The Myth of Perverse Physician Incentives:

Examining Research and Accusations in the Medicare Part B ASP Reimbursement System for Oncology

A frequent accusation aimed at physicians who prescribe and administer medications within the Medicare Part B system is that they are motivated by a perverse incentive of higher reimbursement to prescribe expensive drugs. For oncologists, who utilize potentially life-saving, but increasingly very expensive drugs in treating some of the nation's sickest patients, this is a baseless charge, often made without any evidence to support it.

Cancer drugs are amongst the costliest medications available today. For many patients, the cost of a full course of treatment in the United States can be financially toxic and catastrophic. The country currently sits on the precipice of proposed drug system changes of considerable magnitude and scope. Several proposals under consideration take aim at Part B reimbursement as a means of forcing changes to drug prices and pricing methodologies. These are, ironically, occurring just as the adoption of value-based cancer care programs, such as the Centers for Medicare and Medicaid Services (CMS) Oncology Care Program (OCM), are being increasingly implemented.

To help inform policymakers and stakeholders working to reform our health care system and reduce the total cost of cancer care, the Community Oncology Alliance (COA) has conducted this critical analysis of research studies that are often cited as "evidence" that oncologists prescribing in the Part B system are financially driven, rather than driven to provide the highest-quality cancer care. Evidence and recent studies proving that those assertions are misguided are provided in this paper.

To properly review the studies most commonly cited as "proof" of a perverse physician prescribing incentive, an expert review panel of six medical oncologists with literally decades of clinical and research experience, was assembled. They evaluated the studies, methodology, and data sources for all relevant findings. Their critical insight into the health care history and medical developments that drive prescribing patterns and behavior were critical to this paper. The conclusions included here represent their collective meta-analysis of relevant data.

ASP + 6%: A Brief History and Background

In 2003, Congress enacted the largest single overhaul of Medicare in the public health program's history with the Medicare Prescription Drug, Improvement and Modernization Act, also commonly called the Medicare Modernization Act or MMA. This legislation changed the reimbursement rate for Medicare Part B drugs, which are typically injectable medications such as chemotherapy, administered under a medical provider's supervision. The new reimbursement rate became Average Sales Price (ASP) of the drug plus 6%.

Critics presume the 6% represents "profit" and serves as the driver of prescribing habits. In fact, the 6% add-on was intended to cover the costs associated with the procurement, storage,

inventory, preparation, and waste disposal for these volatile and highly toxic drugs. The reimbursement rate was deliberately set to be revenue neutral with the stated intent to eliminate "profit" through drug selection bias.

Since the 2005 adoption of ASP + 6% as the Medicare drug reimbursement formula, a subsequent and quite significant change in Part B drug reimbursement later became part of Medicare policy. Specifically, the Budget Control Act of 2011 (BCA) mandated a 2% sequestration cut to Medicare reimbursement, which CMS applied, COA believes inappropriately, to Part B drug payments, serving to decrease actual reimbursement for chemotherapy drugs to ASP + 4.3%. The drug costs and administrative fees associated with dispensing cancer drugs remained unchanged as reimbursement declined, resulting in physicians being under-reimbursed on many chemotherapy drugs.

In fact, analyses have verified that many community oncology practices actually lose money on key infusion services and select drugs due to low Medicare reimbursements.[1] A 2018 analysis of reimbursement data by Avalere Health found that practices lose money for 21% of all Part B drugs.[2] That is, for those drugs, the cost of acquisition is less than the reimbursement rate. On average, the difference is 10% per drug; meaning, every time these Part B drugs are prescribed, providers are under-reimbursed. Among the top 10 highest cost cancer drugs, which account for 72% of all cancer drugs and 23% of all Part B drugs in terms of total Medicare spending in 2016, the average estimated difference between drug acquisition cost and Medicare allowable payment amount is 2.4%, or $2.50.

