875 N. Michigan Avenue Suite 3100
Chicago, IL 60611
www.lugpa.org

December 31, 2018

BY ELECTRONIC SUBMISSION

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

Re: Medicare Program; International Pricing Index Model for Medicare Part B Drugs; CMS-5528-ANPRM

Dear Administrator Verma,

On behalf of LUGPA, we thank you for the opportunity to comment on the Proposed Part B Drug Payment Model[1] ("Proposed Model") to be operated by the Centers for Medicare and Medicaid Services through the Center for Medicare and Medicaid Innovation ("CMMI"). As the representative of the nation's leading independent urology practices caring for millions of Medicare beneficiaries stricken with genitourinary disease, we are greatly concerned about the impact that the Proposed Model—if implemented—will have on our ability to provide our patients with access to life-saving and life-prolonging cancer therapies. We believe that the proposed model is, in fact, a nationwide experiment that inappropriately uses CMMI's waiver authority by compelling all physicians in all parts of the country to participate in an untested model of care delivery. Congress granted that authority to test models in which "the Secretary determines that there is evidence that the model addresses a **defined population** for which there are **deficits in care** leading to **poor clinical outcomes**."[2] The entire country is not a "defined population," and CMS has presented no evidence that the current reimbursement system has created deficits in care or poor clinical outcomes. As such, those elements has been satisfied here.

LUGPA is committed to payment reform to make cancer care more affordable, as witnessed by authoring the only urology-specific Alternative Payment Model (APM) submitted to CMS. We share concerns with respect to escalating costs, and our member practices actively participate in a variety of value-based payment arrangements, including Accountable Care Organizations (ACOs) and the Oncology Care Model (OCM). That said, we have made enormous strides in the management of urologic malignancies, and are deeply concerned with the potential unforeseen consequences of The Proposed Model. The Proposed Model will simply cut reimbursement for critical therapies - such as those

[1] CMS-2018-0132; CFR 54546 - 54561
[2] 42 U.S.C. at 1315a(b)(2)(A).

used to treat patients with advanced prostate, bladder and renal cancer – as well as introducing profit-driven middlemen into clinical decision making that must remain between patient and provider. As practitioners who are the principal caregivers for certain advanced genitourinary neoplasms, we are deeply concerned about the impact the Proposed Model will have on our ability to provide care to our most gravely ill patients and urge CMS to defer rulemaking until it addresses with stakeholder input the serious clinical, operational and legal challenges with The Proposed Model as currently framed.

I. As The Voice of Independent, Integrated Urology Practices, LUGPA Opposes a Demonstration That Could Harm Patient Access to Vital Cancer Treatment.

In 2008, when physician leaders of independent urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the purpose of enhancing communication between large urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, developing new business opportunities, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 150 urology group practices in the United States, with more than 2,200 physicians who, collectively, provide over 35% of the nation's urology services.[3]

Integrated urology practices are able to monitor health care outcomes and seek out medical "best practice" in an era increasingly focused on medical quality and the cost-effective delivery of medical services, as well as better meet the economic and administrative obstacles to successful practice. LUGPA practices often include other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care through a one-stop shop for the patient. LUGPA's mission is to provide urological surgeons committed to providing integrated, comprehensive care the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system, including men with prostate cancer, in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, regulatory agencies, and legislative bodies.

LUGPA is extremely concerned about the impact of this rule on independent urology practices. Sixty percent of urologists—and 70% of independently practicing urologists—administer Part B drugs.[4] Part B medications constitute over 20% of Medicare payments to urologists.[5] In addition, as the Proposed Model is intended to be administered by as yet undefined geographic regions, we are deeply concerned that physician practices with multiple offices across a broad geographic footprint will face significant (and expensive) administrative challenges managing payment differentials across office locations while operating under the same taxpayer identification number (TIN).

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

[4] Milliman 2016

[5] 81 Fed. Reg. at 13255 (comparing total drug payment at ASP+6% for urology to total Medicare payment for urology).

