



Submitted Testimony of Dr. Debra Patt on

The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective

Energy and Commerce Health Subcommittee Hearing

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Chairman Pitts and Ranking Member Green, thank you for the opportunity to testify today on behalf of Texas Oncology, The US Oncology Network, the Community Oncology Alliance (COA) and the American Society of Clinical Oncology (ASCO) before the Energy and Commerce Subcommittee on Health on the proposed "Part B Drug Payment Model," and H.R. 5122 sponsored by Congressman Larry Bucshon. The Members of the Health Subcommittee have been especially committed to the nation's cancer patients and care providers over the years and many of the Members on this Committee can take credit for policies that have shaped our world-class cancer care delivery system. Thank you for your dedication and support for Americans and their families fighting cancer and for those of us who work to help patients live longer, happier, healthier lives.

I'm honored to appear before the Committee today. My name is Dr. Debra Patt, and for the last 13 years I have spent the majority of my time taking care of cancer patients as a practicing medical oncologist. On an average day I treat around 30 patients in a 12 hour day. I also donate my free time in different capacities including serving on multiple research, informatics and practice boards, acting as editor-in-chief of the Journal of Clinical Cancer Informatics and various leadership roles in my practice, The US Oncology Network, COA and ASCO. Slightly

more than 50 percent of my patients rely on Medicare. Another 5-10 percent are either covered by Medicaid or are uninsured. Throughout the country, over 60 percent of cancer patients rely on Medicare. Many of our seniors fighting cancer today have complex cases with other diseases and medical conditions, and face sometimes great difficulties navigating the health care system. Fortunately, community oncology clinics, such as the one where I practice, provide access to high-quality, state-of-the-art care close to home at a more affordable cost compared to large health systems.

I am proud to be a part of community oncology—the most effective and successful cancer care delivery system in the world. After nearly 100 years of increasing cancer death rates in the United States, we are turning the corner in this fight: cancer mortality has fallen by 20 percent from a 1991 peak and there are now nearly 14.5 million cancer survivors alive in the US. Cancer patients from around the world seek care here because Americans benefit from the best cancer survival rates in the world. Reasons for the increased survival rate are due in large part to earlier detection, breakthrough treatment options, such as immunotherapies, and the dedication of the nation’s oncology providers.

Despite significant progress in treatment and survival rates, we still have a long way to go in beating this terrible disease. The American Cancer Society estimates that in 2014 nearly 1.7 million Americans will be diagnosed with cancer and more than 595,000 will die of cancer, which is 1 out of every 4 deaths in America. These statistics underscore why the timing, scope, and fundamental structure of the “Part B Drug Payment Model” will be devastating to the advancements made in our continued fight against cancer.

I believe most oncologists share the Administration's concern with the rising cost of cancer care and its impact on Medicare beneficiaries and the Medicare program's sustainability. As community-based cancer care providers, we are well aware that cancer continues to be one of our nation's most costly, serious, and prevalent chronic conditions. The National Cancer Institute states that the U.S. spent over \$125 billion on cancer care in 2010 and projects that cancer care costs will increase to \$156 billion by 2020.¹ With Medicare beneficiaries making up 60 percent of the 14 million Americans living with cancer, and considering the elderly are 10 times more likely to have cancer than the younger population², Medicare must be heavily invested in ensuring access to beneficiaries for high-quality, innovative cancer treatment options close to home.

With all the media attention on the increasing costs of cancer care, especially the prices of new cancer drugs, it is very important for the Committee to understand a recently released study by the actuarial firm Milliman. It shows that from 2004 through 2014 Medicare's cost of treating cancer patients rose at a rate that was no greater—I underscore the words “no greater”—than spending on all Medicare patients, regardless of disease or medical condition.³ And, in fact, if the site of cancer care had not shifted from physician-run community cancer clinics to outpatient hospital departments during this period the per-beneficiary cost of treating a cancer patient would have risen at a lower rate than for all Medicare beneficiaries.⁴ Results from this landmark study should be very important in guiding the Committee's specific response to CMS' proposed “Part B Drug Payment Model” and overall work on solutions to strengthening our nation's cancer care delivery system.

