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May 9, 2016

**BY ELECTRONIC SUBMISSION**

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

RE: Comments to CMS-1670-P

Dear Acting Administrator Slavitt:

On behalf of LUGPA, we thank you for the opportunity to comment on the Proposed Part B Drug Payment Model<sup>1</sup> (“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 and on the growing trend of care shifting from the lower-cost physician office setting to the more expensive hospital setting. We believe that the proposed model is, in fact, a nationwide experiment that inappropriately uses CMMI’s waiver authority. 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** or **potentially avoidable expenditures**.”<sup>2</sup> The entire country is not a “defined population,” and CMS has presented no evidence that the current reimbursement system has created deficits in care, poor clinical outcomes or avoidable expenditures. As such, none of those elements has been satisfied here.

The Proposed Model will simply cut reimbursement for critical therapies—such as those used to treat patients with advanced prostate cancer—while creating windfalls for drugs either incident to care (such as antibiotics for surgical prophylaxis, narcotic opioids used for anesthetic purposes, and perioperative intravenous fluids) or for benign conditions, such as testosterone treatments used to treat loss of sexual function. Our analysis of the Proposed Model indicates that overall, the specialty of



<sup>1</sup> 81 Fed. Reg. 13230.

<sup>2</sup> 42 U.S.C. § 1315a(b)(2)(A).

urology will experience a 0.42% increase in Part B drug compensation;<sup>3</sup> that said, as practitioners who are the principle 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.

Finally, much of the architecture of the Proposed Model conflicts with national payment reform policy reflected in the bi-partisan Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”). In short, CMS should withdraw the Proposed Rule until it addresses with stakeholder input the serious clinical, operational and legal challenges with the proposal as currently framed.

### **I. As The Voice of Independent, Integrated Urology Practices, LUGPA Opposes a Demonstration That Could Harm Patient Access to Vital Prostate 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 136 urology group practices in the United States, with more than 2,000 physicians who, collectively, provide approximately 30% of the nation’s urology services.<sup>4</sup>

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 offer 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.

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<sup>3</sup> Summary of Medicare Experience: Physician Administered Drugs Used by Urologists. Milliman Inc., April 2016. (“Milliman 2016”). This analysis is consistent with the 0.4% overall increase that CMS calculated for urology.

<sup>4</sup> 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>.

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.<sup>5</sup> Part B medications constitute over 20% of Medicare payments to urologists.<sup>6</sup> Although CMS estimates a net reimbursement increase of 0.4% for the specialty of urology as a whole as a result of the proposal,<sup>7</sup> this top-line, aggregated figure masks important details about the distribution of reimbursement cuts and increases. In addition, as the Proposed Model is intended to be administered by new geographic regions that are, in many cases, smaller than existing zip codes, 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).

## II. CMS's Proposed Model Upends a System Designed to Address Physician Costs Associated With Administering Drugs.

Medicare pays for drugs under Part B when they are administered by a physician (or a professional under a physician's supervision) in the office or hospital outpatient setting.<sup>8</sup> Physicians are responsible for the ordering, storage, and handling of these medications. In most cases reimbursement for these tasks is not built into the cost of the medication or under the relevant drug administration code. The existing Part B payment covers: 1) the cost of purchasing the drug, as directly reported by the manufacturer; and 2) the storage, handling, and other overhead costs to the physician of administering the drug.

Congress authorized a modifier based upon the Average Sales Price ("ASP") of the medication.<sup>9</sup> Specifically, Congress created a uniform, objective methodology based on the ASP plus 6% for the vast majority of Part B drugs.<sup>10</sup> Nearly all observers of Part B payment issues have understood that changes to this reimbursement system would require action by Congress.<sup>11</sup> Indeed, ASP+6% has already been reduced to ASP+4.48% through the sequester cuts, yet CMS proposes to layer additional cuts on that lower payment amount. CMS proposes to adopt for three-quarters of the country, a substantially different payment model than the one enacted by Congress after careful deliberation and negotiation when it reformed the Average Wholesale Price payment methodology in the Medicare Modernization Act of 2003.

CMS's new Proposed Part B Drug Payment Model would replace the existing statutory formula with a new experiment based on two proposed interventions: in **Phase I**, the ASP+6% methodology would be replaced with a lower fee of ASP+2.5% plus a flat fee of \$16.80 per dose (resulting in payments of less than ASP+1%, when factoring in the

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<sup>5</sup> Milliman 2016

<sup>6</sup> 81 Fed. Reg. at 13255 (comparing total drug payment at ASP+6% for urology to total Medicare payment for urology).

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 13233.

<sup>9</sup> 42 U.S.C. § 1395w-3a.

<sup>10</sup> 42 U.S.C. § 1395w-3a(b)(1).

<sup>11</sup> See, e.g., MedPAC, June 2015 Report to the Congress ("MedPAC 2015 Report"), p. 88.

sequester cuts);<sup>12</sup> in **Phase II**, CMS would create a variety of value-based payment models assigned to different HCPCS codes.<sup>13</sup> As a result, a provider may be required to participate in multiple forms of value-based payment under Phase II. CMS would then group the entire country (other than Maryland, whose hospitals are paid under a separate system) into four model arms: a control arm; Phase I-only; Phase II-only; and Phase I & Phase II combined.

