The US Oncology Network

May 9, 2016

VIA ELECTRONIC SUBMISSION THROUGH **www.regulations.gov**

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1670-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Part B Drug Payment Model (CMS-1670-P)

Dear Acting Administrator Slavitt:

On behalf of The US Oncology Network, I appreciate the opportunity to comment on CMS-1607-P "Part B Drug Payment Model" (the "Proposed Rule") as published on March 11, 2016 in the *Federal Register*. The proposed rule would authorize the Centers for Medicare and Medicaid Innovation (CMMI) to create and test a five year, two-phase mandatory demonstration project that would modify physician administered drug reimbursement based on geographic areas.

The US Oncology Network is the nation's largest and most innovative network of community-based oncology physicians, treating more than 750,000 cancer patients annually in over 350 locations across 19 states. The Network unites physicians around a common vision of expanding patient access to the highest quality, most cost-effective integrated cancer care to help patients fight cancer, and win.

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 population[2], Medicare must be heavily invested in ensuring access to beneficiaries for high-quality, innovative cancer treatment options close to home.

The proposed "Part B Drug Payment Model," which is aimed at reducing Medicare drug spending, lacks a patient-centered focus. Cancer patients often struggle to access appropriate treatment options to effectively combat their disease and improve their quality of life. Frequently, patients must adjust their course of treatment due to changes in their clinical status or goals of care. Unfortunately, the proposed "Part B Drug Payment Model" could create additional barriers to accessing necessary

[1] The National Cancer Institute http://www.cancer.gov/about-cancer/what-is-cancer/statistics
[2] http://www.allhealth.org/briefingmaterials/CancerandMedicareChartbookFinalfulldocumentMarch11-1412.pdf

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treatments by facilitating underutilization of some cancer therapies and force vulnerable Medicare patients to navigate a complex initiative that may disrupt effective curative and palliative treatments.

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 could result in inferior outcomes for Medicare beneficiaries with cancer. As providers caring for millions of Medicare beneficiaries diagnosed with cancer, we have grave concerns that the proposed randomly allocated "Part B Drug Payment Model" will work counter to CMS' goal of reducing costs and improving outcomes for cancer patients and will impede Medicare patients' access to the most advanced cancer therapies available.

Given these concerns and the specific issues outlined below, The US Oncology Network recommends CMS not finalize the proposed rule. CMS should look to develop value based care initiatives in collaboration with physicians, patients and other stakeholders that do not negatively impact the entire care delivery system.

Coordination, Data and Transparency

The US Oncology Network appreciates that opportunities exist within cancer care to demonstrate value, improve quality, strengthen patient outcomes and hold down costs, however, we are extremely discouraged that CMS and CMMI chose to craft the "Part B Drug Payment Model" in a silo without the expertise or input from the cancer care community. The US Oncology Network, who provides 12 percent of community cancer care across this nation, has long advocated for reimbursement policies for drugs and biologics under Medicare Part B that promote appropriate utilization of therapies. In the proposed rule, CMS expresses concern that providers' prescribing decisions are influenced by incentives for the use of higher priced drugs rather than the clinical considerations that truly influence a provider's choice in prescribing therapeutic alternatives, especially as it relates to cancer.

It is important to note that there is no evidence indicating that the payment changes contemplated by CMS' model will improve the quality of care. Instead, we fear it may adversely impact patients who lose access to their most clinically appropriate treatments. In fact, data suggests 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 stable[3] and Part B drugs account for just 3 percent of total program costs.[4]

Further, there is no evidence that the payment changes contemplated in the "Part B Drug Payment Model" will reduce spending. In fact, a project by UnitedHealthcare implemented within community oncology practices designed to eliminate any "incentive" proved the exact opposite to the CMS assumption. According to the study, "eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy." The spending on drugs increased by 179 percent.[5] What was effective in this pilot was the decrease in total cost of care because of the interventions focused on the entire system of care delivery rather than a singular focus on the cost of

[3] 2015 Medicare Trustees Report
[4] 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.
[5] 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

drugs. CMS should be wary of incentivizing underutilization of certain breakthrough therapies that might be the best solution for a patient's long term care plan, especially in oncology.

While the Affordable Care Act grants broad authority to CMMI to test and evaluate payment and service delivery models to reduce program expenditures, we strongly believe that government-led initiatives should be supported by data. We further believe that such initiatives should be developed and implemented in a targeted, patient-centered and transparent way that accounts for the unique needs of Medicare patients and with input from affected stakeholders. Medicare beneficiaries with cancer have a right to ensure 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. As CMS increasingly moves toward payment models linked to quality or value, it is imperative to ensure transparency and allow for stakeholder input into all payment and delivery reform efforts. We believe this model should not be implemented as a mandate without stakeholder input and without consideration of the impact to the system of care delivery and how it supports the patients we serve.

