Submitted Testimony of Ted Okon

Center for Medicare and Medicaid Innovation:
Scoring Assumptions and Real-World Implications

U.S. House of Representatives – Committee on the Budget

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Chairman Dr. Price and Ranking Member Van Hollen, I thank you for the opportunity to testify today to the House Committee on the Budget (the "Committee"). I am the Executive Director of the Community Oncology Alliance ("COA"), which is a non-profit organization dedicated to fostering quality, affordable, and accessible cancer care to Americans in their own communities. I am not a medical professional but in my role as Executive Director, I am exposed to all facets of this terrible disease including, but not limited to, clinical, treatment, cost, reimbursement, and related issues. I routinely hear directly from people fighting cancer, as well as their families and caregivers, and indirectly via my wife, who is a practicing oncology nurse.

Today, my testimony will focus on the Center for Medicare and Medicaid Innovation ("CMMI") and the proposed Medicare Part B Drug Payment Model (the "Part B Model"). This proposed model, which has garnered a great deal of media attention nationally, is illustrative of a dangerous abuse of the powers endowed to CMMI by the Congress. In order to end-run existing law relating to Medicare reimbursement of cancer drugs, the Centers for Medicare & Medicaid Services ("CMS") is proposing to use CMMI in implementing a national, mandatory experiment on seniors and disabled individuals with cancer and other potentially life-threatening diseases. Before the Committee misinterprets this as a political swipe at CMMI, let me be clear that I enthusiastically support the concept of CMMI and conducting pilot programs designed to test enhancing the quality

and cost-efficiency of medical care. In fact, as I will describe later in this testimony, COA has worked extensively with CMMI on oncology payment reform and the development of the Oncology Care Model (the "OCM"), which we are committed to making a success. However, as I will also describe, the Part B Model stands in stark contrast to the OCM. The Part B Model is not a collaborative test "model" as contemplated by Section 1115A of the Patient Protection and Affordable Care Act (the "ACA"), which created and empowered CMMI, but is rather a vehicle to bypass the Congress and existing law. The problem is that the Part B Model puts a very vulnerable population—seniors and Americans with disabilities covered by Medicare—at grave risk.

In submitting this written testimony, I believe it is very important to thoroughly explain the problems with both the Part B Model and the abuse of CMMI, which sets a very dangerous precedent. In preparing this, I have relied heavily on COA's comments submitted to CMS on the proposed rule on the Part B Model (*Medicare Program; Part B Drug Payment Model* [CMS-1670-P]). I was the lead preparer of those comments, relying in part on the input from COA's attorneys relating to the legal issues with the proposal. As COA has publically stated, and as our leadership of oncologists and practice administrators voiced in meeting with officials from CMS and CMMI, we are vehemently opposed to the Part B Model. In short, we believe that not only is "Phase 1"[1] of the Part B Model an inappropriate, dangerous, and perverse mandatory, national experiment on

[1] Section 1115A of the ACA is divided into two parts or phases: (1) a phase 1 testing of models (referred to as phase 1); and (2) upon the completion of phase 1, an optional phase for the expansion of the duration and scope of a model being tested (referred to as phase 2). However, for the reasons discussed in this testimony, the "Phase 1" of the Part B Model is not a phase 1 test as contemplated by Section 1115A.

the cancer care of seniors and others covered by Medicare, but also the Part B Model raises numerous insurmountable legal issues that have profound consequences.

Bad Medicine, Flawed Economics, and Destructive Policy

As I summarize below, and later elaborate in this testimony, the Part B Model is bad medicine, flawed economics, and destructive policy.

Anyone with an understanding of modern-day cancer care realizes that there are very few instances where global substitution of a less expensive cancer drug is possible, appropriate, and safe. What CMS is doing in the Part B Model is blindly ratcheting down payment for standard-of-care cancer drugs in order to simply cut costs by trying to force oncologists to use less expensive, older therapies, which in some cases is not even possible. The Part B Model is to be conducted as an experiment that randomizes geography to "test" and "control" experimental cells, with three-quarters of the country in the test cell. The experiment is designed to change clinical decision-making to lower Medicare spending on cancer drugs, as well as other Part B drugs. However, unlike the accepted rules and ethics of clinical research on human subjects, seniors covered by Medicare cannot opt out of the experiment and receive no "informed consent" that they are part of a clinical research experiment. It is also alarming that there are no patient safeguards, such as real-time monitoring and public reporting of adverse events, outcomes, and quality. This is simply bad medicine.

