Physician-Focused Payment Model Technical Advisory Committee
LOI: Environmental Scan and Relevant Literature

LUGPA Integrated Practices Comprehensive Care
Letter Dated: 4/14/2017
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The Large Urology Group Practice Association (LUGPA) is a trade association that represents independent urology group practices in the U.S. LUGPA proposes an alternative payment model (APM) that will create episode-based payments for newly diagnosed prostate cancer patients with localized disease and have designed an episode-based payment that aligns incentives for physicians to pursue active surveillance in clinically appropriate patients, allowing these patients to avoid unnecessary interventions. The APM will incentivize patient-physician shared decision-making, compensating physicians for the management time and active surveillance. Practices would be eligible for a performance-based payment if they met certain quality thresholds and if total episode spending is less than the benchmark.

The goal of this APM will optimize outcomes, increase beneficiary satisfaction, and reduce utilization of unnecessary services, while decreasing healthcare spending relative to the current payment system, thereby optimizing both the value and quality of care for newly diagnosed localized prostate cancer patients. The model will include patients with early stage prostate cancer with risk profiles that meet predetermined criteria who would begin their episodes of care at initial prostate cancer diagnosis. The model will be accessible to both independent- and hospital-based urology practices, enabling broad national participation in this APM. The model will include financial parameters to enhance the feasibility of participation by small practices. Also, as more than 40 percent of prostate cancer diagnoses occur before age 65 LUGPA expects that payers other than Medicare will have substantial interest in this model.

Key Search Terms

APMS; CMS; Independent Practice; Collaboration; LUGPA APM; Large Urology Group Practice Association (LUGPA); MACRA Episode-Based Cost Measure; MACRA Final Rule; Medicare; MIPS; Prostate Biopsies; Prostate Cancer; Quality Payment Program (OPP); Specialization; Specialty-focused APMs; Surgical Pathology Services; Urologist Self-Referral; Urology Group Compensation; Urology Practices; Value-based Care; Value-based Care Reimbursement

Research Task	Section	Contents
Environmental Scan	Section 1	Key documents, timely reports, grey literature, and other materials gathered from internet searches (5).
Relevant Literature	Section 2	Relevant literature materials (2).
Related Literature	Section 3	Related literature materials (1).
References	Section 4	References to environmental scan, relevant, and related literature.

Section 1. Environmental Scan

Environmental Scan		
Key words: Medicare; APM; MACRA Implementation; Urology Practices; Quality Payment Program; Value-based-Care Reimbursement		
Organization	**Title**	**Date**
Health Payer Intelligence	Communication Key for Transition to Alternative Payment Models	1/3/2017
Purpose/Abstract		
Background: Along with health insurers, more and more providers are expected to transition to alternative payment models (APMs), especially due to MACRA's Quality Payment Program. For example, urology group practices are likely to adopt advanced alternative payment models under the Quality Payment Program in future years, since the trade organization LUGPA began collaborating with cloud-based technology vendor, Integra Connect, to design alternative payment models. ***Summary:*** In this article, Dr. Neal Shore, president of LUGPA, spoke to HealthPayerIntelligence.com to explain how MACRA legislation and the Quality Payment Program have pushed providers, along with commercial payers, to adopt alternative payment models. He stated that there are only a few advanced APMs being implemented via the Quality Payment Program and none among urology practices. However, LUGPA will be moving forward with assisting urology providers in establishing alternative payment models by working with stakeholders and government agencies.		
Additional Notes/Comments		
Information on the LUGPA press release is available at LUGPA and Integra Connect Announce 2017 Urology-Centric APMs Initiative		

Environmental Scan

Key words: MACRA; CMS; APMs; Urology Practices

Journal	Title	Date
Reviews in Urology	The State of Independent Urology	2016

Purpose/Abstract

Background: With MACRA in place, urologists will now need urology-specific APMs in which to participate. Without these, urologists will be at a financial disadvantage in the future, in that there will be potential financial penalties for lack of APM participation; moreover, lack of participation will deprive practices of the opportunity to grow revenues through these innovative reimbursement models and risk sharing.

Summary: An important evolving focus of LUGPA will be to facilitate and assist in the development of APMs that can be utilized by integrated urology practices. Independent and integrated practices are well positioned to help develop APMs due to experience providing coordinated and cost-effective care to our patients. LUGPA is in the early stages of a multipronged approach to investigate and develop APMs in cooperation with other medical societies, academia, and industry partners. Going forward, it is critical that the urologic community work in concert to actively engage CMS in the rulemaking process as it implements the landmark MACRA legislation.

Additional Notes/Comments

Environmental Scan

Key words: Independent Practice; Collaboration; Value-based Care; Specialization; Urology Group Compensation

Journal	Title	Date
Reviews in Urology	Urology Group Compensation and Ancillary Service Models in an Era of Value-based Care	2016

Purpose/Abstract

Background: Changes involving the health care economic landscape have affected physicians' workflow, productivity, compensation structures, and culture. Ongoing Federal legislation regarding regulatory documentation and imminent payment-changing methodologies have encouraged physician consolidation into larger practices, creating affiliations with hospitals, multidisciplinary medical specialties, and integrated delivery networks. As subspecialization and evolution of care models have accelerated, independent medical groups have broadened ancillary service lines by investing in enterprises that compete with hospital-based (academic and nonacademic) entities, as well as non-physician-owned multispecialty enterprises, for both outpatient and inpatient services. The looming and dramatic shift from volume- to value-based health care compensation will assuredly affect urology group compensation arrangements and productivity formulae.

Summary: Implementing new payment algorithms alongside comprehensive care coordination will assist urology groups in addressing the health care economic cost and quality challenges that have been historically encountered with fee-for-service systems. Improving a comprehensive payment and quality approach to care is a necessary step for implementing value-based care metrics. Urology group leadership and stakeholders will need to adjust internal processes, methods of care coordination, cultural dependency, and organizational structures in order to create better systems of care and management. In response, ancillary services and patient throughput will need to evolve in order to adequately align quality measurement and reporting systems across provider footprints and patient populations. Change and payment model evolution cannot happen instantaneously. To be effective, a transition process is needed for urology groups to process the new value-based paradigms. Rather than immediately moving toward a value-based structure, urology groups must invest time and energy, and emphasize streamlined communication in order to undo ingrained formulae.

Additional Notes/Comments

Environmental Scan

Key words: CMS; MACRA Final Rule; MIPS; APMS; Specialty-focused APMs

Organization	Title	Date
Centers for Medicare Medicaid Services (CMS)	LUGPA Comment Letter re MACRA Final Rule	12/13/2016

Purpose/Abstract

Background: LUGPA submitted a public comment to CMS on the Final Rule Implementing the Merit-based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (PFPMs).
Summary: LUGPA generally supported the policy changes made by CMS in the Final Rule; however, the following concerns were conveyed:

(1) The misalignment of incentives for both specialists and primary care physicians with respect to resource use calculations for new treatment modalities;
(2) Limitations on the metrics used to assess a provider's "resource use" under the MIPS, eliminating a prostatectomy measure and applying a faulty "total cost of care" measure designed to measure the costs of care in ACO models;
(3) Lack of sufficient specialty-focused APMs and diminishing the role of PTAC (LUGPA stated that in the Final Rule, CMS subsumes the PTAC process into its existing CMMI process for evaluation and approving APMs);
(4) Limited detail on the methodology by which MIPS' "exceptional performer" payments will be distributed; and
(5) The missed opportunity to implement regulatory changes to the physician self-referral law (or the Stark Law).

