



March 9, 2016

Mrs. Sylvia Burwell  
Secretary  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Mr. Andy Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

On behalf of the Board of Directors of the Community Oncology Alliance (COA), I am writing to express our vehement opposition to any implementation of the Centers for Medicare & Medicaid Services (CMS) *Medicare Part B Drug Payment Model* by the Center for Medicare & Medicaid Innovation (CMMI). In short, we believe the CMS *Medicare Part B Drug Payment Model* is an inappropriate, dangerous, and perverse mandatory experiment on the cancer care of seniors who are covered by Medicare.

The CMS *Medicare Part B Drug Payment Model* is in fact not a "model" as conceived by Section 3021/11115A of the *Patient Protection and Affordable Care Act* (ACA) that 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)."*

Furthermore, the ACA states:

*"In 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."*

CMMI has taken well over 2 years, and consulted with varied stakeholders, including oncologists, patients, and experts, in developing its oncology payment reform model, the *Oncology Care Model* (OCM). In fact, members of the COA Board and I participated in a MITRE Corporation and Brookings Institution technical expert process in the development of the OCM. Our practice has applied to be a participant in the voluntary 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 CMS *Medicare Part B Drug Payment Model*, which we do not believe was initiated or conceived by CMMI, has not involved any stakeholders or expert opinion, and clearly does not fit the intent of the ACA. According to the ACA:

*“The Secretary shall select models to be tested from 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. [Underline added for emphasis] 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.”*

**The CMS Medicare Part B Drug Payment 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 Medicare Modernization Act (MMA) – that has defined Part B drug reimbursement as average sales price (ASP) plus 6 percent.** For years, the President’s annual budget has contained a cut to Part B drug reimbursement but, fortunately, Congress has always wisely rejected that as misguided.

The proposed cut to the ASP plus 6 percent drug reimbursement rate to ASP plus 2.5 percent plus a flat fee is based on an insulting assumption that community oncologists practice medicine solely by financial incentives, not by what is in the best interests of their patients. This is not only highly offensive and derogatory, but also simply not grounded in fact. CMS should examine a UnitedHealthcare study our practice participated in designed to eliminate any supposed “incentive” to prescribe cancer drugs. The results proved the exact opposite of the CMS assumption. According to the study, *“Eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy.”* In fact, drug spending increased by 179 percent.<sup>1</sup>

I also call your attention to two major cuts that CMS has already made to Medicare Part B drug reimbursement that have effectively lowered payment for cancer drugs today to ASP plus 2 percent. First, when the MMA changed reimbursement for Part B drugs, the majority of which are used in the treatment of cancer, CMS incorrectly interpreted the MMA and mandated that pharmaceutical manufacturers include “prompt pay” discounts they provide to drug wholesalers in the calculation of ASP. Because these discounts are not passed on to providers – they are financing discounts between manufacturers and wholesalers for prompt payment – but are included in the calculation of ASP, they artificially lower the Medicare reimbursement rate for cancer drugs from ASP plus 6 percent to closer to ASP plus 4 percent. Then, when CMS inappropriately applied the 2 percent sequester cut to Medicare drug reimbursement, even though the Medicare drug reimbursement rate is fixed in statute by the MMA, that lowered payment for cancer drugs further, close to ASP plus 2 percent.

**Now, CMS is proposing that the Medicare Part B drug reimbursement rate in at least three-quarters of the country be arbitrarily cut to ASP + 2.5 percent. Factoring in the impact of prompt pay discounts and Medicare sequester cut, this would effectively result in drug reimbursement below ASP.**

Make no mistake about it, these misguided CMS cuts to Part B drug reimbursement have resulted in the consolidation of the U.S. cancer care delivery system into the more expensive hospital setting. From 2006 through 2014, COA tracked 544 community oncology practices (in almost all cases consisting of multiple clinic locations) that have merged or become affiliated with hospitals.<sup>2</sup> An analysis of this data shows that 3 out of 4 acquisitions from 2013 to 2014 were by hospitals participating in the 340B drug discount program. A study of Medicare data by The Moran Company found that in 2005 87 percent of chemotherapy was administered in community oncology practices but by the end of 2011 it had declined to 67 percent.<sup>3</sup> We have data from a study now in progress that shows in 2014 this had fallen to 54 percent, with 46 percent administered in Hospital Outpatient Departments (HOPDs), half of which now receive 340B discounts.

<sup>1</sup> *Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model*. Journal of Oncology Practice, July 2014.

<sup>2</sup> *Community Oncology Practice Impact Report*. Community Oncology Alliance, October 2014.