¹ The National Cancer Institute <http://www.cancer.gov/about-cancer/what-is-cancer/statistics>

² <http://www.allhealth.org/briefingmaterials/CancerandMedicareChartbookFinalfulldocumentMarch11-1412.pdf>

³ *Cost Drivers of Cancer Care: A Retrospective Analyses of Medicare and Commercially Insured Population Claim Data 2004-2014*, Milliman, April 2016.

⁴ Id.

The “Part B Drug Payment Model,” which is aimed at reducing Medicare drug spending is ill-conceived and, most importantly, lacks a patient-centered focus. I am disappointed that CMS has masked their efforts to control rising drug costs by suggesting physicians are not providing their patients with the most appropriate, highest quality medical care but instead prescribe more expensive drugs for “profit.” CMS is absolutely incorrect in its assumptions that reducing reimbursements for Part B drugs will both lower Medicare costs and drug prices. In fact, looking at the oncology landscape documents that the reimbursement cuts proposed by CMS in Phase 1 of the “Part B Drug Payment Model” will actually increase Medicare costs and further fuel drug prices—the exact opposite of what CMS intends. More fundamentally, CMS’ proposal is an experiment on the care of seniors with cancer and other diseases that will hinder their access to life-saving/prolonging new treatment advances, such as the new immunotherapy that has former President Carter’s cancer in remission.

Today, 7 of the top 10 drugs that account for 48 percent of Part B drug spending are used to treat and cure cancer. Limiting an oncologist’s ability to provide current, cutting-edge treatments, as will occur if the “Part B Drug Payment Model” is implemented, will likely result in inferior outcomes for Medicare beneficiaries with cancer. As a provider caring for Medicare beneficiaries diagnosed with cancer, I believe the proposed “Part B Drug Payment Model” is unworkable and ask Congress to please stop this experiment on seniors with cancer and other serious diseases treated with Part B drugs.

I will use my time with you today to discuss why nationwide oncologists agree that the “Part B Drug Payment Model” will work counter to CMS’ goal of reducing costs and improving outcomes for cancer patients and will be detrimental to the medical care provided to the most vulnerable populations—seniors and disabled individuals covered by Medicare.

Oncology Care Model versus “Part B Drug Payment Model”

As a physician, I strive to demonstrate value, improve quality, strengthen patient outcomes, and hold down cancer care costs every day. Community oncologists appreciate programs and models that strive for those goals, as witnessed by the numerous oncology payment models already being implemented with payers such as Aetna, Cigna, Horizon, Humana, PriorityHealth, and UnitedHealthcare, as well as Medicare. In 2013, CMS reached out to the oncology community with the goal of developing an alternative payment model to manage the quality and costs of cancer treatment. My oncologist colleagues and I welcomed this opportunity and assisted the Center for Medicare and Medicaid Innovation (CMMI) in creating and developing the Oncology Care Model (OCM), an episode-based payment model aimed at improving coordination, appropriateness of treatment, and access to care for Medicare beneficiaries undergoing chemotherapy. It was a collaborative effort that involved outside experts, such as the MITRE Corporation and Brookings Institution, and considerable input from oncology providers, patients, and payers.

Unfortunately, CMS took the opposite approach in crafting and announcing the proposed “Part B Drug Payment Model.” The model was introduced to the oncology community for the first time when it was released on March 11, 2016. Oncologists, patients, and others had absolutely no input on the proposed model. While community oncology practices across the country were waiting to hear if they would be accepted into the OCM, CMS revealed the proposed “Part B Drug Payment Model.”

The contrast between the 3 years of collaborative, transparent effort in developing the OCM and the secretive, surprise introduction of the “Part B Drug Payment Model,” obviously developed entirely within CMS and CMML, cannot be more stark.

Given the significant time, resources, and collaboration that went into developing the OCM, I question how CMS will effectively implement and manage these two separate payment models with two distinct and individual goals, not to mention the coming implementation of the new physician payment system under the Medicare Access and CHIP Reauthorization Act (MACRA). I truly believe all these conflicting payment models will have natural consequences on the cancer care delivery system, complicating patient care and making it virtually impossible to measure the results of these payment initiatives.