It is important to note that CMS has already conducted an experiment on cancer care delivery by substantially cutting Medicare Part B drug reimbursement on two previous occasions. In 2005,

CMS required pharmaceutical manufacturers to include wholesaler prompt pay discounts in the calculation of Medicare payment rates, which had the effect of artificially lowering Part B drug reimbursement. Then, in 2012, CMS decided to apply the Medicare sequester cut to underlying drug costs. The CMS experiment in cutting Part B drug reimbursement has resulted in a dramatic shift of cancer care to the more expensive hospital setting. In 2004, 84% of chemotherapy was delivered in independent community cancer clinics, but by 2014 that had fallen to 54%, with the remainder delivered in the far more expensive hospital outpatient setting.[2] This shift in the site of care cost Medicare $2 billion more in 2014—*just one (1) year*—for cancer care than it would have had the site-of-service not shifted to the hospital setting.[3] Given that Medicare is responsible to pay 80% and beneficiaries 20% (the Medicare copayment), a rough estimate is that this shift in the site of care cost beneficiaries $500 million. Furthermore, over the ten (10) plus years that CMS has continued to cut Part B drug payments, cancer drug prices have actually *increased*. This has coincided with the exponential growth of the 340B drug discount program and conclusion of the U.S. Government Accountability Office ("GAO") that 340B hospitals are using more drugs or more expensive drugs.[4] Now CMS intends to cut Part B reimbursement, yet again, with the expressed purpose of lowering Medicare Part B costs and drug prices. The only inescapable conclusion based on history is that the Part B Model will result in higher costs to Medicare and beneficiaries, as well as increased drug prices. As you can see, the economics of the Part B Model

[2] *Cost Drivers of Cancer Care: A Retrospective Analyses of Medicare and Commercially Insured Population Claim Data 2004-2014*, Milliman, April 2016.

[3] Id.

[4] *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.* The U.S. Government Accountability Office, July 2015.

are deeply flawed.

CMS is using Section 1115A of the ACA to effectively overturn legislation that was passed by Congress and signed into law (the Medicare Modernization Act of 2003 (the "MMA"), which fixed Medicare Part B drug reimbursement). If the Part B Model is implemented, the Executive branch could effectively overturn any Medicare law passed by Congress simply by creating a mandatory, national CMMI "model." That is exactly what CMS is doing with the Part B Model by now overturning the MMA that established, by law, Part B drug reimbursement at average sales price ("ASP") plus 6%. CMS is using Section 1115A to effectively overturn the law to change Part B reimbursement to ASP plus 2.5% and a flat fee of $16.80, by implementing a national, mandatory "model." (I note for the record that although CMS proposes a reimbursement rate of ASP plus 2.5% and a fee of $16.80, it knows all too well that the sequester cut makes the effective proposed rate ASP plus 0.86% and $16.53.) The Part B Model is bad public policy and sets a destructive and devastating precedent.

The Part B Model is Legally Invalid

In issuing the Part B Model, CMS relies on Section 1115A of the ACA. The Part B Model exceeds CMS' authority because, among other reasons: (A) the Part B Model is inconsistent with the express mandate of Section 1115A, (B) the Part B Model—by being mandatory in scope and affecting most

of the nation—is not a test or model, and (C) the Part B Model appears not to be based upon a model developed by CMMI, but rather initiated outside of CMMI.

The Secretary[5] *Has No Authority To Waive Medicare Provisions under the Part B Model*. As the Part B Model fails to meet the requirements for "testing," the Secretary has no authority to waive any requirements of the Medicare statute, especially the Part B payment provisions.

The Part B Model Raises Constitutional Concerns. Section 1115A would raise several constitutional concerns if the Secretary or CMS were allowed to modify or amend the Medicare statute, especially in view of the proposal's effect upon 75% of the country.

The Part B Model Contravenes Other Applicable Laws. The Part B Model violates Section 3601 of the ACA, as the implementation of the proposal would affect guaranteed Medicare benefits and other provisions.

As we expressed in a meeting with CMS and CMMI officials, COA is very supportive and open to working on value-based approaches to all facets of cancer care, including both services and drugs. However, for the reasons summarized above and explained in greater detail below, the premise and design of Phase 1 of the Part B Model is fundamentally flawed and must not be implemented. There is no way of changing the reimbursement scheme in Phase 1 of the Part B Model to make it acceptable for oncologists to ensure that they can provide safe and effective

[5] For purposes of the statute, "Secretary" is defined as the Secretary of Health and Human Services, *"except when the context otherwise requires."* 42 U.S.C. § 1301(6).

cancer care to their patients. The Part B Model, by focusing on costs alone, is patently unacceptable, as it ignores the potentially significant negative effects on quality and safety of patient care.

As with the OCM, CMS and CMMI must engage stakeholders, starting with patients and physicians, in an open, transparent, and constructive dialogue. The Part B Model Phase 1 must be withdrawn, and any discussions about a possible phase 2, must start with stakeholder input from the very beginning, not after CMS regulators have designed it internally.

Detailed Comments on the Part B Model

1. The Part B Model is Bad Medicine.

a. The Part B Model, is in actuality, a human clinical research experiment but without any of the required patient disclosure information and safeguards.

The purpose of Phase 1 of the Part B Model is to change the clinical decisions of oncologists and other physicians, as we previously noted. Yet, patients cannot opt out of the experiment and they do not receive any information about the research or their rights, let alone, any protection from the experiment. There is no real-time monitoring of quality impacts, adverse treatment events, and treatment outcomes.

b. The Part B Model inappropriately puts government regulators between physicians and patients in dictating clinical decision-making.

