

Examining Reforms to Improve the Medicare Part B Drug Program for Seniors
Energy and Commerce Subcommittee on Health Hearing
Testimony Summary for Dr. Barry Brooks
June 28, 2013

Background/Practice

- Barry D. Brooks, MD – Partner, Texas Oncology; Chairman, Pharmacy & Therapeutics Committee, The US Oncology Network

Medicare Part B Drug Coverage and Reimbursement

- Medicare Part B coverage for physician-administered drugs is vital for seniors fighting cancer
- Medicare reimbursement for Part B drugs is ASP plus 6% payment to compensate for the operational costs and financial of purchasing, storing, mixing, administering and disposing these drugs
- The ASP-based system has resulted in stable spending and pricing

Recent Shifts in Cancer Care Site of Service and Implications

- In 2005, nearly 90% of outpatient chemotherapy was provided in the community clinic setting but that has decreased significantly over recent years. By 2011, at least a third of outpatient chemotherapy was provided in the hospital outpatient department setting
- HOPD-based chemotherapy results in higher costs for Medicare, seniors and payers

Issues Associated with Current ASP Formula

- Prompt Pay Discount
 - Reduces ASP values by the amount of wholesaler prompt pay discounts (~1-2%)
 - H.R. 800 (Whitfield, Green et al) would make ASP values more accurate
- Two Quarter Lag
 - Current law requires a lag of 4-8 months before sales data is used for reimbursement
 - Reducing this lag would make ASP values more accurate

Issues Associated with Beneficiary Coinsurance

- Beneficiaries are often unable to pay their coinsurance and Medicare does not reimburse physician practices for uncollectible coinsurance like it does in the HOPD setting
- Placing a reasonable cap on beneficiary out-of-pocket responsibility would improve the system

Payment and Policy Advantages for Hospital Outpatient Oncology Services – Unlevel Playing Field

- Medicare pays significantly more for many outpatient oncology services in the HOPD setting
- One-third of hospitals purchase drugs through the 340B program with 31% Medicare margins
- June MedPAC Report addresses site-neutral payments in the outpatient setting

Sequestration

- CMS has implemented the 2% cuts on both acquisition cost of drugs and the 6% services fee, exacerbating pre-existing strains on community cancer care
- The sequester should be properly applied only to the 6% service fee

Support Legislation

- H.R. 800 (Whitfield, Green et al)
- H.R. 1416 (Ellmers et al)
- Site-neutral payments policy to create a level playing field in oncology



**Submitted Testimony of Dr. Barry Brooks on the
Benefits and Challenges of Medicare Part B Drugs
Energy and Commerce Health Subcommittee Hearing
Examining Reforms to Improve the Medicare Part B Drug Program for Seniors
June 28, 2013**

Chairman Pitts and Ranking Member Pallone, thank you for the opportunity to testify today on behalf of The US Oncology Network¹ before the Energy and Commerce Subcommittee on Health on the role and importance of Medicare Part B drugs in community oncology. The Energy and Commerce Committee has always been especially committed to cancer patients and providers over the years and many of the Members on this Committee have been relentless champions for cancer patient access. We appreciate your dedication and support for Americans fighting cancer and for those of us who try to help them live longer, happier lives.

My name is Barry Brooks, and for the last 31 years I have spent the majority of my time taking care of cancer patients. On an average day I work more than 12 hours. Though a lot of my time is spent on administrative tasks, still I see 14-20 patients a day. Slightly over 40 percent of my patients rely on Medicare and another 5-10 percent are either covered by Medicaid or are uninsured. I am proud to be a cog in the world's most

¹ The US Oncology Network is one of the nation's largest networks of community-based oncology physicians dedicated to advancing cancer care in America. Like-minded physicians are united through The Network around a common vision of expanding patient access to high-quality, integrated cancer care in communities throughout the nation. Leveraging healthcare information technology, shared best practices, refined evidence-based medicine guidelines, and quality measurements, physicians affiliated with The US Oncology Network are committed to advancing the quality, safety, and science of cancer care to improve patient outcomes. The US Oncology Network is supported by McKesson Specialty Health, a division of McKesson Corporation focused on empowering a vibrant and sustainable community patient care delivery system to advance the science, technology and quality of care. For more information, visit www.usoncology.com.

effective and successful cancer care delivery system because after nearly 100 years of increasing cancer death rates in the United States, we have started to turn the corner in this fight. Cancer mortality has fallen by 20 percent from a 1991 peak and now cancer patients from around the world seek care here because Americans enjoy the best cancer survival rates in the world.

