Part B payment for drugs in Medicare: Phase 1 of CMS's proposed pilot and its impact on oncology care

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Executive Summary

The recent pilot proposal on Part B drug payment from the Center for Medicare and Medicaid Innovation of CMS has met strong resistance from the lobbies for both pharmaceutical companies and cancer doctors. The "buy and bill" system, the main component under scrutiny, is a reimbursement design in which physicians buy pharmaceutical drugs and submit a bill for reimbursement upon administration to the patient. That bill has two parts: a reimbursement based on the average price of the drug, and a percentage based mark-up, or profit. This latter component is the target of Phase 1 of CMS' pilot.

Given the controversy, empiric information on the proposed pilot might help clarify the source of objections from the drug industry and cancer doctors as well as the pilot's potential impact. In this report, we examine the proposed payment formula change in Phase 1 of the pilot, focusing on drugs used in the care of cancer patients, a subset of all Part B payments (approximately 35%). A future report will address Phase 2 of the pilot. This report addresses five issues important to this discussion.

1) Are there clinical situations in oncology where clinicians can choose between more and less expensive drugs and thus a change in the profit formula might encourage more cost-effective treatment?
2) What is the total profit for doctors and hospitals for "Part B" drugs across their patients with varying types of insurance
3) Which drugs are favored versus disfavored by the change in the profit formula?
4) How do the 'ups' and 'downs' affect the bottom line of doctors treating cancer patients? Do they end up ahead or behind?

April 11, 2016

Drug Pricing Lab
Memorial Sloan Kettering

Introduction:

The pilot proposal on Part B drug payment focuses on the system that goes under the nickname 'buy and bill', under which hospitals and doctors "buy" drugs that are later administered to patients with cancer and other serious conditions. Only after a particular patient is given the drug is a "bill" generated, a part of which is given to the patient and the other is sent to the patient's insurer, such as the Medicare program. The two components of the bill include a reimbursement based on the average price of the drug, and a percentage based mark-up, or profit.

The design of Phase 1 has doctors and hospitals in some regions of the country receiving the current profit level (which the law sets at 6% of the drug's price, and is currently 4.3% due to the 2013 budget sequestration[1]), while in other regions doctors will receive a smaller percentage profit (2.5%, 0.9% under sequestration we estimate). For the latter group, there will also be a flat profit amount of $16.80 (presumably $16.46 under sequestration) paid for each round of treatment. Although this flat fee is intended to compensate for the reduction in the percentage based profit across all treatments, it will do so asymmetrically. Profits associated with the administration of inexpensive drugs will rise, while those with more expensive drugs will fall (the breakeven point is a treatment costing $480, or $484 under sequestration).

Several concerns about the pilot have been raised. Lobbies for cancer doctors such as the Community Oncology Alliance[2] have called the proposal a 'pay cut', meaning Medicare will be paying less to doctors overall, even though the group also argued that the proposal would cost Medicare more money. CMS argues that they have calculated how to pay out the same amount of money as they currently do in total, the payments will just be distributed differently (what CMS means when it says the pilot is 'budget neutral'). Lobbies for drug companies have stated that the pilot will limit beneficiary choice[3] of treatments, even though the pilot explicitly does not alter coverage of drugs. Meanwhile large influential organizations like AARP[4] and the Medicare Rights Center[5] support the pilot program as it reduces the incentive for doctors and hospitals to use more expensive treatments that have higher attendant costs for patients due to the 20% coinsurance patients must pay for Part B drugs.

Analysis:

1) Are there clinical situations in oncology where clinicians can choose between more and less expensive drugs and thus a change in the profit formula might encourage more cost effective treatment?

Background: A number of studies have demonstrated that prescribing practices of hospitals and doctors shift when the profits associated with some treatments change with respect to others[6,7,8]. Despite these data, major physician organizations such as the American Society of Clinical Oncology[9] have argued that there are no meaningful clinical scenarios in which doctors have alternative treatment options with different profit potentials.

We examined the NCCN guidelines[10] and Anthem's AIM Cancer Treatment Pathways[11], two well respected sources of cancer treatment recommendations. We looked for examples of treatments for common cancers such as cancer of the breast, skin, lung and colon where these organizations proposed sets of treatment options that had vastly different price points. We then compared the costs to Medicare and the profits to doctors and hospitals derived from the various choices both under today's profit formula and the one Medicare has proposed (both with and without sequestration, see Appendix for detailed methods).

Findings: We identified a number of representative treatment pairings that major bodies consider clinically substitutable, associated with very large differences in costs to Medicare and Medicare beneficiaries, and attendant large differences in profits for doctors and hospitals. The comparative costs of each regimen are displayed in Table 1. In each case, one treatment choice delivered hundreds of dollars of more profit and in many cases, more than ten thousand dollars in added costs to Medicare (and thus around $2,000 more in added costs to beneficiaries) when compared to a lower cost alternative over a 12-week course of treatment. Under the proposed change to the profit formula, the differences in cost to Medicare largely persist, but the difference in profit to the prescribing physician or hospital was meaningfully attenuated, although not eliminated.

Interpretation: There are important clinical scenarios in which doctors and hospitals face a choice between treatments that are highly costly and those that are substantially less so. Profits favor the former treatments, although less so under the proposed pilot's new profit formula.

Table 1: Comparable regimens and attendant profits under current and proposed profit formula for twelve weeks of treatment.

NSCLC: 1st line therapy for non-squamous metastatic disease

For 12 week-treatment:	Taxol + Carboplatin	Alimta + Cisplatin	Difference
Cost to Medicare:	$280	$19,859	
Current Doctor's Profit:	$17	$1,192	$1,175
Proposed Doctor's Profit	$125	$631	$506
With Sequester:			
Current Doctor's Profit:	$12	$854	$842
Proposed Doctor's Profit	$118	$310	$193

Source: Anthem Lung Cancer Pathway

Breast Cancer: Single agents for recurrent or metastatic breast cancer

For 12 week-treatment:	Paclitaxel	Abraxane	Difference
Cost to Medicare	$201	$16,686	
Current Doctor's Profit:	$12	$1,001	$989
Proposed Doctor's Profit	$72	$484	$412
With Sequester:			
Current Doctor's Profit:	$ 9	$717	$709
Proposed Doctor's Profit	$68	$216	$148

Source: NCCN Breast Cancer Guidelines

Colon Cancer: Primary treatment for unresectable metachronous metastases

For 12 week-treatment:	Avastin	Erbitux	Difference
Cost to Medicare	$14,058	$27,466	
Current Doctor's Profit:	$843	$1,648	$ 804
Proposed Doctor's Profit	$452	$ 888	$ 436
With Sequester:			
Current Doctor's Profit:	$ 605	$1,181	$ 577
Proposed Doctor's Profit	$225	$445	$ 219

Source: NCCN Colon Cancer Guidelines

2. How is the mix of reimbursement for "Part B" drugs distributed across payers and how does it affect the bottom line of doctors and hospitals?

Background: Most discussion of Medicare's reimbursement for Part B drugs focuses only on the profits that Medicare provides. However, consideration of the economics of doctors' offices and hospitals requires a wider view of the acquisition costs for drugs across all treated patients and the attendant reimbursement doctors and hospitals receive overall. We present approximate estimates on the blend of reimbursement for doctor and hospital practices across their patients and insurance types for Part B type drugs, which are based on what publicly available information we could identify on distribution channel proportions and mark-ups. The illustration is also simplified, ignoring for instance, wholesale intermediary mark-ups and spending in the Veteran's Administration.

Findings: The Medicare mark-up of 6% (currently 4.3%) appears to understate the profit associated with the administration of "Part B" drugs, due to higher gross profits to doctors and hospitals from their commercial insurance contracts and steep discounts available to 340B hospitals. The collective gross profit across all patients and care settings is around 49%, but is not evenly applied as the blended profit margin for doctors is around 16% while it is around 140% for hospitals. The sub-category of hospitals in the 340B program earn a blended profit margin of around 210% (other hospitals are at 98%). Figure 1 shows a schematic of the distribution of one-hundred $1 vials of cancer drugs and where they are administered and how discounts and mark-ups add up (see Appendix for methods).

Interpretation: Changes to Medicare's payment formula are only part of the picture of total gross profits for doctors and hospitals from using Part B drugs, Medicare mark-ups are generally smaller than commercial margins. The blend of all payments for doctors and hospitals should be considered when evaluating any change to the Medicare payment formula.

Figure 1: Distribution and mark-up of one-hundred $1 vials by payer and provider

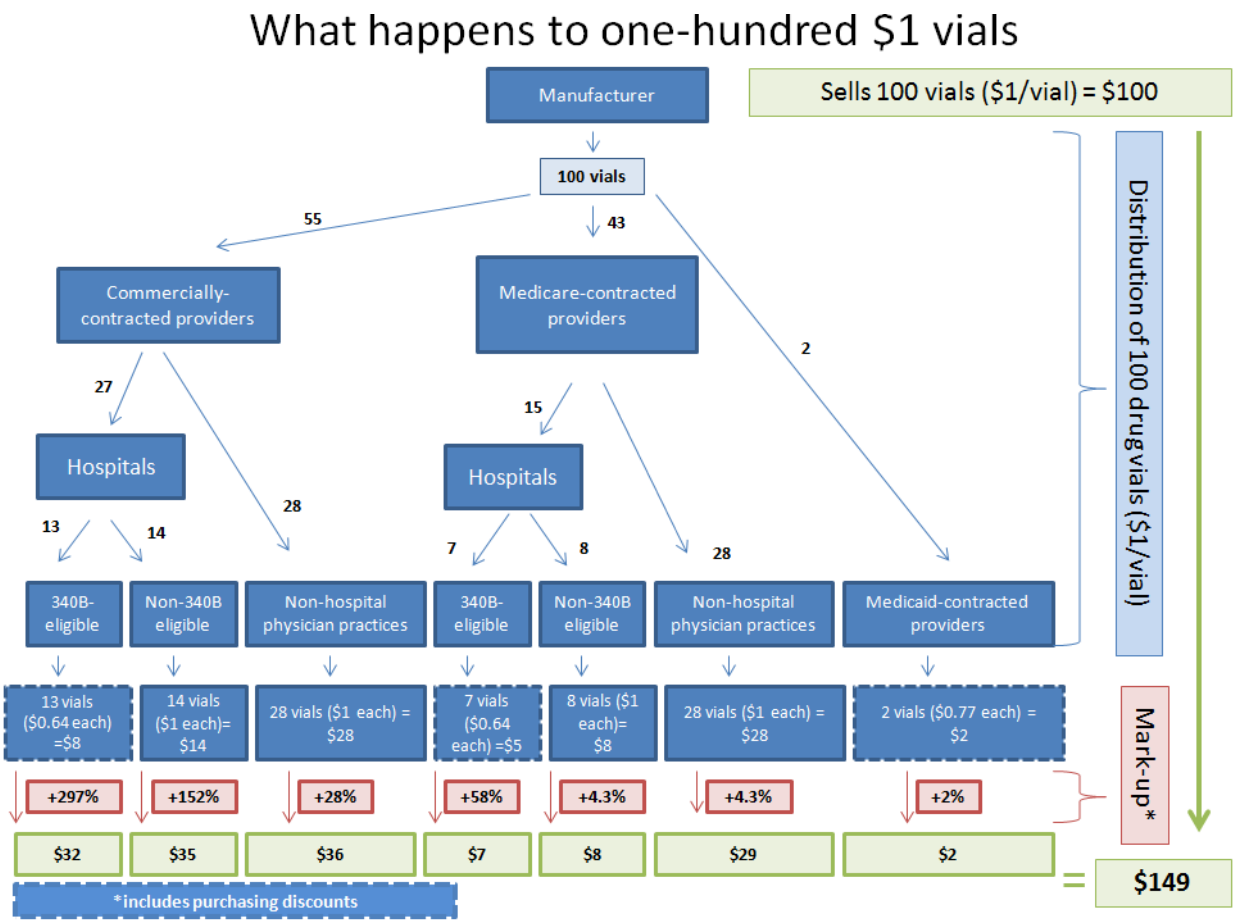
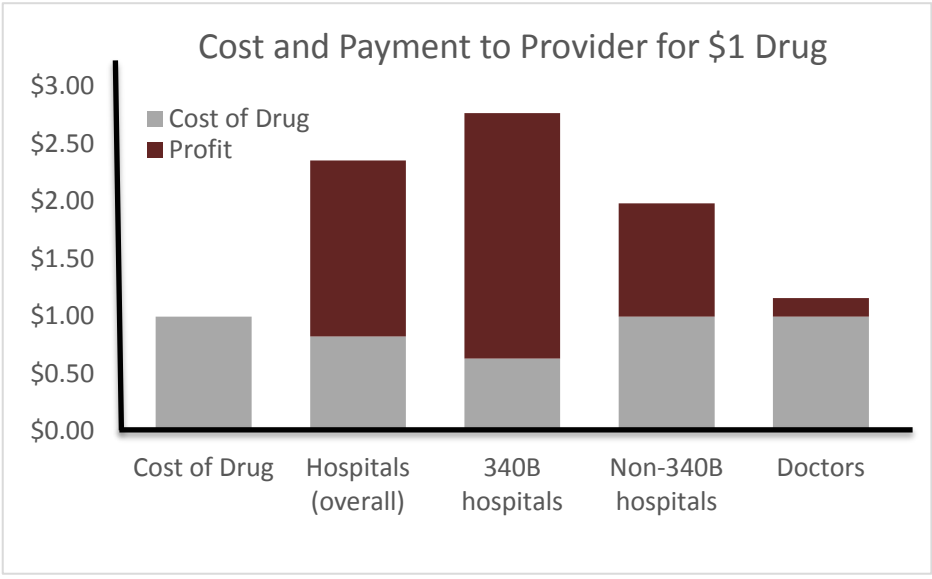


