Integrated urology practices are able to monitor health care outcomes and seek out medical "best practice" in an era increasingly focused on delivery of high quality, cost-effective care. A perfect example is our member practices' treatment of men with prostate cancer—the second leading cause of cancer death in American men.[15] LUGPA practices bring together urological surgeons, pathologists, radiation oncologists, and advanced practice providers in a team approach to coordinate and deliver care with added patient convenience in the physician group practice ("PGP") setting. Our member practices provide or utilize the full range of treatment options to men diagnosed with prostate cancer—from active surveillance, to surgical options, to brachytherapy, to various types of external beam radiation therapy, including 3-dimentional conformal radiotherapy ("3DCRT"), intensity-modulated radiotherapy ("IMRT"), stereotactic radiosurgery ("SRS"), stereotactic body radiotherapy ("SBRT"), proton beam therapy ("PBT"), and image-guided radiation therapy ("IGRT). For purposes of the RO model, while some LUGPA practices provide technical and professional services in joint-venture arrangements, LUGPA practices would most typically be deemed "Dual participants," furnishing the professional and technical components ("PC" and "TC") of radiation therapy services in a Medicare-enrolled PGP identified by a single Taxpayer Identification Number ("TIN").

II. Mandating Participation in the RO Model Across All Sites of Service Raises Serious Clinical Concerns, Will Exacerbate Existing Racial Disparities in Access to Cancer Treatment Technologies, and Is Unwarranted Based on a Careful Review of Medicare Claims Data.

We are alarmed by the mandatory nature and breadth of this untested RO Model. In its report to Congress in November 2017 entitled "Episodic Alternative Payment Model for Radiation Therapy Services," CMS did not suggest—or in any way intimate—that participation in an APM for RT services would require mandatory participation from the outset and cover 40% of all RO episodes. Such a proposal would have been shocking and would have been met with grave concern from the provider community, given that the Innovation Center has never before introduced an APM that broad or mandatory from the outset.

The Innovation Center's statutory charge is to test innovative payment and service delivery models to decrease Medicare program expenditures, but to do so "while preserving or enhancing the quality of care furnished" to Medicare beneficiaries.[16] We are deeply concerned that the RO Model will have the opposite

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

[15] "Key Statistics for Prostate Cancer," *available at* https://www.cancer.org/cancer/prostate-cancer/about/key-statistics.html (last accessed Aug. 26, 2019).

[16] 42 U.S.C. § 1315a(1); id. § 1315(b)(2)(A).

effect, jeopardizing the quality of care furnished to men with prostate cancer, particularly African American men who present with higher grade disease, have a greater chance of dying from prostate cancer and, yet, have far less access to advanced treatment technologies. The RO Model creates these risks while placing enormous burdens on providers forced to participate in a Model with uncertain treatment outcomes. Moreover, subjecting RO episodes for treatment of prostate cancer to the mandatory model across all sites of service is not justified based on a careful review of Medicare utilization and cost data. As we show in Part II(C) below, the RO Model is rooted in outdated data that fails to capture the true driver of cost in the Medicare program—skyrocketing utilization and cost of RT services in the HOPD setting for treatment of cancers *other than prostate cancer*.

A. Medicare Beneficiaries with Cancer Should Not Be Subjected to an Untested, Yet Mandatory, RO Model With Uncertain Treatment Outcomes.

In a section of the Proposed Rule entitled "Aligning Payments to Quality and Value, Rather than Volume,"[17] CMS makes clear that one of the central tenets of the RO Model is to discourage providers from furnishing conventional length treatment regimens for prostate cancer and to shift those patients to higher doses of radiation delivered in fewer fractions, commonly known as "hypofractionation." As the Agency explained "recent clinical trials have demonstrated that, for some patients in clinical trials with low- and intermediate-risk prostate cancer, courses of RT lasting 4 to 6 weeks lead to similar cancer control and toxicity as longer courses of RT lasting 7 to 8 weeks."[18]

The RO Model's presumption that hypofractionation is appropriate for men with low- and intermediate-risk prostate cancer threatens to undermine the quality of care furnished to Medicare beneficiaries. Although hypofractionated treatment might be of similar efficacy for "some patients," the studies on which CMS relies make clear that there is insufficient clinical support for mandating that 40% of RO episodes be assigned to a Model designed to encourage hypofractionation. It is premature to conclude otherwise.

As CMS recognized in the Proposed Rule, there is significantly more academic literature analyzing the efficacy of hypofractionation for breast cancer and bone metastases than for prostate cancer.[19] Neither study CMS cited analyzing the efficacy of hypofractionation for treatment of prostate cancer goes as far as CMS claims in establishing the foundation for an RO Model that presumes a clinical equivalency between courses of RT lasting four to six weeks and longer courses of RT lasting seven to eight weeks.

The 2016 study in the Journal of Clinical Oncology ("JCO") on which CMS relies acknowledged that "[t]he sensitivity of prostate cancer to the RT dose administered at each treatment session has been the subject of considerable controversy and intense interest."[20] The authors of the JCO study noted that ***results from randomized clinical trials "have not confirmed th[e] hypothesis" that "a higher dose per treatment, that is, hypofractionated external RT, would increase the efficacy of RT compared with conventionally delivered external RT***."[21] In fact, the JCO study indicated that although a shorter course of treatment (70 Gy delivered across 28 fractions in 5.6 weeks) provided similar efficacy to a conventional

[17] 84 Fed. Reg. at 34491.
[18] Id.
[19] *Compare* Id. at 34491 nn.8-15 (citing four studies each in support of hypofractionation for treatment of breast cancer and bone metastases) *with* id. nn.16-17 (citing two studies in support of hypofractionation for treatment of prostate cancer).
[20] Id. at 34491 n.17, citing W.R. Lee, et al., Randomized phase III noninferiority study comparing two radiotherapy fractionation schedules in patients with low-risk prostate cancer. J. Clin. Oncol. 34 (July 10, 2016) at 2325-2332, *available at* http://ascopubs.org/doi/full/10.1200/JCO.2016.67.0448 (last accessed Aug. 27, 2019).
[21] Lee, J. Clin. Oncol., at 2328 (emphasis added).

course of treatment (73.8 Gy across 41 fractions in 8.2 weeks), ***the hypofractionated delivery was associated "with an increase in late [gastrointestinal] GI and [genitourinary] GU adverse events***."[22] And, even then, the JCO study was confined to men with low-risk prostate cancer and made clear that "these results should not be extrapolated to men with intermediate- or high-risk disease."[23]

At least insofar as prostate cancer treatment is concerned, CMS was premature in concluding that "the latest clinical evidence suggests that shorter courses of RT … would be equally effective and could improve patient experience."[24] CMS's suggestion of an improved patient experience is belied by the JCO study on which CMS relied, which stated that "increased convenience leads to more treatment-related toxicity."[25] And even the study published in Lancet, which found a hypofractionated course of treatment of 60 Gy over four weeks non-inferior, noted that "five other contemporary phase 3 studies have reported side-effects related to hypofractionated radiotherapy."[26] Moreover, the finding of "non-inferiority" was "primarily applicable to patients receiving short-course androgen deprivation therapy" and "might not be generalizable to populations who do not receive androgen deprivation therapy."[27] In contrast, there is ample literature that supports the long-term safety and efficacy of conventionally-fractionated dose escalation treatment regimens.[28,29,30,31]

CMS stated that one of the rationales for the proposed RO Model was to "encourage[e] physicians to provide high-quality nationally recognized evidence-based care."[32] LUGPA supports this worthy goal, but it is critical for CMS to understand that hypofractionated RT for men with prostate cancer, particularly those with intermediate- and high-risk disease, is neither "nationally recognized" nor "evidence-based." In short, it is premature to assign 40% of Medicare beneficiaries who choose radiation therapy for treatment of their prostate cancer to an untested, mandatory model, when the benefits of hypofractionation for treatment of prostate cancer are far from clear. We are concerned that CMS's quest for a "more efficient" and "higher value" care model risks making hypofractionated treatment the only economically viable model for treating men with low- and intermediate-risk prostate cancer. CMS should not risk

---

[22] Id. (finding that "l]ate grade 2 and 3 GI adverse events were approximately 60% more likely in men who were assigned to treatment with H-RT [hypofractionation] (RR, 1.55 to 1.59)" and "[s]imilarly, late grade 2 and 3 GU adverse events were more likely in men assigned to treatment with H-RT (RR, 1.31 to 1.56)") (emphasis added).