Impact on Existing Innovation Center Payment Models

The US Oncology Network believes that properly constructed alternative payment models have the potential to produce positive effects on patient care while generating savings for 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. As a leader in providing cancer care in the community setting, The US Oncology Network appreciated the opportunity to collaborate with CMS and CMMI on the creation and development of the Oncology Care Model (OCM), an episode-based payment model aimed at improving coordination, appropriateness of treatment, and access to care for beneficiaries undergoing chemotherapy. Participants in the OCM will rely on the most current medical evidence and shared decision-making with the patient to determine whether a beneficiary should receive chemotherapy treatment. CMS will incentivize participating physician practices to effectively address the complex care needs of chemotherapy patients, and heighten the focus on furnishing services that specifically improve the patient's health outcomes.

This past March, 13 US Oncology Network practices with 787 providers across the country were selected to participate in the inaugural OCM pilot set to launch July 1, 2016. The US Oncology Network has invested significant resources to ensure these practices are ready and equipped to successfully participate in the program. These 13 practices have accepted the risk associated with participating in the pilot program and have made a voluntary commitment to the shared goal of improving outcomes for chemotherapy patients while realizing savings for the Medicare program. These 13 practices within our network serve nearly 10 percent of the US cancer population.

The Network has great concern over how CMMI plans to manage the "Part B Drug Payment Model" with the OCM that CMMI will roll out this summer. The proposed rule acknowledges potential overlap but does not recommend excluding beneficiaries or providers participating in the OCM from the "Part B Drug Payment Model." Given the significant time, resources and collaboration that went into developing the OCM, we have serious reservations about how CMS will effectively manage these two separate payment models with two distinct and individual goals. The OCM seeks to incentivize improved care coordination for a six month episode of chemotherapy, from addressing the complex care needs of Medicare patients receiving chemotherapy to furnishing services that specifically improve the patient experience. The "Part B Drug Payment Model" is focused on reducing Medicare drug spending.

We believe these conflicting payment models will have natural consequences on the cancer care delivery system, making it impossible to accurately measure the success of either demonstration throughout the test period. In addition, practices awarded OCM status are already proactively participating in improving value based care. To further destabilize these practices could contribute to failure of the OCM. Should CMS move forward with this proposal, **The US Oncology Network strongly recommends CMS provide certainty to practices participating in the OCM by excluding oncology from the "Part B Drug Payment Model".**

Implementation of Medicare Physician Payment Reform

In addition to the potential interference with other CMMI models, The US Oncology Network is concerned how physicians will manage the "Part B Drug Payment Model" with the significant structural changes taking place in the Medicare physician reimbursement system due to implementation of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). MACRA directs physicians to choose from two new payment paths under Medicare, either the Merit-based Incentive Payment System (MIPS) or through Alternative Payment Models (APM). Many basic aspects of the two systems are still unknown as CMS only recently released the proposed rule for the new Medicare physician payment system. It is still unclear whether CMS will use the current billing structures that make up the infrastructure of the three quality incentive programs that MIPS will be replacing. Payment adjustments under MIPS are set to begin in 2019, and like prior quality incentive programs, will be based on previously reported data. With 75 percent of physicians administering Part B drugs subject to one of three separate payment structures under the proposed rule, it appears that CMS has not thoroughly evaluated how the proposed rule will impact those physicians' ability to successfully participate in the MIPS or APM path.

MACRA represents years of work and countless hours of bipartisan, bicameral negotiations to develop the legislative framework that is the basis of a new system of Medicare physician payment. The healthcare community was deeply engaged in creation and passage of MACRA and is invested in ensuring the success and viability of this new era of physician reimbursement. If properly implemented, the new physician payment system should facilitate the transition to new care and delivery models and promote improvements in the delivery of care for Medicare patients. It would be a disservice to Congress, the Administration and physician and patient organizations who worked diligently to enact this momentous change to the Medicare program if physicians are unable to manage the transition to MACRA due to impediments associated with the "Part B Drug Payment Model." Requiring cancer care providers to navigate through a significant payment experiment during this time of enormous change may jeopardize implementation and adoption of MACRA. There are many alternative payment models like Innovent, Patient Centered Medical Home, or the Patient Centered Oncology Home model that have been studied, have stakeholder input, and positively impact the systems of healthcare delivery and the patients we serve. **The US Oncology Network recommends CMS evaluate how payment reforms already underway impact patient care – then look for additional opportunities to improve the system.**