Figure 2: Payment to provider for $1 drug including blended reimbursement



3. Which drugs are favored versus disfavored by the change in the profit formula for doctors and hospitals?

Background: Most discussions of Part B reimbursement changes consider all Part B drugs as a category. CMS' proposed change to the profit formula affects different drugs differently. The break-even point is a treatment that Medicare pays $480 for under the statutory formula, or about $484 under the sequestration formula. Treatments costing less than this will see attendant gross profits rise, those costing more will see attendant profits fall. How many drugs, and which drugs, are 'up' versus 'down' under the proposed payment is an important question, as is the question of how much different changes influence whether the pilot will lead to greater or lesser aggregate gross profits for doctors and hospitals treating patients with cancer.

Findings (Physicians): Across the individual drugs used to treat cancer and their volumes of utilization in Medicare's 2014 data[12], we find that about half of drug treatments will deliver larger gross profits to physicians, while the other half will deliver lower gross profit. Figure 3 shows the gross profit under the current and proposed models (under sequestration), ordered from the least to most spending for oncology uses in Medicare in 2014. Tables displaying the individual results are included in the Appendix. Figure 5 arrays these drugs cumulatively from least to most 2014 spending and shows the concentration of spending among the top several drugs.

Interpretation (Physicians): Although many drugs that are inexpensive will see larger associated profits, there are a few very expensive drugs at the upper range where aggregate gross profits will be severely curtailed. To the extent that magnitude of profits influence prescribing of these expensive agents, it is reasonable to presume that the pharmaceutical industry would protest diminishments in the profit incentive that currently encourages physicians and hospitals to use these more expensive agents.

Finding (Hospitals): We find that under the new payment model, the gross profits from delivering 21 drug treatments will rise, while for the remaining 51 they will fall under the proposed payment model. Figure 4 displays profits for each drug under both the current and proposed models, again under sequestration, and ordered from least to greatest spending by Medicare in 2014. Figure 6 shows the cumulative spending of drugs, the percentage of payments they represent, and whether the proposed payment model results in

decreased or increased profit for hospitals. Tables displaying the individual results are included in the Appendix.

Interpretation (Hospitals): Under the new payment proposal, and related to cancer treatments specifically, hospitals' gross profits will be decreased to a much larger extent than the gross profits for physicians. This is a direct consequence of the different systems of payments to doctors and hospitals. The hospital reimbursement system does not include a separate payment for inexpensive drugs (those under $100 per treatment currently) and CMS has stated that such treatments are not going to be included in the new payment formula either. This means that where doctors offices will receive a flat fee payment (and small percentage based add-on) under the new formula, hospitals will see no change in their payments for these treatments under the pilot program. As a result there will be essentially no counter-balancing payments for inexpensive drugs to make up for the reduced mark-up for expensive drugs that is present in the physician payment pilot. This makes the total impact of the reduction in profit percentage for drugs more negative for hospitals than doctor's offices.

Figure 3: Drug associated profits to physicians and hospitals under current and proposed payment models (under sequestration)

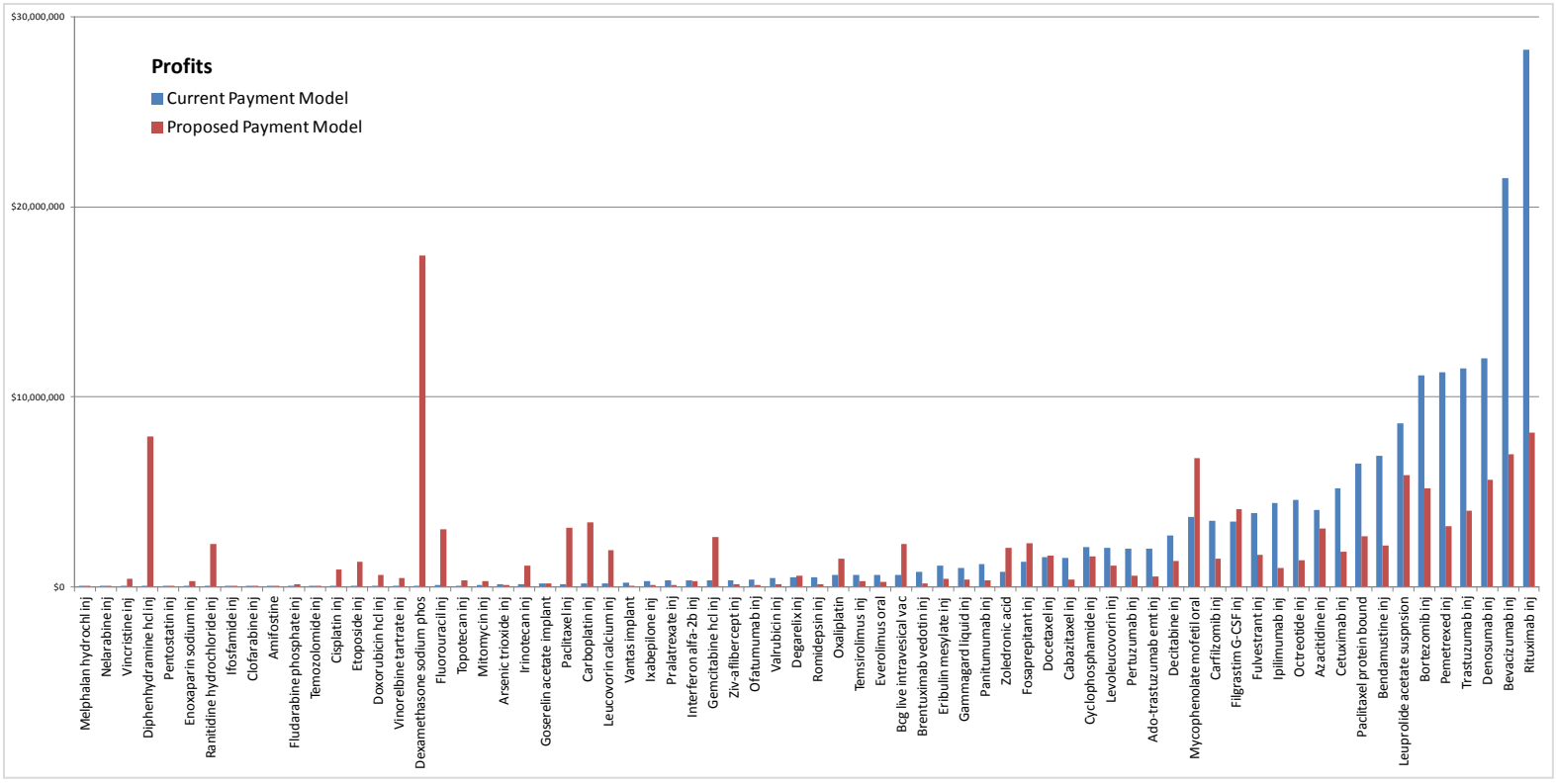


Figure 4: Drug associated gross profits to hospitals under current and proposed payment models (under sequestration)

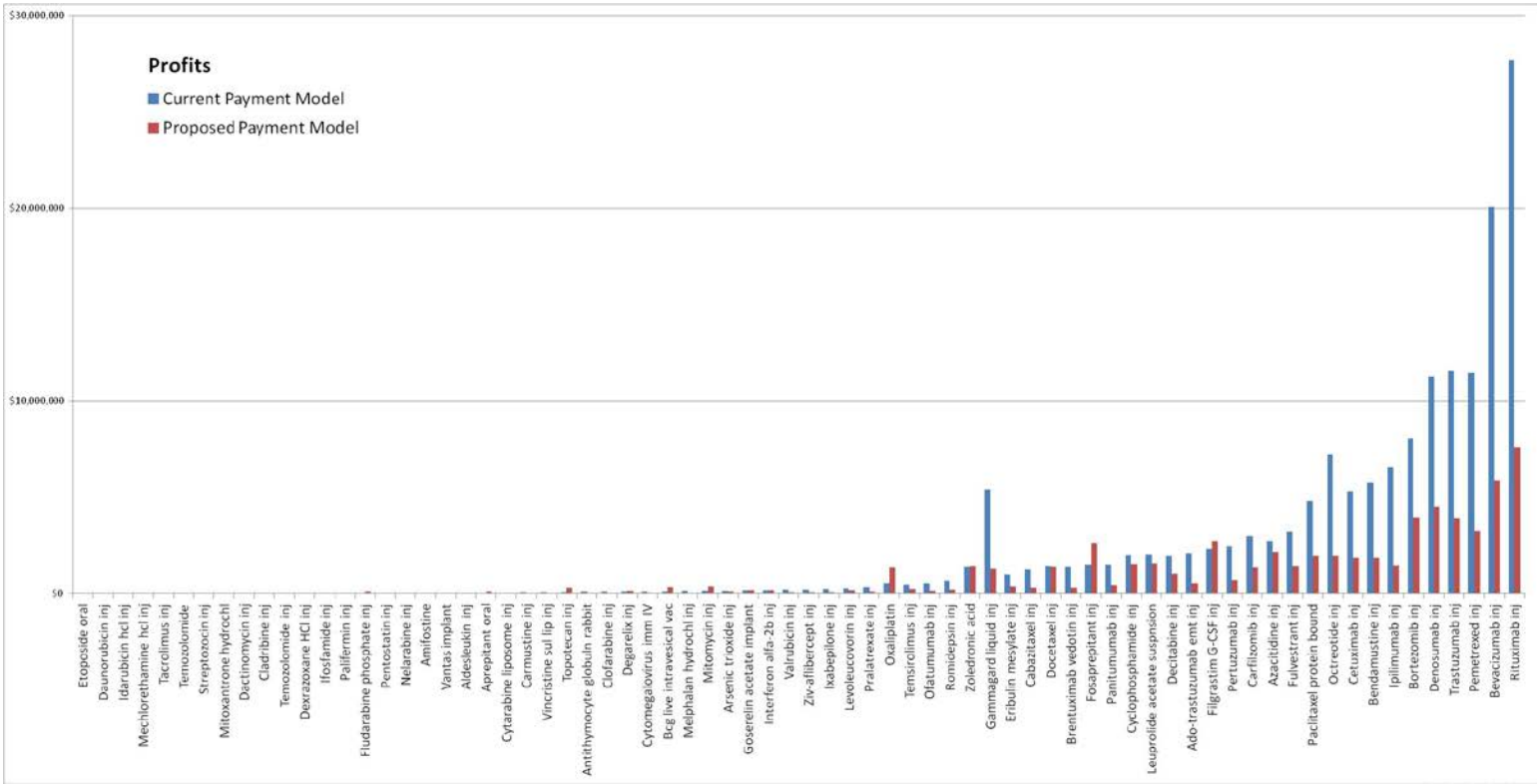


Figure 5: Cumulative payments and encounters across Part B drugs from least to most reimbursed