An Experiment on Patient Care that is Bad Medicine and Unworkable in Cancer Care

Step back for a moment and consider what CMS is proposing in Phase 1 of the “Part B Drug Payment Model.” CMS believes that I, trained at MD Anderson Cancer Center and board-certified in medical oncology, am not treating my patients correctly. I am motivated to use the most expensive drugs, not the most appropriate, effective drugs for my patients. So, they propose to conduct a test to use financial disincentives to change my clinical decision making. Three-quarters of the country will be in a “test” arm and the remainder in the “control” arm. Primary care service areas, which are a collection of zip codes, will be randomized to these “test” and “control” arms. This experiment is clinical research, something I am very familiar with from daily practice. Yet, this is a mandatory experiment, where patients cannot opt out of and receive no “informed consent” on the research and their rights, as is mandatory in all ethical clinical research. As importantly, there is no real-time

monitoring of adverse events, outcomes, or quality. Phase 1 of the “Part B Drug Payment Model” is an experiment on the cancer care of seniors but without all the accepted patient safeguards.

More fundamentally, what CMS is proposing is unworkable in modern-day cancer care. There are few treatment situations where there are true clinical substitutes, with one costing less than the other. For example, multiple myeloma is a cancer of the bone marrow that without treatment has an average survival of 7 months. In the last 13 years the introduction of innovative therapies like bortezomib and lenalidomide has changed the average 3 year survival of myeloma patients from 50% to greater than 88%. It is now common to see patients living with multiple myeloma as a chronic disease for more than a decade. Avoiding these novel high cost therapies in myeloma would cost myeloma patients years of survival⁵.

Phase 1 of the “Part B Drug Payment Model” places the oncologist in an impossible situation. CMS is using a substantial financial disincentive to block use of the most appropriate, often more expensive, standard-of-care treatment in favor of a less appropriate therapy, if one exists at all. This is simply bad medicine.

No Evidence for Phase 1 of the “Part B Drug Payment Model”

While the OCM seeks to incentivize improved care coordination for a six-month episode of chemotherapy, the “Part B Drug Payment Model” is only focused on reducing Medicare drug spending.

⁵ Kumar SK, Rajkumar SV, Dispenzieri A, Lacy M, Hayman S, Buadi F, et al. Improved survival in multiple myeloma and the impact of novel therapies. *Blood*. 2008;111:2516–2520. *Br J Haematol*. 2012 Feb;156(3):326-33. doi: 10.1111/j.1365-2141.2011.08949.x. Epub 2011 Nov 23. A comparison of lenalidomide/dexamethasone versus cyclophosphamide/lenalidomide/dexamethasone versus cyclophosphamide/bortezomib/dexamethasone in newly diagnosed multiple myeloma. Khan ML1, Reeder CB, Kumar SK, Lacy MQ, Reece DE, Dispenzieri A, Gertz MA, Greipp P, Hayman S, Zeldenhurst S, Dingli D, Lust J, Russell S, Laumann KM, Mikhael JR, Leif Bergsagel P, Fonseca R, Vincent Rajkumar S, Keith Stewart A

In the proposed rule, CMS recommends Phase I of the “Part B Drug Payment Model,” which is a reduction in the Part B drug reimbursement rate, because the agency believes that providers’ prescribing decisions are influenced by reimbursement incentives for higher priced drugs. Yet, CMS has yet to produce any evidence indicating that physician prescribing patterns show any correlation to that of choosing higher priced drugs as opposed to appropriate therapeutic treatment for patients. Additionally, there is no evidence that the payment changes contemplated by CMS’ model will improve the quality of care, or for that matter, ensure patients have access to the same level of care they are currently receiving.