What this experiment is saying is that CMS believes it knows better than highly trained physicians and intends to influence or even dictate drug treatment choice rather than such choice residing with the patient's treating oncologist**.** Practicing physicians are in the best position to determine the care patients should receive in close consultation with them—not federal government regulators. This experiment is a misguided government intrusion on the treatment of seniors with cancer and a very dangerous precedent in severing the sacred physician-patient bond.

Make no mistake about it—CMS has designed the Part B Model not as a model of quality cancer care, like the OCM, but as a vehicle to circumvent existing law in a misguided attempt to lower Medicare Part B drug spending. However, in the process, it is inappropriately inserting itself between physicians and patients.

c. The Part B Model presents an experiment that is an operational nightmare and dangerous patient care, disadvantaging patients based on geography.

Given the enormity of implementing a national "model" for essentially all Medicare Part B drugs, CMS has clearly not considered the operational issues and implications for patient care. For example, it will be virtually impossible for CMS to ensure that every medical practice, not just community oncology practices, will be located entirely in either the test group or the control group. Given that practices have facilities in multiple states—for example, OHC, a community oncology practice based in Cincinnati, Ohio, has locations in two (2) states and serves patients from three (3) states—it will be virtually impossible to ensure practices are entirely in either test or control areas. This presents treatment dilemmas for the practice, not to mention a compromised

experimental design. Furthermore, patients who receive treatment in two locations, especially seniors who live in both the south and north by season, will possibly be treated both in a test location and a control location. These are not just pure operational issues; these issues have serious implications for quality patient medical care.

It is not a solution to simply exempt the practices selected to participate in the OCM from the Part B Model. Not only does this compound the operational nightmare described above, but also the surprise release of the Part B Model demonstrates that CMS can change the rules whenever it pleases.

2. The Part B Model is Flawed Economics.

a. The underlying premise of the Part B Model Phase 1 is fundamentally flawed.

The Part B Model contemplates cutting payments for Medicare Part B drugs for three-quarters of the country from ASP plus 6% to ASP plus 2.5% and a flat fee. This proposal is grounded in the CMS implied assumption that community oncologists practice medicine based on financial incentives, not the best interests of their patients.[6] This is not only highly offensive and

[6] CMS states on page 16 of the Part B Model: *"we intend to achieve savings through behavioral responses to the revised pricing, as we hope that the revised pricing will remove any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. In other words, we believe that removing the financial incentive that may be associated with the higher add-on payments will lead to some reduction in expenditures during phase I of the proposed model. An exact estimate of the amount of savings that might be achieved through behavioral responses is not readily available."*

derogatory, but also simply not grounded in fact.

Rather than relying on untested assumptions not based on facts and analyses, CMS should examine a UnitedHealthcare study in which certain community oncology practices participated. This study was designed to eliminate any perceived "incentive" to prescribe cancer drugs by paying for those drugs at acquisition cost (in this case, ASP). By eliminating this perceived "incentive," UnitedHealthcare sought to reduce overall costs of chemotherapy. The results, however, proved just the opposite. According to the published study results, *"[e]liminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy."* In fact, drug spending increased by 179%.[7]

In another study that analyzed oncologists' prescribing under the current Medicare Part B drug reimbursement system, researchers found that, *"[c]hanges in reimbursement after the passage of MMA appear to had less of an impact on prescribing patterns in FFS* [fee-for-service] *settings than the introduction of new drugs and clinical evidence as well as other factors driving adoption of new practice patterns."*[8]

Not only has CMS selectively chosen to ignore these findings, but the agency has also provided no substantive evidence to support its flawed assumption that oncologists prescribe more

[7] *Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model*. Journal of Oncology Practice, July 2014.

[8] *Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?* Journal of Oncology Practice, September 2014.

expensive cancer drugs due to financial "incentives."

I reiterate a point previously made in this testimony: in 2004, when Congress changed to the current ASP-based system, 84% of chemotherapy was delivered in independent community cancer clinics. By 2014, that figure had fallen to 54%, with the remainder delivered in the hospital outpatient setting.[9] If community oncology practices are "profiting" from cancer drugs, as CMS contends, why is cancer care significantly migrating to hospitals?

b. CMS is completely ignoring the real driver of Medicare Part B cancer drug costs.

We are totally perplexed that in discussing its purpose for the Part B Model, CMS states in the proposed rule that the "*significant growth*" in Part B drug spending *"has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion respectively*." So, why is CMS not focused on the hospital market where significant growth in spending has occurred, especially those that are "non-profit," yet extremely profitable, and 340B hospitals that now account for over 60% of all Part B hospital spending on cancer drugs?[10]

We note that 340B discounts on cancer drugs provide an enormous financial incentive for hospitals to acquire community oncology practices and profit from the difference between drug cost and Part B reimbursement. With discounts on drugs that are typically 30-50%, the 340B program

[9] See supra, n.2.