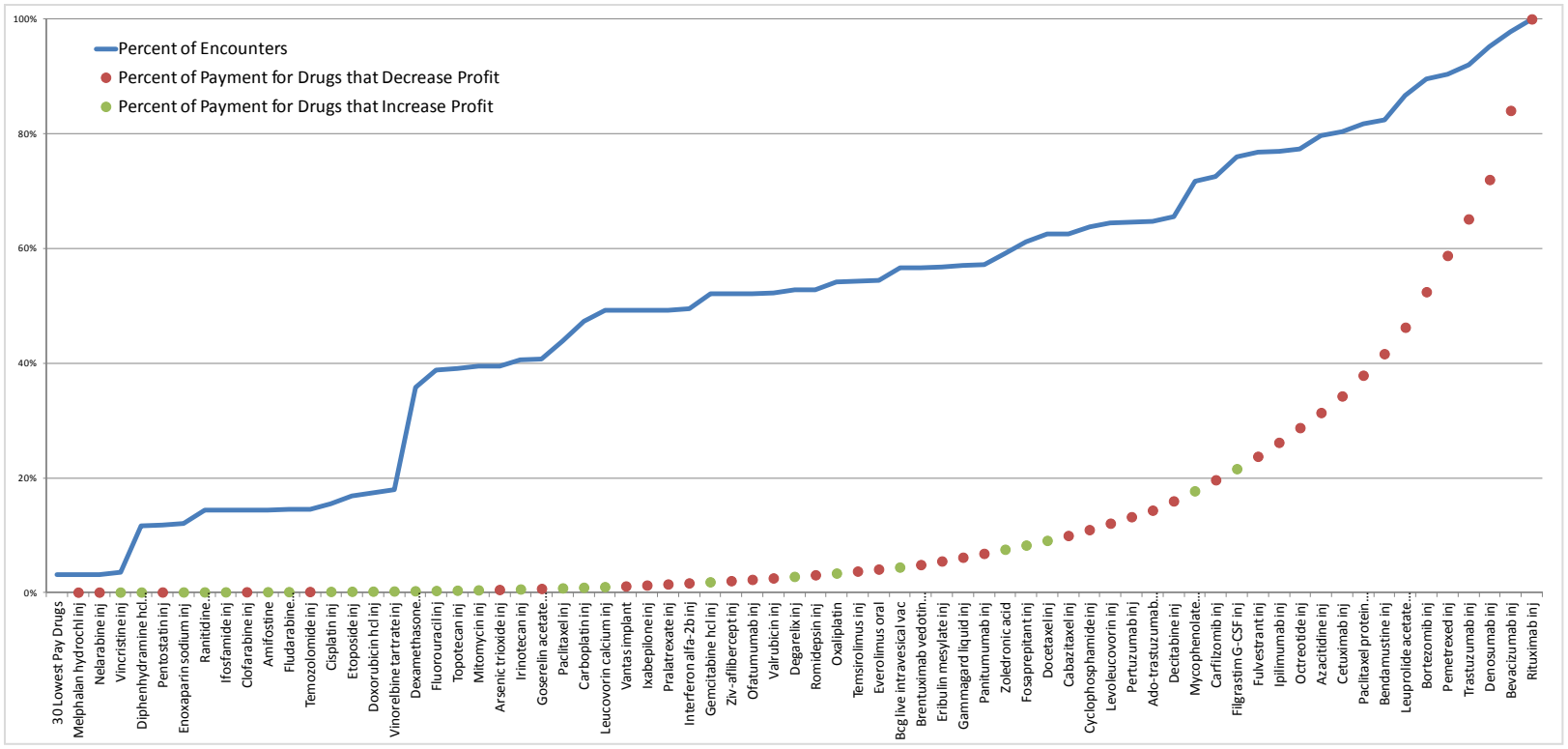
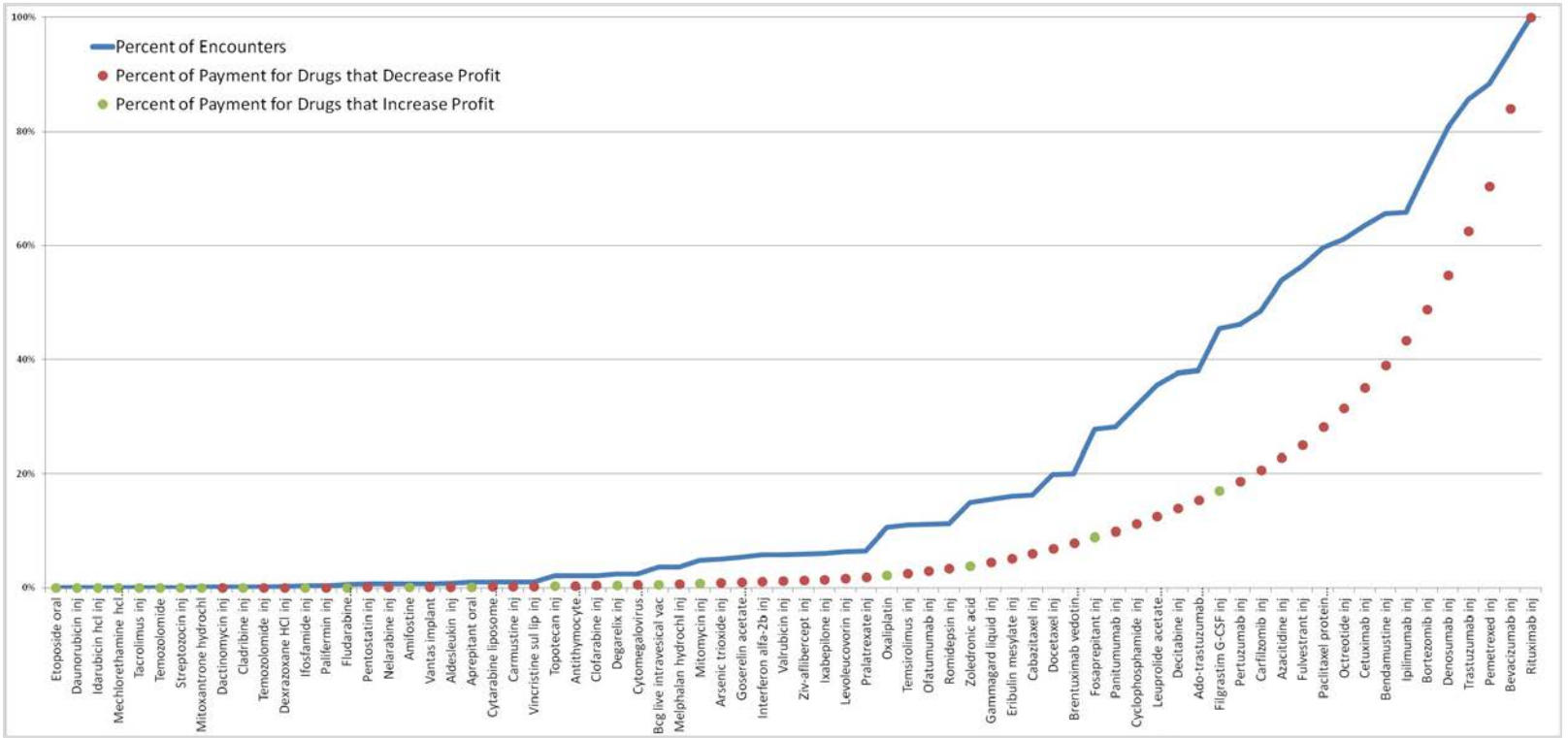


Figure 6: Cumulative payments and encounters for hospitals across Part B drugs from least to most reimbursec



How do the 'ups' and 'downs' affect the bottom line of doctors and hospitals treating cancer patients?

Background: Because some treatments will have greater profits and others lesser profits, and the entire picture of profits and losses under the proposed pilot seems heavily influenced by a few expensive drugs that have high volumes of use, we examined the total effect on profits for doctors and hospitals across drugs in a cumulative fashion, beginning with those drugs that account for the least spending for oncology uses in 2014, through those that account for the most spending.

Findings (Physicians): The sum total of these gains and losses for cancer doctors is that those in pilot regions will see a overall reduction in their payments. Overall drug reimbursement revenue will decrease by 1.02% under sequestration, 1.05% without sequestration. When fees for infusing and administering treatments are also included, reimbursement revenue decreases by 0.9% (under sequestration) Doctors' profits, currently 4.3% under sequestration, will fall by around 24.2% for their Medicare business. When combined with their commercial revenues doctor's gross profits will see a -3% relative decrease (from a gross profit margin of 16.1% to 15.5%)[1] assuming no change in commercial reimbursement rates.

These averages do mask the heavy influence of a few very expensive drugs on the overall impact of the payment formula change. As shown in Figures 7 and 10, the cumulative profit picture for doctors is actually improved for doctors across the first 96 drugs that are used in cancer treatment, but the top four drugs (trastuzumab, denosumab, bevacizumab, and rituximab), that are both expensive and frequently prescribed, turn the analysis negative due to the diminishment in what are currently very large profits associated with their use. The specific distribution of drugs that affect gross profit can be seen in Figures A1 and A2 of the Appendix, with corresponding data in Tables A1 and A2.

Change to reimbursement with pilot formula in cancer care	Doctor's office	Hospital outpatient
Mark-up/profit only	-24.2%	-60.5%
Total drug reimbursement	-1.0%	-2.8%
Drug and infusion fee	-0.9%	-2.6%

[1] Estimate updated on 4/13/16 from 16.2% and 15.7%, respectively

Interpretation (Physicians): Under the proposed pilot profit formula, the flat fee for medical oncologists would need to be raised to $24.43 without sequestration, or $23.74 per treatment under sequestration to bring oncologists back to neutral (Figure 9). Doing so would raise the break-even point to $698, making 54 of the 100 drugs more profitable to oncologists and 46 less profitable. An alternative way of closing this gap might be to add a care management fee for medical oncology, as has been proposed by the American Society for Clinical Oncology[13].