In fact, data suggest that the current Part B drug payment system has been both cost effective and successful in ensuring patient access to their most appropriate treatment, as Part B expenditures remain relatively stable⁶ and Part B drugs account for just 3 percent of total program costs.⁷

Additionally, there is no evidence that the payment changes contemplated in the “Part B Drug Payment Model” will reduce spending. In fact, a recent UnitedHealthcare project, which eliminated any financial benefit from drugs for participating community oncology practices, proved the opposite. According to the study, “eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy.” The spending on drugs increased by 179 percent.⁸ It is critical to note that, although spending on drugs increased by a substantial amount, total cost of medical care decreased by more than 30 percent. This intervention focused on the entire system of

⁶ 2015 Medicare Trustees Report

⁷ Medicare Payment Advisory Commission, “Medicare Drug Spending;” presentation at September 2015 public meeting; available at: <http://www.medpac.gov/documents/september-2015-meeting-presentation-medicare-drug-spending.pdf?sfvrsn=0>.

⁸ Journal of Oncology Practice: Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model. Available at: <http://jop.ascopubs.org/content/10/5/322.full>

care delivery and not solely on the cost of drugs. 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.”⁹

Any government led initiative on significant payment reform must have the appropriate supporting data before nationwide changes to the delivery system are employed. While CMMI has broad authority, any initiatives should be developed and implemented in a more targeted, contained, patient-centered, and transparent way that accounts for the unique needs of Medicare patients and with input from affected stakeholders. Medicare beneficiaries with cancer must be assured the appropriate patient safeguards are in place for any mandatory payment and delivery reform that has the potential to impact their access to care and treatments.

Understanding of the Current Part B Reimbursement Model

Another important piece to note from the “Part B Drug Payment Model” is the incorrect assumption CMS makes about the rate at which physicians are currently reimbursed for Part B drugs.

Specifically, in the proposed rule, CMS states that “we have chosen a 2.5 percent starting point because we agree with MedPAC’s assessment that this value should be sufficient to cover markups from wholesalers, such as prompt pay discounts that are not passed on to the purchaser.” While CMS has included the 2.5 percent to address the prompt pay discount it has not accounted for the 2 additional factors that significantly diminish reimbursement under Part B. These are:

⁹ *Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?* Journal of Oncology Practice, September 2014.

- 1) The 2 percent Medicare sequester cut that CMS decided to apply to the underlying cost of Part B drugs and;
- 2) The six-month lag that occurs between the time when drug prices change in the market place and when CMS updates ASPs.

CMS knew when it proposed the Phase 1 “Part B Drug Payment Model” experimental reimbursement rate of ASP plus 2.5 percent and a flat fee of \$16.80 that the sequester cut alone reduces the real rate to ASP plus 0.86 percent and \$16.53. The impact of the prompt pay discount and the ASP lag places the rate effectively “underwater”—that is, most treatment drugs will be reimbursed less than their acquisition cost. Hopefully, you can understand that this is an unsustainable situation where independent practices could simply not stay financially viable if they do not stop treating Medicare patients.

Additionally, it is important to note that smaller practices purchase many Part B drugs over ASP. These practices are not able to gain price advantages such as volume related discounts available to hospitals and large practices. It is often hospitals that receive Medicaid rebates, 340B discounts, and better prices on drugs, due to the volume of purchase. Many of community oncology practices are currently paying well above ASP for drugs, which is why in oncology we have experienced practice closings and mergers with hospitals over the past 10 years. Further impacting community-based practices are state taxes levied on prescription medicines, gross receipts, and provider services. Any further reductions to reimbursement will make it impossible for them to cover the acquisition cost of many, if not most, cancer treatments.

Site of Service Shift

This Committee is well aware of the recent trend in hospital acquisitions of physician practices and how this has resulted in access and cost issues for Medicare beneficiaries. I would like to commend the Committee for its efforts in understanding and exploring payment differentials and the incentives for hospitals to purchase physician practices. More specifically, I appreciate the work of Congressman Pompeo and others on the Committee for their efforts to ensure patient access to the community-based oncology setting by leveling the playing field in reimbursement for cancer care with the *Medicare Patient Access to Treatment Act* (H.R. 2895).