Misunderstanding of Current Reimbursement Rate for Medicare Part B Drugs

CMS needs to more fully understand the actual Part B reimbursement rate before implementing fundamental changes that may have serious consequences for patients and providers. Under the proposed payment model, Medicare will reduce payment for certain drugs from the current ASP plus 6 percent payment methodology to ASP plus 2.5 percent with a flat fee of $16.80 per drug administered. The reality is this proposed payment cut is much deeper due to existing policies CMS has failed to account for in the proposal. The current ASP methodology includes a customary

distributor prompt pay discount that is not passed on to the provider. Despite the fact that this discount does not reach the end-user, it is accounted for in the way CMS determines the underlying sales price of a drug, thereby impacting the ASP and resulting in an estimated reduction in reimbursement by approximately 2 percent. Additionally, the Budget Control Act of 2011 enacted a mandatory 2 percent sequester cut to Part B drugs. Lastly, the six-month lag in CMS updating ASPs, combined with steadily increasing drug prices, creates a significant misalignment where a provider's drug price increase experienced today will not be recognized by CMS for six months. This results in an additional, unsustainable loss of approximately 1 percent of ASP. Collectively, these flaws in the current ASP-based methodology leaves the current rate of ASP plus 6 percent closer to an actual rate of ASP plus 1 percent.

In the proposed rule, CMS states "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 2.5 percent to take care of the prompt pay discount, it clearly does not account for sequester or the six-month lag. The 2 percent sequester reduction on the proposed 2.5 percent actually puts the reimbursement at a starting point of ASP plus 0.86 percent, not leaving any room to cover the above mentioned six-month lag or to account for markups.

Additionally, it is important to note that community and smaller practices frequently purchase many Part B drugs over the established ASP, it is often hospitals and large practices that receive rebates, discounts and better prices on drugs, due to the volume of purchase. It is therefore entirely possible that a practice is actually paying well above the established ASP for a drug today. Further impacting small and community-based practices are state taxes levied on prescription medicines, gross receipts and provider services. Any further reductions to reimbursement could impede their ability to cover the acquisition cost of some cancer treatments.

After running our current contracted drug prices with the proposed reimbursement methodology, data shows that 5 out of our top 40 used cancer drugs will be newly under water for the entire Network. Treatments for breast cancer, myeloma and lymphoma will be at risk under this new methodology for patients being treated by US Oncology Network physicians. **Before considering adjustments to physician reimbursement for Part B drugs, The US Oncology Network strongly recommends CMS take into account sequester, the prompt pay discount and the six-month lag to ensure an appropriate add on percentage as to not further jeopardize patients' access to the best course of treatment for their specific cancer.**

Utilizing Evidence-Based Medicine to Drive Quality and Value in Cancer Care

Phase II of the "Part B Drug Payment Model" seeks to implement value-based payment tools in conjunction with the variation of the ASP add on percentage to test whether these tools can impact Part B expenditures and outcomes. As CMS looks for ways to improve outcomes and manage costs, it is important to acknowledge opportunities to improve upon strategies that are already working to hold down drug costs in the oncology space.

Nearly a decade ago, physicians in The US Oncology Network recognized an opportunity to strengthen relationships with patients and payers by selecting regimens that demonstrate value over volume and reduce non evidence-based variability in treatment. The result was the development of Level I Pathways, evidence-based guidelines that re-direct the wide range of treatments into more precise, clinically proven treatment options.

The US Oncology Network invested a significant amount of resources developing the original Level I Pathways and, more recently, Value Pathways in partnership with the National Comprehensive Cancer Network (NCCN). Community oncologists worked together to develop these pathways based on significant evidence reviews, best practices and outcomes. The cornerstone of our success remains the thorough review of treatment options, first considering efficacy and toxicity of each regimen. In addition to the effectiveness and toxicity of each regimen considered, evaluation of the cost of the intervention in proportion to the outcome is reviewed. These value assessments allow our clinicians to develop pathways that will improve outcomes and provide higher value. This commonsense approach to fighting cancer reduces costs while utilizing evidence-based medicine and protecting the physician-patient relationship.

Pathways were developed to proactively drive value — more specifically to improve the quality of patient care, which leads to better outcomes and lower costs. In two separate studies, the value of Level I Pathways has been proven to maintain equivalent health outcomes with lower costs.

A joint study with Aetna published in the January 2010 *Journal of Oncology* found that costs were 35 percent lower for non-small cell lung cancer patients treated according to Level I Pathways while maintaining equivalent health outcomes.[6] A similar study published in a special joint issue between the peer-reviewed *Journal of Oncology Practice* and the *American Journal of Managed Care* in May 2011 found that evidence-based care for patients with colon cancer results in equivalent health outcomes and a total cost savings of more than 30 percent, $53,000 for the treatment of adjuvant colon cancer and $60,000 for the treatment of metastatic colon cancer.[7]

It is important to remember that pathways are designed to guide physicians to the best treatment options; however, there are some patients who are best treated outside of the pathway in question. For Value Pathways powered by NCCN, the expectation is that compliance should be approximately 80 percent of cases following pathways. Most pathways have mechanisms to allow for these warranted variations from the pathways process. We must not tie the hands of physicians who are looking to do what is in the best interest of individual patients. The ultimate decision for the appropriate course of treatment should always be left to the physician and patient.