Findings (Hospitals): Similar to the effect on physicians, the sum total of changes in profit under the new payment model will result in an overall decrease in payments. We estimate that revenue will decrease by 2.79% under sequestration, and 2.84% without sequestration. Accounting for infusion fees, hospitals' revenues decrease by 2.6% under sequestration.

Figures 8 and 11 display the cumulative Medicare gross profits to hospitals under the new payment model, with drugs ordered from lowest to highest Medicare expenditures in 2014. The proposed payment system has a significantly different effect on hospitals than on physicians- in hospitals, the decreased profit is not solely attributable to the most expensive drugs. Instead, the majority of the drugs put hospitals in the negative, a change explained not by the fact that the lowest cost drugs will not see an add-on flat fee under the new payment model. The few drugs that do result in increased profit, do so minimally, and are essentially invisible on the plots.

Interpretation (Hospitals): Under the proposed pilot, the flat fee to hospitals would need to be raised to $69.93 under sequestration, or $71.98 without sequestration to make Part B payments budget-neutral. This is more than the flat fee modification we found was necessary to keep the payments budget neutral for doctors who treat cancer patients.

Figure 7: Cumulative Medicare profits to physicians for Part B drugs under current and proposed payment models

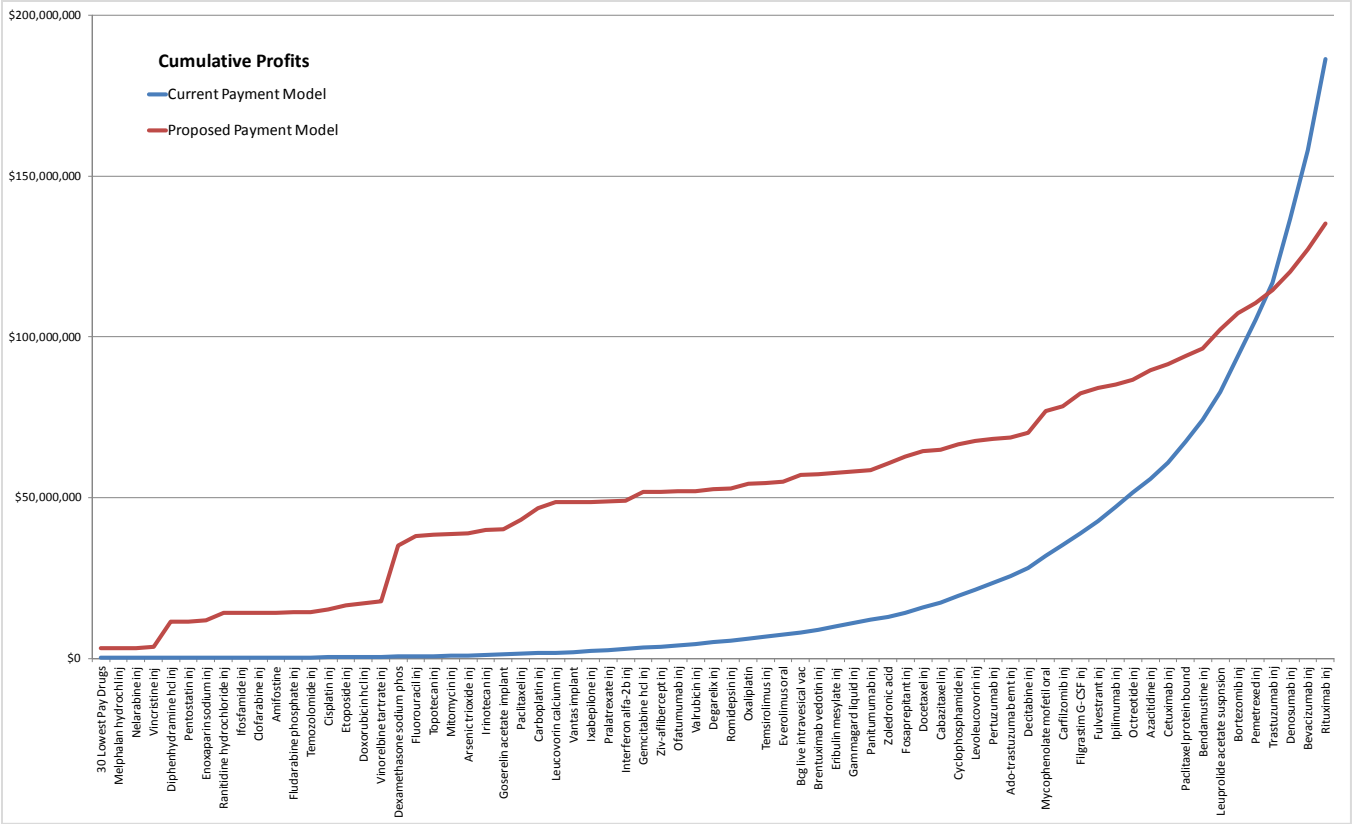


Figure 8: Cumulative Medicare profits to hospitals for Part B drugs under current and proposed payment models

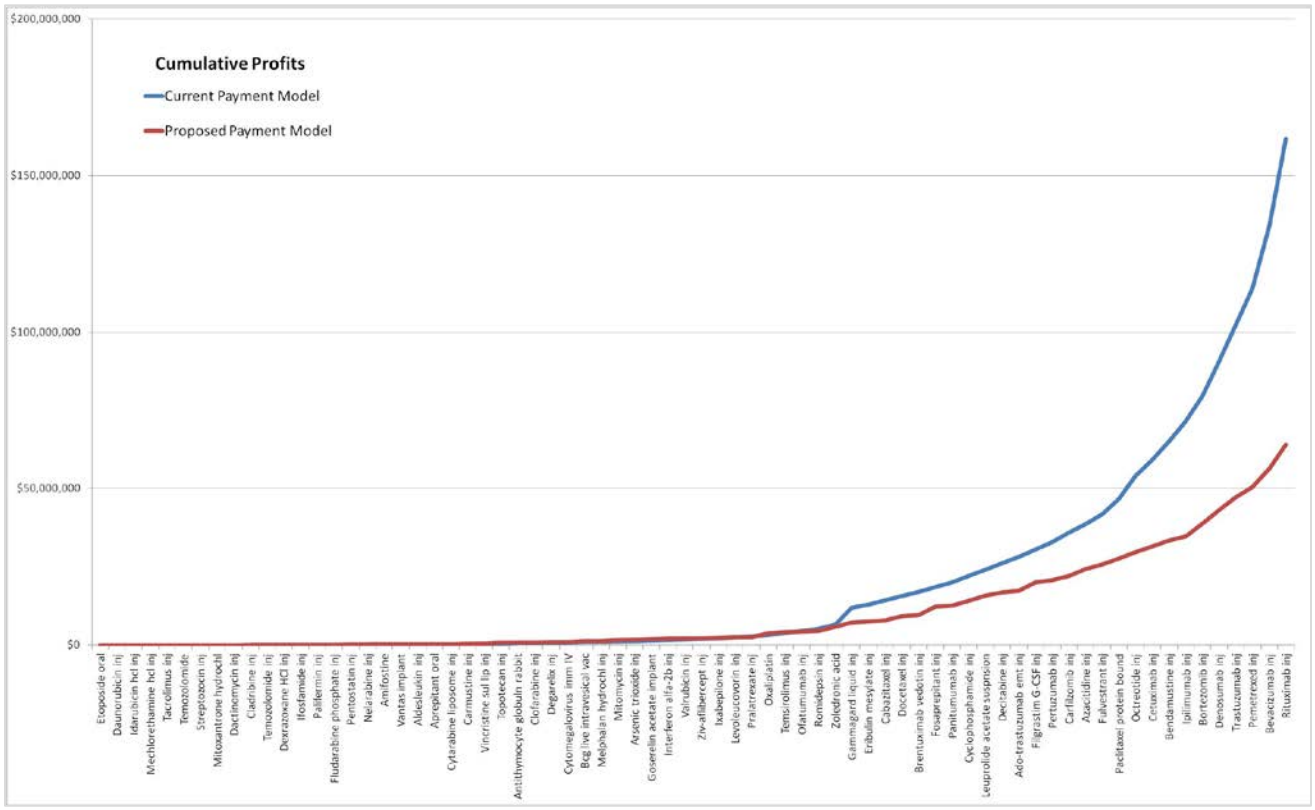


Figure 9: Markup on Part B drugs under current and proposed payment models

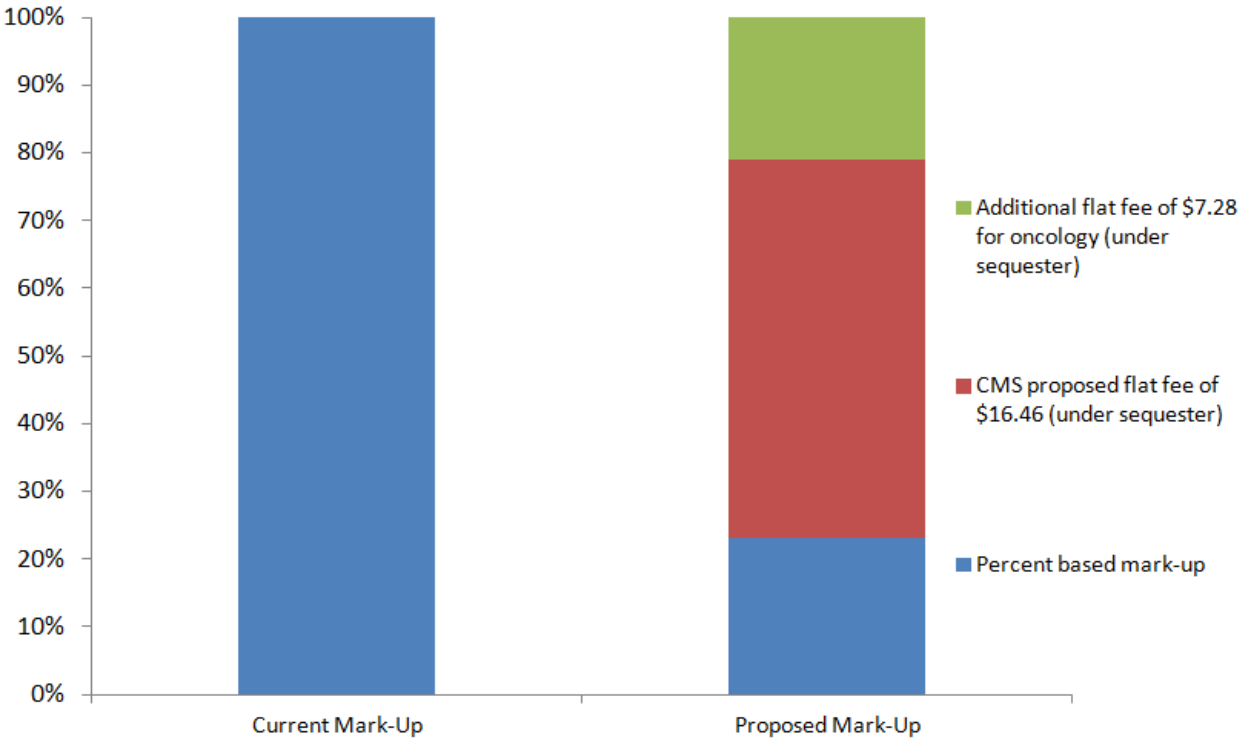


Figure 8: Cumulative Medicare profits for drugs relative to budget neutrality, under proposed payment model