[23] Id. at 2325, 2330.

[24] 84 Fed. Reg. at 34491.

[25] Lee at 2230.

[26] 84 Fed Reg. at 34491, citing D. Dearnaley, I. Syndikus, et al. Conventional versus hypofractionated high-dose intensity-modulated radiotherapy for prostate cancer: 5-year outcomes of the randomized, non-inferiority, phase 3 CHHiP trial. Lancet Oncol. 17 (Aug. 2016), pp. 1047-1060, *available at* http://www.sciencedirect.com/science/article/pii/S1470204516301024 (last accessed Aug. 27, 2019).

[27] Dearnaley at 1058.

[28] Pasalic D, Kuban DA, Allen PK, et al. Dose Escalation for Prostate Adenocarcinoma: A Long-Term Update on the Outcomes of a Phase 3, Single Institution Randomized Clinical Trial. Int J Radiat Oncol Biol Phys. 2019 Jul 15;104(4):790-797.

[29] Spratt DE, Zumsteg ZS, Ghadjar P, et al. Comparison of high-dose (86.4 Gy) IMRT vs combined brachytherapy plus IMRT for intermediate-risk prostate cancer. BJU Int. 2014 Sep;114(3):360-7.

[30] Weg ES, Pei X, Kollmeier MA, et al. Dose-Escalated Intensity Modulated Radiation Therapy for Prostate Cancer: 15-Year Outcomes Data. Adv Radiat Oncol. 2019 Apr 4;4(3):492-499.

[31] Kestin LL, Goldstein NS, Vicini FA, et al. Pathologic evidence of dose-response and dose-volume relationships for prostate cancer treated with combined external beam radiotherapy and high-dose-rate brachytherapy. Int J Radiat Oncol Biol Phys. 2002 Sep 1;54(1):107-18.

[32] Medicare Learning Network Event, "Proposed Radiation Oncology Model (Aug. 22, 2019), slide 5, *available at* https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2019-08-22-Radiation-Presentation.pdf (last accessed Sept. 10, 2019).

undertreating prostate cancer—the second leading cause of cancer death in American men—in the name of efficiency and cost savings.

B. We are Concerned that the Proposal, as Written, will Exacerbate Existing Racial Disparities in Access to Cancer Treatment Technologies.

The existence of racial disparity in cancer treatment has been recognized for some time.[33] That disparity becomes particularly chilling when racial demographics for prostate cancer are considered. It is well established that African-American men present with higher grade and stage of prostate cancer at diagnosis and have a substantially greater chance of dying of their disease.[34] It has been clearly established that for higher-risk patients newly diagnosed with prostate cancer, there continues to be profound racial disparities in access to advanced technology.[35] We are deeply concerned that the methodology used to adjust national trended base rates is not nuanced enough and will disadvantage providers who care for higher risk patients which, in turn, will further exacerbate the racial disparities in access to high quality cancer care.

To start, we support CMS's decision to adjust the 34 trended national base rates to account for each Participant's historical experience and case history in year one of the program.[36] This adjustment is critical—not only because of RO participants' varied historical uses of more or less expensive modalities,[37] but also because treatment decisions are often impacted by patient demographics that vary widely in urban versus rural settings and in different regions in the country.

This potential issue arises in subsequent performance years in the RO Model. CMS proposes to use a practice's own data in the first performance year, but in subsequent years CMS states that "the calculations would update the national base rates using the most recently available claims data of those non-participating providers and suppliers and the volume at which they billed for RT services as well as their corresponding payment rates."[38] We are deeply concerned that this approach may penalize those who treat higher-risk populations, and in particular, jeopardize patient access to disease-specific centers of excellence. This is best illustrated by the graphics below, depicting incidence rates for all cancers and for prostate cancer specifically:[39]

[33] Shavers VL, Brown ML. Racial and ethnic disparities in the receipt of cancer treatment. Journal of the National Cancer Institute. 2002 Mar 6;94(5):334-57.

[34] Chornokur G, Dalton K, Borysova ME, Kumar NB. Disparities at presentation, diagnosis, treatment, and survival in African American men, affected by prostate cancer. The Prostate. 2011 Jun 15;71(9):985-97.

[35] Gerhard RS, Patil D, Liu Y, et al. Treatment of men with high-risk prostate cancer based on race, insurance coverage, and access to advanced technology. In Urologic Oncology: Seminars and Original Investigations 2017 May 1 (Vol. 35, No. 5, pp. 250-256).

[36] 84 Fed. Reg. at 34503.

[37] Id.

[38] Id.

[39] US Cancer Statistics Working Group, US Cancer Statistics Data Visualizations Tool: Centers for Disease Control and Prevention and National Cancer Institute, *available at* https://www.cdc.gov/cancer/dataviz, June 2019 (last accessed Sept. 14, 2019).

