



Evidence Driven  
Drug Pricing Project

# Examining Congressional comments regarding Medicare's Part B pilot proposal

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**Overview:** In four recent letters to CMS, Members of Congress provided conflicting forecasts regarding how the [agency's proposed pilot program](#) of Part B drug payment might affect many aspects of Medicare beneficiary care. We conducted a data driven assessment of these predictions, focusing on those that could be empirically reformulated into hypotheses. As in [our prior report](#), we focused on the area of medical oncology care, which is the dominant category of drug spending in Part B, and on the marginal impact of the reimbursement formula change. We also assumed that CMS would true up their flat fee payment by specialty so that each specialty group was kept budget neutral. Our prior analyses, and those from [Avalere](#) and [MEDPAC](#), suggest that the flat fee should be higher than originally proposed for some specialties such as oncology, and lower for others.

**Findings:**

- 1) Predictions and concerns regarding the new payment formula leading to acquisition problems for certain Part B drugs seems to ignore the impact of pharmaceutical companies choices about how quickly to raise prices, or distributors decisions about how extensively to price discriminate between doctors' offices. Those are the choices that will determine if the payment formula leads doctors to be 'under water' on certain drugs, not the formula itself.
- 2) Predictions regarding the payment formula causing a shift in care of cancer patients from doctor's offices to hospital outpatient departments seem unsupported. We base this on the observation that in 2013, cancer doctors warned that due to budget sequestration there would be a massive shift of patients from offices to hospitals, and moving of patients for their expensive treatment to hospitals causing discontinuity of care. But when we examined care patterns before and after sequestration, we saw no such effects, and sequestration involved an actual reimbursement reduction, while CMS' pilot formula reallocates payments but does not cut total payment, assuming the flat fee is calculated to achieve budget neutrality for each specialty.
- 3) Concerns that the pilot formula will accelerate consolidation of practices into hospitals do not seem supportable. Under the current formula, the reduction in reimbursement for hospitals will be more severe than for physician offices, reducing the arbitrage between the two care settings. This will make acquiring physician offices very slightly less, but certainly not more, attractive to hospitals.





Domains of Concern	1. <a href="#">Letter from Senate: 4/27/16</a>	2. <a href="#">Letter from Senate: 4/28/16</a>	3. <a href="#">Letter from House: 5/2/16</a>	4. <a href="#">Letter from House: 5/9/16</a>
<b>Domain #1: Access will be limited from drugs going ‘under water’</b>	The combined effect of sequestration and the proposed changes to the ASP-based payment methodology may result in some physicians facing acquisition costs that exceed the Medicare payment... potentially limiting beneficiary access. a concern for physicians in small, independent practices and those practicing in rural and/or underserved areas	Phase I ... would harm beneficiary access to vital drugs as many providers would face acquisition costs that exceed the Medicare payment amount.	Phase 1 ... will severely harm patient access to needed drugs ... numerous physicians would face acquisition costs that exceed the Medicare payment amount... [will] especially hurt seniors who depend on doctors in smaller practices or those who live in rural areas.	We do not believe that the model's proposed changes ... will adversely impact beneficiary access to needed care ... this does not limit a doctor's ability to prescribe what they believe to be the most appropriate therapy.
<b>Domain #2: Patients will be sent to hospital outpatient departments from doctor’s offices</b>	Community-based physicians may refer their patients to hospital outpatient departments (HOPDs) to receive Part B medications.	Physicians who have trouble accessing drugs at the reduced ASP payment would likely refer patients to the hospital outpatient department (HOPD).	CMS's proposed Medicare drug experiment would also lead physicians to refer patients to a hospital outpatient department (HOPD).	
<b>Domain #3: Payment change will accelerate consolidation of doctors’ offices into hospitals</b>		Driving care to a less-convenient, more costly setting would reduce beneficiary choice, increase costs, and likely further hospital-physician practice consolidation	Driving more care to an often less convenient, more costly setting makes it more challenging for beneficiaries to access needed care and increases overall Medicare costs. This will lead to further consolidation and less choice for seniors.	





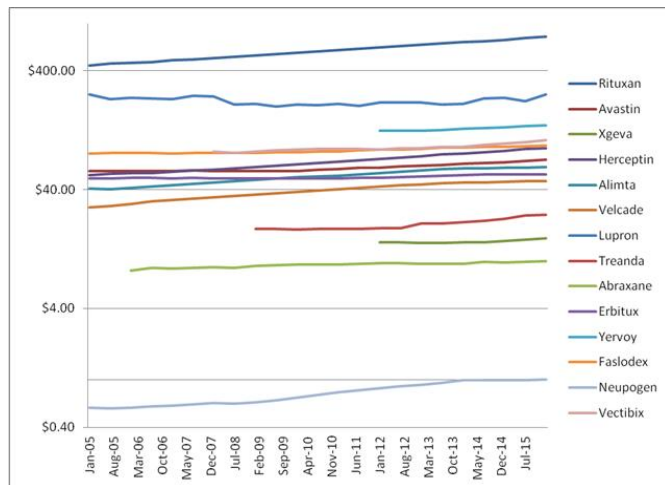
**Domain #1: Limiting Access from doctors being ‘under water’ for some drugs under the new payment model:**

Letters 1, 2 and 3 all expressed some type of concern that the alternative payment formula would lead to a reduction in access to some medications for Medicare beneficiaries, while letter 4 stated that there was no such imminent concern. This concern may rest on some assumptions that are not viable.