Additional Notes/Comments

https://www.regulations.gov/document?D=CMS-2016-0060-4020

Environmental Scan

Key words: APM; PFPMs; MACRA; CMMI; Specialty-focused Care Models

Organization	Title	Date
Centers for Medicare Medicaid Services (CMS)	LUGPA Comments to CMS Re MACRA	6/27/2016

Purpose/Abstract

Background: LUGPA submitted a public comment to CMS offering suggestions to assist in ensuring that specialty providers, generally, and integrated urology practices, in particular, are able to participate meaningfully in the MIPS, APM incentive, and other programs under MACRA.

Summary: LUGPA asked CMS to do the following:

(1) Improve transparency around the model approval process used by CMMI and ensure that APMs proposed by the PTAC and stakeholders are reviewed and acted upon in timely fashion;
(2) Clarify that an APM may define a specialty-focused benchmark for purposes of becoming an Advanced APM, rather than using total Medicare costs as the benchmark, and provide certain other clarifications of the Advanced APM rules;
(3) Use the CMMI waiver to ensure that participants in APMs that start after 2019 are not unduly discouraged from becoming Qualifying Participants;
(4) Provide Clinical Practice Improvement Activities that are more meaningful to urologists and other independent specialty practices, and do not allow the "topped out" rules to penalize specialty practices;
(5) Provide more information on how patients will be attributed to single-specialty practices for purposes of measuring resource use, and how patient relationship codes will interact with the proposed primary care-focused, "two-step" attribution process;
(6) Withhold inclusion of Part D expenditures in the calculation of resource use;
(7) Exercise caution in using United States Preventive Services Task Force (USPSTF) recommendations in constructing quality measures for the MIPS; and
(8) Remove Agency-created barriers to provider alignment and collaboration in the physician self-referral ("Stark") law regulations.

Additional Notes/Comments

Section 2. Relevant Literature

Relevant Literature		
Key words: Prostate Cancer; Payment		
Journal	**Title**	**Date**
BJU international	Risk Of Hospitalisation After Primary Treatment For Prostate Cancer	8/25/2016
Purpose/Abstract		
Objective: To compare the risk of hospitalisation and associated costs in patients after treatment for prostate cancer. ***Methods:*** The authors identified 29,571 patients aged 66-75 years without significant comorbidity from the Surveillance, Epidemiology, and End Results (SEER)-Medicare linked database who were diagnosed with localised prostate cancer between 2004 and 2009. The authors compared the rates of all-cause and treatment-related hospitalisation that occurred within 365 days of the initiation of definitive therapy and used multivariable logistic regression analysis to identify determinants associated with hospitalisation. ***Results:*** Men who underwent radical prostatectomy (RP) rather than radiotherapy (RT) had lower odds of being hospitalised for any cause after therapy [odds ratio (OR) 0.80, 95% confidence interval (CI): 0.74-0.87]. Patients who underwent RP rather than RT had higher odds of being hospitalised for treatment-related complications (OR 1.15, 95% CI: 1.03-1.29). However, men who underwent external beam RT (EBRT)/intensity modulated RT (IMRT) (OR 0.84, 95% CI: 0.72-0.99) had 16% lower odds of hospitalisation from treatment-related complications than patients undergoing RP. Using propensity score-weighted analyses, there was no significant difference in the odds of hospitalisation from treatment-related complications for men who underwent RP vs RT (OR 1.06, 95% CI: 0.92-1.21). Patients hospitalised for treatment-related complications after RT were costlier than patients who underwent RP (Mean $18 381 vs $13 203, P < 0.001). ***Conclusions:*** With the exception of men who underwent EBRT/IMRT, there was no statistically significant difference in the odds of hospitalisation from treatment-related complications. Costs from hospitalisation after treatment were significantly higher for men undergoing RT than RP. Our findings are relevant in the context of penalties linked to hospital readmissions and bundled payment models.		
Additional Notes/Comments		

Relevant Literature

Key words: Prostate Cancer; Payment

Journal	Title	Date
Medical Care	Understanding Regional Variation in Medicare Expenditures for Initial Episodes of Prostate Cancer Care	8/1/2014

Purpose/Abstract

Objectives: This study was conducted to evaluate the contributions of patient and treatment factors to overall expenditures and regional variation for initial treatment of localized prostate cancer (CaP) in the Medicare program.

Methods: Using the Surveillance, Epidemiology, and End Results (SEER)–Medicare database, the authors identified 47,517 beneficiaries with localized CaP during 2005–2009, and matched non-cancer controls. The authors employed hierarchical generalized linear models to estimate risk-standardized cancer-related expenditures for each hospital referral region. To identify key contributors to the variation, the authors sequentially added patient characteristics, treatment intensity (the percentage of patients receiving curative treatments), ancillary procedures (biopsy, hormone therapy, and imaging), and specific treatment modalities into the model. The authors categorized expenditures according to the type of services to identify their relative impact on the expenditure variations.

Results: The mean expenditure on CaP-related care per CaP beneficiary was $15,900, including $1,800 on surgery, $11,200 on radiotherapy, and $1,900 on ancillary procedures. The expenditure difference between quintiles 5 and 1 was $6,200. Patient characteristics explained 8.4% of this difference. Treatment intensity and treatment modalities accounted for an additional 21.2% and 31.2% of the variation, respectively. Between the highest and lowest expenditure quintiles, the difference in radiotherapy expenditure was $5,000, whereas that in surgery or ancillary procedures was less than $200.

Conclusions: There is substantial geographic variation in CaP expenditures, and the specific modality of radiotherapy is the most important contributor to this variation. Efforts to address the CaP care costs, such as bundled payment development, require targeting both treatment intensity and use of costly modalities.

Additional Notes/Comments

Section 3. Related Literature

Related Literature		
Key words: Prostate Biopsies; Surgical Pathology Services; Urologist Self-Referral		
Journal	**Title**	**Date**
Medicare & Medicaid Research Review	Linkages Between Utilization of Prostate Surgical Pathology Services and Physician Self-Referral	2012

Purpose/Abstract

Objective: Federal law prohibits a physician from referring Medicare patients for procedures or services to health care entities in which the physician has a financial relationship. This law has exceptions which enable physicians to self-refer under certain conditions. This study evaluates the effects of self-referral on use rates of surgical pathology services performed in conjunction with prostate biopsies and whether such changes are linked to urologist self-referral arrangements.
Data and Sample: A targeted market area case study design was employed to identify the sample from Medicare claims data. The sample included male beneficiaries who resided in geographically dispersed counties; were continuously enrolled in Medicare fee-for-service (FFS) during 2005-2007; and who met the criteria to be a potential candidate to undergo a prostate biopsy.
Outcomes: Outcomes included prostate biopsy procedures per 1,000 male Medicare beneficiaries in each county; and counts of surgical pathology specimens (jars) associated with prostate biopsy procedures per 1,000 male Medicare beneficiaries in each county.
Findings: Regression analysis shows that the self-referral percentage of total utilization was associated with significant increases in the use rate of prostate surgical pathology specimens ($p<.01$). The use rate of prostate surgical pathology specimens (jars) are expected to be 41.5 units higher in a county where the self-referral share of total utilization was 50% compared to a county with no self-referral (share equals 0%).
Conclusions: The findings show that urologist self-referral of prostate surgical pathology services results in increased utilization and higher Medicare spending. The results suggest that exceptions in federal and state self-referral prohibitions need to be re-evaluated.