We have serious concerns about Phase I of this model from a clinical, operational, and legal perspective. Most importantly, as MedPAC has recognized, changes to the ASP+6% methodology will only influence physician prescribing behavior in those cases where patients and physicians have a meaningful choice of generic or other medications of varying costs to treat the underlying clinical condition.<sup>14</sup> That is simply not the case for the drugs used by urologists to treat prostate cancer. In fact, **there are no generic alternatives available for any of the Part B advanced prostate cancer medications** that represent the largest component of urology Part B drug spending. Yet, the Phase I methodology proposed by CMS would levy its largest cuts on this category of drugs. Moreover, CMS has ignored many of the operational concerns in a “percentage plus flat fee” model that MedPAC raised in its June 2015 Report to Congress. Finally, CMS has not clearly articulated how the Proposed Model fits within CMMI’s legal authority to test models that represent “deficiencies in patient care,” or how the Agency will ensure that patient access to care is not harmed.<sup>15</sup> Indeed, CMS has not promulgated any objective measures to assess the impact of the Proposed Model on patient care or patient-centeredness—an explicit requirement for any CMMI initiative.<sup>16</sup> CMS should not conduct an experiment on three-quarters of the physicians and patients in the country and not measure or evaluate clinical outcomes.

### III. The Proposed Model Would Create Clinically Irrational Policy Results.

#### A. CMS Must Preserve Beneficiary Access to Part B Drugs That Represent Important Clinical Breakthroughs.

It is important to remember the type of patient care at stake as CMS attempts to rewrite the Part B drug payment rules. Prostate cancer is the second leading cause of cancer death in American men.<sup>17</sup> Significant disparities continue to exist in the diagnosis and treatment of the disease, with persistently high rates of mortality among African-Americans.<sup>18</sup> Until the 1980s, based on Nobel Prize-winning research,<sup>19</sup> advanced

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<sup>12</sup> 81 Fed. Reg. at 13239.

<sup>13</sup> *Id.* at 13242.

<sup>14</sup> MedPAC 2015 Report, p. 66.

<sup>15</sup> 42 U.S.C. § 1315a(b)(2)(A) requires models tested under CMMI to address a “defined population” experiencing “deficits of care.”

<sup>16</sup> 42 U.S.C. § 1315A(b)(4)(A)(i) requires an evaluation of each CMMI model including an analysis of “the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.”

<sup>17</sup> American Cancer Society, *Cancer Facts & Figures 2016*, p. 4,

<http://www.cancer.org/acs/groups/content/@research/documents/document/acspc-047079.pdf>.

<sup>18</sup> *Id.* at p. 19.

prostate cancer was treated by reducing the level of circulating testosterone in men afflicted by this disease. Unfortunately, commercially available medications to accomplish this reduction were associated with substantial side effects;<sup>20</sup> as such, the primary treatment for advanced prostate cancer was castration by removal of the testicles.<sup>21</sup> This approach had understandable, untoward psychological side effects.

Fortunately, in the last thirty years, the standard of care for treatment of advanced prostate cancer has shifted to hormone therapies that can be delivered safely in the physician office setting,<sup>22</sup> and, accordingly, are reimbursed under Medicare Part B. Specifically, advanced prostate cancer is primarily treated using drugs that modify the body's levels of luteinizing hormone-releasing hormone ("LHRH"). Four of these drugs are LHRH agonists and one is an LHRH antagonist.<sup>23</sup> Although these drugs all work by reducing serum testosterone levels, each is a distinct pharmaceutical agent; **there are no generic equivalents available for any of these drugs.** Each poses its own specific requirements with respect to storage, preparation, handling, and other overhead costs. As a result, a single fee for all agents irrespective of cost or complexity of handling is an inappropriate reimbursement method, even if global costs remain unchanged.

Patients with bladder cancer—another genitourinary cancer commonly treated by urologists—will also be adversely impacted by the Proposed Model. CMS would cut reimbursement for the bladder cancer medication valrubicin by nearly three percent.<sup>24</sup> Valrubicin is a last-line treatment for bladder cancer that is only used after other medications fail<sup>25</sup>—the preparation of valrubicin used for this purpose is only available in a non-generic form (Valstar®). If valrubicin were not available, the only other option for thousands of Medicare beneficiaries would be radical surgical removal of the bladder. This procedure often requires leaving the patient with a permanent urostomy, which requires collection of urine in an external appliance—objectively, a less-desirable patient outcome.<sup>26</sup> The reimbursement cuts built into Phase I of the Proposed Model will make it significantly more difficult for physicians to afford to purchase, store, and administer medications such as this.

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<sup>19</sup> Huggins CB, Stevens RE Jr, Hodges CV. The effect of castration on advanced carcinoma of the prostate gland. *Arch Surg* 1941 43(2):209-223.

<sup>20</sup> Noller KL, Fish CR. Diethylstilbestrol usage: its interesting past important present and questionable future. *Medical Clinics of North America* (1974) 58 (4): 793-810. July 1974.

<sup>21</sup> Cassileth BR, Soloway MS, Vogelzang NF, et al. Quality of life and psychosocial status in stage D prostate cancer. *Quality of Life Research* 1, no. 5 (1992): 323-330.

<sup>22</sup> NCCN Prostate Cancer Guidelines Version 2.2106, PROS-F, 2 of 4, [https://www.nccn.org/professionals/physician\\_gls/pdf/prostate.pdf](https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf)

<sup>23</sup> The agonists are leuprolide acetate, triptorelin pamoate, histrelin acetate, and goserelin acetate; the antagonist is degarelix acetate.

<sup>24</sup> Milliman 2016.

<sup>25</sup> Brausi M, Witjes JA, Lamm D, et al. A review of current guidelines and best practice recommendations for the management of nonmuscle invasive bladder cancer by the International Bladder Cancer Group. *The Journal of Urology*. 2011 186(6):2158-67.