In an era of hospital acquisitions and consolidation in the oncology space, drastic changes in reimbursement, like those being proposed in the “Part B Drug Payment Model,” will most certainly further push oncology care into the hospital outpatient setting. I note that treating patients in community-based cancer clinics, as opposed to the outpatient hospital setting, results in significantly lower costs to both patients and the Medicare program.

Unfortunately, over the last decade there has been a marked shift in the site of cancer care from independent community cancer practices to more expensive outpatient hospital departments (HOPDs). In 2004, 84 percent of chemotherapy was administered in community cancer clinics but that has fallen to 54 percent by 2014.¹⁰ In 2014, Medicare spending on a per-beneficiary basis for patients receiving chemotherapy was 34 percent higher in HOPDs than independent community oncology practices.¹¹

It is not just the Medicare program paying more for these services, patient out-of-pocket costs are approximately 10 percent lower in community clinics, equaling more than \$650 in savings for each

¹⁰ See *supra*, n.4.

¹¹ See *supra*, n.4.

Medicare beneficiary fighting cancer per year. Additionally, the average out-of-pocket patient cost for commonly used cancer drugs is \$134 less per dose if received in an oncologist's office.¹²

These costs add up. Between 2009 and 2012, Medicare beneficiaries paid \$4.05 million more in out-of-pocket costs because of the higher patient co-payment due to the HOPD for chemotherapy services that could have been performed at a community cancer practice for a fraction of the cost.¹³

This February, a study released by the Health Care Cost Institute, confirmed that increased medical provider consolidation with hospitals and/or health systems results in increased spending on outpatient prescription drug-based cancer treatment. Specifically, that study found that "a one percent increase in the proportion of medical providers affiliated with hospitals and/or health systems is associated with a 34 percent increase in average annual spending per person and a 23 percent increase in the average per person price of treatment."¹⁴

The cost to Medicare of the shift in the site of cancer care is staggering. Looking at just chemotherapy costs alone, if the shift from independent community oncology practices to HOPDs from 2004 to 2014 had not occurred the costs to Medicare of chemotherapy alone would have been \$2 billion less in just 2014.¹⁵

CMS is well aware of this data and the shift of care, especially as it relates to cancer, as I was accompanied by several of my oncologist colleagues in reviewing it with officials from CMS and

¹² Milliman, "Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy," October 2011.

¹³ Berkeley Research Group, "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration," June 2014.

¹⁴ Health Care Cost institute: The Impact of Provider Consolidation on Outpatient Prescription Drug-based Cancer Care Spending; February 25, 2016.

¹⁵ See supra, n.4.

CMMI. It is unfortunate CMS does not seem to recognize this proposal would force some oncologists to close their community-based practices or consolidate with hospital systems that can negotiate much better rates on drugs and charge more for the same service, especially the 50 percent of hospitals with 340B discounts with upwards of 100 percent profit margins on cancer drugs. It is clear, based on empirical evidence and data that the “Part B Drug Payment Model” would end up costing Medicare and the entire health care system more than they hope to save with this proposal.

Value-Based Care

Oncologists have been leaders in the field of medicine when it comes to value-based care. We have worked hard to put systems, pathways, models, and treatment plans in place that provide high quality health care at a lower rate. We applaud CMMI and CMS for looking towards value-based care, and would welcome the opportunity to have a real discussion about what value-based care could look like in the oncology space. I have chaired the breast cancer pathways for The US Oncology Network for a decade and recognize this system as an effective way to deliver excellent cancer care. By using systems to incorporate efficacy, toxicity, and cost (in terms of comparative effectiveness), the pathways system facilitates compliance with evidence based guidelines and value based decision making.