Additional Notes/Comments

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Utilization of Active Surveillance in Low-Risk Prostate Cancer: A Brief Review of the Literature Prepared for the Large Urology Group Practice Association (LUGPA) Preliminary Review Team (PRT)

Purpose

The Large Urology Group Practice Association (LUGPA) has proposed a Physician-Focused Payment Model (PFPM) that promotes active surveillance (AS) over active intervention (AI) for "clinically appropriate patients with low-risk, localized prostate cancer." To assist in reviewing the LUGPA proposal, the Preliminary Review Team (PRT) requested that Social & Scientific Systems, Inc. (SSS) respond to the following:

> *The proposal assumes that there is a patient population [with prostate cancer] in AI who should not be. Would SSS review the literature to try to better understand the magnitude of this problem?*

To address the PRT's request for information, SSS conducted a review of the literature to understand the following: (1) the prevalence of low-risk, localized prostate cancer (in the United States, in the Medicare-eligible population), and (2) current treatment practices for low-risk, clinically localized prostate cancer, particularly the extent to which AS (and watchful waiting [WW]) is currently used when indicated versus more AI as the initial treatment strategy. The methods guiding this literature review can be found in Appendix A.

LUGPA addresses the potential overuse of AI by introducing a care management fee structure to surveil clinically appropriate patients with low-risk, clinically localized prostate cancer. The LUGPA Advanced Payment Model (APM) aims to promote appropriate utilization of AS and reduce utilization of AI by providing incentives for eligible professionals (EPs) to participate in patient-physician shared decision-making and to perform enhanced services needed to appropriately surveil beneficiaries.

Background

Over the past decade, the rates of both prostate cancer and low-risk prostate cancer have increased. Hayes et al. (2010), for example, estimated that of the 192,000 men diagnosed in 2009 with prostate cancer, approximately 70 percent had low-risk, clinically localized disease. There has also been growing support for the use of AS as the initial management strategy for patients with localized, low-risk prostate cancer. Annually, over 100,000 men diagnosed with prostate cancer in the United States are thought to be candidates for AS (Ganz et al., 2011). Yet, according to a National Institutes of Health (NIH) (2011) Consensus and State-of-the-Science Statement, only 10 percent of men with localized prostate cancer elected AS as a treatment strategy, but this estimate may not reflect current care practices or patient preferences.

Treatment of Low-Risk Prostate Cancer

Three strategies are generally utilized in the management of patients with prostate cancer: (1) WW, (2) AI, and (3) AS. WW consists of observation with minimal monitoring (Bruinsma et al., 2017).[1] AI includes surgery, radiation therapy, or focal therapy treatment aimed to cure cancer. AS attempts to bridge the gap between AI and WW, and is intended to delay curative treatment for selected patients with ongoing surveillance until there is increased risk of disease (Tosoian et al., 2016).

AS vs. AI: Risks vs. Benefits

Recent guidelines from the American Urological Association (AUA), American Society for Radiation Oncology (ASTRO), and the Society of Urologic Oncology (SUO) outline several recommended approaches for men with low-risk prostate cancer: (1) Localized prostate cancer patients who are less than 65 years of age or are expected to live at least 10 years are more likely to experience cancer control benefits from prostatectomy than older men, and (2) Clinicians should recommend AS as the "preferable" care option for most low-risk, localized prostate cancer patients and as the "best available" care option for very low-risk, localized prostate cancer patients (Sanda et al., 2017). Elderly patients with low-risk cancer have a very small likelihood of dying from prostate cancer as the primary cause, and are therefore especially recommended to use AS (Jacobs et al., 2013; Lu-Yao et al., 2009). These elderly patients would comprise the vast majority of Medicare beneficiaries for whom LUGPA is interested in creating an APM. However, the treatment of elderly cancer patients in particular appears to frequently diverge from guidelines, suggesting a need to focus on appropriateness of care and use of AS in the elderly population (Fang et al., 2017).

AS is increasingly recommended as most prostate cancers have been found to be slow growing with very small or minimal increases in mortality rates among populations who receive AS versus AI (Ganz et al., 2011; Garisto & Klotz, 2017). In one study, there was only a 0.7 percent difference in overall survival rate between immediate surgery (AI) and AS for low-risk prostate cancer (Wilt et al., 2017). Even in the absence of treatment, low-risk prostate cancers tend to grow slowly (Klotz, 2010) and are not the primary cause of death for 50 percent to 60 percent of diagnosed patients (Lu-Yao et al., 2009). The length of time for subclinical cancer progression is thought to be at least 20 years followed by a clinical progression often lasting 15 years, suggesting that most patients have a "long window of curability" (Klotz, 2010).

In comparison, patients who receive AI are exposed to side effects or complications after treatment (Klotz, 2010). As such, management of low-risk patients with AS reduces the risk of over-treating

[1] In previous years, the term active surveillance (AS) was interchangeable with watchful waiting (WW), as both indicated no immediate curative treatment. However, in recent years, WW has been defined as observation with a lesser degree of monitoring compared with those enrolled in AS.

patients with clinically insignificant disease, while keeping the option of definitive therapy for patients who show signs of increased disease progression during surveillance (Klotz et al., 2015). In one study, for example, among 980 patients newly diagnosed with prostate cancer, approximately 40 percent were diagnosed as low-risk (Yamamoto et al. 2016) and were treated safely with AS, including 30 patients who developed disease progression via metastasis for which they were treated.[2] If initially treated with AI, however, patients with no signs of increased disease progression or associated clinical problems may, however, be unnecessarily exposed to the risk of significant side effects (Klotz, 2010). After receiving radical therapy (AI), for example, approximately 60 percent of patients experience consequent erectile dysfunction and 30 percent experience consequent symptoms of urinary incontinence (Barrett & Haider, 2017**;** Hugosson, Stranne, & Carlsson, 2011) and likely have a lower quality of life and functional ability. It is important to note, however, that information is limited on long-running cohorts to demonstrate the long-term safety of the different treatment approaches (Barrett & Haider, 2017; Godtman, Holmberg, Khatami, Pihl, Stranne, & Hugosson, 2016).

Han, Parihar, and Kim (2013) examined several institutional protocols focused on low-risk prostate cancer with AS and presented all results in a comparison table. The comparison table highlighted differences among institutional protocols with regard to the clinical criteria that were used to determine utilization of AS, the type and frequency of monitoring procedures that constitute AS, as well as the approach and criteria for identifying disease progression. Since eligibility criteria for AS enrollment differ by institution, there are no consistent criteria to take patients off AS or to prompt AI enrollment (Barrett & Haider, 2017; Babaian et al., 2015; Han, Parihar, & Kim, 2013). This may also contribute to the underutilization of AS and the overtreatment with AI.

Extent of AI Overuse and Possible Reasons

Despite the fact that AS is increasingly considered to be the best initial management strategy for men with low-risk prostate cancer, findings from several peer-reviewed studies (Godtman, 2016; Dall'Era, 2008, 2011; Shao, 2010; Miller, 2006; Barocas, 2008) demonstrate a strong and continued preference for AI. In an older study, Cooperberg, Broering, and Carroll (2010) found that only 810 men (6.8%) out of 11,892 men chose AS. The use of AS as the initial management strategy for low-risk prostate cancer exists but with large variation: Utilization of AS ranged from 9 percent to 75 percent of the observed patient population, with 16 percent to 60 percent of patients receiving AI initially.[3] Although there are more recently established guidelines by AUA, ASTRO, and SUO (2017), differences may still exist with the criteria used to define low-risk population and could account for some of the wide variation in AS use. In a recent study using the National Cancer Database, among 448,000 patients who had low-risk prostate

[2] This study defined low-risk prostate cancer as those with a Gleason Score ≤ 6 and a PSA ≤ 10.

[3] The percentages of AS utilization vary depending on the patient population observed by the studies conducted by Godtman, Holmberg, Khatami, Pihl, Stranne, & Hugosson, 2016; Dall'Era et al., 2011; Shao et al., 2010; Dall'Era et al., 2008; Miller et al., 2006; and Barocas, Cowan, Smith & Carroll, 2008. Some studies focused on only low-risk populations, whereas others included every risk category.

cancer and 40,000 patients who met the criteria for AS, only 14 percent received AS and up to 52 percent of very low-risk patients still received radical prostatectomy (Parikh et al., 2017). There was, however, a secular trend of increasing use of AS from 11.6 percent in 2010 to 27.3 percent in 2013.