<sup>26</sup> Novotny V, Hakenberg OW, Wiessner D, et al. Perioperative complications of radical cystectomy in a contemporary series. *European urology*. 2007 Feb 28;51(2):397-402.

## B. The Proposed Phase I Methodology Penalizes Physicians Who Provide Patient-Centered Treatment for Advanced Prostate Cancer Care.

Perhaps most perplexing from a clinical perspective, the new payment system proposed by CMS would reimburse different preparations of the *same drug* differently. Worse, the Phase I methodology will cause reimbursement for more frequent, less-convenient administrations of cancer medications to *increase* while reimbursement for less-frequent, more convenient administrations to *decrease*.

Many drugs may be administered in different preparations depending on clinical indications and patient convenience. Below are the five commonly used medications to treat advanced prostate cancer (all are within the LHRH agonist drug class with the exception of degarelix acetate, which is an LHRH antagonist). Each of these agents has certain unique characteristics that may make them more or less appropriate for any particular physician's office or patient:<sup>27</sup>

HCPCS	HCPCS Description	Units/ASP	Brand Name	Months Supplied
J9217	Leuprolide Acetate <sup>28</sup>	7.5 mg	Lupron®, Eligard®	1,3,4 ,6
J3315	Triptorelin Pamoate	3.75 mg	Trelstar®	1,3,6
J9225	Histrelin Acetate	50 mg	Vantas®	12
J9202	Goserelin Acetate	3.6 mg	Zoladex®	1,3
J9155	Degarelix Acetate	1.0 mg	Firmagon®	1

Table 1: Commonly Used Part B Medications Used to Treat Advanced Prostate Cancer

An analysis of 2014 Medicare claims data reveals that multi-month preparations of these drugs were overwhelmingly used if available. In fact, of the more than 120,000 Medicare beneficiaries treated with LHRH agonists, about 93% received their medication in a multi-month preparation.<sup>29</sup> Even when we take into account LHRH antagonists (which are *only* available on a monthly basis), about 86% of advanced prostate cancer hormone administrations were provided on a multiple-month basis.<sup>30</sup>

This practice pattern makes sense because a) it is significantly more convenient for patients; and b) it is substantially more cost effective. In a single office visit, a patient will receive months of therapy, obviating the need for multiple office visits—an important consideration for patients with advanced cancer whose mobility may be limited. In addition to the added convenience to the patient, this approach further reduces expense by greatly reducing the number of required office visits and injections (each of

<sup>27</sup> For example, histrelin requires a minor surgical procedure to create an implant under the skin of the patient; goserelin is an implant that requires a much larger bore needle than the other drugs; the LHRH agonists sometimes require additional oral agents to block a temporary condition known as “flare” to name but a few.

<sup>28</sup> Leuprolide acetate also is used to treat endometriosis; this is a different preparation which uses HCPCS code J1950.

<sup>29</sup> Milliman 2016.

<sup>30</sup> *Id.* A beneficiary would require 12 monthly, four 3-month, three 4-month, two 6-month or one 12-month injection per year; beneficiary counts are approximate as patients may switch between preparations in a single year and others may not complete 12 months of treatment.

which carries CPT codes that would be billed separately in connection with the administration of the pharmaceutical agent).

Unfortunately, the Proposed Model would penalize physicians for employing a more patient-centered approach to drug treatment. Under the proposal, reimbursement for monthly administrations of LHRH therapies would increase while reimbursement for multiple-month treatments would decrease significantly. Since LHRH agonist therapy is paid on a multiple of the one-month ASP pricing, physicians who opt to use multi-month treatments for patient convenience will be financially penalized for doing so, as illustrated in the table below:<sup>31</sup>

HCPCS Code	HCPCS Description	% Change in Reimbursement by Drug and Months Supplied, Current vs Proposed				
		1	3	4	6	12
J9217	Leuprolide Acetate	4.03%	-0.86%	-1.47%	-2.08%	
J3315	Triptorelin Pamoate	6.54%	-0.02%		-1.66%	
J9225	Goserelin Acetate	4.16%	-0.81%			
J9202	Histrelin Acetate					-2.74%
J9155	Degarelix Acetate	2.62%				

**Table 2: % Change in Medications to Treat Advanced Prostate Cancer, by Drug and Months Supplied**

Based on the above utilization pattern, the impact on reimbursement for medications used to treat advanced prostate cancer is illustrated below:<sup>32</sup>

HCPCS Description	Current	Proposed	Δ	%Δ
Leuprolide Acetate	\$189,320,337.93	\$186,596,771.34	\$(2,723,566.59)	-1.4%
Triptorelin Pamoate	\$10,730,776.95	\$10,661,615.33	\$(69,161.63)	-0.6%
Histrelin Acetate	\$5,471,296.43	\$5,321,263.46	\$(150,032.97)	-2.7%
Goserelin Acetate	\$2,655,079.58	\$2,639,194.90	\$(15,884.68)	-0.6%
Degarelix Acetate	\$11,173,678.35	\$11,259,801.10	\$86,122.75	0.8%
<b>Total</b>	<b>\$219,351,169.25</b>	<b>\$216,478,646.12</b>	<b>\$(2,872,523.13)</b>	<b>-1.3%</b>

**Table 3: Proposed CMS Rule on Reimbursement for Medications Used to Treat Advanced Prostate Cancer**

In fact, the impact on physician reimbursement is much greater than described above because the physicians must acquire the medication. As such, the physician's true reimbursement is the difference between the overall Medicare Part B payment (i.e., Medicare allowable amount less sequester) and the purchase price of the drug (i.e., ASP). This net amount represents the portion of Part B reimbursement intended to compensate

<sup>31</sup> Percent change calculated by the difference in 106% of 4th quarter 2014 ASP drug price and the 102.5% of 4th quarter 2014 ASP drug price plus \$16.80, reduced by 2% for sequestration.