As I continue to actively participate in crafting the scientific and policy agendas at the largest cancer organizations across this county, The US Oncology Network, COA and ASCO, we strive to find more value in cancer care every day. Our organizations have taken concrete steps to achieve this goal. The US Oncology Network has developed value-based pathways that serve to strengthen relationships with patients and payers by choosing regimens that demonstrate value and reduce non evidence-based variability in treatment. ASCO has put forward the Patient Centered Oncology

Payment (PCOP) model and—for more than a decade—has helped oncologists measure and improve performance through the Quality Oncology Practice Initiative (QOPI), and the QOPI Certification (QCP) program. As a board member for COA and in partnership with this Committee, we help craft a bipartisan congressional oncology payment reform bill, the *Cancer Care Payment Reform Act* (H.R. 1934), based on the Oncology Medical Home—a model actually successfully tested by CMMI in enhancing the quality of care and reducing costs. I want to thank Congresswoman Cathy McMorris Rodgers on her commitment to cancer care with this legislation.

There is no shortage of ideas from the oncology community on how we can drive value in cancer care. This Committee has been very open to those ideas and committed to preserving access to high-quality, affordable health care. As CMS and CMMI look to change those dynamics and dictate a top down approach with no input from stakeholders, it will become extremely hard for community oncologists to continue practicing appropriate medicine.

Conclusion

The National Cancer Institute estimated that there were approximately 13.7 million Americans living with cancer in the U.S. last year. About 8 million of those are over the age of 65 and approximately half of all cancer spending is associated with Medicare beneficiaries.¹⁶ As the baby boomers continue to age, this challenge will only become greater. Now is the time for Congress to ensure Medicare beneficiaries can continue to get the care they need—in the communities where they live and work—and that their providers have the tools and ability to choose the best treatment plan for their unique circumstances. The government should be

¹⁶ Mariotto AB, et al. Projections of the Cost of Cancer Care in the United States: 2010–2020, *J Natl Cancer Inst* 2011;103:1–12. Online at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3107566/>

helping us deal with the expanding cancer population, not throw obstacles in our way, such as the “Part B Drug Payment Model.”

Please know that community oncology providers stand ready to partner with CMS and CMMI on value-based strategies for cancer care, including ways to address cost of drugs and services. We remain concerned with the increased cost of cancer care, especially as it relates to escalating drug prices, but any reform efforts must first do no harm—and must assure Medicare patients’ access to care that is vital to their quantity and quality of life. The proposed “Part B Drug Payment Model” does neither.

On behalf of oncologists nationwide, I appreciate the Committee’s leadership and dedication to our nation’s health care system in examining this issue. Thank you to those that have weighed in with CMS on your concerns with the proposed rule, and thank you to Congressman Bucshon for sponsoring H.R. 5122, which would prohibit the proposed “Part B Drug Payment Model” from advancing. It is important to look at the big picture: I believe there are serious flaws in the proposal that could affect our most vulnerable seniors in the middle of treatment. CMS should work with oncologists, and all affected stakeholders, especially patients, in crafting true value-based treatment going forward. When community cancer clinics close their doors, access to care is compromised for all cancer patients, but especially for our vulnerable seniors. The continued shift to hospital-based care doesn’t just reduce access to care for cancer patients, especially in rural areas, but it also increases costs to Medicare, taxpayers, and beneficiaries.

Finally, in addition to H.R. 2895 and H.R. 1934 mentioned above, I would like to highlight and thank several members of this Committee who have written legislation and signed letters that assist in preserving community cancer care. Specifically, H.R. 696, sponsored by Congressmen Whitfield, Green, and DeGette, which would result in a more accurately aligned Part B drug reimbursement by removing any discount between the manufacturer and distributor that is included in ASP but not passed on to the provider. H.R. 1416, introduced by Congresswoman Renee Ellmers, which would remove CMS' decision to apply the 2 percent sequestration cut to the underlying cost of cancer drugs. On behalf of all the community cancer clinics struggling to keep their doors open, I urge the Committee and the Congress to enact these pieces of legislation to sustain community cancer care. Without your action, community cancer clinics will continue to close and care will continue to shift to the more expensive, less-accessible hospital outpatient setting. Americans fighting cancer will experience diminished access to care, and patients, payers, and taxpayers will pay more.

My oncology colleagues across the country and I are doing our very best to help patients fight cancer, and win. In order to continue to provide the world's best cancer care in America, we need your help. Once again, thank you for the opportunity to address the Committee. I am happy to answer any questions the Committee has regarding my testimony.