Yet, there remains much work to do to realize our potential of eradicating cancer. The American Cancer Society estimates 1.6 million Americans will be diagnosed with cancer and more than 580,000 will die of cancer in 2013. As has been the case for decades, only cardiovascular disease will kill more Americans. To step up and win this important fight, we need a stable and sustainable cancer care delivery system. That's where community cancer care and Medicare Part B coverage for physician-administered drugs comes in. Community based cancer care provides patients with convenient, comprehensive, state-of-the-art cancer treatment close to home. And more than 60 percent of US cancer patients rely on Medicare to pay their medical bills. That makes Medicare policy for chemotherapy and other intravenous drugs a huge issue for a lot of Americans.

Medicare Part B Drugs Generally

The Medicare program is the primary source of health coverage for most senior citizens. Part A of the program covers inpatient services, while Part B focuses on the services of physicians and other treatments received in the outpatient setting. Most coverage of prescription drugs is provided separately under Medicare Part D while drugs that require

physician administration are covered under Part B. Part B coverage is particularly important for cancer patients: chemotherapy drugs and anti-cancer therapies account for 7 of the top 10 therapies covered by Part B.²

Medicare Reimbursement for Part B Drugs

In the Medicare Modernization Act of 2003 (MMA), Congress enacted the Average Sales Price (ASP) reimbursement methodology for Part B drugs. ASP reflects the average price of a drug's sales to all purchasers in the United States. Based on data received directly from manufacturers, the Centers for Medicare and Medicaid Services (CMS) calculates the ASP for each Healthcare Common Procedure Coding System (HCPCS) code covered under Medicare Part B. A HCPCS code may include drugs from more than one manufacturer in the case of multiple source drugs, or in the case of single source drugs that shared the same HCPCS code prior to enactment of the MMA.

Pursuant to the MMA statute, Medicare reimburses physicians for cancer drugs at average sales price (ASP) plus a 6 percent services payment to compensate community cancer clinics for the operational complexity and financial risks associated with purchasing, storing, mixing, administering and disposing of these highly potent and effective therapies. Community oncology practices buy the drugs on behalf of CMS and CMS pays an additional six percent above acquisition cost to manage the product and prepare it for administration to patients. This six percent is incredibly important because

² Moran Company analysts tabulated the top ten drugs based on Part B spending in 2009. Six of the top ten drugs were chemotherapy agents. Two were drugs designed to treat chemotherapy related anemia.

none of the work that must occur to prepare chemotherapy for administration to a patient is otherwise reimbursed by Medicare. For the most part, state laws require very specific infrastructure and personnel for the storage and preparation of these drugs. The drugs must be stored at controlled temperatures, mixed to the proper dose and bagged for administration by trained pharmacists and admixture technicians within approved clean rooms that often cost tens of thousands of dollars in investments in pharmacy hoods and double negative pressure areas to prevent the toxic materials from harming staff and other patients. Even in small clinics with one or two medical oncologists, the ancillary staff to do all the above can be 4-5 highly trained professionals and in larger clinics, the staffing is accordingly much bigger. Even if every drug were ready to be administered to a patient at the moment it arrived on the doorstep of the practice, paying exactly only acquisition cost for the drug would still be problematic and would not properly reflect the financial costs of inventory as well as the significant infrastructure investment to manage and control this unique inventory.

The current Medicare reimbursement structure for Part B drugs is not perfect, but it has achieved many of the goals of those who designed it back in 2003. It has clearly created a more accurate reimbursement approach than the prior system and it has attenuated the prior significant growth rate of Part B drug units and spending, creating stability in the costs to Medicare and the patients who rely on it. A recent study of Medicare data indicates that “[o]ver the past several years, total payments and units have remained stable, while changes in the weighted average ASP show that pricing in the aggregate for

drugs and biologics in Medicare Part B...has remained flat.”³ The current ASP system has also diminished overall IV drug prices and price increases, notwithstanding the typical media coverage of new high-priced therapies. The same analysis of Medicare data demonstrates “while CPI-M has gradually been increasing from 2006 to the present, the volume-weighted ASP has maintained a much flatter line.”⁴ ASPs have been steady, or decreasing, for the last two quarters according to CMS.⁵ In other words, price decreases associated with generic transitions have offset price increases and the introduction of new, high-priced drugs over the past decade, just as one should expect from a mature and healthy system that balances innovation with access.