<sup>32</sup> Current reimbursement is the product of 106% of 4<sup>th</sup> quarter 2014 ASP drug price and total units given, reduced by 2% sequestration; proposed pricing is the sum of the product of sum 102.5% of 4<sup>th</sup> quarter 2014 ASP drug price and total units given and \$16.80 times total administrations, each reduced by 2% for sequestration.

physicians for handling, storage, product loss, spoliation, and other overhead expenses. This is illustrated in the table below:

HCPCS Description	Current	Proposed	Δ	% Δ
Leuprolide Acetate	\$7,071,264.07	\$4,347,697.47	\$(2,723,566.59)	-38.5%
Triptorelin Pamoate	\$400,802.99	\$331,641.36	\$(69,161.63)	-17.3%
Histrelin Acetate	\$204,357.24	\$54,324.27	\$(150,032.97)	-73.4%
Goserelin Acetate	\$99,169.32	\$83,284.64	\$(15,884.68)	-16.0%
Degarelix Injection	\$417,345.71	\$503,468.46	\$86,122.75	20.6%
<b>Total</b>	<b>\$8,192,939.32</b>	<b>\$5,320,416.19</b>	<b>\$(2,872,523.13)</b>	<b>-35.1%</b>

**Table 4: Change in Reimbursement Net of ASP for Medications Used to Treat Advanced Prostate Cancer**

Even as it penalizes physicians who administer drugs in a more patient-centered and cost efficient way, the Proposed Model contemplates significantly higher reimbursement when these medications are administered more frequently. Thus, if all urologists shifted to less-convenient (but still medically appropriate) monthly administrations of these medications, the impact to the Medicare program would be as follows:

HCPCS Description	Current	Proposed	Δ	% Δ
Leuprolide Acetate	\$189,320,337.93	\$196,942,748.94	\$7,622,411.01	4.0%
Triptorelin Pamoate	\$10,730,776.95	\$11,432,130.53	\$701,353.57	6.5%
Histrelin Acetate	\$5,471,296.43	\$5,321,263.46	\$(150,032.97)	-2.7%
Goserelin Acetate	\$2,655,079.58	\$2,765,638.42	\$110,558.84	4.2%
Degarelix Injection	\$11,173,678.35	\$11,259,801.10	\$86,122.75	0.8%
<b>Total</b>	<b>\$219,351,169.25</b>	<b>\$227,721,582.44</b>	<b>\$8,370,413.19</b>	<b>3.8%</b>

**Table 5: Reimbursement Change if One-Month Medication Used, Where Available**

This example illustrates the disconnect between the Proposed Model and the goal of incentivizing high quality, efficient patient care. Even as it penalizes providers who engage in existing, patient-centered models of practice that are the standard of care, CMS proposes creating an incentive of over \$11 million<sup>33</sup> to less-convenient models of care delivery. This is to say nothing of additional costs due to more frequent drug administrations and office visits.

Ultimately, rather than saving any costs, the Agency's proposal will result in large cost increases for the Medicare program. This analysis is all the more troubling because there are no generic alternatives to these medications. As MedPAC has acknowledged, a payment incentive will only change physician behavior where true clinical alternatives to a medication are available.<sup>34</sup>

<sup>33</sup> This incentive represents the enhanced reimbursement that would occur from more frequent plus the elimination of the decreased reimbursement currently in the Proposed Model (\$8,370,413.19 + \$2,872,523.13, or \$11,242,936.32)

<sup>34</sup> MedPAC 2015 Report, p. 66.

### C. The Proposed Demonstration Project has an Inappropriate Impact on Cancer Medications.

Of the 75 Part B drugs administered by urologists in 2014, 13 would receive payment reductions under the Phase I methodology and 62 would receive increases.<sup>35</sup> Below is a list of the 13 agents for which reimbursement would be reduced under the Proposed Model:

HCPCS	HCPCS Description	Indication	Cancer Related
J9217	Leuprolide Acetate	Prostate Cancer	Yes
Q2043	Sipuleucel-T Auto	Prostate Cancer	Yes
J0897	Denosumab	Prostate Cancer	Yes
J9357	Valrubicin	Bladder Cancer	Yes
J9225	Histrelin Acetate	Prostate Cancer	Yes
J0775	Collagenase, Clost Hist Inj	Peyronie's Disease	No
J9214	Interferon $\alpha$ -2B	Bladder Cancer	Yes
J3315	Triptorelin Pamoate	Prostate Cancer	Yes
J1950	Leuprolide Acetate/3.75 Mg	Endometriosis	No
J0585	Onabotulinum Toxin A	Overactive Bladder	No
J9202	Goserelin Acetate	Prostate Cancer	Yes
J2796	Romiplostim	Idiopathic Thrombocytopenic Purpura	No
J7325	Synvisc or Synvisc-One	Osteoarthritis	No

Table 6: Medicare Part B Medications Used by Urology with Proposed Reduced Reimbursement Under Phase I

The cumulative payment reduction for these 13 agents translates to an estimated \$7.26 million.<sup>36</sup> Three of these 13 agents with reported use by urologists are used for non-urologic indications. Most significantly, **eight of the ten urologic medications with proposed payment reductions are used for the treatment of advanced cancers.** This differential is even more stark when reimbursement is considered: of these 13 agents, \$7.12 million of the total \$7.26 million (98%) reduction falls on the eight cancer drugs.<sup>37</sup> This underscores the fact that Phase I of the demonstration project will overwhelmingly cut reimbursement for what may be the only meaningful treatment available for patients with complicated diseases who have failed primary therapy.