Commonly Cited Studies – and Their Shortcomings

Critics that claim a perverse incentive exists affecting which Part B drugs patients are prescribed have consistently referenced the same five studies to support their argument. Additionally, a new study that reaches the same suspect conclusions was recently published. The studies are as follows:

1. "Practice Patterns for Older Adult Patients with Advanced Cancer: Physician Office versus Hospital Outpatient Setting." Allison Lipitz-Snyderman; Coral L. Atoria; Stephen M. Schleicher; Peter B. Bach; Katherine S. Panageas.[3]
2. "How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment." Mireille Jacobson; Craig C. Earle; Mary Price; Joseph P. Newhouse.[4]
3. "Physician Response to Financial Incentives When Choosing Drugs to Treat Breast Cancer." Andrew. J. Epstein; Scott J. Johnson.[5]
4. "Reduction in Physician Reimbursement and Use of Hormone Therapy in Prostate Cancer." Sean P. Elliott; Stephanie L. Jarosek; Timothy J. Wilt; Beth A. Virnig.[6]
5. "Infused Chemotherapy Use in the Elderly After Patent Expiration." R.M. Conti; M.B. Rosenthal; B.N. Polite; P.B. Bach; Y.C. Shih.[7]
6. "Impact of Payment Reform on Chemotherapy at the End of Life." Carrie H. Colla; Nancy E. Morden; Jonathan S. Skinner; J. Russell Hoverman; Ellen Meara.[8]

The studies have been cited in pseudo-analyses and quoted as evidence by those seeking to influence health care policy, presenting presumptions and conclusions about physician prescribing as fact while ignoring contributing factors beyond drug prices. In many cases, study

authors – most of whom are neither practicing physicians nor oncologists – demonstrate a lack of clinical knowledge and judgement that influence the treatment decisions oncologists and their patients make in determining optimal cancer treatment. This leads the studies to confuse or conflate correlation with causation in prescribing where none exists.

Another problem with some of these studies is the "cherry picking" of items and data to focus on without explaining sources of potential bias that can confound complex results. For example, excluding confounding factors, such as major reimbursement changes, i.e., the MMA, the introduction of groundbreaking new therapeutic treatment options, or even changes in clinical guidelines.

A majority of the most commonly cited studies are more than a decade old and/or utilize data as much as two decades old. Drawing on data for any patient prior to implementation of key MMA provisions in 2005, which fundamentally and radically changed Part B drug reimbursement, means the authors are drawing conclusions about prescribing patterns based on a reimbursement system completely different from the current ASP system of today. Additionally, since the two decades on which the older studies draw, treatment protocols have often dramatically changed and/or advanced so substantially that the study conclusions may no longer be applicable to current cancer care decision-making and prescribing.

Finally, the studies collectively often ignore contributing factors in drug selection. These include criteria such as patient status, drug toxicity, drug efficacy, changes in treatment protocols, and the development of newer, better drugs; all of which can be part of the process of drug selection and utilization. Again, this demonstrates a lack of clinical oncology knowledge when casting aspersion on physician behavior that is actually driven by guidelines and best practices at the time of treatment.

In the following sections, we will specifically examine what each of these studies purports, whether any evidence truly exists of a perverse financial incentive in Part B prescribing, and what additional or contributing factors must be considered.

1. Practice Patterns for Older Adult Patients with Advanced Cancer: Physician Office versus Hospital Outpatient Setting

What the study says:

> *"Compared with patients treated in a hospital outpatient department, those treated in a physician's office setting were more likely to receive erythropoiesis-stimulating agents (odds ratio, 1.72; 95% CI, 1.53 to 1.94) and granulocyte colony–stimulating factors (odds ratio, 1.28; 95% CI, 1.18 to 1.38). For combination chemotherapy and nanoparticle albumin-bound–paclitaxel in patients with breast cancer, there was a trend toward higher use in physicians' offices, although this was not statistically significant. Chemotherapy-related hospitalizations and hospice did not vary by setting. "*
>
> *"We found somewhat higher use of several drugs for patients with advanced cancer in physicians' office settings compared with hospital outpatient departments. Findings support research to dissect the mechanisms through which setting might influence physicians' behavior… Although the reasons for differences in physicians' behavior*

by oncology practice setting are unclear, research has shown that physician behavior is influenced by payment incentives."