[10] *340B Growth and the Impact on the Oncology Marketplace: Update*. Berkeley Research Group, December 2015.

provides hospitals with upwards of 100% profit margins on cancer drugs. To put that in perspective, depending on the type of cancer treated when a 340B hospital acquires a five (5) physician community oncology practice, the hospital is able to bill substantially more for oncology drugs, providing significant additional pure profit of upwards of $10 million annually on cancer drugs alone to the hospital. Add to this the higher service and facility fees billed under the Hospital Outpatient Prospective Payment System ("HOPPS"), and the profitability to the hospital increases even more, as costs to Medicare and seniors increase dramatically. A recent study by the Berkeley Research Group ("BRG") found that in 2014, 340B hospitals cost Medicare 51% more on a per beneficiary per day basis for chemotherapy compared to community oncology practices.[11]

Studies by Avalere Health, BRG, Milliman, The Moran Group, as well as the GAO have specifically documented the higher cost of cancer care when delivered in outpatient hospital facilities. The cost to Medicare and beneficiaries is even higher in 340B hospitals, as reported by the GAO:

> *The financial incentive to maximize Medicare revenues through the prescribing of more or more expensive drugs at 340B hospitals also raises concerns... Not only does excess spending on Part B drugs increase the burden on both taxpayers and beneficiaries who finance the program through their premiums, it also has direct financial effects on beneficiaries who are responsible for 20 percent of the Medicare payment for their Part B*

[11] Id.

drugs. Furthermore, this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries.[12]

Another study by the GAO documented the significantly higher costs to beneficiaries and Medicare by the eleven (11) prospective payment systems ("PPS") exempt cancer hospitals ("PCH") compared with a comparable set of teaching hospitals. GAO found in part that:

In 2012, Medicare payments—both inpatient and outpatient—were substantially higher at PCHs than at PPS teaching hospitals in the same geographic area for beneficiaries with the same diagnoses or services. GAO estimated that...Medicare outpatient payment adjustments to PCHs resulted in overall payments that were about 37 percent higher, on average, than payments Medicare would have made to PPS teaching hospitals for the same set of services... If, in 2012, PCH beneficiaries had received inpatient and outpatient services at nearby PPS teaching hospitals—and the forgone outpatient adjustments were returned to the Supplementary Medical Insurance Trust Fund—Medicare may have realized annual savings of almost $0.5 billion. Until Medicare pays PCHs to at least, in part, encourage efficiency, Medicare remains at risk for overspending.[13]

We note that the PCHs were compared with teaching hospitals billing under the HOPPS, and therefore, cost beneficiaries and Medicare even more than cancer care provided in community

[12] *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.* The U.S. Government Accountability Office, July 2015.

[13] *Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency.* The U.S. Government Accountability Office, February 2015.

oncology practices.

In choosing to completely ignore the clear, documented consolidation of cancer care into the more expensive hospital setting, especially those with 340B discounts, CMS persists in accelerating cancer care cost increases to both Medicare and beneficiaries with the misguided Part B Model.

c. The Part B Model will severely restrict use of new, standard-of-care cancer treatments.

Not only is the underlying premise of the Part B Model fundamentally flawed, but also its purpose of paying for "value" is equally flawed in modern-day cancer care. To illustrate this point, COA worked with practicing medical oncologists and practice administrators to model the impact of the Part B Model. In the COA comment letter to CMS on the proposed rule on the Part B Model, we provided an analysis of three (3) standard-of-care treatments (i.e., cancer regimens) for specific cancers: breast, lung, and multiple myeloma. This analysis shows the significant reimbursement cuts to the most highly valued cancer drugs and significant payment increases for the lowest valued ancillary drugs, which is the exact opposite of paying for value. Generic drugs, such as diphenhydramine and dexamethasone, used to facilitate administration of the main cancer treatment drugs, such as Perjeta and Herceptin, will receive increased reimbursement, while the main treatment drugs receive decreased reimbursement.

Additionally, with the comment letter to CMS, we provided an analysis of over two hundred (200) drugs used in cancer treatment, including treatment drugs, supportive care agents, and treatment facilitating drugs. The analysis shows the drugs that would be cut and increased in payment in the

Part B Model. This list clearly shows that standard-of-care treatment drugs would be significantly cut in payment while older drugs and facilitating agents would be increased.

Furthermore, we also provided a list of forty-seven (47) cancer drugs that not only would be cut in reimbursement, but also would be "underwater"—that is, reimbursed less than their acquisition costs. These represent some of the most frequently prescribed cancer treatment drugs precisely because they are evidence-based, standard-of-care therapies.