Another factor that may contribute to the underuse of AS is the psychological burden experienced by prostate cancer patients and their physicians. At the moment of treatment choice, the main reason for rejecting AS is fear of disease progression (Esserman, Shieh, & Thompson, 2009; Klotz, 2013). Patients often opt for treatment due to the psychological burden of living with cancer rather than the true risk of biological progression of the disease (Barrett & Haider, 2017). The prevalence of depression and anxiety in prostate cancer patients being managed with AS is estimated to be as high as 13 percent and 22 percent, respectively. Psychological distress is also a significant predictor of AS patients transferring to definitive treatment (Watts et al., 2014). Furthermore, surveillance fatigue may be experienced by AS patients due to the fear and uncertainty about their disease status, and desire to avoid repeated biopsies (Choyke & Loeb, 2017).

Several factors contribute to variation in shared decision-making between physicians and patients enrolled in AS. Loeb et al. (2016) reported eight factors: (1) Physician comfort with AS, (2) Protocol selection, (3) Beliefs about the utility and quality of testing, (4) Years of experience and exposure to AS during training, (5) Concerns about inflicting 'harm', (6) Patient characteristics, (7) Patient preferences, and (8) Financial incentives.

Conclusion

This review supports the contention that AS continues to be substantially underutilized in the management of patients with low-risk prostate cancer although overtreatment is likely to be decreasing over time. Factors contributing to this underutilization were found to include the variability in guidelines for AS enrollment and subsequent intervention, psychological distress among patients who are diagnosed with prostate cancer, the perception that AS is a "do nothing" approach to treatment of prostate cancer, and factors contributing to differences in physician decision-making and shared decision-making. Additionally, AS is especially underused for the elderly patient population due to the low risk of mortality due to prostate cancer relative to other causes. While LUGPA acknowledges an upward trend of interest in AS by both physicians and patients, the proposed APM addresses the ongoing need to promote AS to both eligible professionals and patients by remunerating providers for implementing AS via a management fee and performance-based payments. Thus, LUGPA suggests that Medicare spending will be reduced as quality of care is improved when patients shift from AI to AS enrollment within the proposed model.

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Appendix A. Methods

SSS performed a literature review to understand the evidence of enrollment rates of active surveillance (AS) and active intervention (AI). The literature search strategy included 28 peer-reviewed articles relevant to "low-risk, clinically localized prostate cancer" using PubMed and Google Scholar. Since the number of relevant literature dated within the five-year publication period was few, there are articles cited in this literature review that are dated beyond the five-year period. Publications included in this review are dated from 2002 to the present. The keywords utilized in this literature review are listed below and were used in combination or independently of each other:

- active intervention
- active surveillance
- anxiety
- criteria
- clinically localized
- curative treatment
- definitive therapy
- delayed intervention
- disease progression
- eligibility
- enrollment
- initial management
- immediate treatment
- incidence
- initial treatment
- long-term
- low-risk
- mortality rates
- newly diagnosed
- overtreatment
- percentage
- prostate cancer
- prostate-specific antigen
- quality of life
- side effects
- symptoms
- strategies
- therapy
- underutilization

All articles included in this literature review discuss prostate cancer and encompass all or some of the following components: the levels of risk stratification (i.e., very low, low, moderate, or high); localized or regional prostate cancer; and variability in characterizing low-risk prostate cancer.

PHYSICIAN-FOCUSED PAYMENT MODEL TECHNICAL ADVISORY COMMITTEE (PTAC)

PRELIMINARY REVIEW TEAM (PRT)

CONFERENCE CALL

LARGE UROLOGY GROUP PRACTICE ASSOCIATION (LUGPA) PRT CALL WITH UROLOGY EXPERT

Friday, October 20, 2017
3:30 p.m.

PRESENT:

PAUL CASALE, MD, MPH, PTAC Committee Member
KAVITA PATEL, MD, PTAC Committee Member
SARAH SELENICH, Office of the Assistant Secretary for Planning and Evaluation (ASPE)
ADELE SHARTZER, PhD, Urban Institute

PHILLIP MUCKSAVAGE, MD, Perelman School of Medicine, University of Pennsylvania

ANJALI JAIN, MD, Social & Scientific Systems, Inc. (SSS)

P R O C E E D I N G S

[3:35 p.m.]

DR. CASALE: So it's 3:35. We can get started, and I'm sure Kavita will join in shortly.

So, before we get started, I know there are a few other people on the phone. So, if you want to just introduce yourselves, please?

DR. SHARTZER: Sure. This is Adele Shartzer. I'm an Urban Institute employee helping staff the ASPE (Office of the Assistant Secretary for Planning and Evaluation) PTAC (Physician-Focused Payment Model Technical Advisory Committee) process, and I'll mainly be listening in.

We [unintelligible] your time, Dr. Mucksavage.

DR. MUCKSAVAGE: Thanks.

DR. CASALE: Anyone else on the phone?

MS. TIMMONS: Hi, this is Vanessa Timmons with SSS. I'm actually getting ready to jump off the call. I just wanted to make sure that everything got kicked off okay.

DR. CASALE: Okay.

Anyone else?

There's a transcriptionist on the phone.

Just so you know, the call will be transcribed.

And Kavita just texted me. She's at an airport, and she's being held up at security, so we'll see if she -- hopefully, she'll get through okay.

So -- and just my background -- so I'm a cardiologist. I'm up in New York, in New York Presbyterian, and we have a preliminary review team for each of the models, and so I am on this particular preliminary review team, as is Dr. Patel.

So, just to get started, before I ask anything specific, I just wondered, do you have any sort of just overall reactions once you read the -- [unintelligible] related to sort of the clinical model?

DR. MUCKSAVAGE: Yeah.

Can you just hold one second? I have to do something clinically. One second.

DR. CASALE: Oh, sure.

DR. MUCKSAVAGE: I'm sorry.

DR. CASALE: That's okay.

[Pause.]

DR. MUCKSAVAGE: Sorry. I'm at the VA

(Veterans Administration). I'm covering a case, but it's okay.

DR. CASALE: Okay.

DR. MUCKSAVAGE: I mean, I think, you know, I like the idea of the proposal in the sense that it's trying to incentivize, you know, practices to shift from active intervention for prostate cancer to active surveillance. And, I think, you know, in general, that seems to be the trend. You know, I think more people are -- you know, the public itself, as well as practitioners, are kind of leaning that way, but this can kind of be like a little bit of a nudge in order to help, you know, some of the practices, you know, either financially incentivize them to do it -- Because I guess if you -- if you treat prostate cancer, you know, obviously there's a financial incentive to it, as the way to kind of, you know, get some incentives to shift people more towards active surveillance. Which, in a lot of cases, is probably the right thing to do for, you know, a vast number of patients that have low risk and sometimes even low -- low-volume, intermediate-risk prostate cancer, you can even consider active surveillance.

So, I mean, I think it's a good start in terms of, you know, again, making that shift, which is happening already, but this is -- this may, you know, just, you know, help with the -- help with the push.

DR. CASALE: Mm-hmm. So one of the questions was that the model -- the model begins with a biopsy. That sort of triggers --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: -- the model, and, you know, one of the questions was, you know, was it -- does it make sense to begin with the actual biopsy result, or is it -- is there an opportunity to begin this model sort of further upstream in terms of whether --

DR. MUCKSAVAGE: I mean, I thought there -- one was with the PSA (prostate-specific antigen).

Can I --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: Can I put you on hold for one second? I'll be -- I'll be right back. I'm sorry. I've got to do two things at once, but I'll be right back.