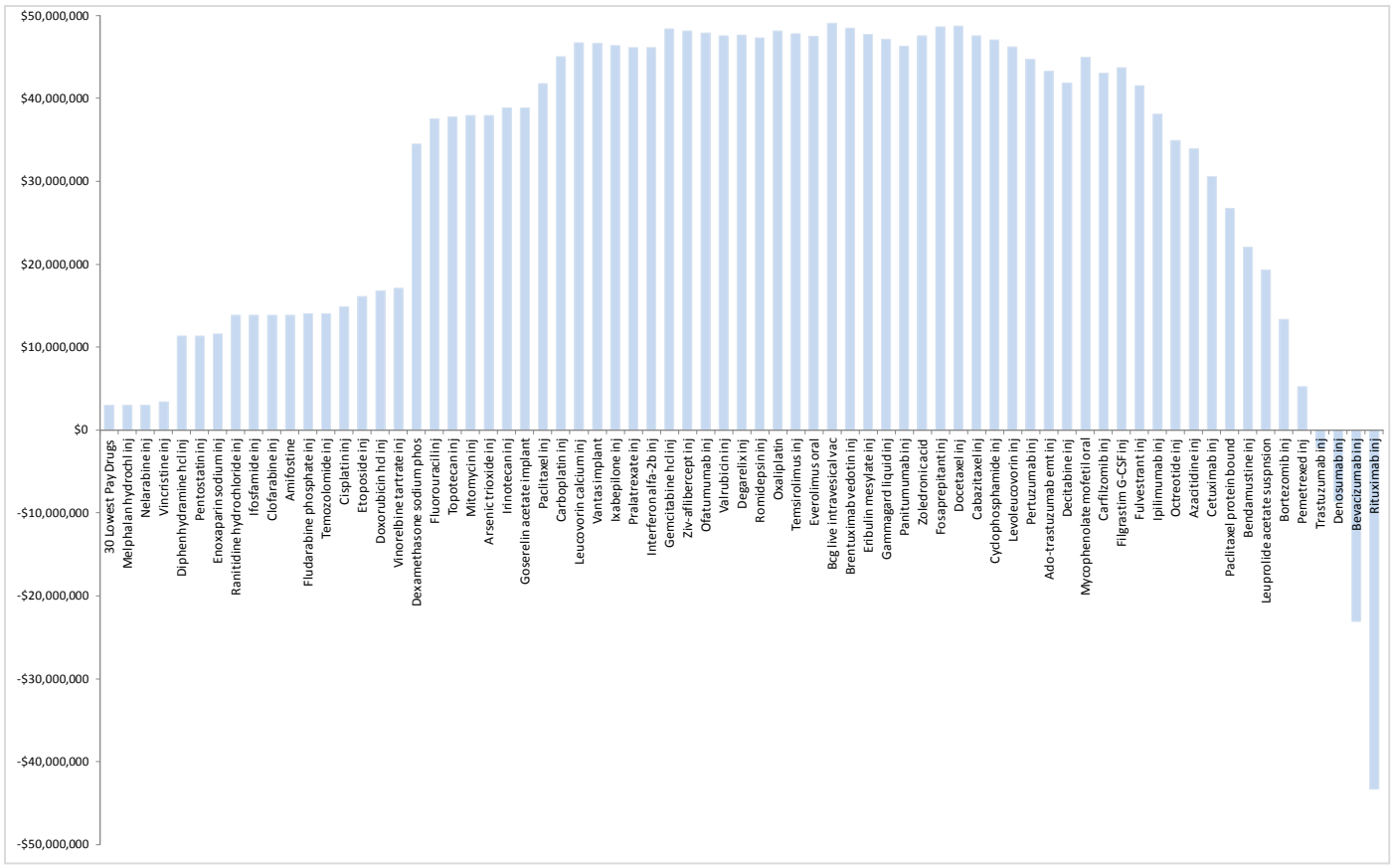
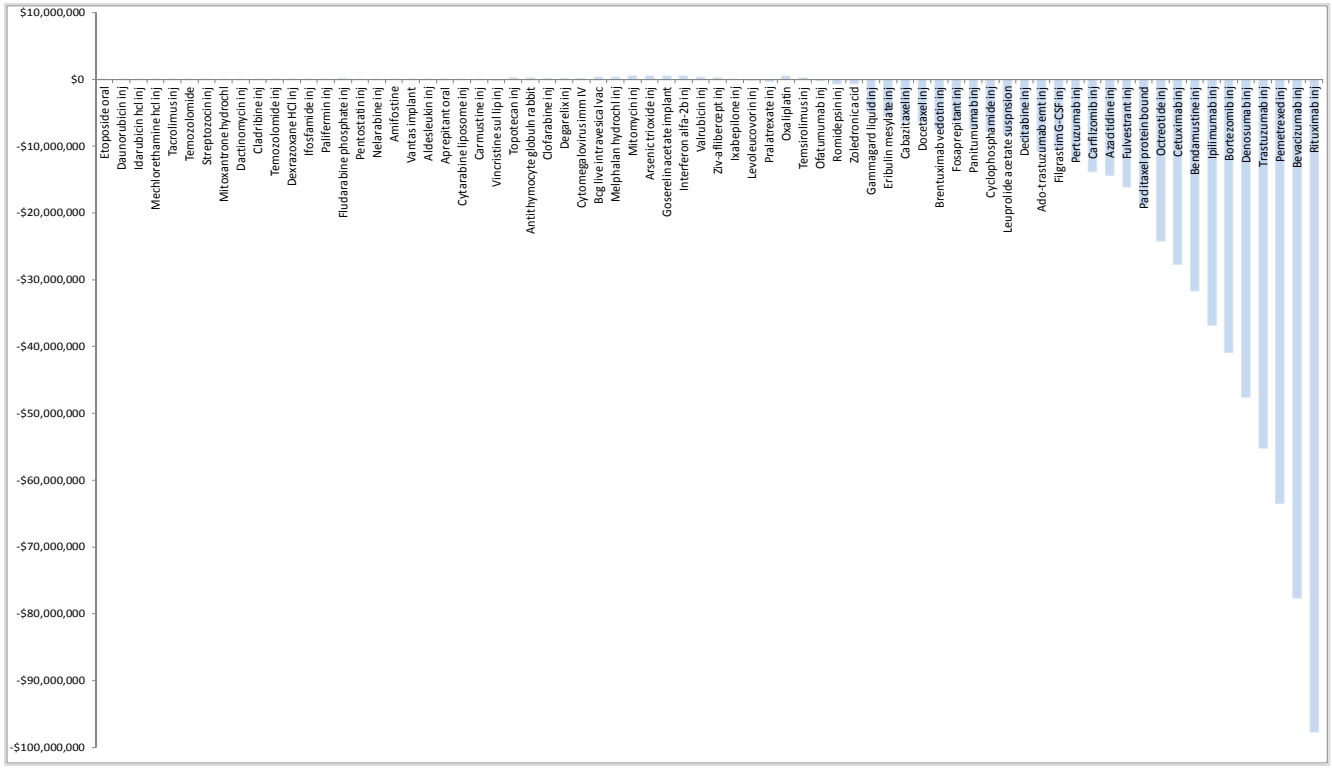


Figure 11: Cumulative Medicare profits to hospitals for drugs relative to budget neutrality, under proposed payment model



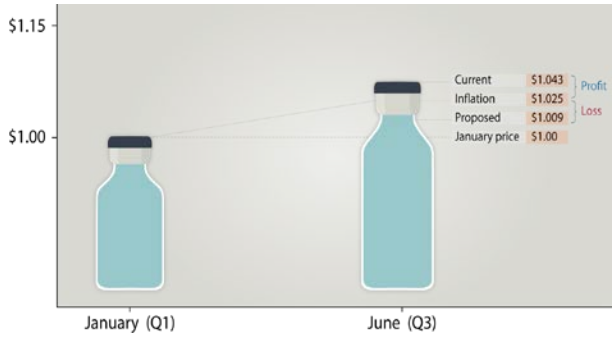
4. How might reducing the percentage based profit affect price inflation for Part B drugs?

Background: Numerous stories in the media over the past year have noted how pharmaceutical companies raise prices for their approved products after they enter the marketplace. These stories have almost entirely focused on prices for prescription drugs. Infused drugs administered by physicians have not been examined in terms of how much companies are raising prices, or how the proposed profit formula change by CMS could change the rate of inflation.

The reason this is of interest is that the formula for determining payment rates for Part B drugs has an unusual feature that would naturally be anticipated to counter inflationary trends in this category of drugs. The amount reimbursed is based on the average selling price of the drug from half a year earlier, not in the present. Technically reimbursement in a particular quarter is anchored to average prices from two quarters earlier. In other words, for a drug purchased and administered today, the 104.3% of the sales price is based on sales prices from six months ago.

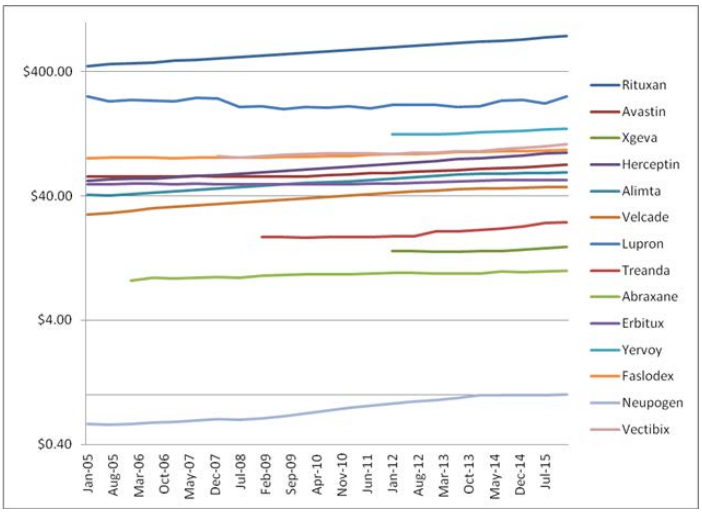
This lag leaves only a small amount of headroom for companies to raise their prices over that six month period. For instance, if companies raise their prices 2.5% over that time period, it will eat into the 4.3% profit Medicare provides, but leaving gross profits still positive at 1.8%. But the proposed change to the profit formula (and under sequestration) has doctors and hospitals only being paid 0.9% above the average sales price from two quarters earlier, so if companies raise prices 2.5% over that period, doctors and hospitals will see a 1.6% loss (Figure 12).

Figure 12: Hypothetical impact on profit or loss for doctors under different profit formulas in the



These two alternatives make a consideration of inflationary trends worthwhile in the context of evaluating the change in the profit margin for Part B drugs. To gain a better understanding, we examined for the top drugs in terms of revenue for practicing oncologists.

Figure 13: Inflation of ASPs of Part B drugs



Findings: There is a highly consistent pattern of price increases by an average of 1.7% every two quarters (3.3% per year) for the top 14 Part B drugs used by oncologists that have not been affected by entry of generic substitutes. Figure 13 below illustrates these price increases focusing on the reimbursement rates per unit and displaying the findings on a log scale so that inflationary trends can be compared across different price ranges.

Interpretation: Rising prices of Part B drugs over time are likely compressing the profit margins for medical oncologists and hospitals from below. One possible benefit of the lower profit percentage in the Medicare pilot might be that it will discourage pharmaceutical manufacturers from raising prices further, which would lead to savings for Medicare and beneficiaries (the flat fee add-on contributes little to this phenomenon for very high priced drugs).