Additionally, today there is a great degree of variability among oncology experts and societies regarding the assessment of value in cancer care that will make it difficult to implement a value based system. There are standard measures of comparative effectiveness that could be used in 'pathways' systems that could allow for a value assessment, but are best positioned within a payment model that would have influence over the system of care delivery, not just Part B drugs**. For this reason, The US Oncology Network urges CMS to ensure provider and patient engagement before moving forward with proposals to implement value-based purchasing tools on Medicare Part B drugs.**

[6] Neubauer MA, Hoverman JR, Kolodziej M, et al. (2010) Cost effectiveness of evidence-based treatment guidelines for the treatment of non–small-cell lung cancer in the community setting. J Oncol Pract 6:12–18. http://m.jop.ascopubs.org/content/6/1/12.abstract

[7] Hoverman JR, Cartwright TH, Patt DA, et al. Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. *J Oncol Pract.* 2011;7 (suppl 3S):52s-59s.

Ensuring Patient Access in Appropriate Setting of Care

The sheer breadth and speed of the proposed "Part B Drug Payment Model" are cause for serious concern. The proposed rule calls for a five year, two-phase mandatory demonstration project based on geographic areas. With Phase I set to begin as soon as Fall 2016, affecting 50 percent of Medicare patients treated with Part B drugs, followed quickly by Phase II in January 2017 and encompassing 75 percent of Medicare patients receiving Part B drugs, we are concerned that these changes would be implemented too quickly. The proposed rule does not take into account the market consequences that will result from a demonstration model this size and how that will affect the quality and cost of cancer care for patients based solely on their zip code.

In an era of hospital acquisitions and consolidation in the oncology space, drastic changes in reimbursement could further push oncology care into the hospital outpatient setting. As you know well, 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 more than 30 percent swing of oncology care from the lower cost physician setting to the more expensive hospital outpatient department.[8] Total Medicare spending on patients receiving chemotherapy in the community clinic is 14.2 percent lower than the hospital outpatient department (HOPD), which equals $623 million in Medicare savings per year.[9] In addition, an April 2012 study released by Avalere Health[10] found that chemotherapy provided in a physician's office costs, on average, 24 percent less than chemotherapy provided in the hospital outpatient setting. Patient co-payments are approximately 10 percent lower in the clinic, equaling more than $650 in savings for each 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.[11]

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.[12]

Unfortunately, the differential in reimbursement for the same service isn't the only downside to shifting care to the hospital setting. According to a Moran study from 2013, not only was chemotherapy administration 42 to 67 percent higher in the hospital outpatient department (HOPD) setting, the drug spend was between 25 to 47 percent higher in an HOPD than in the physician office setting.[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

[8] The Moran Company: Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries; May 29, 2013.
[9] Milliman Client Report: Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy. October 19, 2011. Kate Fitch and Bruce Pyenson. http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf
[10] Avalere Client Report: Total Cost of Cancer Care By Site of Service. March 2012. http://www.avalerehealth.net/news/2012-04-03_COA/Cost_of_Care.pdf
[11] Milliman, "Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy," October 2011.
[12] Berkeley Research Group, "Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration," June 2014.
[13] The Moran Company: Cost Differences in Cancer Care Across Settings; August 2013

increase in the average per person price of treatment."[14] Cuts to community physicians have and will continue to lead to consolidation and community practices affiliating with hospitals. **The US Oncology Network continues to encourage CMS to reject policies that jeopardize access to the community setting and ensure quality care at a lower cost for patients and the Medicare program.**

Conclusion

The US Oncology Network believes there are serious flaws in the proposed "Part B Drug Payment Model" that could affect our most vulnerable seniors in the middle of treatment. For that reason, we would encourage CMS not to finalize this proposed rule and work with stakeholders on a true value based treatment method going forward. On behalf of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians and cancer care specialists nationwide, thank you for the opportunity to provide our comments on Proposed Rule CMS-1607-P. We are grateful to be able to engage in substantive discussions and welcome practice site visits with CMS officials. Any questions about the issues, concerns and suggestions raised in this letter should be directed to Ben Jones at 281.863.5666 or ben.jones@usoncology.com.

Sincerely,

Lucy Langer, MD
Chair, National Policy Board
The US Oncology Network

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