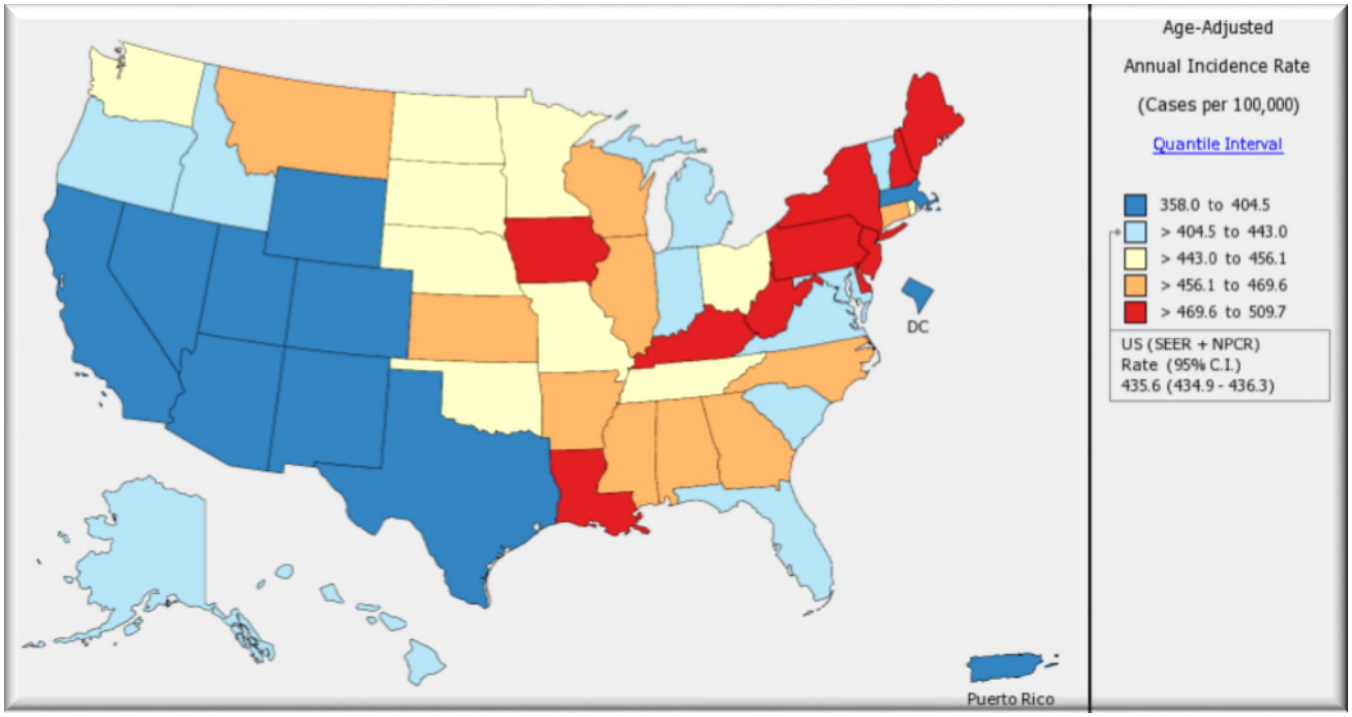


Figure 1: Overall Cancer Incidence/100,000 People, 2016

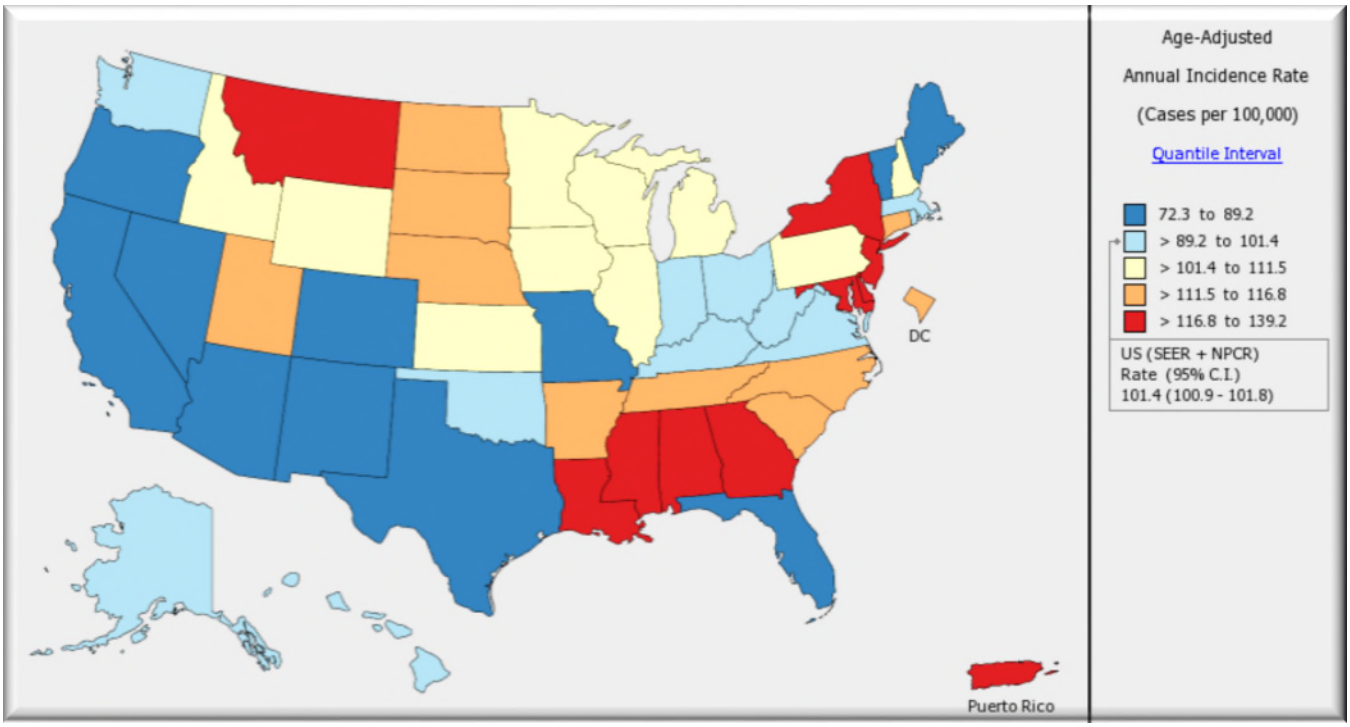


Figure 2: Prostate Cancer Incidence/100,000 Men, 2016

It is not difficult to see that the demographic incidence of prostate cancer is not the same as that of cancers *in toto*. As prostate cancer requires the use of greater levels of technology (IMRT) than other cancers, CBSAs with higher incidences of prostate cancer could be disadvantaged in future adjustments if providers in the "comparison" group treat fewer such patients than providers forced into the "participant" group.

This flaw in the RO Model's design becomes even more acute when racial demographics are considered:

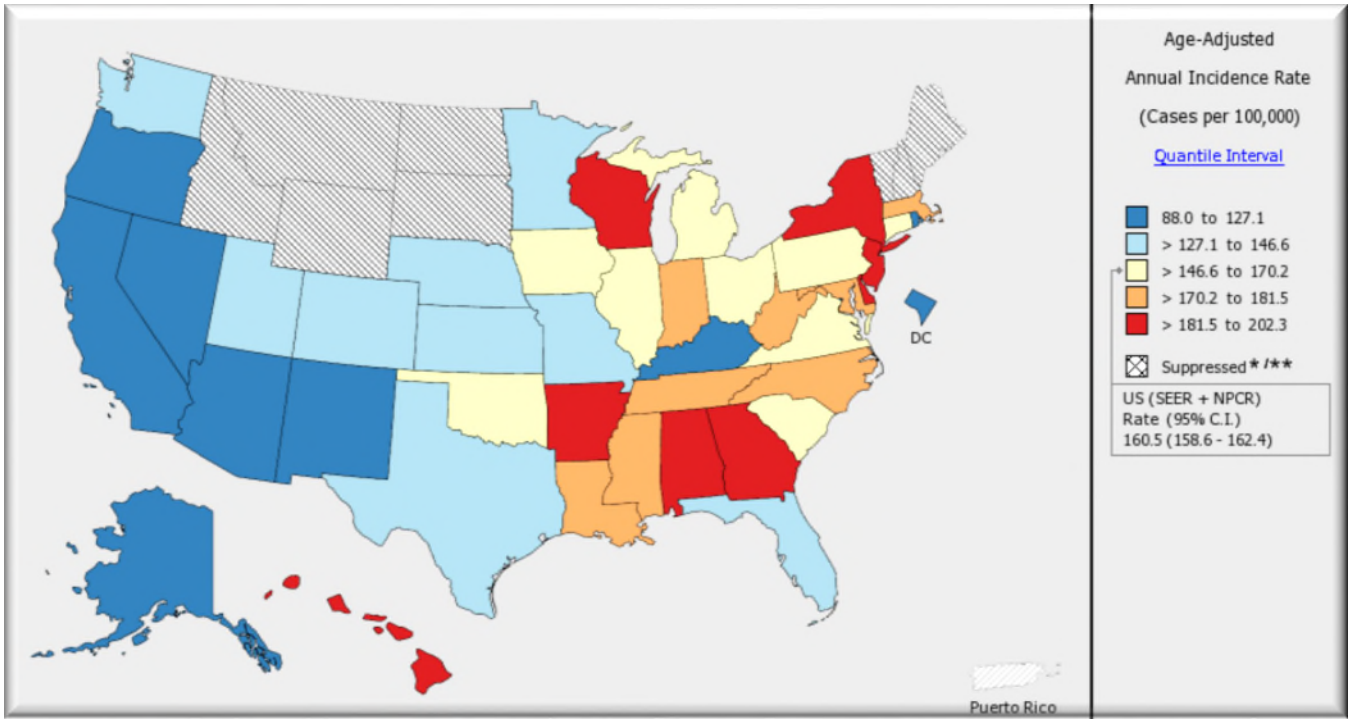


Figure 3: Prostate Cancer Incidence/100,000 African-American (Including Hispanic) Men, 2016

Figure 3 clearly illustrates that the racial demographic of patients newly diagnosed with prostate cancer is not uniform across CBSAs and not only does not match the overall incidence of other cancers, it does not match the overall incidence of prostate cancer alone. It would be virtually impossible to create a hybridized model of the different cancers included in the RO Model that is demographically matched in control and demonstration CBSAs (i.e., the "participant" and "comparison" groups).