CMS stresses the point that the overall proposal is budget neutral; however, as illustrated in the table below, the medications with the highest percent increase in reimbursement is revealing (with certain drugs receiving a 919% to 47,000% increase):

<sup>35</sup> Milliman 2016.

<sup>36</sup> Id.

<sup>37</sup> Id.

HCPCS	HCPCS Description	% Change	HCPCS	HCPCS Description	% Change
J2001	Lidocaine HCl	47255.7	J1170	Hydromorphone	912.7
J2795	Ropivacaine HCl	13996.7	J2920	Methylprednisolone	861.3
J0461	Atropine Sulfate	7301.0	J0696	Ceftriaxone Sodium	706.5
J7050	Normal Saline Solution	4202.4	J0690	Cefazolin Sodium	653.5
J2250	Midazolam HCl	3726.8	J0290	Ampicillin	636.1
J1100	Dexamethasone Sodium	2185.1	J2930	Methylprednisolone	583.1
J7040	Normal Saline Solution In	2118.4	J3010	Fentanyl Citrate	518.3
J1885	Ketorolac Tromethamine	2013.1	J2370	Phenylephrine HCl	515.1
J7030	Normal Saline Solution	1240.2	J3260	Tobramycin Sulfate	483.6
J0744	Ciprofloxacin IV	1221.9	J3411	Thiamine HCl	483.1
J7120	Ringers Lactate Infusion	1199.4	J1030	Methylprednisolone	476.8
J2550	Promethazine HCl	1032.5	J1644	Heparin Sodium/ 1000U	437.9
J3480	Potassium Chloride	960.6	J3301	Triamcinolone Acetate	380.7
J1580	Garamycin	938.2	J0692	Cefepime HCl	354.7
J3420	Vitamin B12	919.8	J2175	Meperidine HCl	319.9

Table 7: Medicare Part B Medications Used by Urology with Highest % Proposed Reimbursement Increase

These massive increases in payment percentages are driven by the \$16.80 flat payment add-on, which dwarfs the entire cost of many of these drugs. These agents generally do not have a primary therapeutic indication. Of the 30 medications listed, 14 are most commonly used during the perioperative period for sedation, pain control or cardiovascular management; six are used for surgical antimicrobial prophylaxis; five are injectable steroids; and two are vitamins.<sup>38</sup> Most concerning, however, three of the medications with the highest percent increase are narcotics.<sup>39</sup>

CMS has an obligation to consider more than cost control when evaluating the substantive effects of its policy on access to specific drugs. And, disturbingly, under Phase I of the Proposed Rule, the greatest harm falls squarely on the sickest patients in need of those medications with no generic alternatives. As MedPAC acknowledges, the most expensive medications paid under Part B are virtually all therapeutic medications to treat cancer.<sup>40</sup> Reimbursement for these important therapies would fall precipitously. Meanwhile, in order to preserve budget neutrality, CMS would dramatically increase reimbursement for the drugs that are currently least expensive. This creates an arbitrary, clinically incoherent result in which the Agency transfers reimbursement from sophisticated therapies that are primary cancer treatments to fairly common medications that primarily support the administration or the efficacy of other therapies.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* Hydromorphone, fentanyl and meperidine are opioids.

<sup>40</sup> MedPAC 2015 Report, p. 66.

#### **D. The Proposal May Further Increase Costs by Shifting Services to the More Expensive Hospital Setting.**

It is well-established that the costs of delivering services in a hospital facility are far greater than providing the equivalent services in physician offices.<sup>41</sup> This cost differential is particularly troubling as payment models shift towards value-based, rather than volume-based, reimbursement for services. In an analysis of group practices that assumed risk contracts with Medicare, APMs managed by independent physicians were found to be higher in quality and lower in cost than those run by hospitals.<sup>42</sup> The greatest differential existed in cancer treatments, which were as much as 36% less expensive in the physician office setting.<sup>43</sup> A recent analysis found that there existed a consistent pattern of higher spending on patients receiving chemotherapy in hospital outpatient facilities than those receiving chemotherapy in physician offices as well as a trend toward the use of these higher cost hospital outpatient facility settings.<sup>44</sup>

This trend is particularly troubling when addressing agents used for the treatment of genitourinary malignancies. Although urologists commonly treat genitourinary malignancies, these diseases may be treated by other specialists as well. And while the cancer medications listed for payment reduction in Table 6 above are overwhelmingly used in the physicians' office setting by urologists, as illustrated below, this is not necessarily so when these agents are administered by other specialties.<sup>45</sup>

HCPCS	HCPCS Description	% Total Units Given by Non-Urologists	% Non-Urologist Units Given in HOPD
J9202	Goserelin Acetate	75.2%	68.8%
Q2043	Sipuleucel-T	62.5%	40.0%
J3315	Triptorelin Pamoate	40.3%	41.5%
J9217	Leuprolide Acetate	35.6%	56.5%
J9225	Histreltin Acetate	12.3%	100.0%

**Table 8: Percent of Genitourinary Drugs Administered by Non-Urologists Overall and in Hospital Setting**

This data shows that: 1) non-urologists are substantial contributors to utilization of these cancer drugs; and 2) the hospital setting is a common (in some cases, the *most* common) setting for administration of these drugs by non-urologists. For example, the most commonly utilized medication to treat genitourinary cancers is leuprolide acetate; urologists are responsible for roughly 65% of utilization for this medication, which is almost always administered in the physician office. By contrast, nearly 57% of utilization of this drug by non-urologists occurs in the more-expensive hospital setting. Policies that encourage a site-of-service shift will only create greater incentives for use of

<sup>41</sup> See e.g., MedPAC, March 2014 Report to Congress, pp. 51-54.