Recent Shifts in Site of Service for Part B Drugs

There are also challenges that impede access to life-saving and life-lengthening therapies that we offer. Recent weeks have raised the national consciousness about the tremendous strain imperiling our nation’s cancer care delivery system. Just 8 years ago, 87 percent of cancer care occurred successfully in cost-effective community oncology practices.⁶ In recent years, this percentage has dropped significantly as Medicare policies have created an environment where doctors break even or operate at a loss when helping seniors fight cancer.

³ Trends in Weighted Average Sales Prices for Prescription Drugs in Medicare Part B, 2006-2012, The Moran Company, December 2012. Online at: <https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/cef337d0-5331-4659-8cb5-cfa3ca2e8f62.pdf>

⁴ *ibid*

⁵ CMS ASP Drug Pricing Files, July and April 2013. Online at: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2013ASPFiles.html>

⁶ Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries; The Moran Company, May 2013. Online at: <https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/01655fe9-7f3d-4d9a-80d0-d2f9581673a1.pdf>

The data are clear: our world-class community cancer care delivery system is struggling to survive. Since 2008, 1,338 community cancer care centers have closed, consolidated, or reported financial problems. Over the past several years, the country has experienced a shift of outpatient cancer care delivery from the physician office to the hospital outpatient department; 288 oncology office locations have closed, 407 practices merged or were acquired by a corporate entity other than a hospital, and 469 oncology groups have entered into an employment or professional services agreement with a hospital.⁷ By 2011, nearly a third of Medicare's outpatient chemotherapy and anti-cancer drugs had moved to the hospital setting, a more than 150 percent increase for HOPDs. Medicare payments for chemotherapy administration services in hospital outpatient settings have more than tripled since 2005, while payments to community cancer clinics have actually decreased by 14.5 percent.⁸ And sadly the flight from community oncology did not end in 2011. Since early 2012, there has been a 20 percent increase in clinic closings and hospital acquisitions, which means increasingly more patients are facing reduced access and more expensive care.⁹

When clinics close their doors, access to care is compromised for all cancer patients, but especially vulnerable seniors. This shift to hospital-based care doesn't just reduce access to care for cancer patients, it also increases costs to Medicare, taxpayers and patients.

Recent studies show hospital-based cancer care costs Medicare \$6,500 more per

⁷ Community Oncology Alliance Practice Impact Report, June 25, 2013. Online at:

http://www.communityoncology.org/UserFiles/Community_Oncology_Practice_Impact_Report_6-25-13F.pdf

⁸ Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries; The Moran Company, May 2013.

⁹ Community Oncology Alliance Practice Impact Report, June 25, 2013.

beneficiary and seniors \$650 more out of pocket per patient annually.¹⁰ These differences are even greater for care covered by private insurers. The fact of the matter is that there is no clinical justification for migration of outpatient cancer care to the hospital setting. Patients don't want to be in a hospital and there is simply no advantage to driving care into a more expensive setting.

Issues with the ASP Formula

Even prior to the sequestration policy currently in effect, Medicare's drug payment rate at ASP plus 6 percent has failed to reimburse adequately for the total costs incurred by community cancer clinics in acquiring essential cancer-fighting therapies. Due to technical flaws in the ASP formula, plus 6 in theory is not plus 6 in reality. The ASP formula produces ASP values below the prices clinics can obtain. CMS has interpreted the ASP formula to require the ASP value to be reduced by any wholesaler prompt pay discounts – which typically fall in the range of 1-2 percent of wholesale acquisition cost, but these discounts pharmaceutical manufacturers extend to distributors of chemotherapy drugs for timely payment are not extended to clinics. This artificially lowers Medicare payment for life-saving anti-cancer drugs and results in reimbursement below cost for many critical cancer drugs. Changing the ASP methodology as proposed by Rep. Ed Whitfield (R-KY) through HR 800 would make ASP values and Medicare Part B reimbursement more accurate.