There are very few situations in cancer treatment when alternative drugs exist that are differentiated in price/cost. So, the Part B Model, while ostensibly focused on controlling costs, is valuing less-important drugs—mostly facilitating agents—and not the most important, highest-valued cancer treatment drugs that are standard-of-care therapy. For example, Keytruda, the new immunotherapy that former President Jimmy Carter received as part of his treatment for metastatic melanoma, is significantly cut in reimbursement under the Part B Model and will be reimbursed at less than cost. Under the Part B Model, CMS is using financial disincentives to pressure physicians to not prescribe these newer therapies for seniors covered by Medicare, such as Keytruda, thus significantly reducing the "value" of the cancer care provided to Medicare beneficiaries.

As a side note, despite our country being in the middle of an opioid crisis, it is ironic that controlled substances reimbursed under Part B, such as morphine, would receive substantial increases in reimbursement. While Congress is working on legislation to tackle that crisis, it appears imprudent to increase reimbursement on controlled substances by almost 3,400% in one case. To us, this is

further evidence that CMS, in a rush to create the Part B Model with no stakeholder input, has failed to understand the unintended consequences of its regulatory actions.

3. The Part B Model is Destructive Policy.

a. The Part B Model is a dangerous abuse of regulatory policy. CMS is inappropriately using Section 1115A to effectively overturn existing law on Medicare Part B drug reimbursement.

The Part B Model is not a "model" as conceived by Section 1115A, the provision which created, empowered, and financed CMMI. According to the ACA:

> *The purpose of the CMI* [CMMI] *is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).*[14]

Furthermore, Section 1115A of the ACA states:

> *In carrying out the duties under this section, the CMI shall consult representatives of*

[14] Section 1115A(a)(1).

relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums . . .[15]

CMMI has taken over three (3) years, and it has consulted with varied stakeholders, including oncologists, patients, and experts, to develop its oncology payment reform model, the OCM. In fact, members of the COA Board of Directors participated in a MITRE Corporation and Brookings Institution technical expert process in the development of the OCM. Although community oncologists have concerns about certain design aspects of it, the OCM was developed in a deliberative, thoughtful process by CMMI.

This stands in stark contrast to the Part B Model, which we do not believe was initiated or conceived by CMMI and has not involved any stakeholders or expert opinion, and clearly does not fit the intent of the ACA. According to Section 1115A of the ACA:

The Secretary shall select models to be tested from models where the Secretary determines that there is <u>evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures</u>. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title.[16] (Underline emphasis added.)

[15] Section 1115A(a)(3).

[16] Section 1115A(b)(2)(A).

The Part B Model has nothing to do with outcomes or quality. It is simply a vehicle to circumvent Congress and its legislative action on Medicare Part B drug reimbursement—the MMA—that has defined Part B drug reimbursement as ASP plus 6%. This means that going forward, CMS can use Section 1115A to effectively overturn any existing Medicare law by simply designing and implementing a mandatory, national "model" to circumvent the law. Then, after the "model" demonstration period is completed, the underlying "model" being tested becomes law: in this case, Medicare Part B drug reimbursement will change from ASP plus 6% to ASP plus 2.5% and a flat fee.

4. Legal Issues and Reasons the Part B Model is Invalid.

In issuing the Part B Model, CMS expressly relies on Section 1115A for authority.[17] According to Section 1115A, the Secretary cannot select for testing any model it chooses. The Secretary is permitted to select for testing only *"models where 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."*[18] In addition to these criteria, in phase 1 of a test, the Secretary is required to undertake an evaluation of each model involving the *"quality of care furnished under the model, including measurement of patient-level outcomes . . . ,"* and

[17] In the Summary of the Part B Model, CMS states *"[t]his proposed rule discusses the implementation of a new Medicare payment model under section 1115A of the Social Security Act (the Act)."* 81 FR 48, 13230.

[18] Section 1115A(b)(2)(A).

changes in spending.[19] While the Secretary may waive specified statutory requirements in phase 1, such waiver is limited. The waiver applies only *"as may be necessary solely for purposes of carrying out"* (Underline emphasis added.) the testing in phase 1.[20]

If the Secretary elects to proceed to phase 2, Section 1115A expressly requires the Secretary to conduct rulemaking, and the Secretary may undertake phase 2 expansion only if the Secretary determines that such expansion is expected to reduce spending under Medicare without reducing the quality of care or improve the quality of patient care without increasing spending.[21] The Secretary cannot waive statutory requirements in phase 2 because the statute permits waivers *"solely for the purposes of testing."*[22]

Section 1115A was designed to encourage innovation in payment and service delivery models. However, this innovation is limited. For several reasons explained below, the Part B Model exceeds the statutory limits on phase 1 testing.

A. The Part B Model Exceeds CMS' Statutory Authority.

[19] Section 1115A(b)(4)(A)(i) and (ii).

[20] Section 1115A(d)(1) (*"The Secretary may waive [specified statutory requirements] as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)."*).

[21] Section 1115A(c).

[22] Section 1115A(d)(1).

The Part B Model is inconsistent with the express mandate of Section 1115A.

As discussed above, the Secretary cannot select for testing any model it chooses. The Secretary is permitted to select models for testing only where it determines *"deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."* This determination is to be made before selecting the models for testing, not during or after model testing. Having reviewed the Part B Model, there is no evidence to suggest that the Secretary has made a determination of any deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.