<sup>42</sup> McWilliams JM, Chernew ME, Zaslavsky AM, et al. Delivery system integration and health care spending and quality for Medicare beneficiaries. (2013) JAMA Internal Medicine, 173(15), 1447-1456

<sup>43</sup> Id.

<sup>44</sup> Fitch K, Pelizzari P, Pyenson B. Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014 Accessed at: <http://www.communityoncology.org/pdfs/Trends-in-Cancer-Costs-White-Paper-FINAL-20160403.pdf>.

<sup>45</sup> Milliman 2016. Medications that may be used for non-genitourinary cancers excluded from this table.

medications administered primarily in the physicians' office setting to shift to the less convenient, more expensive hospital outpatient setting.

MedPAC identified such site-of-service shifts as a potentially significant concern with this model in its June 2015 Report. The change in drug prices would adversely impact those practices that purchase expensive drugs at price points above the ASP, such that "variation in drug acquisition prices across providers **would likely mean** that some providers, especially small providers, would not be able to purchase some expensive drugs at prices within the Medicare reimbursement amount."<sup>46</sup>

This variation is particularly concerning for physician offices, given that Medicare supports hospital purchasing of drugs through the 340B program. The 340B program provides large discounts on pharmaceuticals to hospitals that serve certain populations of Medicaid beneficiaries.<sup>47</sup> This gives 340B hospitals significantly greater ability than other providers to absorb purchase and overhead costs, even for very expensive drugs. As MedPAC observed, "Medicare pays the same rates (ASP + 6 percent) for Part B drugs to 340B hospitals and non-340B hospitals, even though 340B hospitals are able to purchase outpatient drugs at **steep discounts**."<sup>48</sup> Indeed, *MedPAC estimates that 340B hospitals are able to purchase outpatient drugs at a price that is, on average, at least 22.5% below ASP*.<sup>49</sup> For the most expensive medications, the discount averages closer to fifty percent.<sup>50</sup> An increasing number of hospitals now utilize the 340B program to access these discounts.<sup>51</sup> For example, between 2004 and 2013, Medicare spending for Part B drugs provided in 340B hospitals grew "from \$0.5 billion to \$3.5 billion, or 543%."<sup>52</sup>

The Proposed Model will benefit 340B hospitals, whose unique purchasing supports will mitigate the effect of steep reimbursement cuts, making it even more difficult for physician practices to compete. Furthermore, if CMS drug policy drives services into the more-expensive outpatient hospital setting, the demonstration will not achieve the system-wide cost savings that CMS desires. It will only exacerbate the already uneven playing field created by the 340B program.

#### **IV. CMS Has Failed to Address Essential Operational Considerations Associated With the Proposed Model.**

##### **A. CMS Ignores Many Concerns MedPAC Articulated With Regard to a Percentage-Plus Flat Fee Model.**

In creating Phase I, CMS appears to have adopted a portion of a payment reform proposal set forth in MedPAC's June 2015 Report to Congress. MedPAC devoted a major portion

<sup>46</sup> MedPAC 2015 Report, p. 70.

<sup>47</sup> *Id.*, p. 71. Note that although eligibility for the 340B program is based on Medicaid population, Medicare will pay its normal reimbursement rates for these drugs.

<sup>48</sup> *Id.*, xiii (emphasis added).

<sup>49</sup> *Id.*, p. 63.

<sup>50</sup> *Id.*, p. xiii (emphasis added).

<sup>51</sup> *Id.*, p. 71.

<sup>52</sup> *Id.*

of that Report to a thoughtful and detailed discussion of the Part B drug payment system and potential value-based reforms.<sup>53</sup> However, CMS cites only a small portion of this extensive discussion to support its creation of the Part B drug payment program.<sup>54</sup> In doing so, CMS does not address a large number of important policy considerations identified by MedPAC as cornerstones for a successful value-based payment approach to Part B drugs.

CMS claims that its demonstration is needed because, “[t]he ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.”<sup>55</sup> Notably, MedPAC did not find conclusive data suggesting that this kind of incentive truly exists in *any* context.<sup>56</sup> But as MedPAC repeatedly pointed out, this logic would only possibly apply when “there are alternative drugs with different prices available to treat a particular patient’s condition.”<sup>57</sup> Unfortunately, this means that in those cases where only one drug is clinically appropriate to treat a patient, or where clinically similar drugs have similar prices, the modified “Phase I” methodology cannot and will not have any true impact.

In those cases where the only clinically appropriate drug is therapeutic medication with no generic alternative, CMS’s Phase I policy will lead to nothing more than a large cut in reimbursement that produces no meaningful information to study. The worst case *clinical scenario* for this proposed policy would be for patients to lose access to a singular therapeutic medication simply because providers are unable to afford the costs associated with its purchase, storage, handling, and administration. Relatedly, the worst case *economic scenario* is for patients to continue to receive these drugs, but only in the hospital outpatient setting at a much higher cost to patients and the Medicare program.

We note that CMS proposes to carve out from the Proposed Model a number of administrative exceptions, including certain contractor-priced drugs, drugs used to treat end-stage renal disease, immunizations, blood products, and drugs identified by the FDA to be in “short supply.”<sup>58</sup> However, CMS has not created any flexibility or exception for medications with no clinical substitutes (including the cancer drugs listed in Table 6 above for treatment of prostate and bladder cancer). We do not see how a demonstration that fails to allow such basic flexibility can satisfy the triple aim’s requirement of providing “better care to patients.”