¹⁰ K. Fitch and B. Pyenson, Milliman Client Report, Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy (Oct. 19, 2011), available at <http://publications.milliman.com/publications/health-published/pdfs/site-of-service-cost-differences.pdf>

Additionally, Medicare reimbursement rates for Part B drugs are set using reported average sales prices from two quarters prior to the reimbursement quarter. The result is that at any given time Medicare is paying for Part B drugs on the basis of prices that are 4-8 months old. As prices for pharmaceuticals increase, providers are essentially covering the difference for the government until the ASP formula catches up. This lag in the ASP values also creates a significant incentive at the end of a product's exclusivity period where Medicare pays brand-based prices for several months after a product has gone generic. Reducing the amount of time between the collection of the data and its use to set reimbursement rates would make ASP values and Medicare Part B more accurate.

These issues with the ASP formula are not new. As early as 2007, MedPAC found that with reimbursement set at ASP plus 6 percent, the difference between acquisition costs and payment was "slim" and some products could not be purchased below the payment rate.¹¹ When this difference is "slim" or negative, it means there is either no payment for the substantial services provided to store and prepare the drug for administration, or worse that the practice is paying to provide those services and also paying for a portion of the patient's needed therapy instead of Medicare. After the sequester cuts, the payments are well below break-even.

Issues with Beneficiary Coinsurance

¹¹ MedPAC Report to Congress January 2007: Impact of Changes in Medicare Payments for Part B Drugs. Online at: http://www.medpac.gov/documents/jan07_partb_mandated_report.pdf

While the prompt pay discount problem and two-quarter lag problem makes it difficult for community oncology clinics to break even at ASP plus 6 percent, it is quite rare for practices to be able to collect the entire Medicare allowable rate for Part B drugs. This is principally due to the 20 percent coinsurance responsibility facing beneficiaries, often on very expensive therapies. It has been the experience of practices in The US Oncology Network that approximately 25 percent of the beneficiary coinsurance (approximately 5 percent of the Medicare allowable) is uncollectible and ends up as bad debt. While this is meaningful even in the context of services that involve a physician's time, a nurse or therapist's time and fixed assets that constitute capital expenditures, it is even more meaningful in the context of Part B drugs where the practice buys the drug on behalf of CMS and is then reimbursed for it by Medicare (80 percent) and the beneficiary (20 percent). Unlike hospitals, Medicare does not reimburse physician offices or community cancer clinics for uncollectible beneficiary coinsurance.

Ironically, with the introduction of federally-mandated out-of-pocket caps on all private insurance coverage through the ACA starting January 1, Medicare coverage may actually leave a cancer patient most exposed to the threat of bankruptcy. The US Oncology Network would strongly support efforts to cap Medicare beneficiary out-of-pocket responsibility at a reasonable amount.

Issues with Medicare Payment and Policy Advantages Based on Site of Service

Another key driver of the shift from community clinics to hospital outpatient departments is the steady erosion of revenues in the physician office setting due to significant changes in Medicare payment policies for outpatient services. Additionally, the wide variation of reimbursement for the same services in different outpatient settings compounds the problem. For example, the 2013 Medicare Physician Fee Schedule rate for 1 hr of chemo infusion by iv is \$143.24 but the payment rate for the same service under the 2013 Hospital Outpatient Prospective Payment Schedule (HOPPS) fee schedule is 61 percent higher at \$230.50. These types of discrepancies in reimbursement throughout oncology and other specialties greatly advantage hospital outpatient departments and in effect subsidize and encourage inefficiency. We know the committee is familiar with this facet of the problem and has supported policies to equalize E&M payments across care settings. The US Oncology Network applauds the Medicare Payment Advisory Commission's recent recommendation to level the playing field for outpatient services, including oncology services. We also strongly support current efforts of committee members to take an urgent approach to site-neutral payment in the oncology space and look forward to working with you to achieve that policy goal.

In addition to these code and service specific payment differentials outlined by MedPAC, hospitals enjoy other advantages relative to government policies around Part B drugs that push more patients and physicians into that setting. Approximately, one third of US hospitals purchase chemotherapy drugs through the 340B program at discount up to 50 percent, typically more than 30 percent below the Medicare reimbursement rate of ASP +

6 percent.¹² For 340B hospitals, the margin on Medicare drugs is over 30 percent, where for community clinics the margin is zero to negative 2 percent. It is no wonder that drug spending is increasing so rapidly in the hospital outpatient setting and that care is moving in that direction.