DR. CASALE: Okay.

DR. MUCKSAVAGE: Sorry.

DR. CASALE: No problem.

[Pause.]

DR. MUCKSAVAGE: Hello? Sorry. We're usually done by now, but there's a -- there was an add-on case, so --

DR. CASALE: Okay. Sure.

DR. MUCKSAVAGE: Sorry about that.

DR. CASALE: Yeah.

DR. MUCKSAVAGE: Yeah. So one of the questions was, you know, whether this should start with PSA screening. I think, you know, as an urologist, most of the patients that we get with PSA screening -- you know, I actually don't do a lot of PSA screening. I see patients that have already been screened. So, I mean, this is a urology, you know, initiative.

The majority of patients come in with a -- an elevated PSA, and then we talk about, you know, whether to do a biopsy. Considering should this proposal start with the consideration of biopsy, I think that's a good question, you know, because -- but that would add a lot of -- you know, a whole -- you know, different factors involved in terms of,

you know, whether, you know, you should -- you should biopsy this person versus not biopsy them. There's other, you know, lab tests that they can do or molecular tests in order to consider doing a biopsy.

I mean, I kind of like the idea that it's -- you know, it starts with the diagnosis of prostate cancer, you know, because I think it makes it just -- the proposal a little bit cleaner in terms of, you know, managing the prostate cancer patients.

DR. CASALE: Yeah.

DR. MUCKSAVAGE: Whereas, if you get into the PSA biopsy, one, that's -- it's going to increase the number of patients that, you know, you're dealing with, and, you know, how do you manage that? It's almost like two separate problems. It would almost need like a separate, you know --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- proposal, I think, in order to do that, because I think it would just be too complicated in that sense.

DR. CASALE: Okay. I appreciate that.

You know, one of the questions was, you know, once you have the biopsy result and then you wanted the -- you wanted to get a sense of the decision-making process --

DR. MUCKSAVAGE: Yes.

DR. CASALE: -- whether you go for active intervention versus active surveillance, and I know the proposers have sort of provided this modified version of an NQS (National Quality Strategy) measure, and I didn't know if you had any thoughts around, you know, does that -- would that capture adequately this shared decision-making process, or is there something that might be better, just to be sure -- you know, whenever you change a payment model, you may change incentives that --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: -- which may have unintended consequences. It's just to be sure that there's good shared decision-making, so --

DR. MUCKSAVAGE: Yeah. What was -- I saw it referenced, but I didn't see what the NQS model was that they -- is it -- was it in the proposal?

DR. CASALE: It was -- yeah.

Adele, can you help me where the -- or

where it is that they referenced the --

DR. SHARTZER: Yeah. I'll look it up --

DR. CASALE: Okay.

DR. SHARTZER: -- and be back with you in a minute.

DR. CASALE: Okay. That's fine.

So, anyway -- so it -- well, on another area, do you think there are any potential unintended consequences of being -- of this type of model? Could it, you know, potentially lead to increased number of biopsies because, all of a sudden, there's a payment based on, you know, a biopsy trigger for -- you know, just as an example? As you think about this model, is there --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: -- some concerns around some unintended consequences?

DR. MUCKSAVAGE: I think, you know, they mention a few of them that -- you know, that -- could patients have delays in care because of the fear of, you know, taking people off active surveillance? I mean, that's one potential, and, you know, they mention that they would, you know, screen for that.

Other -- the general kind of consensus about active surveillances or active surveillance of biopsies -- and everyone seems to -- there's really no standard guidelines right now for, you know, what -- what should be done for active surveillance. Everyone has kind of a, you know, what-they-do type of thing. You know, even some of the criteria for patients that are eligible for active surveillance, you know, differs.

The two main sites are from Hopkins and from -- in Canada, in Toronto.

DR. CASALE: Mm-hmm.

DR. MUCKSAVAGE: The Hopkins has a very strict criteria for active surveillance, which is basically a biopsy. You know, after you've been initiated into active surveillance, you know, a biopsy yearly, PSAs every six months. Whereas the one in Toronto is a little bit less restrictive -- or a little bit less, you know, biopsy heavy in terms of biopsy. They consider biopsies every one to two years, and I think most providers are doing biopsies every one to two years.

So I don't think, you know, once you're on active surveillance that -- you know, I mean, that

is a potential problem if you're increasing the number of biopsies, but, you know, I couldn't see someone starting to do biopsies every six months because they're in this protocol or on this -- on this proposal here because I think that's just overkill. And they can even screen for that, you know, like they are for delaying treatment.

You know, so it's --

DR. CASALE: I think -- sorry. I was thinking more that people with a, you know, mildly elevated PSA -- is there a possibility that people might be encouraged to do biopsies? Because then, all of a sudden, they're in this model because the biopsy --

DR. MUCKSAVAGE: Oh. You mean initially getting into -- yeah.

DR. CASALE: Against -- yeah.

DR. MUCKSAVAGE: Yeah. I mean, that could be -- that is a potential where you would see, you know, patients with -- who don't fit the criteria for a standard biopsy meeting -- do they have a 10-year, you know, overall survival, you know, benefit to getting treated for prostate cancer?

So, you know, you see like an 85-year-old

guy getting a biopsy.

DR. CASALE: Right.

DR. MUCKSAVAGE: That is a potential. Yeah. I mean, that could be a potential where they would, you know, try to find patients that otherwise, you know, you wouldn't biopsy or you would follow their PSA or even -- even not even consider biopsying. Could be -- you could over-utilize just to get them into it.

I mean -- I mean, there are methods to -- to kind of screen for that. I mean, you know, again, age, the age criteria kind of -- and some of the guidelines just from AUA (American Urological Association) or NCCS (National Coalition for Cancer Survivorship) or whatever for, you know, prostate, for a prostate biopsy, which I don't think would be too hard to screen for.

DR. CASALE: Yeah.

DR. SHARTZER: This is Adele.

I just wanted to follow up that the patient provider measure is in Appendix 1 on page 22 of the proposal. It's a like four-item proposed survey.

DR. CASALE: Oh, that was it. Right,

right.

This gets to the shared decision-making, and it's four questions. You know, “Did your health care provider talk to you about prostate cancer treatment options?”

DR. MUCKSAVAGE: Oh, okay. That little -- yeah. I think I kind of glazed over it.

DR. CASALE: Does that -- yeah. I just didn't know if you had any reaction to that. Is that a sufficient tool for being sure there's shared decision-making?

DR. MUCKSAVAGE: Okay. Yeah, I am sorry I glazed over that part. Here you go.

DR. CASALE: Kavita, did you join? I heard a beep.

DR. PATEL: I just did. So hi.

DR. CASALE: Yeah.

DR. PATEL: Sorry, Dr. Mucksavage. I'm -- I had the wrong call-in, so I apologize.

DR. MUCKSAVAGE: No problem.

DR. CASALE: Well, Kavita, I know you can only stay on for a few minutes. We were just talking -- I asked him about the shared decision-making tool, if that was adequate given the

importance of that as we get towards the, you know, surveillance versus intervention. And then we also just talked about unintended consequences. You know, could people be encouraged to do a biopsy for an elevated PSA because you'll get them into the model even though their risk of dying from, you know --

DR. MUCKSAVAGE: Other problems, yeah.

DR. CASALE: -- for their risk is pretty low. So, anyway, those are the only things we covered, so --

DR. MUCKSAVAGE: Yeah. I mean, this -- this question -- and it actually seems pretty reasonable. I mean, it's -- I guess the patients would get this after their visit and fill this out?

DR. CASALE: Yeah.