Moreover, the Part B Model appears to be in conflict with the national payment reform policy reflected in the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”). MACRA calls for all physician payments made under Part B to be shifted to either the Merit-Based Incentive Payment System (“MIPS”) or an Alternative Payment Model (“APM”). Providers have begun significant (and often costly) efforts to prepare for this enormous shift towards value-based payment. Because physician resource use

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<sup>53</sup> MedPAC 2015 Report pp. 61-114.

<sup>54</sup> See e.g., 81 Fed. Reg. 13241, citing MedPAC 2015 Report pp. 65-72.

<sup>55</sup> 81 Fed. Reg. at 13231 (emphasis added).

<sup>56</sup> MedPAC 2015 Report, p. 92.

<sup>57</sup> *Id.*; see also p. 69.

<sup>58</sup> 81 Fed. Reg. at 13235.

will be subject to nationwide ranking under the MIPS,<sup>59</sup> CMS has proposed to use a “payment standardization” methodology to facilitate this nationwide comparison.<sup>60</sup> The complicated methodology, released by CMS late last year, presumes that payment for Part B drugs will not require any adjustment because “the Medicare allowed amount on the claim is already free of geographic adjustments and special program payments.”<sup>61</sup> This assumption would be invalidated if CMS now mandates differences in reimbursement over small geographic areas. Unless CMS now further complicates this policy to account for small-area differences, this mismatch will cause physicians paid under the MIPS to receive either a penalty or windfall based purely on their random assignment to either a “model” or “control” arm under the demonstration.

Another operational concern unique to this proposal regards the geographical distribution of the model or control arms. As these arms are to be determined by small geographic areas, it is possible (if not probable) that physician practices, particularly those that a) are in densely populated regions; b) have a wide geographical footprint; or c) both, may find themselves facing different reimbursements for different providers in different offices. This scenario is particularly troublesome for integrated urology groups, many of which cover a broad geographic footprint. This simply will not work from an administrative standpoint as adjudication of these claims may not be possible through commercially available electronic health records.

## **B. CMS's Attribution Methodology Is Not Appropriate For Specialty Care**

CMS intends to divide regions of the country into control and model arms on the basis of Primary Care Service Areas (“PCSA”).<sup>62</sup> PCSAs are tools used by academic researchers and the HHS Health Resources and Services Administration (“HRSA”) to study primary care workforce issues based on “areas that reflect patients’ travel to primary care.”<sup>63,64</sup> PCSAs should not be used as part of the architecture of a new drug payment policy; they are far too granular to support the wide variations in substantive payment policy contemplated by CMS here—particularly for the many Part B medications administered by specialists.

PCSA methods were not designed to support the kind of randomized distribution of multiple payment methodologies CMS contemplates here, particularly when these decisions carry serious implications for access to *specialty* care, including life-saving cancer treatment. As HRSA’s own documentation states, “[p]rimary care is the most localized medical service. PCSA methods were designed to identify small areas that are relatively self-

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<sup>59</sup> 42 U.S.C. § 1395w-4(r).

<sup>60</sup> “Basics of Payment Standardization,” CMS, <http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPPage%2FQnetTier4&cid=1228772057350>.

<sup>61</sup> *Id.*, p. 11.

<sup>62</sup> 81 Fed. Reg. at 13238. CMS plans to stratify this distribution methodology by the number of Medicare beneficiaries receiving Part B drugs and the mean Part B drug expenditures per beneficiary.

<sup>63</sup> Dartmouth University, Primary Care Service Area (PCSA), <http://tdi.dartmouth.edu/research/evaluating/health-system-focus/primary-care-service-area>.

<sup>64</sup> Health Resources and Services Administration, <http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html>.

contained markets for primary care in which the residents are likely to seek care from within PCSA primary care providers.”<sup>65</sup> PCSAs are determined solely by reference to CPT codes associated with primary care, leading to extremely small service areas, which are simply not appropriate as a tool to assign payment policy for less-common specialty providers.<sup>66</sup> For example, the median land area of a PCSA is only 158 square miles (or a radius of about 7 miles).<sup>67</sup> Of the roughly 7,000 PCSAs, over 4,000 had a radius of less than ten miles.<sup>68</sup>

The Proposed Model will have serious implications for specialty care, given that specialists (such as urologists) will draw patients from many different PCSAs. As a result, providers will face difficult administrative tasks associated with billing under different payment methods, particularly for medical practices that administer drugs in multiple office locations potentially stretching across dozens of PCSAs. Payment rules will potentially change significantly over very small geographic areas. In certain cases, such as in New York City, the Part B drug payment methodology could vary wildly within a matter of blocks. Even smaller cities will cover multiple PCSAs. The issue is particularly complicated for areas adjacent to the state of Maryland, which is entirely excluded from the Proposed Model.<sup>69</sup> In short, the Proposed Model should be withdrawn until CMS, with input from stakeholders, can conduct a careful analysis of how the setting of drug payment policy on the basis of PCSAs will impact the delivery of specialty care.

## **V. 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**.”<sup>70</sup> And, CMMI’s exercise of that discretion is subject to judicial review.<sup>71</sup>

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 or potentially avoidable expenditures. This certainly is not true for genitourinary tumors

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<sup>65</sup> Health Resource and Services Administration, “PCSA Version 3.1 Methods,” available at: <http://datawarehouse.hrsa.gov/data/datadownload/pcsas2010download.aspx>.

<sup>66</sup> *Id.* at p. 2. PCSAs only reflect distance traveled to access CPT codes 99201-99205 and 99211-99215.