Issues with the Federal Budget Sequester

The most recent challenge to access to Part B drugs and the viability of community cancer care comes of course through the federal government budget sequestration policy, and in particular, the administration's decision to apply this cut to both the 6 percent services payment and also the acquisition cost of the underlying Part B drugs purchased on behalf of CMS. We support thoughtful deficit reduction and we are not here to request a repeal of or exemption from the sequester. However, the administration's implementation of this policy is effectively forcing cancer clinics to subsidize Medicare — that is, to make up the difference between what Medicare pays and the actual cost of cancer drugs.

Health care providers are never comfortable talking about their work in purely economic terms, but the fact remains that community cancer clinics are small businesses held to the economic reality that operating at a loss cannot be sustained. It is hard to imagine any business—small or otherwise—accepting a policy that requires operating at a loss.

Oncologists should not be put in the untenable position of continuing to treat patients at

¹² OIG Memorandum Report: Payment for Drugs Under the Hospital Outpatient Prospective Payment System OEI-03-09-00420, October 22, 2010. Online at: <http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf>

a loss, which will result in clinic closings, or sending seniors fighting cancer to the hospital for treatment in order to keep the clinic doors open.

It would be one thing for community oncologists to absorb the 2 percent Medicare sequester applied to physician and provider services, but it is entirely another for the sequester cut to apply to the underlying drug acquisition costs paid by practices on behalf of CMS. This is unlike any other payment reduction to Medicare and has had an inordinate impact beyond 2 percent. Medicare reimbursement for cancer drugs is specifically fixed by law at ASP plus 6 percent, as opposed to services or budgets cut by sequestration. The reduction of the 6 percent add-on to effectively 4.3 percent (after sequestration is applied) is a 28 percent cut to the clinic's payment for managing the drugs, not a 2 percent cut. This has put many drugs underwater on acquisition cost alone and has resulted in zero payment for the costs associated with storing and preparing the drugs for administration to patients. We look forward to working with the committee to pass legislation that changes the way the administration implements the sequester so that it properly applies to the 6 percent services payment but not the acquisition costs of the underlying Part B drugs.

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.¹³ As the baby boomers continue to reach 65 those numbers will only increase. So, now is the time for Congress to act to ensure the future of community based care and stop the site of service shift into more costly hospital outpatient departments.

Several Members of this Committee have written legislation and signed onto letters that assist in preserving community cancer care. Specifically, H.R. 800, sponsored by Congressman Whitfield, Green and DeGette and 54 additional co-sponsors, would result in a more accurately aligned Part B drug reimbursement by removing any discount between the manufacturer and distributor that is included in the ASP formula but not passed on to the provider. Over 30 Members of this Committee signed a letter to CMS questioning how the Administration handled the sequestration cuts on Medicare Part B drugs, while Congresswoman Ellmers introduced H.R. 1416 and garnered 91 co-sponsors which would remove the 28 percent service cut community oncologists are dealing with under sequestration. Lastly, at a time when access and cost issues are intertwined, we appreciate the support from several on the committee that believe it is important that payment amounts be commensurate with actual services provided, not the site of care. Preferentially paying higher amounts in certain settings will predictably lead to the expansion of higher cost centers. The result will be further increases in the cost of cancer care for those who pay for it – patients, private and government payers.

The primary purpose of a doctor is to relieve suffering. My 10,000 oncology colleagues across the country and I are doing our best. In order to continue to give cancer care to

¹³ 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/>

America's elderly and under-served, we need your help. Thank you again for the opportunity to address the committee, when it is appropriate I am happy to answer any questions the committee has regarding my testimony or community oncology.

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1. Background on The US Oncology Network: www.usoncology.com
2. Moran Study on Site of Service Shift:
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4. CMS ASP Drug Pricing Files, July 2013: <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2013ASPFiles.html>
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13. Congressional Letter to CMS on Sequestration Cuts:
<https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/d4863fed-bfaa-4a21-84b8-3f9e8eab2305.pdf>