CMS's proposal to use utilization patterns for a control CBSA with potentially lower-risk patients as a benchmark for a CBSA with higher-risk patients could have potentially devastating consequences in subsequent years of the Model. This is particularly true as the principle savings methodology is hypofractionation. As we previously discussed, hypofractionation in prostate cancer is far from being the standard of care and has not been thoroughly evaluated in higher-risk patients. This is especially true of African-American men; there is virtually no data suggesting that hypofractionation is appropriate for this demographic.[40]

C. CMS's Proposal to Make the RO Model Mandatory for All Sites of Service is Based on Outdated Utilization and Cost Data and Does Not Account for the Fact that the Utilization and Cost of RT Services is Being Driven by HOPDs.

In addition to our strong clinical reservations about mandating participation in the RO Model, we do not believe that Medicare utilization and cost data supports implementing a mandatory RO Model in the freestanding radiation center and PGP settings. CMS explained during its August 22, 2019 listening session that it proposed the RO Model "to address concerns raised in the report" that CMS had submitted to Congress in November 2017 entitled "Episodic Alternative Payment Model for Radiation Therapy

[40] Stokes WA, Kavanagh BD, Raben D, Pugh TJ. Implementation of hypofractionated prostate radiation therapy in the United States: A National Cancer Database analysis. Practical radiation oncology. 2017 Jul 1;7(4):270-8.

Services."[41] The 2017 Report to Congress (much like the RO Model Proposed Rule) emphasized the rapid growth in utilization of—and Medicare Part B spending on—RT services from 2000 to 2010.[42] Both documents singled out IMRT as a cost driver, noting that "from 2000 to 2010 Medicare Part B spending on radiation therapy services increased 216% due primarily to the adoption and uptake of IMRT."[43] The Proposed Rule singles out freestanding radiation therapy centers as the purported driver of IMRT utilization, claiming that such centers (as contrasted with HOPD facilities) "use more IMRT" and "perform more fractions (that is, more RT treatments) than HOPDs."[44] Respectfully, CMS's analysis is outdated and flawed.

LUGPA has undertaken a comprehensive analysis of utilization and cost of RT services in the Medicare program for the period 2005 through 2017. That analysis—drawn from the Medicare 5% data sample—shows that there is no justification for forcing physicians in the Office setting (freestanding radiation centers and PGPs) to participate in a mandatory payment model when utilization of RT services in the HOPD setting is the clear driver of cost to the Medicare program.[45]

1. IMRT Utilization for Non-Prostate Cancer is Skyrocketing in the HOPD Setting.

In its November 2017 Report to Congress and again in the RO Model Proposed Rule, CMS expressed concern with the utilization and associated cost of IMRT services, particularly in the office setting. Analysis of the Medicare 5% data sample[46] suggests that there is only one alarming trend in utilization of IMRT—the skyrocketing use of IMRT for treatment of cancers other than prostate cancer in the HOPD setting.

Figure 4 below shows similar increases in the total number of IMRT line items in the HOPD and office settings from 2005 through 2010—an expected trend given the shift away from older 3D XRT technology to more advanced IMRT. Then, from 2011 to 2017, we see (i) a significant *decrease* in the number of line items for treatment of prostate cancer ("Pca") in the Office setting, (ii) stable utilization of IMRT for treatment of non-prostate disease in the Office setting, and (iii) an increase in IMRT utilization for treatment of prostate cancer in the HOPD setting from 2015 through 2017 after an initial decline from 2011 through 2013. The decreased utilization of radiotherapy to treat prostate cancer directly coincides with the preliminary United States Preventive Services Task Force ("USPSTF") issuance of a Grade "D" recommendation for prostate cancer screening which resulted in substantially fewer patients newly diagnosed with prostate cancer.[47]

[41] Id. at slide 4, referencing Episodic Alternative Payment Model for Radiation Therapy Services (November 2017) ("2017 Report to Congress"), available at https://innovation.cms.gov/Files/reports/radiationtherapy-apm-rtc.pdf (last accessed Aug. 28, 2019).
[42] 2017 Report to Congress at 3; 84 Fed. Reg. at 34502.
[43] 2017 Report to Congress at 11; 84 Fed. Reg. at 34502.
[44] 84 Fed. Reg. at 34490.
[45] Milliman, Inc. was retained to access and summarize Medicare 5% sample data files for the years 2005-2017. LUGPA analyzed this data in accordance with accepted peer-reviewed methodology.
[46] Kapoor DA, Holton M, Albala D, et al. Utilization Trends in the Treatment of Prostate Cancer, 2005-2017. Rev Urol, in press.
[47] Fleshner K, Carlsson SV, Roobol MJ. The effect of the USPSTF PSA screening recommendation on prostate cancer incidence patterns in the USA. Nature Reviews Urology. 2017 Jan;14(1):26.