<sup>67</sup> *Id.* at p. 9.

<sup>68</sup> *Id.*

<sup>69</sup> 81 Fed. Reg. 13240.

<sup>70</sup> 42 U.S.C. § 1315a(b)(2)(A).

<sup>71</sup> 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).

such as prostate cancer; as illustrated below, the death rate from prostate cancer has steadily declined with advances in diagnostic and therapeutic modalities:<sup>72</sup>

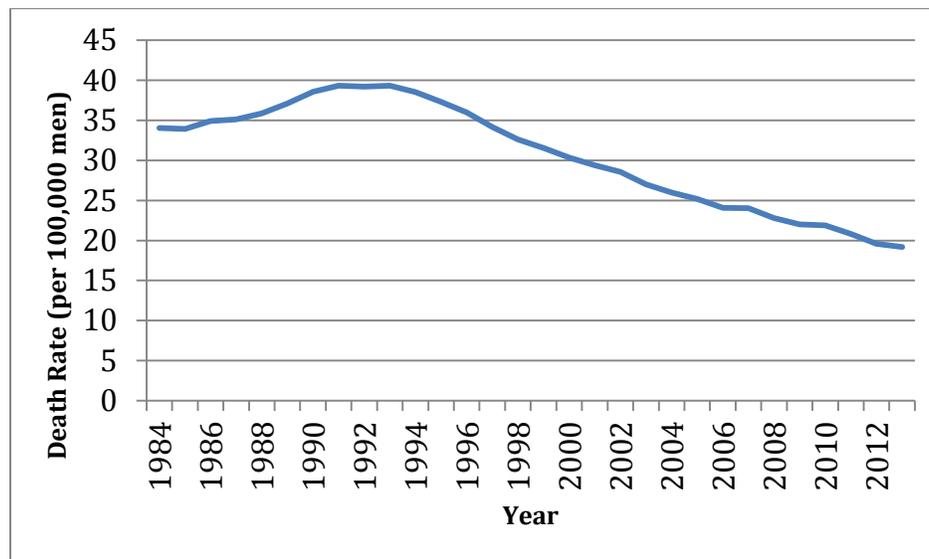


Figure 1: Death Rate From Prostate Cancer per 100,000 Men, 1994-2013

As the death rate from prostate cancer in 2013 was the lowest ever recorded, and because medications that were critical to achieving this result do not have generic equivalents, we do not believe the Secretary can reasonably conclude that “poor clinical outcomes” or “potentially avoidable expenditures” exist to justify use of the waiver.

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.<sup>73</sup> 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.”**<sup>74</sup> 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. CMMI’s own statement of its intent is that the model will test “whether the

<sup>72</sup> National Cancer Institute, Surveillance Epidemiology End Results. SEER Stat Fact Sheets: Prostate Cancer. <http://seer.cancer.gov/statfacts/html/prost.html>.

<sup>73</sup> 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](http://seer.cancer.gov/csr/1975_2013/browse_csr.php?sectionSEL=23&pageSEL=sect_23_zfig.01.html).

<sup>74</sup> 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

alternative drug payment designs discussed in this Proposed Rule will lead to better value for drugs paid under Part B, **that is, a reduction in Medicare expenditures**, while preserving or enhancing quality of care provided to Medicare beneficiaries.”<sup>75</sup> This description 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.”

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 use of waiver authority. Indeed, we find it difficult to understand how a policy calling for a wholesale shift away from reimbursement for cancer medications could genuinely address a “deficit in care.” Moreover, even under CMMI’s stated intent, it is difficult to identify the scope of any genuine “test,” particularly when CMS is claiming that Phase I is budget neutral. If the model is not designed to save money, and no patient health outcomes will be monitored or evaluated through any objective criteria, then the proposal cannot fairly be deemed a bona fide “demonstration model.” This is all the more concerning because the five year demonstration is an excessive amount of time—potentially spanning three presidential administrations—before CMS is required to ascertain whether to make the model permanent and subject the remaining one-quarter of the country to the scheme.

In the past, CMMI has designed 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.<sup>76</sup> The associated waivers were also narrowly tailored to preserve the bulk of the existing statutory regime.<sup>77</sup> 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

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<sup>75</sup> 81 Fed. Reg. at 13251. Emphasis added.

<sup>76</sup> See *e.g.*, the 33 separate quality metrics applicable to Accountable Care Organization models, available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Shared-Savings-Program-Quality-Measures.pdf>.

<sup>77</sup> See *e.g.*, the list of detailed fraud and abuse waivers published by CMS at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html> or the Next Generation ACO Benefit Enhancements published by CMS at: <https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/index.html>.

population for which there are deficits in care leading to poor clinical outcomes”—can be lawful under the Agency’s statutory authority.

Although it is clear that cuts in reimbursement for the most expensive drugs will cause Medicare expenditures to decrease, if CMS wants to evaluate the impact of that phenomena, it merely needs to evaluate changes in prescribing behavior and clinical outcomes, if any, associated with the sequester cuts which reduced reimbursement from ASP+6% to ASP+4.48 percent. No further demonstration is necessary.

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 applied to 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. The demonstration proposal should be withdrawn.

## VI. Request for Action

LUGPA supports CMS’s important efforts to move the nation to a true, value-based system of healthcare payment. Nevertheless, LUGPA believes it is necessary for CMS to withdraw the Proposed Rule until the Agency addresses with stakeholder input the serious clinical, operational and legal challenges with the proposal as currently framed. Medicare beneficiaries—especially those who count on Part B drugs to treat cancer—deserve at least that much from the Agency.

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

Respectfully submitted,



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