[1] The Sequester. 2016. at https://www.whitehouse.gov/issues/sequester.
[2] 300+ National & State Organizations Ask Congress: Stop the CMS Drug Payment Proposal! 2016. at http://www.communityoncology.org/site/blog/detail/2016/03/17/300-national-state-organizations-ask-congress-stop-the-cms-drug-payment-proposal.html.
[3] Medicare Monday: 3 things to know about the government's Medicare payment change. 2016. at http://catalyst.phrma.org/medicare-monday-3-things-to-know-about-the-governments-medicare-payment-change
[4] AARP Supports CMS' Medicare Part B Demonstration Project. 2016. at http://www.aarp.org/about-aarp/press-center/info-03-2016/aarp-supports-cms-medicare-part-b-demo-project.html.)
[5] Medicare Rights Center Endorses CMS Proposal to Test Value-Based Payment Strategies for Part B Medications. 2016. at http://www.medicarerights.org/newsroom/press-releases/4616-2.
[6] Jacobson, Mireille, et al. "How Medicare's payment cuts for cancer chemotherapy drugs changed patterns of treatment." *Health Affairs* 29.7 (2010): 1391-1399.
[7] Conti, Rena M., et al. "Infused chemotherapy use in the elderly after patent expiration." *Journal of Oncology Practice* 8.3S (2012): e18s-e23s.
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[11] AIM Cancer Treatment Pathways. 2016. at https://anthem.aimoncology.com/pdf/pathways/All_Pathways_Worksheets.pdf.
[12] FY 2014 Final Rule Data Files. 2016. at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteinpatientPPS/FY-2014-IPPS-Final-Rule-Home-Page-Items/FY-2014-IPPS-Final-Rule-CMS-1599-F-Data-Files.html.
[13] Transforming Oncology Payment. at http://www.asco.org/sites/www.asco.org/files/2016-pcop-brochure.pdf.

Appendix

Table A1: Change in physician profits for Part B drugs

HCPCS	DESCRIPTION	TOTAL PAYMENT	CHANGE PROFITS	CHANGE PROFITS PER DOSE
J9310	Rituximab inj†	$677,879,209.34	-$20,172,554.03	-$151.71
J9035	Bevacizumab inj†	$511,731,742.22	-$14,519,563.65	-$96.24
J0897	Denosumab inj†	$296,748,026.92	-$6,419,047.52	-$34.03
J9355	Trastuzumab inj	$270,612,603.37	-$7,472,347.79	-$76.14
J9305	Pemetrexed inj	$268,489,386.36	-$8,092,396.69	-$157.70
J9041	Bortezomib inj	$263,115,224.17	-$5,940,124.80	-$34.35
J9217	Leuprolide acetate suspension	$195,980,648.23	-$2,729,849.03	-$11.04
J9033	Bendamustine inj	$159,639,351.53	-$4,691,168.04	-$102.76
J9264	Paclitaxel protein bound	$153,547,964.44	-$3,845,739.38	-$48.99
J9055	Cetuximab inj	$122,766,230.57	-$3,351,055.27	-$73.01
J9025	Azacitidine inj	$111,698,251.29	-$987,155.04	-$7.36
J2353	Octreotide inj†	$109,122,976.51	-$3,153,794.20	-$112.58
J9228	Ipilimumab inj	$103,351,291.80	-$3,442,903.98	-$1,087.81
J9395	Fulvestrant inj	$91,576,261.26	-$2,165,357.88	-$39.90
J1442	Filgrastim G-CSF inj	$82,361,288.20	+$652,882.89	+$3.19
J9047	Carfilzomib inj	$81,855,269.94	-$1,963,580.34	-$41.51
J7517	Mycophenolate mofetil oral	$74,612,251.64	+$3,104,200.69	+$8.50
J0894	Decitabine inj	$68,777,593.67	-$1,363,193.38	-$28.59
J9354	Ado-trastuzumab emt inj	$48,264,679.95	-$1,498,505.74	-$230.54
J9306	Pertuzumab inj	$47,989,291.90	-$1,425,828.20	-$137.85
J0641	Levoleucovorin inj	$47,692,381.34	-$902,046.42	-$20.92
J9070	Cyclophosphamide inj	$43,486,144.10	-$491,529.87	-$7.03
J9043	Cabazitaxel inj	$36,321,039.80	-$1,137,785.04	-$254.65
J9171	Docetaxel inj	$34,687,940.16	+$107,148.74	+$1.32
J1453	Fosaprepitant inj	$30,916,222.17	+$1,005,998.45	+$8.14
J3489	Zoledronic acid†	$30,609,839.66	+$1,268,260.04	+$10.99
J9303	Panitumumab inj	$28,403,432.19	-$838,476.65	-$122.37
J1569	Gammagard liquid inj†	$27,934,126.06	-$589,940.21	-$50.34
J9179	Eribulin mesylate inj	$26,676,199.84	-$703,733.69	-$63.09
J9042	Brentuximab vedotin inj	$18,346,855.64	-$602,910.31	-$487.40
J9031	Bcg live intravesical vac	$15,023,363.41	+$1,605,061.46	+$12.55
J7527	Everolimus oral	$14,796,949.21	-$362,753.26	-$45.76
J9330	Temsirolimus inj	$14,673,492.03	-$323,026.36	-$30.61
J9263	Oxaliplatin	$12,711,002.20	+$858,363.51	+$10.44
J9315	Romidepsin inj	$11,910,484.34	-$374,842.12	-$215.06
J9155	Degarelix inj	$11,466,141.43	+$104,673.63	+$3.42
J9357	Valrubicin inj	$10,765,055.78	-$319,145.38	-$122.28
J9302	Ofatumumab inj	$9,467,039.92	-$295,634.14	-$236.51
J9400	Ziv-aflibercept inj	$8,435,186.62	-$223,445.65	-$68.58
J9201	Gemcitabine hcl inj	$8,156,184.29	+$2,291,012.28	+$14.77
J9214	Interferon alfa-2b inj	$8,022,458.83	-$52,752.76	-$3.94
J9307	Pralatrexate inj	$7,940,761.26	-$252,370.96	-$274.32
J9207	Ixabepilone inj	$6,723,927.89	-$195,180.93	-$107.18
J9225	Vantas implant	$4,991,737.54	-$138,962.12	-$79.82
J0640	Leucovorin calcium inj	$4,721,224.46	+$1,733,867.94	+$15.17
J9045	Carboplatin inj	$4,556,728.48	+$3,220,187.01	+$15.71
J9265	Paclitaxel inj	$4,196,903.91	+$2,937,554.02	+$15.80
J9202	Goserelin acetate implant	$3,936,761.45	-$11,763.13	-$1.53
J9206	Irinotecan inj	$3,714,224.20	+$955,049.90	+$14.68
J9017	Arsenic trioxide inj	$2,835,160.09	-$43,551.03	-$12.81
J9280	Mitomycin inj	$2,633,881.85	+$202,153.23	+$11.75
J9351	Topotecan inj	$2,069,952.63	+$257,773.26	+$13.38
J9190	Fluorouracil inj	$1,942,004.68	+$2,947,230.91	+$16.10
J1100	Dexamethasone sodium phos†	$1,659,721.77	+$17,388,017.20	+$16.41
J9390	Vinorelbine tartrate inj	$1,232,100.50	+$411,989.67	+$14.92
J9000	Doxorubicin hcl inj	$985,427.73	+$609,150.01	+$15.64
J9181	Etoposide inj	$876,573.49	+$1,282,272.83	+$16.10
J9060	Cisplatin inj	$869,880.67	+$867,018.94	+$15.94
J9328	Temozolomide inj	$795,872.06	-$19,721.94	-$35.92
J9185	Fludarabine phosphate inj	$682,056.26	+$112,759.64	+$13.87
	Bottom 40 Drugs	$5,963,416.28	+$13,901,682.25	
	Total	$4,253,949,399.51	-$43,289,428.43	

† Drugs have been adjusted to only include uses in oncology, see Methods for further details.

Table A2: Change in physician profits for lowest 40 drugs by payment

HCPCS	DESCRIPTION	TOTAL PAYMENT	CHANGE PROFITS	CHANGE PROFITS PER DOSE
J0207	Amifostine	$505,801.59	+$10,710.98	+$6.32
J9027	Clofarabine inj	$479,749.27	-$14,863.62	-$165.15
J9208	Ifosfamide inj	$320,535.66	+$43,939.79	+$13.27
J2780	Ranitidine hydrochloride inj†	$314,457.25	+$2,255,424.42	+$16.38
J1650	Enoxaparin sodium inj	$313,052.36	+$277,404.83	+$15.94
J9268	Pentostatin inj	$299,732.95	-$6,658.95	-$31.12
J1200	Diphenhydramine hcl inj†	$278,239.83	+$7,921,152.88	+$16.44
J9370	Vincristine inj	$260,069.70	+$421,529.04	+$16.17
J9261	Nelarabine inj	$249,922.68	-$7,848.76	-$237.84
J9245	Melphalan hydrochl inj	$242,387.33	-$7,884.24	-$119.46
J9015	Aldesleukin inj	$238,664.57	-$7,890.88	-$51.24
J9050	Carmustine inj	$237,599.60	-$10,354.93	-$116.35
J9065	Cladribine inj	$186,298.84	+$6,319.97	+$8.49
J8501	Aprepitant oral	$174,704.63	+$2,141.83	+$4.26
J9178	Epirubicin hcl inj	$173,074.64	+$32,802.03	+$13.96
J9098	Cytarabine liposome inj	$172,375.45	-$5,076.62	-$73.57
J9293	Mitoxantrone hydrochl	$150,041.93	+$12,925.80	+$12.01
J0850	Cytomegalovirus imm IV /vial	$148,231.02	-$4,285.09	-$112.77
J1190	Dexrazoxane HCl inj	$145,059.02	$1,109.60	+$2.98
J9130	Dacarbazine inj	$131,080.20	+$75,925.70	+$15.63
J9209	Mesna inj	$125,483.74	+$62,567.89	+$15.44
J9040	Bleomycin sulfate inj	$122,665.22	+$60,399.67	+$15.40
J9320	Streptozocin inj	$104,585.74	+$845.46	+$3.00
J9360	Vinblastine sulfate inj	$98,183.59	+$78,965.83	+$15.59
J9260	Methotrexate sodium inj	$88,116.35	+$526,416.52	+$16.38
J9371	Vincristine sul lip inj	$84,102.31	-$6,750.37	-$160.72
J0461	Atropine sulfate inj	$83,110.54	+$807,026.18	+$16.40
J9120	Dactinomycin inj	$77,753.47	-$2,688.39	-$99.57
J9250	Methotrexate sodium inj	$53,550.71	+$1,108,953.96	+$16.44
J2425	Palifermin inj	$24,996.29	-$561.36	-$33.02
J9100	Cytarabine hcl inj	$24,553.40	+$32,955.06	+$16.07
J9211	Idarubicin hcl inj	$14,452.24	+$811.54	+$9.55
J2765	Metoclopramide hcl inj	$10,910.92	+$221,094.15	+$16.43
J9230	Mechlorethamine hcl inj	$8,984.06	+$841.67	+$8.95
J8540	Dexamethasone oral	$6,077.03	+$9,967.42	+$15.87
J9150	Daunorubicin inj	$4,720.10	+$299.70	+$11.10
J8530	Cyclophosphamide oral	$4,578.44	+$1,010.92	+$14.24
J7525	Tacrolimus inj	$3,685.96	+$334.16	+$11.93
J1260	Dolasetron mesylate	$1,684.20	+$2,442.95	+$16.07
J8610	Methotrexate oral	$143.47	+$225.52	+$16.11

† Drugs have been adjusted to only include uses in oncology, see Methods for further details.