II. CMS Has Exceeded Its Legal Authority By Misusing CMMI Waiver Authority to Contradict A Clear Statement of Congressional Intent.

CMMI's authority allows the Secretary of HHS to waive almost any Medicare statutory rule "solely" for the purpose of testing a model authorized by Section 1115A of the Social Security Act. CMMI is empowered to test a model only if "the Secretary determines that there is evidence that the model addresses a **defined population** for which there are **deficits in care** leading to **poor clinical outcomes** or **potentially avoidable expenditures**."[6] And, CMMI's exercise of that discretion is subject to judicial review.[7]

We are concerned that the proposed demonstration does not meet this standard. CMS does not include any determination that a "defined population" exists that is experiencing "deficits in care," or that such deficits (if any exist) are leading to poor clinical outcomes.

In fact, it is likely that the Proposed Model would actually create *deficits* in care. Despite advances in prostate cancer treatment, in 2013, the prostate cancer death rate in African-American men was **more than double that** for Caucasians.[8] Data strongly suggests that the discrepancy in death rate correlates strongly with intensity of care rendered, with researchers stating just last year that **"for non-Hispanic black men, disparity in mortality can be attributed to treatment differences."**[9] Specifically, the study found that non-Hispanic African-American men with advanced prostate cancer are already undertreated when compared to other ethnicities. Accordingly, we are concerned that making medications used for treatment of advanced prostate cancer more difficult to access in the physician office setting may exacerbate rather than ameliorate an already existing deficit in care in this defined population.

Furthermore, it is extremely unlikely that the Proposed Model could satisfy the statutory standard. Within the proposal, CMS acknowledges that, "Congress created the Innovation Center for the purpose of testing innovative payment and service delivery models that are expected to reduce program expenditures while preserving or enhancing the quality of care for Medicare beneficiaries."[10] However, the Proposed Model is entirely inconsistent with CMMI's legislative obligations. CMMI has not identified any "defined population" that is experiencing a "deficit in care" justifying an intervention model that may be studied. Instead, the Agency proposes to apply this new model to nearly every drug administered in every physician office or hospital outpatient setting across the entire country on an entirely random basis. This expansive interpretation raises serious questions of what limits, if any, CMMI believes apply to the term "defined population."

Moreover, because the demonstration is so sweeping it will be impossible to fully ascertain its impact, as the changes to the experimental sites will have substantial ramifications to the "control" areas theoretically not in the tested sites. Clearly, a CMS's projected 30 percent reduction to Part B spending in half the country will substantially lower the ASP reimbursement to control areas. As such, physician practices in the control areas will be underwater when they prescribe Part B drugs because the ASP reimbursement formula requires manufacturers to include "all price concessions" in the U.S. This will either dramatically harm patient access to physician-administered drugs or compel all practices in all parts of the country to

[6] 42 U.S.C. at 1315a(b)(2)(A).
[7] See e.g., Beno v. Shalala, 30 F.3d 1057, 1066 (9th Cir. 1994) (analyzing waivers by the Department of Health and Human Services of certain Medicaid and other social program statutory obligations).
[8] 39.1 vs 18/100,000 for African-Americans and Caucasians, respectively. Surveillance Epidemiology End Results. SEER Delay Adjusted Incidence and US Death Rates Cancer of the Prostate, by Race. http://seer.cancer.gov/csr/1975_2013/browse_csr.php?sectionSEL=23&pageSEL=sect_23_zfig.01.html.
[9] Chhatre S, Bruce Malkowicz S, Sanford Schwartz J, et al. Understanding the Racial and Ethnic Differences in Cost and Mortality Among Advanced Stage Prostate Cancer Patients (STROBE). Medicine (Baltimore). 2015 Aug;94(32):e1353
[10] https://www.federalregister.gov/d/2018-23688/p-211

abandon the long-standing "buy-and-bill" practice and be served by untested and unidentified vendors. Just as important, it offers no real opportunity to compare the model to existing delivery model, which would be possible if it was limited to several discrete locations (e.g. 5 MSAs and several rural areas).