Moreover, Section 1115A expressly requires that a phase 1 testing model address a *"defined population for which there are deficits in care."*[23] While the Part B Model establishes a "test" area—beneficiaries in approximately 75% of the country who take a Part B drug—this does not address the requirements of Section 1115A. Specifically, Section 1115A does not permit the selection or designation of any test area. Rather, the Secretary must have determined in advance that the group to be tested has deficits in care. Merely statistically selecting areas without regard to this determination fails to meet the statutory requirements. This Part B Model ignores the statutory requirements, as it would cover beneficiaries in approximately 75% of the country who take a Part B drug, regardless of whether any of these beneficiaries has a *"deficit in care."* This is a random selection made without regard to the Secretary's statutory charge to select a *"defined population"* with *"deficits in care."*

[23] Section 1115A(b)(2)(A).

More importantly, the Part B Model focuses on cost aspects of care, not the quality, sufficiency, or effect on care. The Part B Model is devoid of any significant reference to the effects on care, let alone the provision of findings with regard to existing deficits of care.

a. The Part B Model—by being mandatory in scope and affecting most of the nation—is not a test or model.

CMS proposes to subject 75% of the country to the Part B Model. This proposal goes well beyond what could reasonably be considered a "test." A test is the essence of phase 1. Section 1115A contemplates a two-step process. A smaller test in phase 1, expanded through rule making if the following requirements are met:

> (1) *the Secretary determines that such expansion is expected to—*
>
> (A) *reduce spending under applicable title without reducing the quality of care; or*
>
> (B) *improve the quality of patient care without increasing spending;*
>
> (2) *the Chief Actuary of the Centers for Medicare and Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and*
>
> (3) *the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable titles for applicable individuals.*[24]

[24] Section 1115A(c)(1)-(3).

Despite the statutory mandate of Section 1115A, the Secretary has opted to bypass a controlled "test" geography, making this an "expansive" experiment affecting 75% of the country, without addressing the requirements set forth above. It is clear that by reading Section 1115A as a whole these requirements are expressly imposed upon the Secretary before it can make a test expansive, and these requirements cannot be ignored.[25]

While CMS cites a recent MedPAC[26] report suggesting an add-on model, it does not focus on an earlier 2012 MedPAC report, which discussed a concern about the scope of a test related to Medicare-Medicaid dual eligible models. Even though the planned scope of the dual eligible models was much smaller than the Part B Model—about 1/3 of dual eligibles—MedPAC expressed concern with the sample size as follows:

> *Most states pursuing the capitated model are proposing to enroll most or all dual-eligible beneficiaries in a state or entire subgroups of beneficiaries (such as disabled individuals under the age of 65) in a state into a* [demonstration] *health plan. However, the varied and complex needs of many of these individuals leads us to question whether care management models should be tested on large numbers of dual-eligible beneficiaries or entire subgroups within a state. In addition, the large scope also makes the demonstrations appear to be*

[25] "It is, however, a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute." Williams v. Taylor, 529 U.S. 362, 404 (2000) (internal quotations and citations omitted).

[26] See 81 FR 48, 13231 (citing MedPAC Report to the Congress: Medicare and the Health Care Delivery System (June 2015)).

large-scale program changes rather than true demonstrations.[27] (Underline emphasis added.)

Beyond the MedPAC report expressing alarm with regard to large test populations, courts have also stressed the need for tests to be of a controlled size and duration.[28]

The Part B Model goes well beyond a geography of limited duration and is exactly the type of test arrangement with respect to which MedPAC and the courts have expressed concern. Accordingly, the mandatory nature of a test constituting of 75% of the county is well beyond what the courts, MedPAC, and others have considered acceptable for testing and thus cannot constitute a test.

b. The Part B Model appears not to be based upon a model developed by CMMI, but rather initiated outside of CMMI.

[27] MedPAC, Report to the Congress: Medicare and the Health Care Delivery System (June 2012) at 64 (emphasis added).

[28] See Bay Ridge Diagnostic Laboratory, Inc. v. Dumpson, 400 F. Supp. 1104 (E.D.N.Y. 1975) (implementation of the program in limited locality under Section 1115); Am. Acad. Of Ophthalmology, Inc. v. Sullivan, 998 F.2d 377, 384 (6th Cir. 1993) (finding that "[t]he Demonstration does not alter or modify the whole Medicare program, it does not affect Medicare's coverage of all medical services, medical items, and health care provides. Instead, the Demonstration touches only cataract surgeries and, in fact, only specified varieties of cataract surgeries. Further, patient as well as health care provider participation is strictly voluntary in the Demonstration.") (emphasis added).