This study though just recently released, relies on old data from 2004 – 2011, which is an eternity in modern-day cancer treatment. Standards of care, site of care, and attitudes on low-value care in older adults who often present with co-morbidities that increase the occurrence of complications necessitating multi-drug combination treatment, have changed profoundly since that period.

Since 2011, there have been many changes within the reimbursement landscape, including changes in Erythropoiesis-Stimulating Agents' (ESA) coverage, MMA, sequestration, the introduction of oral oncolytic therapies, and more rapid adoption of new therapies that impact supportive care. The availability of immuno-oncology therapies has significantly reduced the quantity of supportive care medications required due to a reduction in drug-related side effects. The use of such old data results in an examination of prescribing and treatment patterns long since supplanted and taints the study conclusions.

The authors claim that there is a "trend" towards greater use of combination chemotherapy in patients treated in the physician office setting versus the hospital outpatient department. However, this cannot be called a "trend" because the results are not statistically significantly different.

The study's stated intent was to determine if patients treated in the physician office setting versus the hospital outpatient department setting were more likely to receive what the authors deemed to be "low-value" erythropoiesis-stimulating agents and granulocyte colony-stimulating factors. However, the authors make no mention of important clinical information that would have driven these treatments, such as the incidence of admissions for neutropenic fever or the issue of red blood cell transfusions. The analysis also fails to adjust for line-of-therapy where the cancer patient could be represented more than once in cases where higher-cost therapies may be administered after the failure of lower-cost options.

The authors also fail to mention that within the 2004 – 2011 study time frame, the standard of care for patients with stage IV breast carcinoma requiring chemotherapy, often correctly utilized combination therapeutic approaches. In fact, a 2009 peer-reviewed study concluded and confirmed that multi-drug combinations were the often-favored standard of care and were not reflective of a therapeutic choice influenced by profit-motivated care.[9]

The authors also cite the American Society of Clinical Oncology (ASCO) "Choosing Wisely" campaign list as "long standing" evidence that the drugs were low-value. However, they fail to note that the ASCO list came out in 2013, well after the study time period of 2004 – 2011. Reflecting on guideline-driven, physician prescribing patterns well after new consensus has emerged is nonsensical.[10]

It is also disconcerting that the authors appear to "cherry pick" data sets and periods to evaluate without reason or explanation. While stating that they will evaluate treatment interventions by site of service, the authors then only report on a selected few and make sweeping generalizations in the conclusions and discussions sections. Similarly, with SEER-

Medicare claims data available through 2016, raises the question of why the authors did not extend their study period to include more years of recent data.[11]

In addition, while the authors' application of a mixed effects model is appropriate, their attribution to bias is substantially limited. Other confounders that could have been assessed that would have influenced supportive care utilization, such as transfusion burden, febrile neutropenia, or other infectious illnesses, were not evaluated. All of these would have been available in the data set. The authors also failed to evaluate the conditions that would necessitate supportive care and alternative outcomes that patients may have faced, such as transfusion or infectious complications.

Finally, the Charlson Comorbidity Index (CCI) used by the authors to reach their conclusions may have been incorrectly modified in some way, resulting in skewed results. When using online tools, every patient in the study should have had a score of at least 8 (+2 for age greater than 60 and +6 for metastatic cancer). If the score for age was omitted, then patients treated in the physician office setting would have had a higher CCI and, therefore, would have likely benefited from higher levels of supportive care with G-CFS and ESA to reduce the risk of complications resulting in hospitalizations and/or emergency room visits. This latter benefit was identified by the authors' findings.