DR. MUCKSAVAGE: Yeah. I mean, you know, whenever I talk to my patients about prostate cancer, I mean, I'm assuming they would hit -- you know, hit these as -- as all positives, meaning that they would --

DR. CASALE: Okay.

DR. MUCKSAVAGE: -- say that we had a talk about every little, you know, possibility. So I

think -- I think this is reasonable, you know, and it especially highlights the active surveillance role.

DR. CASALE: Okay.

DR. MUCKSAVAGE: I mean, I think most providers talk about -- talk to patients about that. I mean, it's --

DR. CASALE: Uh-huh.

DR. MUCKSAVAGE: -- even patients, you know, now -- it's been so kind of popularized in the press and lay press that, you know, patients come in even -- you know, I even see patients with high-risk cancer that, you know, "Can we watch this?" And, you know, it's like, "No, not really."

DR. CASALE: Right.

Kavita, again, I know you don't have much time to be on the phone. Is there anything in particular you wanted to clarify or ask?

DR. PATEL: Sure.

So maybe just a step back. Do you have a sense -- so one of the things that we always struggle with is like an alternative payment model --

DR. MUCKSAVAGE: Mm-hmm.

DR. PATEL: -- is a sense of like how -- what like a rate of adoption could be, and I know we're not asking you to estimate, you know, what proportion of the country do you think is interested in this, but --

DR. MUCKSAVAGE: Yes.

DR. PATEL: -- in your -- since you're obviously an expert in the area, what is your sense about kind of proportion of oncologists -- let me rephrase this -- proportion of urologists as well as maybe any other kind of oncology specialties, sub-specialists who might be interested in something like this.

And does it in your mind come into conflict? I had logged on, I had just dialed in when you were talking about how, you know, without this type of kind of rigorous -- I'll call it evidence-driven, like active surveillance --

DR. MUCKSAVAGE: Yes.

DR. PATEL: -- that the real incentives financially are to just re -- I mean, I see this at Hopkins all the time. They just re-biopsy, redo, re this, re that.

DR. MUCKSAVAGE: Yeah.

DR. PATEL: And how -- so what is your sense about the populations who might be interested in this, and then in thinking about your peers, kind of where some of the resistance might be? Maybe that's not a fair question to ask, but I am just curious what your thoughts are.

DR. MUCKSAVAGE: Yeah. I mean, I think -- I mean, this is the general trend. It's been going on for the last five or so years, is that, you know, more patients are going into active surveillance. More providers are putting people into active surveillance. So I think this is where, you know, the pendulum is kind of swinging, you know, swinging back for prostate cancer in terms of watching and not treating the low-risk prostate cancer.

So I think -- overall, I think there's a big interest in it, you know, and I think a lot of people would adopt it if it, you know, is -- you know, for this model, or they can be financially incentivized to adopt it.

So I think overall, I mean, most -- I think most groups would be, you know, interested in adopting this. I think it's a -- kind of a trend

that's just happening all over that's going to continue to happen, and patients are actually demanding it, as I was mentioning before, you know, but there is -- you know, we talked about -- I did mention Hopkins, that they seem to over-biopsy. You know, they basically recommend biopsies --

DR. PATEL: Yeah.

DR. MUCKSAVAGE: -- once a year.

DR. PATEL: Right.

DR. MUCKSAVAGE: But, you know, that -- I mean, you know the kind of the protocols are really, you know, biopsies one to -- one to two years. So, I mean, I guess you could get into the problem with groups over-biopsying because they're into this program, but in general, I mean, you know, the guidelines -- and there's no -- there are no guidelines right now for, you know, active surveillance. I mean, they have, you know, certain -- like at Hopkins has a big one, and Toronto has a big one. But, you know, I think it's probably going to be going to the one- to two-year biopsies, PSAs, you know, generally every six months.

So, you know, if they can -- if we -- if there's a standardized protocol in terms of how to

follow the active surveillance, then I think, you know, there's -- there'll be less chances for abuse.

DR. PATEL: And is that the -- is that the issue that there is also -- Paul and I -- probably the three of us spend a lot of time at this intersection of like what -- what's really happening clinically and then what is nonsensical about our current payment system that makes doctors frustrated.

DR. MUCKSAVAGE: Yeah.

DR. PATEL: Is it more about -- can you just tell us in your -- you're really our expert. Can you tell us if some of the issues are really around, you know, this is kind of becoming standard of care, most of us get it, but our payment model just rewards the opposite type of care? Or is it also that, you know, we have people with -- you know, this concept of active surveillance is something that we think everyone should have; therefore, making it kind of a part of the payment system will accelerate its adoption?

I guess -- and that -- I don't know if you understand my distinction, but is this like, hey,

you know, people who do this are not being rewarded right now -- in fact, you're penalized in a way -- or is this --

DR. MUCKSAVAGE: Yeah.

DR. PATEL: -- we want our profession to really make this part of -- I'll use the analogy in internal medicine. Paul, you probably have one in cardiology. You know, we know vaccinations are good. So, you know what? We're going to try to pay people to like actually get vaccines and make it easy --

DR. MUCKSAVAGE: Yeah.

DR. PATEL: -- and, you know, is that --

DR. MUCKSAVAGE: Yeah.

DR. PATEL: Does that make sense?

DR. MUCKSAVAGE: You know, it's -- you know, one, it's tough for me in an academic setting. I'm -- you know, I'm not as incentivized to -- I mean, I do have an incentive, but I'm not as incentivized to kind of push people towards active treatment. So I think in some of the academic settings, you know, patients, people are -- are better at kind of adopting the active surveillance.

But I think -- I mean, just, you know, in general, I think this is kind of -- it's moving that way where, you know, patients and -- you know, patients are demanding it, and doctors and urologists are just -- are doing it just because it makes sense that we should intrigue these low-risk prostate cancer patients.

So I'm not really sure how -- you know, for me and my colleagues, you know, when I'm counseling a patient about treatment options, I mean, if you think about it, really an active surveillance protocol, I think in the long term with the number of biopsies that you may end up doing if you're following patients for many years, you're actually going to be paid more, you know, if you look -- not -- I mean, most of this protocol looks at just one year, where they really talk about the first year. But, I mean, most -- if you're on active surveillance, 20 to 30 percent of people will fall off of active surveillance, either because you find more cancer or they decide they don't want to watch it anymore. They're worried. So you're really -- you know, it's really you're getting a couple more biopsies out of this, and

then you may be getting, you know -- you know, incentivized for treatment down the line.

So there's always -- it's always like there's like a carrot at the end of the -- at this -- you know, there's a -- it's a carrot with the end of the stick there that, hey, this guy doesn't want to have treatment right now, but in a few years, he may need treatment. And too, even if he doesn't get treatment, you know, the question is, How long do we follow people on active surveillance? No one knows that.

I mean, right now, it's you have to keep following them because you don't know how much they die from something else, but you don't know, you know, what the outcome is. I just -- one of the Hopkins guys was at a conference this morning, and he said really they're just starting to look at their data now that it's becoming more mature. It's that, you know, after four or five years, it's almost like you can almost stop active surveillance. That those people that -- those low-risk cancers probably aren't going to do any -- nothing is going to happen to them, so --

I don't know if that answers your

question.

DR. PATEL: No, that's helpful. Thank you. I know it's a hard question to answer.

DR. MUCKSAVAGE: Yeah. And it's hard for -- you know, I'm not -- it's I'm in a different -- you know, I'm not incentivized to push people towards treatment. I mean, I -- I'm -- I have that ability to talk to people and, you know, put them on active surveillance if I think it's right or -- and I don't feel the financial pressure not to put them on active surveillance, you know, in the long run, where some of the -- someone in a private practice group may.

DR. CASALE: So, I mean, that's an interesting -- that whole -- and I think they brought it up even in their model because part of the description of, you know, why have a new model was while they get, you know, sort of -- you get paid to do the intervention, and you need to be encouraged not to do the intervention.