Section 1115A provides for the creation of CMMI within CMS. CMS itself has explicitly recognized the mandate for CMMI to develop models:[29]

> *"[p]ayment and service delivery models are developed by CMMI in accordance with the requirements of section 1115A of the Act. During the development of new models, CMMI builds on the ideas received from internal and external stakeholders and consults with clinical and analytical experts."*[30]

Despite the requirement that CMMI develop the models, CMS Deputy Administrator and Medicare Director Sean Cavanaugh, was quoted in an article appearing in InsideHealthPolicy on April 28, 2016. This article states that on April 11, 2016, in response to a question about whether President Obama personally directed CMS to weigh in on Part B drug prices with a pilot program, Mr. Cavanaugh stated *"[y]ou're correct, . . . [t]he president has been very supportive generally of the value agenda at CMS, and all of HHS for that matter, and was very much one to say 'don't leave out prescription drugs.'"*[31]

[29] Section 1115A further provides that *"[i]n carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties."* Section 1115A(a)(3).

[30] 80 FR 132, 39869.

[31] InsideHealthPolicy, *Senate Democrats Criticize Proposed Part B Drug Demonstration*, April 28, 2016.

CMS has publicly stated that CMMI is responsible for developing models, yet the statements of the Administration suggest strongly that CMMI did not develop this model. Accordingly, the Part B Model would not constitute a "model" under Section 1115A.

B. The Secretary Has No Authority to Waive Medicare Provisions Under the Part B Model.

In order for the Secretary to have the authority to "waive" requirements of Medicare, the Secretary must be doing so "*solely for the purpose of carrying out this Section with respect to testing models described in subsection (b).*" (Underline emphasis added.).[32] The Secretary has opted to bypass a limited test phase, instead implementing what amounts to a program change affecting, on a mandatory basis, 75% of the country.

Section 1115A (b) (4) is clear that any waiver authority of the Secretary, applies solely with respect to testing. As I have earlier discussed, the Part B Model is not a phase 1 "test" and, accordingly, the Secretary cannot use any waiver authority for this model. Thus, any attempt to change the reimbursement method for Part B drugs does not apply.

C. The Part B Model Raises Constitutional Concerns.

For the reasons described above, the Secretary cannot use the waiver authority in Section 1115A in the manner proposed. Assuming for the sake of argument that the Section 1115A waiver

[32] Section 1115A(d)(1).

provision did apply to the Part B Model and permitted the Secretary to waive the applicable Medicare provisions—which COA disputes—the attempted exercise of any such authority would raise serious constitutional concerns.

a. The waiver provision violates Article I of the Constitution.

The Secretary's proposal to waive the statutory payment mechanism for Part B drugs and substitute a new payment methodology through the Part B Model, is effectively a repeal of a statutory provision of the Medicare statute and enactment of what amounts to new statutory language. This raises significant constitutional concerns. The Supreme Court has recognized that *"repeal of statutes, no less than enactment, must conform to Art. I."*[33] Under the Constitution, legislation must be passed by both the House and Senate and signed by the President, absent the override of a veto.[34] These constitutional requirements also apply to repealing existing legislation.[35] Following this constitutional principle, the Supreme Court struck down the Line Item Veto Act, which permitted the President to cancel certain provisions of duly enacted statutes.[36]

[33] INS. v. Chadha, 462 U.S. 919, 954 (1983).

[34] U.S. Const., art. I, § 7.

[35] Chadha, 462 U.S. at 954.

[36] Clinton v. City of New York, 524 U.S. 417 (1998).

If Section 1115A were interpreted to permit the waivers in the Part B Model, Section 1115A would have the same constitutional concerns as the Line Item Veto Act. Also, it would present the added issue of CMS attempting to enact new statutory language to replace the provisions of the Medicare statute that the Secretary or CMS proposed to "waive" (*i.e.,* repeal).

b. The Part B Model raises additional constitutional concerns.

CMS bases its authority for the Part B Model on Section 1115A, which can be viewed as an unconstitutional delegation of legislative power. Article I, Section 1 of the Constitution, prohibits Congress from delegating its legislative powers to other bodies, including executive agencies like CMS.[37] Given this constitutional constraint, if Congress seeks to delegate its legislative power to an executive agency like CMS, the legislation must contain an "intelligible principle" to guide the agency's decision-making.[38] The requisite specificity of the "intelligible principle" depends on the amount of power that Congress is delegating.[39] In other words, the more power Congress is delegating, the more specific its guidance must be.[40] If the interpretation CMS proposes to give to Section 1115A is correct, then, in drafting Section 1115A, Congress failed to provide a sufficiently specific intelligible principle to CMS and CMMI to guide its decision making

[37] Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 472 (2001) (internal quotation omitted).

[38] Id.

[39] Id. at 475.

[40] Id.

(including with regard to the waiver authority), and, consequently, Section 1115A as interpreted by CMS and the Part B Model would be unconstitutional.