2. How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment

What the study says:

> *". . . the Medicare reform law aimed to lower Medicare spending by reducing reimbursements for specific drugs. It also aimed to reduce the incentive to prescribe certain drugs that afforded particularly higher margins for the doctors and clinics but did not offer any clear clinical advantage for patients."*

This is an old study, first published in 2005. The study focuses heavily on the increased use of docetaxel, a successor drug more expensive than its predecessor, paclitaxel, as substantiation of a perverse incentive.[12] The increased use more correctly reflected the change in the clinical standard of treatment since 2005.[13] The study conflicts with itself as it asserts both that the premise of the MMA was that ASP + 6% was designed to cover costs and result in a "break even," no matter the cost of the drug and that there is a perverse incentive to make drug selections that garner a higher profit.

3. Physician Response to Financial Incentives When Choosing Drugs to Treat Breast Cancer

What the study says:

> *"Physicians have explicit financial incentives attached to each potential drug treatment, with profit margins ranging more than a hundred-fold."*
>
> *"We find that increasing physician margin by 10% yields between an 11 and 177% increase in the likelihood of drug choice on average across drugs. Physicians were more likely to use drugs with which they had experience, had more citations, and were FDA-*

approved to treat breast cancer. Oncologists are susceptible to financial incentives when choosing drugs, though other factors play a large role in their choice of drug."

This again, is an old study examining even older data from 1992 - 2002. No treatment domain has changed more in the last 20 years than breast cancer care, making most of the study conclusions obsolete. Additionally, reimbursement, the standards of care, and pathways have also changed dramatically since this study was published. Simultaneously, a substantial increase in treatment options offering newer, better drugs serves as the true driver of prescriber preferences, despite the drugs being costlier. To presume that drug choice is based on a perverse incentive ignores other important drug selection factors such as patient status, drug toxicity, and efficacy.

4. Reduction in Physician Reimbursement and Use of Hormone Therapy in Prostate Cancer

What the study says:

"In this example of hormone therapy for prostate cancer, decreased physician reimbursement was associated with a reduction in overtreatment without a reduction in needed services."

This 2010 study is yet another old study reviewing data collected from 1992 - 2005. Again, as with breast cancer, dramatic changes in prostate cancer treatment have evolved since the study period. The conclusions reached in this study are suspect because patient results from Prostate-Specific Antigen (PSA) testing were not included in the examined data.

Additionally, this study is another instance where toxicity as a basis for drug choice was not considered in the study conclusions. The current earlier detection of prostate cancer, resulting in stage migration, thus increasing the number of patients eligible for treatment, was also not considered.

5. Infused Chemotherapy Use in the Elderly After Patent Expiration

What the study says:

"The generic entry of irinotecan resulted in a 17% to 19% decrease ($P < .001$) in use among elderly patients with MCRC compared with oxaliplatin."

"This study provides novel and robust estimates of the decline in use of a chemotherapy to treat a common cancer in the elderly after patent expiration. The results suggest estimates from a previous Office of the Inspector General report of the potential savings derived from the generic entry of irinotecan for public payers are an overestimate, likely confounded by oncologists' response to financial incentives, changes in scientific evidence, and promotional activities."

The study authors readily admitted that a drug option, the widespread use of oxaliplatin, was frequently preferred because of lower toxicity with similar efficacy.[14] Oxaliplatin became available concurrent with the patent expiration of irinotecan. The two concurrent events, a patent expiration and the availability of a costlier new drug, were not related. Physician drug

preference was based on lower toxicity and the widespread clinical pattern of utilization of oxaliplatin and did not focus on financial motivations.

6. Impact of Payment Reform on Chemotherapy at the End of Life

What the study says:

> *"In physician offices, where drugs generate the majority of revenue and prescribing patterns can determine physician income, use of chemotherapy at the end of life fell significantly after reimbursement reductions; no concurrent change occurred in hospital outpatient departments. These results suggest that payment reform may be used to better align appropriate financial incentives with better quality of care."*

This study, published in 2012, addresses the impact of post-MMA reimbursement on chemotherapy utilization during the last 14 days of life. The study authors immediately confuse high drug revenues with high drug profits. The study references evidence showing no decline in chemotherapy services or access to chemotherapy consequent to the implementation of MMA.