Also, because the drugs at issue here are extremely diverse and cross a wide range of specialties, we believe it is nearly impossible to identify a specific "deficit in care" associated with the entire Medicare population. Although CMMI asserts (without evidence) that the ASP + 6% methodology may lead to "potentially avoidable expenditures," it fails to demonstrate how these expenditures could be linked to "deficits in care"—a clear requirement in order to justify waiver authority. Indeed, we find it difficult to understand how a policy calling for a wholesale shift away from reimbursement for cancer and other physician-administered medications for diseases as diverse as macular degeneration, Crohn's Disease, rheumatoid arthritis and multiple sclerosis could genuinely address a "deficit in care."

In designing this model, CMS appears to have ignored the extensive case law concerning HHS's use of its waiver authority. The Agency must act consistent with the statute in waiving elements of the Social Security Act, because it represents an "all-encompassing series of statutory requirements." In waiving laws for purposes of testing a model, the Agency must demonstrate that the test is consistent with statutory authorities. CMS cannot simply use a waiver to facilitate a "simple benefits cut," but instead must design a model that genuinely attempts to "learn something new."

In the past, CMMI has clearly satisfied this standard by designing programs that are usually voluntary and linked to well-defined clinical outcome measures. Models like the various Accountable Care Organization initiatives represent genuine attempts to address gaps in care coordination by facilitating new forms of collaboration among providers. They include objective metrics to evaluate the impact of the resulting, novel care delivery models on cost *and* quality. The associated waivers were also narrowly tailored to preserve the bulk of the existing statutory regime. Neither appears to be the case here. Instead, CMS proposes a mandatory, national model that applies to nearly all drugs across all specialties, with no regard for clinical utility, using an intervention that does nothing more than modify levels of reimbursement for existing services, all without objective metrics to analyze the effect on patient care. We doubt that a model of this nature—that is not limited "to a defined population for which there are deficits in care leading to poor clinical outcomes"—can be lawful under the Agency's statutory authority.

Simply put, the purpose of CMMI is not to implement policies that will achieve a reduction in Medicare expenditures by changing the payment parameters enacted by Congress. Rather, CMMI is designed to *test innovative models* with unknown impacts—in a responsible and limited fashion—to understand their effects before they are employed on the broader Medicare population. The Proposed Model does not create such a test; it is a wholesale change to reimbursement for the vast majority of physicians and patients under the guise of a demonstration. Respectfully, we believe that is a job for Congress, not CMS.

III. Introduction of For-Profit Middlemen will Compromise Access to Cancer Care

CMS previously instituted a Competitive Acquisition Program (CAP) that proved to be administratively unwieldy and ineffective and was terminated after just three years of operation due to lack of interest from both physicians and vendors. Under the IPI Model, CMS is reviving the previous failed CAP to contract with private-sector "vendors" to act as middlemen between manufacturers, physicians, HOPDs, and other providers for the drugs and biologic products included in the Proposed Model

LUGPA has grave concerns with respect to introducing for-profit vendors between patients and their providers. Gravely ill Medicare Beneficiaries should have timely access to cancer treatments as determined by the precepts of shared decision making; introducing corporate entities that have no relevant clinical

by the precepts of shared decision making; introducing corporate entities that have no relevant clinical experience cannot help but introduce an additional administrative burden on practitioners and add unnecessary complexity and anxiety to patients already under emotional duress due to the severity of their illness.