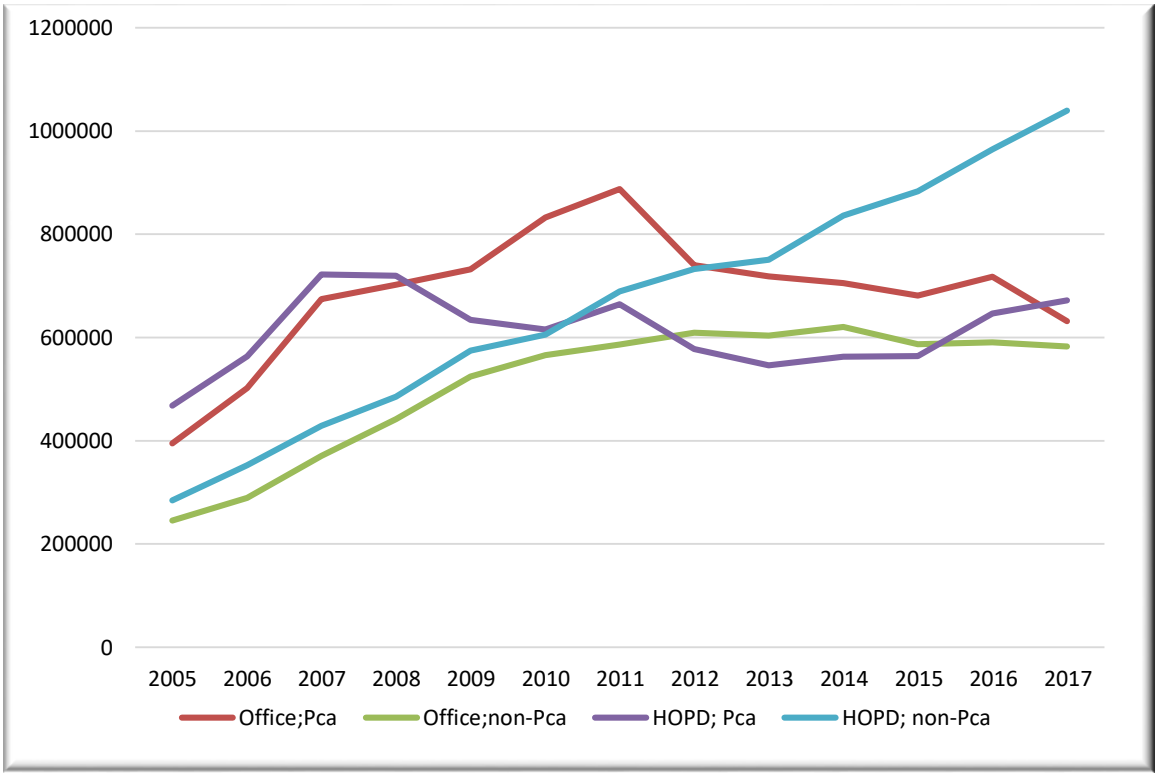


Figure 4: IMRT Line Items by Disease State and Site of Service

There are two particular trends of note in this analysis. First is that the only significant increase in IMRT utilization during the period 2011 through 2017 was in the HOPD setting for treatment of non-prostate disease where there was a massive increase in the number of line items, continuing a trend of dramatic increases in utilization in the HOPD setting over the entire 12-year study period. Second is that subsequent to 2012, IMRT use to treat prostate cancer in the office setting declined while its use in the HOPD setting increased; this is most likely driven by hospital acquisition of physician practices[48] to acquire additional ancillary service revenue.[49] In fact, by 2017, prostate cancer line items in the HOPD setting surpassed those in the office setting for the first time in a decade.

2. The Number of Fractions Delivered for Treatment of Prostate Cancer Has Held Constant Across Sites of Services and Does Not Reveal a Shift in the Standard of Care to Hypofractionation.

CMS proposed the RO Model with the aim of "aligning payments to quality and value, rather than volume,"[50] but the Agency's assessment of what constitutes "quality and value" is flawed. CMS makes clear in the Proposed Rule that "quality and value"—at least with respect to treatment of prostate and breast cancer—mean incentivizing physicians to employ treatment plans that "require[] fewer services."[51] We have already shared our strong reservations as to whether the current clinical literature supports CMS's premise that shorter courses of RT for prostate cancer (i.e., hypofractionation) are "equally effective and

[48] Carlin CS, Feldman R, Dowd B. The impact of hospital acquisition of physician practices on referral patterns. Health economics. 2016 Apr;25(4):439-54.
[49] Price J, Buchsbaum R, Price K. Medicare's site-neutral payment: impact on hospital outpatient services. Healthcare Financial Management. 2016 Nov 1;70(11):80-7.
[50] 84 Fed. Reg. at 34491.
[51] Id.

could improve the patient experience" when compared with longer-course treatments.[52] Not only is there insufficient evidence in the academic literature to justify a push towards hypofractionated treatment of prostate cancer, particularly for men with intermediate- and high-risk disease, but it is also clear from Medicare claims data that shorter-course RT treatments have not been adopted in the Office or HOPD settings.[53]

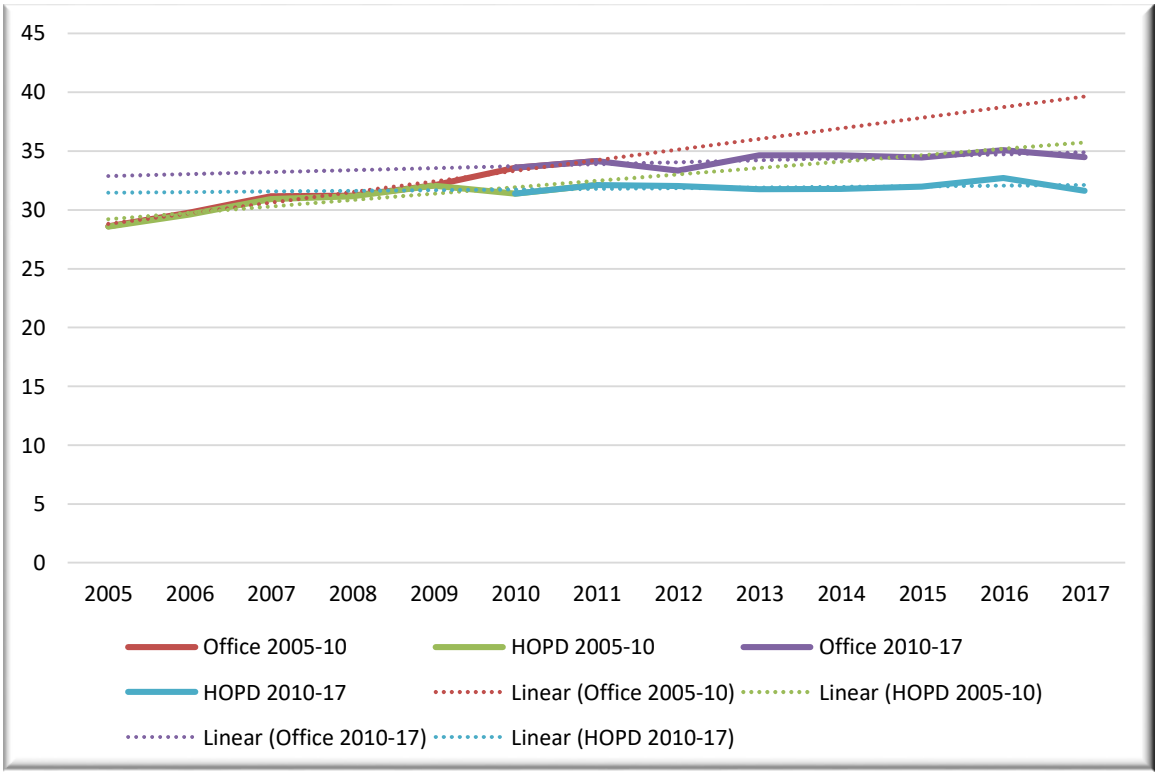


Figure 5: Fractions/patient/year by Site of Service with Split-regression Analysis

Figure 5 illustrates a split-regression analysis indicating that while the number of fractions/patient increased from 2005 through 2009 similarly in all sites of service, there was an inflection point in 2010 after which the number of fractions/patient remained constant. The increased fractions prior to 2010 is consistent with previously cited scientific knowledge evolving during that time that higher doses of radiation produce higher cure rates.[54] From 2010 through 2017, the number of fractions held constant in the Office and HOPD settings, with no suggestion that there has been a shift in the standard of care towards hypofractionated treatment regimens in either setting.[55]

The fact that the number of fractions has held constant for nearly a decade, regardless of site of service, is contrary to CMS's analysis that, with respect to treatment for prostate cancer, physicians furnishing IMRT in the HOPD setting have adopted hypofractionation protocols to a significant degree. This leads to our belief that it is a serious mistake to mandate that 40% of all RO episodes participate in an untested demonstration project predicated on the unsubstantiated premise—in either the academic literature or Medicare data—that hypofractionated treatment is now the *de facto* standard of care.

[52] Id.
[53] Op. Cit. Kapoor, Rev Urol.
[54] See, *supra*, nn.28-31.
[55] This analysis understates fractions per course of therapy as it is based on fractions/patient/year; as such, patients whose treatments bridge a calendar year reduce the aggregate average of fractions/patient/year.

3. Affirmative Use of Radiotherapy to Treat Prostate Cancer Has Decreased Significantly Over the Last Decade, Further Demonstrating that Mandatory Participation in the RO Model Is Not Warranted.