<sup>3</sup> *Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries*. The Moran Company, May 2013.

If CMS is correct in its belief that community oncology practices are incentivized to use more expensive drugs because of profits from the multiplier on ASP, then why is cancer care shifting to the hospital setting? We will answer that in three parts.

First, the multiplier on ASP, as we have documented, is in reality not 6 percent; it is closer to 2 percent. This is due to CMS requiring pharmaceutical manufacturers to include prompt pay discounts (not passed on to providers) in the calculation of ASP, as well as the application of the sequester cut to Medicare drug payments based on ASP. Additionally, the ASP multiplier is a service fee that has to cover the very real costs of drug procurement, handling, storage, inventory, preparation, and waste disposal. The net result is that now, even before this latest CMS payment cut, many cancer drugs are actually reimbursed by Medicare at less than cost. There is simply no financial incentive.

Second, hospitals have had huge economic incentive to purchase community oncology practices due to CMS' continued disparity in payments between HOPDs and community oncology practices. The data is startlingly clear: acquiring existing community oncology practices is the fastest, most efficient way for hospitals to expand cancer treatment services and increase profits. Once acquired, any off-campus facilities can then be billed under the more expensive Medicare Hospital Outpatient Prospective Payment System (HOPPS), as well as generally much higher private insurance contracts.

Thankfully, Congress has stepped in to correct a portion of this payment disparity going forward with a site-neutrality provision in the Bipartisan Budget Act, which was signed into law last year. However, payment disparities still remain. For example, a commonly billed oncology service is the first hour of chemotherapy administration. **The hospital billing (APC code) for this service under the HOPPS is 105.9 percent higher than the physician billing (CPT code) under the Medicare Physician Fee Schedule.** We analyzed the top billed oncology codes for the administration of chemotherapy and the results show that **Medicare pays 75.2 percent more for the same services when provided in HOPDs versus community oncology practices.** Additionally, HOPDs bill "facility fees" that further increase how much more Medicare overpays for cancer care in the hospital setting. Most importantly of all, these increased costs are then passed on to seniors who are responsible for the 20 percent Medicare co-payment.

A study by Milliman in 2011 found that Medicare pays \$6,500 more and senior beneficiaries pay \$650 more out-of-pocket on an annualized basis for just chemotherapy administered in HOPDs versus when administered in community oncology practices.<sup>4</sup> Just this month yet another study was published on the issue by the Health Care Cost Institute and National Academy for State Health Policy. Conducted by researchers at the University of Chicago, the study not only documented the consolidation in outpatient cancer treatment but also found that a *"one percentage increase in the proportion of medical providers affiliated with hospitals and/or health systems is associated with a 34 percent increase in average per person annual spending and a 23 percent increase in average per person price of treatment."*<sup>5</sup>

Third, 340B discounts on cancer drugs provide enormous financial incentive for hospitals to acquire community oncology practices. With discounts on drugs that are typically 30 to 50 percent, the 340B program provides hospitals with upwards of 100 percent profit margins on cancer drugs. To put that in perspective, depending on the type of cancers treated, an average oncologist accounts for \$4 million dollars of drugs per year. When a 340B hospital acquires a 5-physician community oncology practice, the practice provides \$6 million to \$10 million in pure profit annually on cancer drugs alone to the hospital. Add to this the higher service and facility fees billed under the 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 found that in 2014, 340B hospitals cost Medicare 51 percent more on a per beneficiary per day basis for chemotherapy compared to community oncology practices.<sup>6</sup>

Studies by Avalere Health, The Moran Group, as well as the U.S. Government Accountability Office (GAO) have specifically documented the higher cost of cancer care when delivered in HOPDs. The cost to Medicare and beneficiaries is even higher in 340B hospitals, as reported by the GAO:

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<sup>4</sup> *Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy*. Milliman, October 2011.

<sup>5</sup> *The impact of provider consolidation on outpatient prescription drug-based cancer care spending*. Health Care Cost Institute, February 2016.

<sup>6</sup> *340B Growth and the Impact on the Oncology Marketplace: Update*. Berkeley Research Group, December 2015.

*“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 drugs. Furthermore, this incentive to prescribe these drugs raises potential concerns about the appropriateness of the health care provided to Medicare Part B beneficiaries.”<sup>7</sup>*

Another study by the GAO documented the significantly higher costs to beneficiaries and Medicare by the 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.”<sup>8</sup>*

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 oncology practices.