Table A3: Change in hospital profits for Part B drugs

HCPCS	DESCRIPTION	TOTAL SPENDING	CHANGE PROFITS	CHANGE PROFITS PER DOSE
J9310	Rituximab inj†	$562,175,937.92	-$20,102,339.27	-$183.39
J9035	Bevacizumab inj†	$475,035,651.13	-$14,175,040.97	-$137.95
J9305	Pemetrexed inj	$272,756,127.27	-$8,210,145.58	-$159.30
J9355	Trastuzumab inj	$272,595,627.44	-$7,640,015.95	-$84.12
J0897	Denosumab inj†	$208,629,894.18	-$6,759,082.38	-$51.82
J9041	Bortezomib inj	$191,060,914.28	-$4,086,905.51	-$29.54
J9228	Ipilimumab inj	$153,049,340.22	-$5,096,799.89	-$1,076.41
J9033	Bendamustine inj	$134,245,655.53	-$3,932,642.23	-$102.45
J9055	Cetuximab inj	$126,265,861.14	-$3,482,266.02	-$78.66
J2353	Octreotide inj†	$114,300,063.11	-$5,279,552.82	-$189.45
J9264	Paclitaxel protein bound	$113,538,064.97	-$2,818,176.80	-$47.69
J9395	Fulvestrant inj	$76,071,889.36	-$1,791,387.43	-$39.62
J9025	Azacitidine inj	$74,980,771.06	-$551,766.00	-$5.67
J9047	Carfilzomib inj	$70,956,251.50	-$1,652,629.50	-$37.74
J9306	Pertuzumab inj	$58,460,956.46	-$1,726,423.89	-$132.92
J1442	Filgrastim G-CSF inj	$55,938,194.87	+$383,138.23	+$2.83
J9354	Ado-trastuzumab emt inj	$50,099,802.57	-$1,550,186.08	-$228.47
J0894	Decitabine inj	$49,947,744.16	-$930,484.90	-$24.26
J9217	Leuprolide acetate suspnsion	$47,122,338.64	-$508,024.23	-$7.47
J9070	Cyclophosphamide inj	$44,058,175.69	-$480,231.76	-$7.16
J9303	Panitumumab inj	$35,400,799.13	-$1,048,025.68	-$125.17
J1453	Fosaprepitant inj	$35,384,934.54	+$1,153,100.11	+$8.14
J9042	Brentuximab vedotin inj	$32,847,542.00	-$1,070,082.80	-$444.94
J9171	Docetaxel inj	$32,038,288.15	-$37,582.97	-$0.57
J9043	Cabazitaxel inj	$30,210,386.45	-$942,753.41	-$237.29
J9179	Eribulin mesylate inj	$23,947,839.29	-$621,006.52	-$58.47
J1569	Gammagard liquid inj†	$20,718,952.63	-$4,139,786.26	-$460.27
J3489	Zoledronic acid†	$17,587,278.11	+$21,002.55	+$0.31
J9315	Romidepsin inj	$15,799,566.81	-$498,083.98	-$218.36
J9302	Ofatumumab inj	$12,943,850.72	-$405,744.20	-$237.56
J9330	Temsirolimus inj	$11,709,555.84	-$255,318.06	-$30.03
J9263	Oxaliplatin	$11,418,884.65	+$788,461.69	+$10.55
J9307	Pralatrexate inj	$8,181,923.44	-$258,907.23	-$247.05
J0641	Levoleucovorin inj	$6,616,141.78	-$126,235.29	-$21.28
J9207	Ixabepilone inj	$5,756,467.26	-$167,753.05	-$109.14
J9400	Ziv-aflibercept inj	$4,631,246.80	-$122,553.49	-$68.43
J9357	Valrubicin inj	$4,207,426.34	-$124,261.95	-$122.31
	Bottom 35 Drugs	$37,576,924.04	+$487,443.86	
	Total	$3,498,267,269.52	-$97,757,958.37	

† Drugs have been adjusted to only include uses in oncology, see Methods for further details.

Table A4: Change in hospital profits for Part B drugs for lowest 35 drugs by payment

HCPCS	DESCRIPTION	TOTAL SPENDING	CHANGE PROFITS	CHANGE PROFITS PER DOSE
J9214	Interferon alfa-2b inj	$4,078,180.18	-$21,570.62	-$3.06
J9202	Goserelin acetate implant	$3,441,773.12	-$7,004.68	-$1.02
J9017	Arsenic trioxide inj	$3,033,115.92	-$38,644.27	-$9.45
J9280	Mitomycin inj	$2,940,261.70	+$266,429.42	+$12.30
J9245	Melphalan hydrochl inj	$2,760,062.68	-$78,372.33	-$100.87
J9031	Bcg live intravesical vac	$2,470,567.32	+$262,593.36	+$12.54
J0850	Cytomegalovirus imm IV	$2,230,930.03	-$63,038.71	-$95.37
J9155	Degarelix inj	$1,987,577.29	+$27,984.85	+$4.76
J9027	Clofarabine inj	$1,865,434.16	-$56,640.77	-$145.98
J7511	Antithymocyte globuln rabbit	$1,811,010.09	-$50,349.63	-$70.22
J9351	Topotecan inj	$1,786,667.51	+$256,261.11	+$13.71
J9371	Vincristine sul lip inj	$1,096,858.16	-$34,320.68	-$182.56
J9050	Carmustine inj	$981,616.41	-$36,085.19	-$154.21
J9098	Cytarabine liposome inj	$937,061.00	-$25,895.04	-$73.99
J8501	Aprepitant oral	$918,869.15	+$38,095.87	+$8.95
J9015	Aldesleukin inj	$889,310.95	-$25,235.29	-$53.24
J9225	Vantas implant	$619,093.83	-$17,160.74	-$79.82
J0207	Amifostine	$489,064.13	+$9,906.85	+$6.16
J9261	Nelarabine inj	$482,107.76	-$14,848.90	-$176.77
J9268	Pentostatin inj	$471,412.83	-$10,455.17	-$31.12
J9185	Fludarabine phosphate inj	$447,592.40	+$69,503.83	$13.74
J2425	Palifermin inj	$360,986.36	-$7,808.41	-$29.80
J9208	Ifosfamide inj	$320,634.96	+$29,515.00	+$12.15
J1190	Dexrazoxane HCl inj	$306,775.26	-$1,957.85	-$3.76
J9328	Temozolomide inj	$196,473.84	-$4,147.79	-$23.70
J9065	Cladribine inj	$181,425.16	+$8,033.75	+$9.60
J9120	Dactinomycin inj	$148,692.08	-$3,723.22	-$30.27
J9293	Mitoxantrone hydrochl	$125,118.50	+$9,617.83	+$11.64
J9320	Streptozocin inj	$89,739.23	+$891.14	+$3.70
J8700	Temozolomide	$32,948.54	+$1,164.92	+$9.63
J7525	Tacrolimus inj	$23,576.24	+$2,124.28	+$11.93
J9230	Mechlorethamine hcl inj	$17,616.30	+$606.94	+$7.68
J9211	Idarubicin hcl inj	$12,568.24	+$1,072.23	+$11.29
J9150	Daunorubicin inj	$10,957.21	+$733.42	+$11.28
J8560	Etoposide oral	$10,845.54	+$1,259.66	+$12.85

† Drugs have been adjusted to only include uses in oncology, see Methods for further details.

Figure A1:
Distribution of drugs resulting in increased profi for physicians

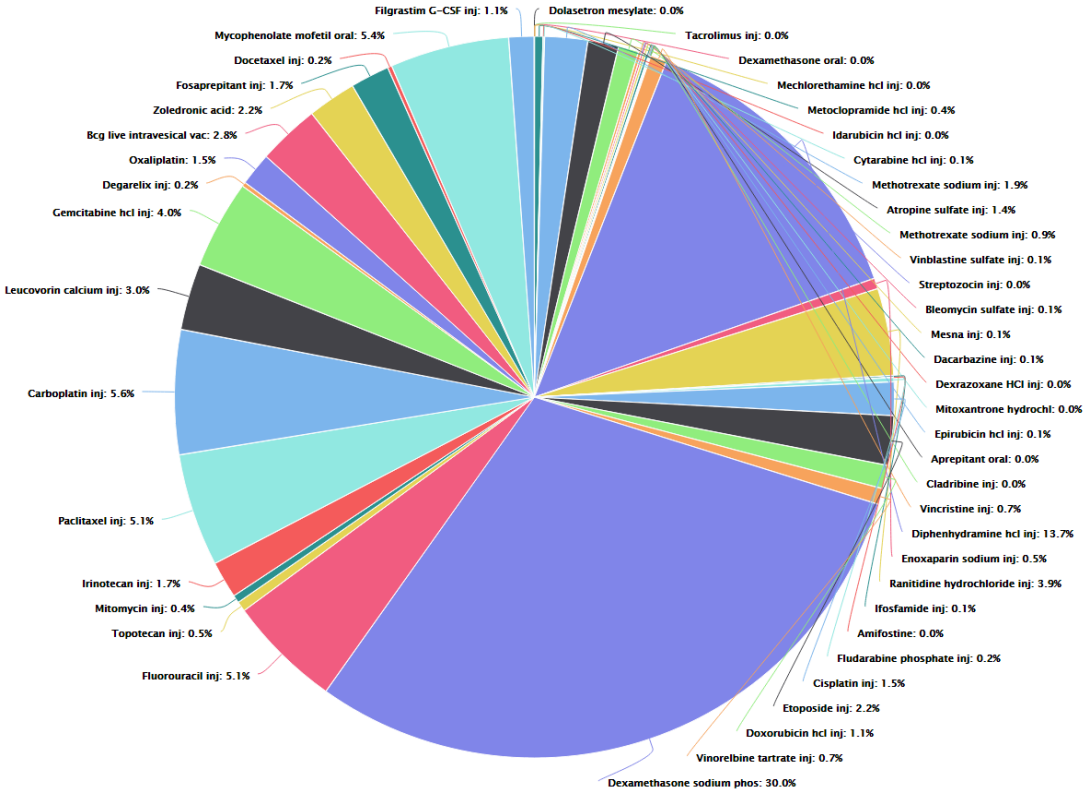
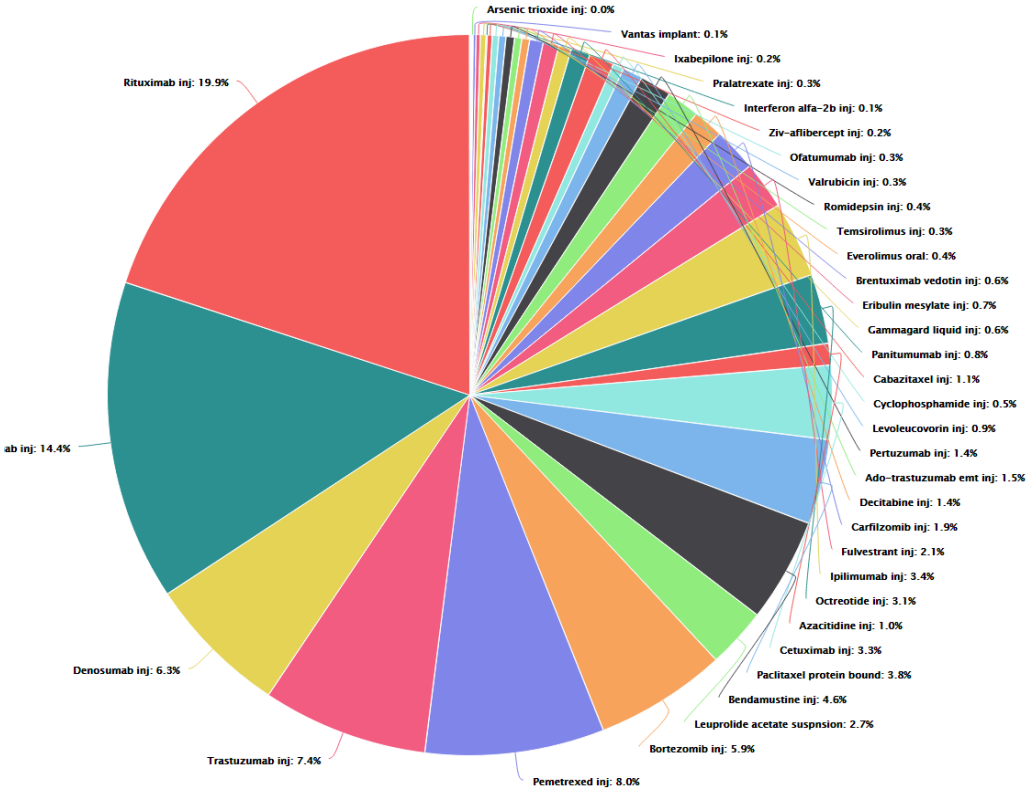