And your other comment about being in an academic medical center -- and I spoke informally to the urologist here who had the same -- I think the same sentiment that you were expressing that --

and correct me if I'm wrong -- that the urologists at the academic medical center, in general, the percent that are in active surveillance is much higher --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: -- than in the community urology practices.

DR. MUCKSAVAGE: Yeah. And I think this is a good -- the proposal is a good idea if you try to push more patients in the community towards active surveillance. I think, you know, so it is kind of a double-edged sword. But, you know -- but I agree we definitely -- you know, in academics, we have more leeway in terms of getting, you know -- not having to worry about the financial incentives of treating patients.

So -- but, yeah, in general, I think it's -- you know, it's like 40 percent or higher. I can't remember the exact numbers, but -- of patients, you know -- you know, on active surveillance in academic centers versus like that 20 percent that they're quoting, 26 percent or so in their proposal. So it is much -- it is higher in academic centers.

DR. CASALE: So one of their part of the payment is this monthly care management fee, which they say -- you know, which they say is required to appropriately do surveillance?

DR. MUCKSAVAGE: Yeah.

DR. CASALE: And again, any -- I just -- either a comment on whether that fee seems adequate or how that --

DR. MUCKSAVAGE: I mean, so most surveillance patients are -- you know, you see them every six months. It's a six-month visit. They're often fairly quick visits. It's a PSA check, a -- you know, an office visit, and then, you know -- you know, a digital rectal exam to ensure nothing is really changing, and then to go ahead with the decision to do another biopsy versus -- or even an MRI(magnetic resonance imaging), you know, the prostate.

So, you know, I'm not sure why they need a monthly -- I mean, you still -- they still get the office visit, right, reimbursed? Is that how that works? Again, I don't -- I don't understand how these incentive payments and things like that work, but I think that's just a way to, you know,

incentivize people to get them on that active surveillance, you know.

DR. CASALE: Yep. Again, I don't know. You would -- you know, in terms of is there a -- do you need to hire people to like call these patients to be sure they come in and that kind of thing? I guess I was thinking part of this care management fee was to have the --

DR. MUCKSAVAGE: Wants to do that to make sure they --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: I mean, most --

DR. CASALE: You're --

DR. MUCKSAVAGE: Yeah. I mean, there's always a loss of -- loss of follow-up, but I think most patients with, you know, the prostate cancer diagnosis are fairly --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- they're fairly good at coming back --

DR. CASALE: Right.

DR. MUCKSAVAGE: -- you know, for their PSA checks and things like that --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- you know, when you give them a cancer diagnoses.

So, I -- you know, I'm not -- I'm not quite sure where that -- you know, that extra money comes into and what they actually would need, you know --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- versus, you know, like a guy who you are following for routine elevated PSA that, you know, had a negative biopsy. I mean, you essentially get PSAs every six to 12 months and see them back then.

DR. CASALE: Yeah. Okay.

So just turning to another topic -- and again, this is related to the payment part, but on page 18 of their proposal, when they talk about integration and care coordination, they say that the urologist basically, or the entity, would be at risk for beneficiary's total cost of care for 12 months.

So the question then, at least in my experience, urologists have not been -- I don't think felt that they were the ones to be responsible for total cost of care. They talk

about collaborating with their primary care physicians, but I just wondered your reaction to the idea on the payment side that the urologist would be sort of at risk for total cost of care.

DR. MUCKSAVAGE: Yeah. You know, I saw that question, and I didn't quite understand what that meant because, you know, they mentioned, you know, the stop gap, the 20 percent plus or minus or 125 percent. I was hoping you can elaborate --

DR. CASALE: But even putting that side, I guess just clinically --

DR. MUCKSAVAGE: Mm-hmm.

DR. CASALE: Again, in my -- I mean, my -- you know, the idea that the urologist would sort of be directing the -- assuming risk for total cost of care meaning -- and part of that is collaborating with primary care, but presumably would have a very active participation in care --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: -- potentially not related to the prostate cancer in order to be sure that -- you know, since they're the one sort of at risk for the -- for the cost.

DR. MUCKSAVAGE: So the -- I mean, you

know, for these patients that are on active surveillance, it's -- you know, it's -- even if you -- six months, even if they have -- you know, so you missed high-risk cancer on a biopsy. Generally, six months to a year wouldn't change anything. So, you know, per year, I think that's why they assume that -- I think the -- assuming total costs overall would be very low, and I think that's what most of the groups would think when they saw that.

So, I think -- yeah. I mean, I -- again, I'm not sure what exactly that means. I mean, do they have to pay if something goes wrong? Even if they get -- if they have a heart attack, they get issued -- they have -- they get penalized --

DR. CASALE: Well --

DR. MUCKSAVAGE: -- or is it just prostate cancer --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- related?

DR. CASALE: No. It just says total cost of care. That would be -- you know, so if you have a Medicare patient with six comorbid conditions, including cardiac disease and they end up with a

heart attack, that would be part of their total cost of care.

DR. MUCKSAVAGE: Yeah. That's a little unusual, I think, you know. I would -- I thought they were assuming, you know, total cost of like prostate cancer care, but yeah. I mean, I don't see -- you know, as a urologist, especially in a busy private practice group, you know, really assessing -- I mean, most of the patients you put on active surveillance, you know, even if -- or you're not treating their prostate cancer and you're assuming, you know, they put them on the active surveillance, I mean, some of them are patients that don't have, you know, good comorbidities or we assume won't be alive in 10 years so that's why you don't treat them. You know, so that's a little bit unusual in terms of them assuming all the costs of care.

That's why I didn't quite understand. I think that's why I didn't understand the question, is because, yeah, I don't see why urologists would want to assume, you know, total cost of care.

DR. CASALE: Right, right.

Kavita, are you still on? I just got --

DR. PATEL: I am.

DR. CASALE: Oh, okay.

DR. PATEL: I am.

DR. CASALE: Fine.

DR. PATEL: No, I'm curious, actually if there's a -- even in your own practice kind of, you mentioned that like active surveillance and then even patients, obviously, are kind of in the shared decision-making space, kind of demanding to have these conversations.

DR. MUCKSAVAGE: Yeah.

DR. PATEL: Do you have a gut sense about -- and this is totally asking for you to kind of think about anecdote. Do you think in retrospect or reflection that these visits where you're having these conversations, et cetera, and think about time kind of pre-active surveillance --

DR. MUCKSAVAGE: Yeah.

DR. PATEL: -- What's the time commitment on your part? How much more time on your part as a physician does this take?

DR. MUCKSAVAGE: You know, I think it -- you know, it does -- it does take more time because you're kind of throwing a lot of stuff at a

patient, you know. One, you know, if the patient isn't well educated on active -- on prostate cancer that, you know, they hear the "cancer" word and, you know, they think they need to be treated, and it's almost like talking them out of treatment.

So it does require a little bit more time rather than just saying, "Yeah, you need your prostate taken out." Or, "You need to be radiated." So, it would probably add, you know, five or ten more minutes, you know, to an office visit to explain, "Hey, this is a low-risk cancer. You know, we don't need to treat this. You know, so you can avoid some of the risks of treatment." So, there is -- there is a cost -- I mean, there is a time sync involved in that.

And then there's also a time sync in terms of patients on active surveillance when, you know, they really should come off active surveillances. You know, this is -- you're -- or a patient who's -- you know, wants active surveillance and is not an appropriate candidate for active surveillance. There is a little bit of a time sync in terms of talking to patients about that and getting them to decide for treatment or to come off treatment.