Pathway changes have evolved since this study leading to a now greater emphasis on end-of-life palliative care and the associated deployment of earlier integration of palliative care and hospice into end-of-life care planning. Because of these treatment changes, as well as changes in physician and patient attitudes about end-of-life care management, it is reasonable to conclude that physicians may currently approach treatments during the last few weeks of life quite differently than in the past. Finally, the authors readily admit that *"the simultaneous cultural shift in the oncology community driven by end-of-life cost/benefit concerns and emerging models addressing the demands for better physician and patient communication"* were not fully implemented during the study period.

This study raises the question of whether a physician might be incentivized to prescribe a more toxic, less effective drug because it is cheaper. Based on this study alone, the answer would appear to be "yes". However, no thoughtful physician would use an older, more toxic, less effective drug when a newer, less toxic, and more effective one is available.

Often Overlooked – or Omitted – Contrasting Studies

A number of studies on physician prescribing under the Medicare Part B reimbursement system have been published in recent years, all of which reach dramatically differing conclusions on physician prescribing patterns. To help inform policymakers, COA has compiled the following summary and analysis of recent evidence on the issue.

1. "Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount?" Xcenda
2. "Providing High Quality Care in Community Oncology Practices/An Assessment of Infusion Services and Their Associated Costs." Avalere Health
3. "Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model." Lee N. Newcomer, MD; Bruce Gould, MD; Ray D. Page, DO, PhD; Sheila A. Donelan, MS; Monica Perkins, PhD

4. "Unintended Consequences in Cancer Care Delivery Created by the Medicare Part B Proposal: Is the Clinical Rationale for the Experiment Flawed?" Lucio Gordan, MD; Amy Grogg; Marlo Blazer; Barry Fortner
5. "Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing?" Mark C. Hornbrook; Jennifer Malin; Jane C. Weeks; Solomon B. Makgoeng; Nancy L. Keating; Arnold L. Potosky

1. Medicare Physician-Administered Drugs: Do Providers Choose Treatment Based on Payment Amount? [15]

What the study says:

> *"Overall, treatment choice does not appear to be driven by the margin physicians are paid on a drug, indicating that the ASP+6% payment rate does not drive high-cost drug utilization."*
>
> *"These findings call into question claims made by some that the ASP+6% add-on payment rate for prescription drug reimbursement in Medicare Part B distorts prescribing decisions."*

This 2018 study researched the very premise that physicians select more expensive drugs because with Part B drug reimbursement of ASP + 6% they can financially benefit. The study conclusions were clear, *"findings indicate that there is no meaningful correlation between drug payment and utilization, challenging the theory that physicians significantly favor drugs with high add-on payments."*

2. Providing High Quality Care in Community Oncology Practices/An Assessment of Infusion Services and Their Associated Costs [16]

What the study says:

> *"The services required to deliver quality oncology care to patients exceed simply administering chemotherapy and other therapeutics. The comprehensive suite of services involves patient and family counseling, nutrition advice, care coordination with other healthcare providers, palliative care, telephone support, financial counseling, and other services that assist patients through their treatment regimen"*

Avalere Health worked with COA to design and administer a survey to identify the complete suite of infusion-related services available at community oncology practices and to capture detailed costs associated with delivering high-quality cancer care. The survey looked specifically at the resources needed to deliver infusion services, beyond the task of administering chemotherapy and other medications, and counseling patients during evaluation and management visits.

When comparing the difference in current Medicare payments to practice costs collected in this survey, Avalere found that the sampled practices would receive payment equivalent to only 56.53% of the costs incurred to provide infusion services. Thus, they are actually losing money on the drug reimbursement.

3. Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model [17]

What the peer-reviewed study says:

> *"This program had two objectives. The primary objective was to decrease the total medical cost by using aligned financial incentives supported by actionable use and quality information. This goal was met, as demonstrated by a 34% reduction of the predicted total medical cost. The secondary objective was to remove the linkage between drug selection and medical oncology income. Without this linkage, it was expected that CDC [chemotherapy drug cost] trends would decrease. Paradoxically, the pilot resulted in 179% more CDC than predicted when compared with the controls. Despite the additional $13 million for chemotherapy drugs, the total medical costs were reduced by $33 million."*

The importance of this study, which served to demonstrate that when any link between drug choice and physician profit was removed, chemotherapy drug utilization (and costs) went up, not down. Even the study authors conclude *"modifying the current fee-for-service payment system for cancer therapy with feedback data and financial incentives that reward outcomes and cost efficiency resulted in a significant total cost reduction. Eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy* [emphasis added]*."*

4. Unintended Consequences in Cancer Care Delivery Created by the Medicare Part B Proposal: Is the Clinical Rationale for the Experiment Flawed? [18]

What the peer-reviewed study says:

> *"For the largest Medicare oncology drug expenditures, there is not a lower-cost option with equal efficacy for their primary indications. Without lower-cost alternatives, the unintended consequence of this CMS experiment may include curtailing access to care or an increase in patient/program costs. The CMS proposal, by simply lowering reimbursement for drugs, does not acknowledge the value of these agents and could unintentionally reduce quality of care. Alternative approaches to value-based care, such as the Oncology Care Model and similar frameworks, should be explored."*

The premise that the current ASP + 4.3% reimbursement model has encouraged the use of higher-priced drugs is not supported by existing evidence. An examination of the study conclusions suggests the driving force in product selection is clinical effectiveness and that the current ASP payment methodology has not stimulated use of higher-priced drugs.

5. Did Changes in Drug Reimbursement After the Medicare Modernization Act Affect Chemotherapy Prescribing? [19]

What the peer-reviewed study says:

> *"Changes in reimbursement after the passage of the MMA appear to have had less of an impact on prescribing patterns in Fee for Service (FFS) settings than the introduction of new drugs and clinical evidence as well as other factors driving adoption of new practice patterns."*

The main driver of prescribing is the introduction of new drugs and clinical evidence in such areas as toxicity, as well as other factors that are driving adoption of new practice patterns.

Summary

There is no compelling evidence of a perverse incentive in oncology prescribing within the Medicare Part B reimbursement system. If finances are not the primary driver of drug selection, then other factors must be. It is important to recognize those variables in order to develop a correct working hypothesis as to the reasons why physicians prescribe what they prescribe, before there can be any real payment reform that avoids unintended consequences. For example, federal reimbursement policy must be examined holistically, including profit incentives created in the federal 340B Drug Pricing program or the utilization of middlemen like pharmacy benefit managers (PBMs).

The following have been identified by oncologists as drivers of drug selection:

- Highest-quality patient care;
- Most effective treatment options;
- Best expected outcome;
- Best tolerated, least toxicity or permanent ill effects;
- Care regimen least disruptive to daily life;
- Most cost-effective option for the patient;
- Financial cost to the patient; and
- Changing physician and patient expectations about cancer care.

Many of the newest cancer drugs, which currently have no alternatives, have achieved unprecedented survival rates and have advanced the state of cancer care. Inevitably, these new drugs are almost always more expensive than existing therapies. However, to presume that new drugs that are proven to save lives and/or improve quality of life are prescribed because the oncologists benefit financially is simply unproven and not true. In fact, as referenced in this paper, multiple studies have proven the exact opposite.

Cancer care costs and drug prices are too high, by any standard. Change is necessary, and COA is leading the way towards a solution that ensures patients have access to the highest-quality, most accessible, and most affordable cancer care. If we are to make progress, all stakeholder parties must understand and discuss how drug pricing and patient costs, including non-drug costs of hospital-related costs, factor into cancer treatment planning and joint decision-making with patients.

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