CMS's proposal that 40% of all RO episodes be subjected to an untested payment model is driven, in large measure, by Medicare data showing substantial increases in IMRT utilization during the period 2000 to 2010.[56] That increase is readily explained when analyzed alongside changes in utilization of other RT modalities and, even more importantly, is not nearly as significant as the decrease in the number of Medicare beneficiaries treated for prostate cancer with radiotherapy from 2011 through 2017—a fact that that CMS overlooked in the Proposed Rule:

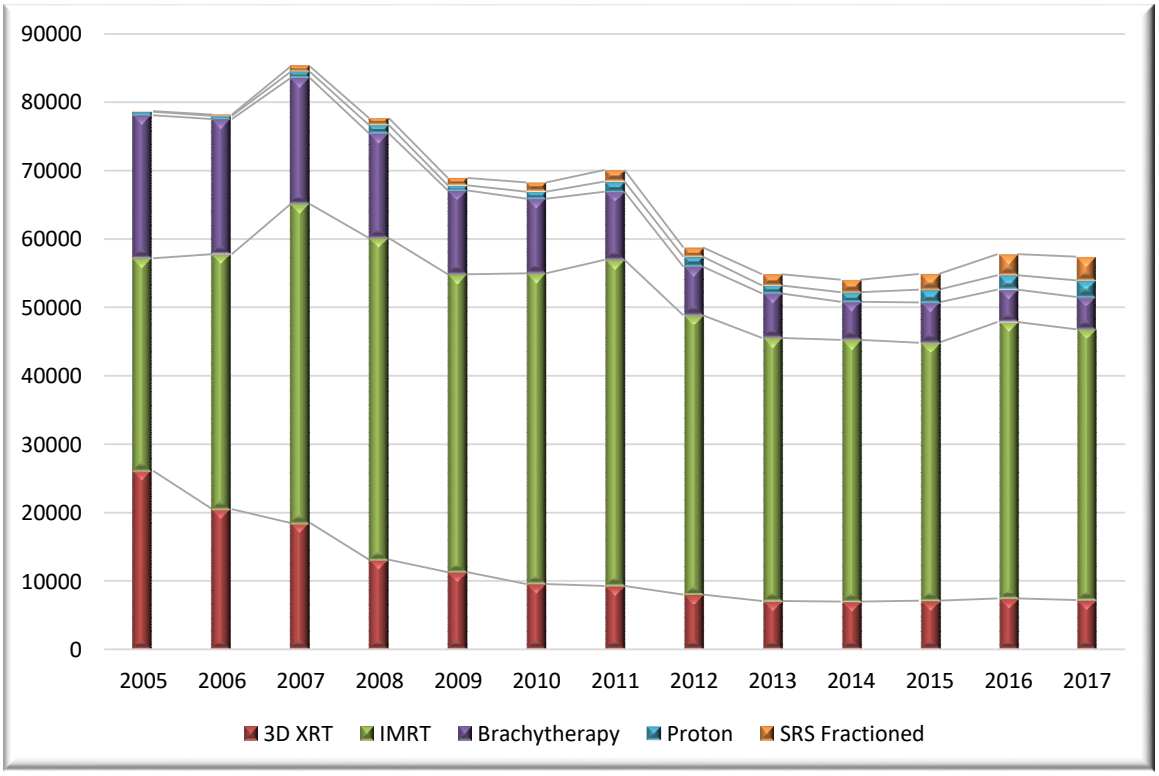


Figure 6: Medicare Beneficiaries Treated for Prostate Cancer with Radiotherapy, 2005 - 2017

Figure 6 shows that the significant increase in IMRT utilization from 2005 through 2011 was offset by a corresponding decrease in older 3D XRT technology such that the total number of beneficiaries receiving external beam radiotherapy ("EBRT") via 3D XRT or IMRT was virtually identical in 2011 as compared to 2005. The National Comprehensive Cancer Network made clear in its 2010 Guidelines that what had occurred in treatment of prostate cancer during this time period was a shift in the standard of care to a more advanced technology, stating, "the second generation 3D technique—intensity modulated radiation therapy (IMRT)—is now state-of-the-art and required."[57]

Perhaps even more significant is the global trend towards decreased use of EBRT. From 2005-17, the combined use of 3D XRT or IMRT to treat prostate cancer decreased by 18.2 percent. Of note is that during this same time period, use of PBT to treat this disease increased by over 369 percent.

Specifically, with respect to evaluating IMRT use in determining whether to make the RO Model mandatory and to do so for 40% of all RO episodes, there was a 16.9% decrease in the total number of

[56] 2017 Report to Congress at 11; 84 Fed. Reg. at 34502.
[57] NCCN Clinical Practice Guidelines in Oncology, Prostate Cancer V.1.2010, pMS-5.

Medicare beneficiaries receiving IMRT from 2011 through 2017. The nominal increase in use of radiotherapy in 2016 and 2017 coincides with increased numbers of patients being diagnosed with prostate cancer as the medical community reevaluated the appropriateness of the USPSTF recommendation regarding prostate cancer screening.[58]

4. Medicare Cost Data Does Not Support Mandating Participation in the RO Model in the Office Setting.

CMS suggests that although the per unit cost of RT services is higher in the HOPD setting, freestanding radiation centers are the more expensive site of service, thereby justifying mandatory participation in the RO Model in the Office setting.[59] The Agency explains this paradox by pointing to trends in hypofractionation; yet, as illustrated in Figure 5 above, those purported trends do not exists with respect to RT for prostate cancer.

In actuality, analysis of Medicare cost data suggests that the differential cost of treatment for prostate cancer on a per beneficiary basis is stable between the office and HOPD settings:[60]

Year	Office			HOPD		
	Bene Count	Spend ($)	Spend/Bene ($)	Bene Count	Spend ($)	Spend/Bene
2015	19,780	539,600,784.80	27,280.12	17,640	523,766,537.59	29,691.98
2016	20,460	521,042,166.00	25,466.38	19,780	583,417,049.46	29,495.30
2017	18,320	484,594,373.20	26,451.66	21,240	602,677,184.85	28,374.63
Total	**58,560**	**1,545,237,324.00**	**26,387.25**	**58,660**	**1,709,860,771.90**	**29,148.67**

Table 1: Beneficiary Count and Medicare Spend for IMRT Treatments for Prostate Cancer, 2015-2017

This cost data shows a steady climb in aggregate cost for treatment of prostate cancer in the HOPD versus Office settings for the period 2015 through 2017, and the total spend per beneficiary was, on average, 10% higher in the HOPD setting over the course of the three-year period. This data shows why CMS should move to a site-neutral payment system for delivery of RO services in the HOPD and Office settings, but the data does not justify mandating that physicians in the lower-cost Office setting participate in an untested demonstration project.

CMS emphasized throughout the Proposed Rule and during its August 22, 2019 listening session that the goal of the RO Model is to decrease the incentive to over-utilize RT services. A careful examination of Medicare data for the period 2010-2017 reveals that if a concern exists about the utilization and cost of RT services, such concern lies squarely in the HOPD setting, at least with respect to the treatment of Medicare beneficiaries with newly-diagnosed prostate cancer. To mandate participation in the RO Model for LUGPA practices committed to prostate cancer centers of excellence in the Office setting would be to base Medicare policy on outdated data.

Moreover, LUGPA's analysis of Medicare claims data calls into question two of the fundamental premises on which the RO Model is based. As we showed above, it is not true that there are different utilization trends in the number of fractions delivered in the Office and HOPD settings. Nor are costs being driven

[58] Barocas DA. Throwing out the baby with the bathwater: a critical appraisal of the USPSTF recommendation against screening for prostate cancer. ASCO Post; April. 2016 Apr;10.
[59] See 84 Fed. Reg. at 34490.
[60] Op. cit. Kapoor, Rev Urol (analyzing cost data based on HCPCS codes identified in Table 2 of the CMS Radiation Oncology Model Proposed Rule, 84 Fed. Reg. at 34501-02).

by utilization patterns in the Office setting; to the contrary, the vast majority of increased utilization is occurring in the more expensive HOPD setting. Simply put, the number of fractions being furnished has remained constant—indicating no change in the clinical standard of care—yet the number of patients being treated is exploding in the HOPD setting. If there are grounds for testing a demonstration project to "reduce Medicare program expenditures and preserve or enhance the quality of care for beneficiaries,"[61] CMS should reframe the RO Model to focus on the HOPD setting.