So, you know, I -- I've been practicing mainly with the active -- in the active surveillance era, so I think maybe I'm a little bit more used to it, but I think, you know, I can definitely see, you know, before where, you know, you have low-risk prostate cancer, you need surgery or radiation, you know, talk to the radiation oncologist if you want radiation versus now it's you're adding in this kind of "We're not treating your cancer. There's a low risk it's going to spread." So, yeah, it definitely does add time to -- to what you're doing.

DR. CASALE: On the -- on page 19 -- Do you have the proposal there in front of you by any chance?

DR. MUCKSAVAGE: Yeah.

DR. CASALE: Okay. Great.

On page 19, it's about patient safety, you know, with -- and, you know, ensuring, you know, sort of patients aren't harmed, and so a couple of things. One is they said they proposed a measure -- a quality measure related to time on active surveillance, and I wondered what you thought of that as a quality measure.

And then further down, they talk about proposing a monitoring strategy that would allow CMS (Centers for Medicaid & Medicaid Services) to create corrective actions and possible financial penalties for patients that delay necessary treatment to reduce expenditures.

DR. MUCKSAVAGE: Yeah.

DR. CASALE: I mean, is that even possible to -- I mean, how would you, you know, figure that out? So, I guess I'm looking for your reaction to those things. One is a time [unintelligible] --

DR. MUCKSAVAGE: Yeah. That was -- I thought I brought that up earlier that I thought that was kind of interesting, you know, one of the abuses that could be, is a patient who should come off active surveillance, but they keep them on it just so they can hit their targets.

DR. CASALE: Okay.

DR. MUCKSAVAGE: You know, I think -- you know, if you have -- if you have access to the PSA data, I mean, it would require, you know, kind of sifting through that, the PSA data and the biopsy data, you know, and making sure that patients are getting biopsies or have PSAs that haven't changed,

or MRIs that are okay. That would be the only way to really see if there is, you know -- if they are delaying to keep them on the protocol.

You know, time on active surveillance, that's -- you know, again, you know, most people when they go on active surveillance, I mean, I think the first year -- you know, most people are on it for a year. If -- you know, as I was saying, if you're not off of it by year three or four, you know, you're probably not going to come off of it.

DR. CASALE: Yeah.

DR. MUCKSAVAGE: So there is a -- and there's about a 20 or 30 percent dropout, meaning people getting treated at that point.

So, I mean, I think, you know, this is great if you look at after four years, but the first few years, I think, you know, there is a -- there is a one-in-five chance you're going to need to get treatment. And that's just, you know, from disease progression or you find higher-risk disease, you know, on follow-up biopsy.

So, I think I'm not sure how, you know -- you know, time on active surveillance is -- you know, that -- I mean, I think that it's good for

the patients that need it, but there are patients that, you know, should be treated. I'm not sure how much of a performance -- I think if you -- if you kind of -- if you build a performance model where the patients are getting, you know, a prostate biopsy, that, you know, they maintain their -- their Gleason score and -- or their PSA hasn't changed, that might be a different -- different way to measure performance.

DR. CASALE: Yeah.

And then -- sorry. And I'm also still -- back on page 6 --

DR. MUCKSAVAGE: Mm-hmm.

DR. CASALE: -- where they talk about the major barriers, you know, to changing physician -- or practice patterns?

DR. MUCKSAVAGE: Yeah.

DR. CASALE: You know, the first line says it's to “assure that physicians are financially viable.” So, does it make sense to -- I mean, so, is that really -- I guess I'm looking for your reaction. Is that justification for this type of model? And it says “truly those --

DR. MUCKSAVAGE: Yeah. I mean, I --

DR. CASALE: -- particularly those practices with integrated ancillary services," so --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: I don't know. I'm just -- I guess I'm looking for exact --

DR. MUCKSAVAGE: Well, I guess what they mean is the integrated -- the ancillary service of a radiation center, I think, and I think a lot of --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: You know, that's kind of been cracked down on. So most urology practices aren't -- don't have integrated -- I'm sorry -- radiation centers anymore.

But, you know, in terms of active surveillance, my kind of gut feeling about it is in the long term, if people are on it long enough, you know, it actually costs -- probably costs more --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- over many, many years rather than getting treated. You know, after you get your -- your radical prostatectomy, I mean, it's basically a PSA test, you know, every three to

six months, you know, for a couple years and then, you know, yearly. Versus this is PSAs, prostate biopsies, MRIs, you know. In the broader picture, you know, for the health care system, it's actually -- you actually probably spend more money.

Does the doctor make more? I mean, I'm not sure how many biopsies you need to do to get paid for a --

DR. CASALE: Yeah.

DR. MUCKSAVAGE: -- you know, a radical prostatectomy, but, you know, over a few years, it may add up. It's probably still a little bit less, but definitely with radiation, I mean, I think if they have an integrated radiation center, they will lose money over time. I mean, I think that's what their point is there. It's really to compensate the groups that own radiation centers that potentially will lose money by not giving radiation.

DR. CASALE: Right. But I'm trying to understand why that would be a reason to have a new payment model.

DR. MUCKSAVAGE: Yes. I think --

DR. CASALE: You want to do what's right

for the patient, right? And so what you're saying --

DR. MUCKSAVAGE: Yes.

DR. CASALE: -- is that one active intervention versus active surveillance, it may not be necessarily one that's, you know, in the long run has lower cost than the other. You're just trying to do what's best for the patient.

But in this particular situation where the urology practice has ancillary services, that in particular, you know, would favor one over the other in terms of intervention versus surveillance. Do I understand --

DR. MUCKSAVAGE: Yeah.

DR. CASALE: Is that -- is that – so, you think part of what's driving the higher rate of active intervention in the community versus the academic center is this -- and I don't want to put -- is that it, the ownership of ancillary services?

DR. MUCKSAVAGE: Yeah, it is. I mean, it's potentially the ownership of the radiation centers --

DR. CASALE: Yeah. Right.

DR. MUCKSAVAGE: -- which, I think is

going away, but, you know, what -- you know, and the data shows that once a urology group buys a radiation center --

DR. CASALE: Uh-huh.

DR. MUCKSAVAGE: -- the number of radical prostatectomies goes down significantly, almost like, you know, zero.

DR. CASALE: Right.

DR. MUCKSAVAGE: Basically, everyone gets shuttled into radiation. So I think it's more for, you know, to compensate for loss of revenue from a radiation center.

DR. CASALE: Mm-hmm. Yeah. Okay. That's helpful.

Kavita, are you still on? I know you said you had to drop off. I don't know if you've dropped off yet.

[No response.]

DR. CASALE: Yeah, I think she did. I think she had to get on a flight.

Well, I don't have any other questions.

Sarah, I don't know -- or, Adele, do you have any questions?

DR. SHARTZER: I don't, Paul.

MS. SELENICH: None from me.

DR. CASALE: Okay.

Well, thank you very much for being on the call. This has been very helpful for me, and I know it's been challenging being -- doing clinical work and being on the call, so we appreciate you --

DR. MUCKSAVAGE: Yeah, I know. It's the VA, you know. I'm just supervising, but yeah, if you have -- if there's any other questions, I mean, I -- you know, I think this is a little bit complicated for me. I mean, I don't know any of these targeted, these, you know, performance things. You know, I'll be honest, I don't -- I don't follow a lot of this stuff, but I hope I provided some clinical background for you.

DR. CASALE: Yeah, yeah. It was very helpful. Yeah. That was great.

Thank you so much, and have a good weekend.

DR. MUCKSAVAGE: Okay.

DR. CASALE: Thanks.

DR. MUCKSAVAGE: All right. Thank you. All right.

DR. CASALE: Bye now.

DR. MUCKSAVAGE: Okay. Bye.

DR. SHARTZER: Thanks.

[Whereupon, at 4:18 p.m., the conference call concluded.]