Figure A2:
Distribution of drugs resulting in decreased profit for physicians†



†All drugs result in decreased profit for hospitals except: filgrastim G-CSF, fosaprepitant, zoledronic acid, oxaliplatin, mitomycin, bcg live intravesical vaccine, degarelix, topotecan, aprepitant, amifostine, fludarabine phosphate, ifosfamide, cladribine, mitoxantrone hydrochloride, streptozocin, temozolomide, tacrolimus, mechlorethamine hcl, idarubicin hcl, daunorubicin, etoposide

Methods

1) Are there clinical situations where there are legitimate clinical choices between more and less expensive drugs, and if there are, how does the current versus the proposed reimbursement approach potentially affect them?

Drug regimen pairs were chosen based on guidelines from Anthem's AIM Cancer Treatment Pathways[1] and NCCN Guidelines[2]. All pairs were recommended for treatment of the same clinical scenario. The quarterly ASP files released by the Center for Medicare and Medicaid Services provide 106% of the Average Sales Price per unit of Part B drugs. In this case, calculations were based on the latest ASP file, from April 2016. The dosing schedule for the indication was drawn from the latest-approved FDA labels, which are available online at Drugs@FDA[3]. Dosing for the average patient was calculated assuming a body weight of 70kg and body surface area of 1.7 m^2.

The cost of 12 weeks of treatment for the average patient was calculated based on the recommended dosing frequency. The costing for the four different scenarios (current: 106% ASP, current under sequester: 104.3%, proposed: 102.5% + $16.80, proposed under sequester: 100.9% + $16.46) was accomplished by first back-calculating the 106% ASP cost in the CMS files to 100%, and then sequentially adding on the various markups. The flat fee was added on a per-dose basis, for all doses administered within 12 weeks.

2) How is the mix of reimbursement for "Part B" drugs distributed across all payers and how does it affect the bottom line of doctors and hospitals?

To estimate the percentage of drug sales distributed to patients through each provider type, we utilized rituximab (Rituxan) sales as an approximate representation. National spending on rituximab in the United States was approximately $3.5B in 2014 (IMS), of which Medicare Part B payments comprised $1.5B[4] (43.3%) and Medicaid comprised 8.4M[5] (2.4%). The remainder, composed primarily of commercial payers, out-of-pocket expenses to patients, etc. accounted for the other 54.3% of total national spending, or $1.9B. Of federal Medicare spending on rituximab, 35% went to hospitals, while 65% went to doctors' offices[6] (Magellan 2014 report pg 8). Similarly, for commercial payers, 49% of spending on rituximab went to hospitals, while 51% went to doctors' offices[6] (Magellan Health 2014 report, pg 8). Additionally, we accounted for hospitals eligible for the 340B federal drug discount program, which requires that substantial discounts (on average, 33%) be passed on to facilities that qualify, most often because they treat a disproportionately large population of low-income residents. For both Medicare and commercial payers, we estimated that 48% of Part B sales are through contracted hospitals eligible for 340B discounts[7]. Using this information, we estimated the percentage of drug sales distributed through each provider type or location. We then estimated the percent markup for each type of provider basing our estimate on Medicare's reimbursement rates and estimated commercial reinsurance rates from an article published by United Healthcare.[8] We then calculated the total markup for each dollar of drug produced by the manufacturer.

3) Which drugs are favored versus disfavored by the change in the profit formula for doctors and hospitals?

4) How do the 'ups' and 'downs' affect the bottom line of doctors and hospitals treating cancer patients?

Data Sources

This analysis used data from CMS's October 2014 ASP file[9] and Summary Data for 2014 MPFS Drug Codes used in the Part B Drug Payment Model[10]. From the ASP file, we used the HCPCS code dosage information and the Average Sales Price (ASP) payment limit (ASP+6%).

The Summary Data for the Part B Drug Payment Model includes information by HCPCS on utilization, charge and payment. In our analyses we used number of encounters, units and Medicare payment information for the MPFS setting. This file includes total payments of ASP+6%.

We considered only Part B cancer-related drugs, including all chemotherapy drugs (J8521-J9999) and other cancer-supportive, non-chemotherapeutic drugs (J0207, J0461, J0594, J0640, J0641, J0850, J0882, J0894, J0897, J1100, J1190, J1200, J1260, J1442, J1446, J1453, J1455, J1569, J1650, J2353, J2405, J2425, J2765, J2780, J3489, J7511, J7517, J7525, J7527) that we selected based on our clinical knowledge of cancer care. Drugs were further excluded from analyses if they were not included in either of our sources of data or had zero encounters or Medicare payments in 2014 in the physician setting. This comprised the denominator for all analyses (n=100 HCPCS).

We then adjusted the volume of drugs for which there are uses outside of oncology. Examples of such drugs include bevacizumab for eye disease, rituximab for rheumatoid arthritis, and dexamethasone that has numerous uses. Overall we examined all drugs that have non-cancer uses and resulted in a change of payments of $1 million or more. To do so we analyzed the 5% random sample of 2013 Medicare Part B physician claims to adjust volumes by determining the proportion of doses and average doses of uses that were for cancer and for other indications.

Analyses

For each HCPCS, we calculated the total payment to physician under four scenarios: 1) current reimbursement, 2) current reimbursement under sequestration, 3) proposed reimbursement (from CMS Part B Proposed Rule) and 4) proposed reimbursement under sequestration.

$$\text{Units per Encounter} = \frac{\text{\# Units}}{\text{\# Encounters}}$$

$$\text{Dose per encounter } = \text{Units per Encounter} * \text{HCPCS code dosage}$$

Payment per encounter:

$$1)\ \ ASP + 6\% = \text{Units per Encounter} * \text{ASP Payment Limit Oct 2014}$$

$$2)\ \ ASP + 4.3\% = \text{Units per Encounter} * \left(\frac{\text{ASP Payment Limit}}{1.06} * 1.043\right)$$

$$3)\ (ASP + 2.5\%) + \$16.80 = \text{Units per Encounter} * \left(\frac{\text{ASP Payment Limit}}{1.06} * 1.025\right) + \$16.8$$

$$4)\ (ASP + 0.9\%) + \$16.46 = \text{Units per Encounter} * \left(\frac{\text{ASP Payment Limit}}{1.06} * 1.009\right) + \$16.46$$

Lorenz Curves

Drugs were sorted by Medicare payment to physicians in 2014. From lowest to highest payment, we calculated both the cumulative percentage of encounters and payments that each drug accounted for of our cancer-drug denominator. Effectively, we created a set of Lorenz curves that can be interpreted as the percentage of encounters/payments (y-axis) attributed to 'x' percentage/number of cancer-related drugs.

Part B Proposal Impact

Based on the proposed reimbursement of (ASP + 2.5%) + $16.80 per encounter, we determined which drugs, on a per encounter basis, that doctors will be above/below current ASP + 6% payment; drugs that doctors will lose or gain profits on.

$$ASP * 0.06 = ASP * 0.025 + 16.8$$

$$\text{Budget Neutral ASP} = \frac{\$480}{\text{Encounter}}$$

This net gain/loss under the Proposed Rule is represented in the plot by the two different color dots (green indicating gain, red indicating loss) on the cumulative percent of payment line.

We then repeated this analysis assuming the proposed reimbursement under sequestration of (ASP + 0.9%) + $16.46 per encounter, we determined which drugs on a per encounter basis that doctors will be above/below the current sequestration ASP + 4.3% reimbursement.

$$\text{Budget Neutral ASP under Sequestration} = \frac{\$484}{\text{Encounter}}$$

Impact on Profits for Doctors and Hospitals

For each HCPCS, we calculated the change in profits for doctors both annually and per encounter for each proposal. For each of the four scenarios, we calculated profits as:

$$\text{Profits Per Encounter}_{\text{Scenario}} = \left(\frac{Payment_{\ SCENARIO}}{Encounter} - \frac{\text{ASP Payment Limit}}{1.06}\right)$$

$$\text{Total Profits}_{\text{Scenario}} = \#\ \text{Encounters} * \left(\frac{Payment\ _{SCENARIO}}{Encounter} - \frac{\text{ASP Payment Limit}}{1.06}\right)$$

And change in profits as the difference in the proposed versus current scenarios:

$$\text{Change in Profits} = \text{Profits}_{\text{PROPOSED}} - \text{Profits}_{\text{CURRENT}}$$

We also calculated the impact on doctors profits overall for each proposal:

$$\%\ \text{Profit Change} = \frac{\sum_{\text{HCPCS}}(Change\ in\ Total\ Profits)}{\sum_{\text{HCPCS}}(\text{Total Profits}_{\text{CURRENT}})}$$

Impact on Revenue

The impact on revenue for Part B cancer-related drugs was calculated based on the sum of the difference in payment, weighted by the number of encounters, and divided by the 2014 Medicare payments for these drugs:

$$\%\ \text{Revenue Change} = \frac{\sum_{\text{HCPCS}}\left(\frac{Payment\ _{PROPOSED}}{Encounter} - \frac{Payment\ _{CURRENT}}{Encounter}\right) * \#\ Encounters}{\sum_{\text{HCPCS}}(Medicare\ Payments_{CURRENT})}$$

How might reducing the percentage based profit affect price inflation for Part B drugs?

We identified the top 30 infused cancer drugs with the highest reimbursements from Medicare Physician Fee Schedule records. Using the FDA Orange Book[11] we were able to find 14 of the infused drugs that had not yet undergone patent expiry or termination of FDA exclusivity. Reimbursement limits for each drug (106% average sales price as reported quarterly by CMS[12]) were recorded for every half-year and plotted over the 11-year period from 2005 to 2015.

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[2] NCCN Guidelines. 2016. at http://www.nccn.org/professionals/physician_gls/f_guidelines.asp.
[3] Drugs@FDA: FDA Approved Drug Products (Accessed 8/4/2015, at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.)
[4] Medicare Drug Spending Dashboard. 2015. at https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-12-21.html.

[5] Medicaid.gov. Medicaid Drug Programs Data & Resources. 2015.
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[8]Newcomer LN. Changing physician incentives for cancer care to reward better patient outcomes instead of use of more costly drugs. Health Affairs. 2012;31(4):780-5.
[9] ASP October 2014 (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2014ASPFiles.html)
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