D. Participation in the RO Model Should Be Voluntary for Freestanding Radiation Centers and Physician Group Practices; At a Minimum, Participation Should Not Be Mandatory in These Sites of Service until the Fourth Performance Year.

We oppose CMS's plan to make participation in the RO Model mandatory in the Office setting.[62] At a minimum, participation in the RO Model should be voluntary in the Office setting (i.e., freestanding radiation centers and PGPs) for the first three performance years before transitioning to a mandatory participation model for the fourth and fifth years. At the same time, given the need to test a site-neutral payment model, we recognize the need for CMS to make the RO Model mandatory in the HOPD setting or else risk little or no participation from HOPDs.

Revising the RO Model so that participation in the Office setting is voluntary for the first three performance years will not limit CMS from expanding the RO Model in later years. Congress provided the Secretary with the authority, through rulemaking, to expand the duration and scope of a model that is being tested to the extent the Secretary determines that such expansion is expected to (A) reduce spending without reducing the quality of care or (B) improve the quality of patient care without increasing spending.[63]

CMS has a series of options available to it that are preferable to the current proposal that forces 40% of all eligible RO episodes into an untested, yet mandatory, payment and care delivery model that is set to begin on January 1 or April 1, 2020.

- Start the RO Model as a voluntary model for the first three years and evaluate after the second performance year whether it would be advisable to switch to mandatory participation for some segment of the country beginning with the fourth year.
- At a minimum, permit PGPs that furnish RT services in "participant" and "comparison" CBSAs to opt out from participation to avoid the complexities of a single group practice having to develop the clinical protocols and technological infrastructure to operate in two fundamentally different payment models.
- Start the RO Model (whether mandatory or voluntary) on July 1, 2020 to provide CMS and RO participants with sufficient time to prepare.

III. CMS Should Delay the Start of the First Performance Year until July 1, 2020, Given the Complexities Involved in Preparing for and Operationalizing the RO Model.

CMS has underestimated the practical challenges of readying for and operationalizing the RO Model. Neither of the proposed start dates of January 1 or April 1, 2020,[64] will provide RO Model participants with enough time to prepare for implementation. **Accordingly, we ask that CMS delay implementation until July 1, 2020, which will result in a 6-month first performance period.** RO participants will need that

[61] 84 Fed. Reg. at 34490 & 34494.
[62] Id. at 34480, 34490, 34494.
[63] 42 U.S.C. § 1315(c)(1).
[64] 84 Fed. Reg. at 34493.

much time once they learn whether they fall within (i) a CBSA that has been randomly selected to participate in the RO Model, (ii) a CBSA that will remain in the fee-for-service ("FFS") payment system, or (iii) both types of CBSAs, which we expect will happen to many LUGPA member practices that furnish RT services to Medicare beneficiaries in medical offices located in different CBSAs.

It is unreasonable to expect providers—especially those in smaller practices with less administrative support than hospital systems—to transition to a new reporting and payment system with no more than several months' notice. Yet, this is what the Proposed Rule contemplates for those providers who will learn late this year that they are being required to participate in the RO Model.

It is also unreasonable to require participation in the RO Model as soon as January 1 or April 1, 2020, when there is so much that is still unknown about how the Model will work, the HCPCS codes that will be used, the payment rates, and the reporting requirements. CMS states that "[l]ists of RO Model-specific HCPCS codes would be made available on the RO Model website prior to the model performance period" and that the Agency "expect[s] to provide RO participants with additional instructions for billing the RO Model-specific HCPCS codes through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website,"[65] without any indication of how far in advance of the start date the new codes and training programs will be available.

Pushing back the start date of the first performance period to July 1, 2020, is particularly important for those RO participants that treat Medicare beneficiaries with prostate, breast, or lung cancer as well as bone and brain metastases, given CMS's proposal to require those participants to collect and report clinical information not available in claims or captured in the proposed quality measures.[66] CMS's discussion of this planned data collection/reporting requirement further underscores how much work is yet to be done before the RO Model can be operationalized. As CMS explained, "[t]o facilitate data collection, we plan to share the proposed clinical data elements and reporting standards with EHR vendors and the radiation oncology specialty societies prior to the start of the Model. Our goal would be to structure data reporting standards so that existing EHRs could be adjusted in anticipation of this Model."[67]

So many questions remain unanswered. When does CMS plan to share the clinical data elements and reporting standards, given that CMS has invited public comment and, therefore, cannot reasonably be expected to finalize those elements and standards until later this Fall? What testing, if any, has CMS done at this point to test whether existing EHRs can reasonably be expected to be adjusted in anticipation of the Model? And what if existing EHRs are not able to be adjusted in advance of the January 1 or April 1 start date? To be sure, the collection and reporting of clinical data elements are worthy goals, but ultimately the burden falls on providers who face the prospect of being forced into this new Model just a handful of months after learning whether their participation is mandated and without adequate time to prepare to meet their obligations under the Model.

The complexities involved in preparing for and operationalizing the RO Model underscore the value in making the RO Model voluntary in the Office setting for at least the first three performance periods. Allowing for optional participation at the outset would give freestanding radiation centers and PGPs flexibility if, for whatever reason, they are not ready to participate in the RO Model by July 1, 2020. At

[65] Id. at 34513.
[66] Id. at 34518.
[67] Id. at 34519.

the same time, the shift to mandatory participation in the fourth performance period would mean that these providers would not be absolved from having to participate in the Model.

IV. CMS Should Finalize its Proposal to Apply a Site-Neutral Payment Structure to the RO Model.

LUGPA has long believed that the most appropriate way to address hospital-physician vertical consolidation and bring down the overall cost of care is through equalizing payment rates across sites of service. For its part, CMS has expressed concern that "payment incentives, rather than patient acuity or medical necessity, may be affecting site-of-service decision-making."[68] The Agency has rightly articulated the goal of "attaining site neutral payments to promote a level playing field."[69] Dr. Mark Miller, Executive Director of the Medicare Payment Advisory Commission ("MedPAC"), echoed this sentiment in Congressional testimony four years ago when he stated that "in principle, the Medicare program should pay the same amount for the same service, regardless of the setting in which it is provided, unless payment differentials are justifiable by differences in patient mix, provider mission (e.g., maintaining stand-by capacity for emergencies), or other justifiable factors."[70]

Applying a site-neutral payment structure for delivery of RT services is more critical than ever as Congress and CMS continue to work to "curb the practice of hospital acquisition of physician practices that then result in receiving additional Medicare payment for similar services."[71] In section 603 of the Bipartisan Budget Act ("BBA") of 2015, Congress based its goal of establishing a site-neutral payment structure on studies by HHS-OIG, GAO, and MedPAC, showing that (i) utilization has increasingly shifted from the physician office to the more-expensive hospital outpatient setting;[72] (ii) the number of Medicare services provided in more expensive HOPDs increased by a third;[73] (iii) the number of vertically consolidated hospitals grew by about 20%;[74] and (iv) the number of physicians practicing in HOPDs nearly doubled.[75]

Notwithstanding Section 603 of the BBA and CMS's implementing regulations, there is little doubt that hospital-physician consolidation continues to drive up the cost of health care in the Medicare program. In its June 2017 Report to Congress, MedPAC expressed concern over physician-hospital vertical consolidation resulting in higher costs for Medicare and commercial insurers and recommended "implement[ation] of site-neutral pricing in response to vertical consolidation, ending financial incentives to purchase physician practices."[76] For its part, CMS has presented disturbing data and findings that underscore the need for further action to reign in the volume and cost of services furnished in the HOPD setting:

- From 2011 through 2016, combined program spending and beneficiary cost-sharing on services covered under the OPPS increased by 51 percent, from $39.8 billion to $60.0

[68] 83 Fed. Reg. 37046, 37139 (July 31, 2018).
[69] See, e.g., 82 Fed. Reg. 33558 33985 (July 20, 2017).
[70] Miller ME. "Context for Medicare Payment Policy and Recommendations," (Dec. 9, 2014), *available at* http://docs.house.gov/meetings/IF/IF14/20141209/102787/HHRG-113-IF14-Wstate-MillerM-20141209.pdf (last accessed Aug. 26, 2019).
[71] 81 Fed. Reg. 45604, 45684 (July 14, 2016).
[72] Government Accountability Office, *Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform*, GAO-16-189 (December 2015) ("GAO 2015 Report"), pp. 1, 9; HHS Office of Inspector General, *CMS Is Taking Steps To Improve Oversight of Provider-Based Facilities, But Vulnerabilities Remain*, OEI-04-12-00380 (June 2016) ("OIG 2016 Report"), p. 1; MedPAC, *March 2014 Report to Congress* ("MedPAC 2014 Report"), p. 75.
[73] OIG 2016 Report, p. 1.
[74] GAO 2015 Report p. 9
[75] Id. p. 1.
[76] MedPAC, *June 2017 Report to Congress: Medicare and the Health Care Delivery System*, Chapter 10, "Provider Consolidation: The Role of Medicare Policy" ("MedPAC 2017 Report").

billion, with a "large source of growth…appear[ing] to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs";[77]

- Total spending under the OPPS is projected to increase further by more than $5 billion from approximately $70 billion in CY 2018 through CY 2019 to nearly $75 billion—approximately twice the total estimated spending a decade ago.[78]

Without question, the site-of-service payment differential "incentivize[s] Medicare providers and suppliers to deliver RT services in one setting over another, even though the actual treatment and care received by Medicare beneficiaries for a given modality is the same in both settings."[79] The discrepancy in payments for identical radiation therapy services furnished in the HOPD and Office settings is not new, with GAO having noted six years ago that from 2007-2010 despite a 17% decrease in services, hospital IMRT expenditures increased by 3.1% while overall IMRT expenditures decreased by $20 million.[80] The GAO explained this paradox by stating that "[r]eimbursement rates for IMRT services have been increasing for services performed in hospital outpatient departments and declining for those performed in physician offices."[81]

We agree with CMS that a site-neutral payment policy for delivery of RT services "would address the site-of-service payment differential that exists under the OPPS and PFS by establishing a common payment amount to pay for the same services regardless of where they are furnished."[82] But CMS's proposal, as currently framed, does not go far enough. Establishing site-neutral payments for radiation therapy services furnished in the HOPD, freestanding radiation center, and PGP settings should not be limited to those providers who are required to participate in the RO Model; rather, **site-neutral payments for RT services should be applied to all providers, regardless of the CBSAs in which they furnish RT services and regardless of whether the provider is assigned to the "participant" or "comparison" group.** CMS does not need to test site-neutral payments for RT services for five years in order to conclude that payment rates for such services under the OPPS and MPFS should be equalized.

V. We Agree with CMS's Proposal to Include Proton Beam Therapy in the RO Model.

We agree with CMS that the RO Model should include proton beam therapy ("PBT"). The value of the RO Model would be undercut significantly if CMS were to exclude PBT—one of the most expensive RT modalities.

As CMS recognizes, there has been significant debate regarding the benefits of proton beam relative to other, less expensive modalities. PBT was one of three case studies MedPAC examined as part of its June 2018 Report to Congress in which MedPAC analyzed the impact of low-value care on Medicare coverage policy.[83] MedPAC observed that "[f]rom 2010 to 2016, spending and volume for proton beam therapy in FFS Medicare grew rapidly, driven by a sharp increase in the number of proton beam centers and Medicare's relatively broad coverage of this treatment."[84] Prostate cancer was by far the most common

[77] 83 Fed. Reg. at 37140 (citing MedPAC, *March 2018 Report to Congress*, p. 72).
[78] Id. at 37139.
[79] 84 Fed. Reg at 34491; see also 83 Fed. Reg. at 37141 (CMS acknowledging in CY 2019 OPPS Proposed Rule that "the higher payment that is made under the OPPS, as compared to payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting").
[80] GAO 13-525, pp. 35-36 Figures 4 & 5 (July 2013).
[81] Id. at 36.
[82] 84 Fed. Reg. at 34491.
[83] MedPAC, June 2018 Report to Congress, ch. 10 "Medicare coverage policy and use of low-value care," *available at* http://medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf (last accessed Sept. 3, 2019).
[84] MedPAC June 2018 Report at 294.

cancer treated by PBT in the Medicare population, despite a lack of evidence that PBT offers a clinical advantage over alternative types of treatments.[85] As illustrated in Figure 6 earlier, PBT showed the highest percent change in utilization of any prostate cancer RT modality.

If one of the purposes of the RO Model is to test whether financial incentives are driving clinical decision-making, then we believe it is critical to include PBT—a high-cost treatment option with questionable clinical benefits for various cancer types—as one of the treatment modalities subject to payment under the Model. To the extent certain stakeholders press CMS to exclude PBT from the Model, those stakeholders' concerns should be allayed by the Model's inclusion of an historical experience adjustment that is designed to account for RO participants' use of more expensive modalities.

VI. Request for Action

LUGPA strongly supports the testing of an RO Model aimed at delivering higher-value care for patients with cancer while reducing provider burden. A patient-centric Advanced APM focused on RT services is worthy of testing, but we cannot support the RO Model in its current form. It is unprecedented for the Innovation Center to mandate participation—and to do so across 40% of all providers—when there are such serious clinical, logistical and economic ramifications to forcing providers into this untested Model.

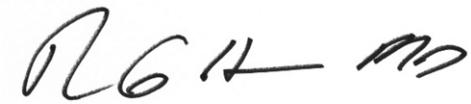
By way of summary:

- The proposed RO Model, if finalized, will compromise access to advanced treatment technologies for vulnerable populations such as African-American men newly diagnosed with prostate cancer. CMS must study this issue further before finalizing an RO Model that could have such serious implications for cancer treatment in racially diverse and underserved regions of the country. At a minimum, for performance periods two through five CMS must consider alternative options to using CBSAs in the "comparison" group to benchmark adjustments for groups in the "participant" arm;
- CMS should modify the RO Model so that participation is mandatory only in the HOPD setting for the first three performance years; at the end of the second year, the Agency should reexamine whether to mandate participation in the RO model in the freestanding radiation center and physician group practice settings for the fourth and fifth performance years;
- CMS should finalize the proposal to test a site-neutral payment structure in the RO Model across HOPD, freestanding radiation centers, and physician group practices, but go a step farther and apply site-neutral payments to all providers furnishing RT services, regardless of whether they are in the "participant" or "comparison" group;
- CMS should have the first performance period begin on July 1, 2020, rather than the proposed start dates of January 1 or April 1, 2020, in order to provide Participants with enough time to prepare for and operationalize the RO Model;
- CMS should finalize the proposal to include proton beam therapy as one of the RT modalities; and
- CMS should not impose special payment reductions on providers that are arbitrarily selected and forced to participate in the RO Model.

[85] Id. at 294-95.

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

Respectfully submitted,



Richard G. Harris, M.D.
President

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

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