Further, the Part B Model denies those beneficiaries and others who are forced to participate in the Part B Model, the potential right to equal protection of the laws in violation of the Due Process Clause of the Fifth Amendment to the Constitution. The beneficiaries and others who are forced to participate in the model are not treated equally with those who are not required to participate. As explained above, among other things, the beneficiaries forced to participate will run the risk of receiving less favorable care than those beneficiaries who are not compelled to participate. Even assuming that the Part B Model is authorized by Congress, it is one situation to have a congressionally authorized, limited "test" of a new payment methodology; it is quite another situation to propose a scheme that treats 75% of the country disparately from the other 25%. The latter is, at a minimum, an abuse of discretion; and, more importantly, a direct violation of the right to equal protection of the laws.

Moreover, courts have long recognized the need to narrowly construe statutes to avoid constitutional challenges. CMS' interpretation of the statute to permit a large-scale application of the Part B Model to 75% of the country and implementation on a mandatory basis is inconsistent with the concept of a "test," and the language of the statute would need to be construed narrowly to avoid a violation of the Constitution.

D. The Part B Model Contravenes Other Applicable Laws.

a. The Part B Model contravenes Section 3601 of the ACA.

Even if CMS could be found to have the authority to implement the Part B Model and Section 1115A could be found to pass Constitutional muster, neither of which we believe, the Part B Model would violate Section 3601 of the ACA ("Section 3601"), as the implementation of the Part B Model would affect "guaranteed" Medicare benefits. Section 3601 prohibits another provision of the ACA from reducing "guaranteed benefits" under Medicare. Specifically, Section 3601 states:

> *Protecting Guaranteed Medicare Benefits. Nothing in the provisions of, or amendments made by, this Act shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act*.[41]

The Medicare statute expressly covers the provision of drugs under Part B of the Medicare law. While the term "guaranteed benefits" is not defined by Section 3601, beneficiaries are entitled to coverage for Part B drugs by Medicare and, as such, these benefits are "guaranteed" to beneficiaries.[42] Moreover, this provision embodies the assurance that the ACA would not reduce "guaranteed benefits" as advanced by the legislative members and the President when the passage of the ACA was being considered. Effectively, through the Part B Model, CMS is creating a mechanism for it to influence clinical decision-making and direct patients away from a guaranteed benefit. The consequences of CMS' proposal would be a violation of Section 3601.

[41] Pub. L. No. 111-148 (2010).

[42] See 42 U.S.C. §§ 1832 and 1842.

b. The Part B Model likely contravenes other laws.

Beyond the contravention of Section 3601, the Part B Model contravenes other laws. Among other things, the Part B Model likely impairs a Medicare beneficiary's right to select health care services as guaranteed under the Medicare Act. Specifically, 42 U.S.C. § 1395a provides:

> *Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services*.[43]

As I discussed earlier, the Part B Model attempts to steer physicians to select lower cost drugs for patients. Beneficiaries desiring these drugs from a particular physician may not be able to obtain them because of CMS' financial penalties imposed by the Part B Model upon the prescribing physician and, thus, the Part B Model impairs the beneficiary's selection right.

Closing Comments

Personally, I am very concerned—as are all affiliated with COA—about the increased cost of cancer care, especially escalating prices of drugs. I hear about drug prices all the time as do the oncologists, practice administrators, and other providers navigating an increasingly complex environment to provide cancer care to seniors and others. However, I call the Committee's attention to the study released earlier this year by the actuarial firm Milliman on the cost drivers

[43] 42 U.S.C. § 1395a(a).

of cancer care previously cited in this testimony. Although drugs are the most rapidly increasing cost component of cancer care, they only account for upwards of 20% of total spending on cancer care.[44] A Herculean effort that would reduce drug spending by 25%, would only reduce the overall cost of cancer care by 5%, which is not nearly enough to address the growing healthcare spending problem on cancer care. Therefore, it is critical that policy makers and regulators take a holistic view and consider all of the cost drivers of cancer care, including the increased costs attributed to the site of cancer care delivery.

As I have stated, the Part B Model will not address the problem of cancer drug costs. It will exacerbate it. Frankly, I am stunned that any physician, policy maker, regulator, or expressed advocate for seniors and cancer patients can support what is a clear experiment on patient care, without patient knowledge, understanding, and safeguards. The solution to address the cost of cancer drug pricing lies in the same path COA has been pioneering in paying for cancer care services and that is synching payment with value. However, a rush to do "something" about drug prices should not be an experiment that clearly presents a danger to cancer patients.

No one can say that COA is not committed to oncology payment reform. Currently, we have close to 70% of the OCM cancer facilities networked in a cooperative group to share information, enhance cancer care delivery, and ensure success of the CMMI OCM initiative. Additionally, we are working with private insurers on payment reform pilots and implementation of their OCM models. We are totally committed to transforming the payment for cancer care but only with a focus on quality cancer care delivery that places patients first. Unfortunately, the Part B Model

endangers patient care, will only increase costs to Medicare and its beneficiaries, and sets a terrible precedent that rattles the very foundation of the Constitution. Regardless of what side of the aisle you sit on, this should be a grave concern.

I once again thank the Committee for the opportunity of sharing my views on CMMI and the Part B Model. I will answer any questions the Committee has regarding this testimony.