**It is extremely disconcerting that CMS persists in its misguided focus of cutting drug and service reimbursements to community oncology practices while turning a blind eye to the unmistakable fact that the consolidation on our nation’s cancer system into hospitals – especially those with 340B discounts – is what is really costing Medicare, seniors, and taxpayers more for cancer care.**

In choosing to completely ignore the clear, documented consolidation of cancer care into the more expensive hospital setting, CMS persists in accelerating cancer care cost increases with the misguided CMS *Medicare Part B Drug Payment Model*. It is hypocritical that CMS, which justifies this model based on so-called “incentives” for community oncologists to use more expensive drugs, is proposing to use financial incentives to actually shift drug treatment choice.

**What this experiment is saying is that CMS believes it knows better and intends to dictate drug treatment choice rather than the patient’s treating oncologist.** As practicing physicians, we are in the best position to determine the care our 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. And make no mistake about it – CMS has designed the *Medicare Part B Drug Payment Model* not as a model of quality cancer care, like the OCM, but as a blind experiment to force cancer treatment to meet CMS’ definition of value; not the best, most appropriate cancer treatment as determined by oncologists in collaboration with their patients.

If CMS is truly interested in successful ways to reduce the cost of cancer care, it should look at the payment reform initiatives community oncology practices across the country have been leading the way in for years. For example, our practice and 6 others participated in the CMMI *COME HOME* project based on the Oncology Medical Home (OMH) model that community oncologists created and continue to advance. Furthermore, COA has worked with the American College of Surgeons’ Commission on Cancer to develop a thorough, tested accreditation program for the OMH. To date, our practice and 8 others across the country have now received OMH accreditation. COA also has a standing OMH Steering Committee, comprised of representatives from the patient, provider, and payer communities, which has

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<sup>7</sup> *Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*. The U.S. Government Accountability Office, July 2015.

<sup>8</sup> *Payment Methods for Certain Cancer Hospitals Should Be Revised to Promote Efficiency*. The U.S. Government Accountability Office, February 2015.

identified, developed, and endorsed 18 measures of quality and value in cancer care. Additionally, COA has developed a specialized cancer patient satisfaction survey, based on the national CAHPS survey, which is available in 5 different languages and has been administered close to 70,000 times.

Community oncology practices are also engaged in numerous payment reform projects with private payers such as Aetna, Horizon, Priority, and UnitedHealthcare that are designed to enhance the quality of cancer care while actually decreasing costs. As noted earlier, these projects have produced results that CMS should examine closely before implementing any misguided experiment on cancer care for seniors.

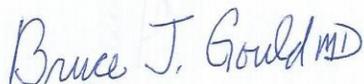
In closing, I want to convey that we welcome the opportunity to meet with you in Washington, DC to discuss the innovation in oncology payment reform, our comments in this letter, and what is really driving the cost of cancer care. In fact, of particular and timely interest to you should be a forthcoming study by the actuarial firm Milliman looking at the cost drivers of cancer care. The study, which will be completed towards the end of March, will document the changing landscape and dynamics behind the increasing cost of cancer care. I will personally lead a group of community oncologists from around the country in taking time away from our patients to come to DC and to have a constructive dialogue with you about oncology payment reform, the findings from the Milliman study, and our concerns with CMS policy.

**That said, please understand that we are actively pursuing every legal, legislative, and related option to stop the CMS Medicare Part B Drug Payment Model, which is nothing more than a perverse experiment on cancer care provided to seniors.** For the sake of all of our patients, we simply cannot let CMS proceed with the dangerous Medicare Part B Drug Payment Model, which is not a true “model” in the CCMI legislative charter but simply another disguised cut to Medicare Part B reimbursement for cancer care. It is very revealing that CMS did not engage any patient and provider stakeholders in developing this perverse experiment, but is now seeking comment at the 11<sup>th</sup> hour in a “proposed rule.”

Additionally, we have put our full support behind the bipartisan congressional oncology payment reform bill, the *Cancer Care Payment Reform Act* (H.R. 1934). This is a true model of cancer care reform, developed with physician and patient input and based on quality and value metrics designed to enhance patient care. We are also convening a meeting of oncology practices to seriously consider not participating in the forthcoming OCM, given what we believe has proven to be an exceptionally bad faith relationship between CMS and the oncology community.

If you would like to set up time to discuss these issues further, arrange an in-person meeting, or have any questions answered, I can be contacted directly at [big83@ngoc.com](mailto:big83@ngoc.com) or through the COA offices at (202) 756-2258. You can also contact COA Executive Director Ted Okon at [tokon@COAcancer.org](mailto:tokon@COAcancer.org) or at (757) 822-6134.

Sincerely,



Bruce Gould, MD  
President

CC:  
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