Congress created the Part B drug benefit for distinctly different patient populations than Part D. As such, there are currently no formulary or other limitation to limit patient access to appropriate medicines in Part B. Under the Proposed Model, CAP vendors would be able to directly or indirectly dictate the choice of therapies in the model, thereby introducing non-clinicians into the decision-making process. LUGPA is concerned that the CAP vendors will essentially function as Pharmacy Benefit Managers (PBMs) and restrict access to medications through formulary control. CMS has provided robust data suggesting that these middlemen are driving up costs in Part D by reaping rebates from manufacturers that do not make it to the patient. In contrast, the ASP formula requires all discounts, rebates and price concessions to be calculated in ASP and patients benefit from that discounting at the point-of-sale. At present, the three largest PBMs control 80 percent of health plan-related drug purchases.[11] They are CVS Health (aka Caremark), Express Scripts, and OptumRx (a subsidiary of UnitedHealth). Reports suggest Express Scripts reported a profit of $3.4 billion in 2016, up 34 percent from 2015. OptumRx reported an operating profit of $2.7 billion in 2016, up from $1.7 billion the year before.[12] Indeed, the CEO of the Pharmaceutical Care Management Association (the lobbying entity for PBMs) stated, "We are encouraged the Administration is exploring greater use of competitive pharmacy benefit manager (PBM) tools in Medicare Part B."[13] LUGPA cannot see the wisdom in transferring clinical decision making from patients and providers to non-accountable corporate middlemen.

IV. International Indexing is not an Appropriate Method to Set Prices for Part B Drugs

While LUGPA is committed to the responsible stewardship of the nation's healthcare resources, we do not believe that indexing drug costs to international costs represents a viable approach to controlling rising Medicare Part B expenditures. In many countries, there is inconsistent availability of medications, which can result in variable mechanisms for creating an index price for different agents. CMS has indicated that if there is no international pricing data for a drug, the model payment amount would be calculated by multiplying a standard factor. For example, CMS could assume the same ratio for the new drug as the IPI, which would be the average volume-weighted payment across all Part B drugs included in the model. LUGPA is concerned that this approach may result in arbitrary payment amounts that could effectively limit the ability to purchase critical medication at commercially available prices.

This payment indexing may well have an untoward effect on accessibility to drugs. Patients in the United States obtain access to 88 percent of new drugs within three months of their launch; patients in the 16 other countries referenced in the ASPE report had access to an average of 48 percent of new drugs, and it took an average of 17 months to gain access to those drugs.[14] Without appropriate testing, it is unclear whether the Proposed Model will adversely affect the ability of Medicare Beneficiaries to access life-saving therapies in a timely fashion.

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[11] Keller Rohrback, LLP. Five things to know about Pharmacy Benefit Managers (PBMs). Accessed at: https://www.krcomplexlit.com/2017/11/pharmacy-benefit-managers-pbms-explained/

[12] Michael Hiltzik. How 'price-cutting' middlemen are making crucial drugs vastly more expensive. Los Angeles Times, June 9, 2017. Accessed at: https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html.

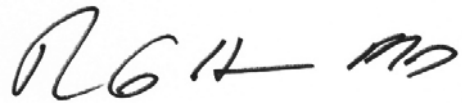
[13] PCMA Statement of the Administration's Proposed Medicare Part B Pricing Model. Accessed at: https://www.pcmanet.org/pcma-statement-on-the-administrations-proposed-medicare-part-b-pricing-model/

[14] Tara O'Neill Hayes. "Is an International Price Index the Solution to High Drug Prices?" Accessed at: https://www.americanactionforum.org/insight/is-an-international-price-index-the-solution-to-high-drug-prices

V. Request for Action

LUGPA joined 338 organizations supporting CMMI efforts to test patient-centered, voluntary, reforms that can be fully evaluated. However, LUGPA cannot support implementation of a mandatory national model that forces patients and providers to rely on for-profit corporate entities that have already been demonstrated to reduce access and increase costs. LUGPA urges CMS to further engage with patient and provider stakeholders to develop responsible models that first and foremost protect clinical outcomes while respecting patient's rights to shared decision making.

Respectfully submitted,



Richard G. Harris, M.D.
President

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