**Assuming doctors will go ‘under water’ under a new formula means assuming that drug companies will continue to raise the prices of existing products as rapidly as they have been:**

As we detailed in [our report on Phase 1 of the pilot](#), steady price hikes imposed by pharmaceutical companies average 1.7% every two quarters, which consumes nearly half of the 4.3% mark-up Medicare provides for Part B drugs. This is because Medicare reimburses drugs based on their sales prices from two quarters earlier. So if a drug sells for \$1 in the first quarter of a year, it will be reimbursed at \$1.043 in the third quarter of the year. But when companies raise prices over that time period the acquisition price in the third quarter is higher than the cost basis on which Medicare bases reimbursement. At an average price hike of 1.7%, acquisition of a vial that cost \$1 in the first quarter costs

\$1.017 by the third quarter, meaning doctors only have around \$0.026 cents cushion between Medicare’s reimbursement and drug companies new pricing (\$1.043-\$1.017). Our graph of the inflationary patterns for major Part B cancer drugs over the past 11 years is reproduced to the right – for a full description [see our report](#).



Since these price hikes are not a natural phenomena, but rather occur because they can be accommodated by the reimbursement margin, it is reasonable to postulate that a smaller margin add-on, as Medicare contemplates, might lead to lower rates of price inflation for Part B drugs.



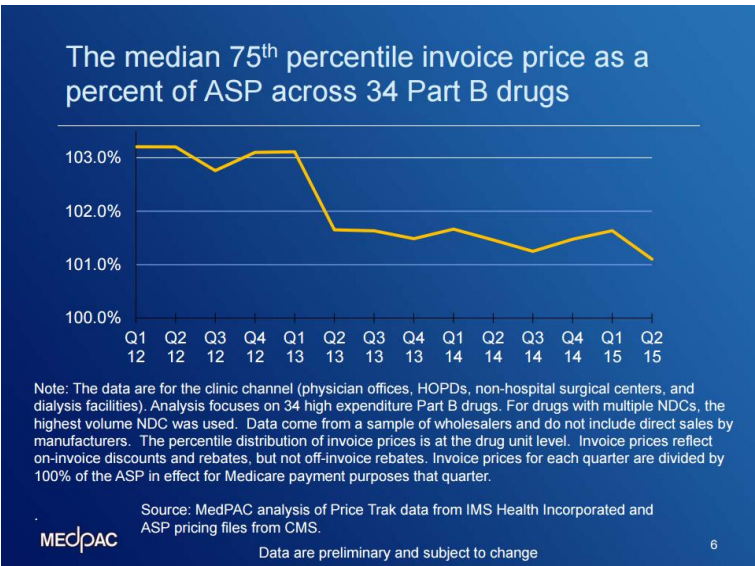


Slowing price inflation of pharmaceutical products is a means by which Medicare and patients could save money over the long term without any change in prescribing patterns, and thus may be a beneficial effect of the alternative payment formula. But it should be noted that this will only occur if the pilot has sufficient scope that the net impact is to discourage price inflation.

**Assuming some doctors will go ‘under water’ under a new formula means assuming that intermediary distributors will continue to price discriminate in the marketplace as they have been:**

Along with an assumption of ongoing price inflation, the letters contain an assumption that variation in acquisition price, where some physicians end up under water and others do not, is a naturally occurring phenomenon. But in the case of expensive cancer drugs, even the smallest doctors’ offices are still buying hundreds of thousands of dollars in drug per year per doctor, and they come in small packages that are easy and inexpensive to transport. So in truth there are no natural economies of scale favoring larger buyers. Rather, price discrimination is imposed by distributors, coupled with off-invoice volume based rebates in many cases, in order to enhance market share and earn fees from manufacturers. In other words, the intermediary distributors do not need to price discriminate, but they have an interest in doing so when they can.

Empiric evidence from [a recent MEDPAC report](#) supports the view that price discrimination is being acomodated by the margin Medicare provides on Part B drug. MEDPAC found that when that margin was abruptly reduced, the upper end of the acquisition price for Part B drugs fell in lockstep. In other words, a smaller reimbursement cushion led to a reduction in the magnitude of price discrimination. The example comes from budget sequestration, where in





April 2013 Medicare reimbursement for Part B drugs fell by 2% – the formula reduced payment from 106% of ASP to 104.3% of ASP, or 1.7%. As shown (above), the upper range of acquisition prices, as shown by the 75<sup>th</sup> percentile value, fell by nearly the same amount, around 1.7%. In other words, a reduction in reimbursement margin reduced price discrimination. In our view, even without these data policymakers can safely assume that distributors will find ways to accommodate a narrower reimbursement margin so as to not lose large segments of their distribution channel.

**Assuming doctors will go ‘under water’ under a new formula means assuming that the best way to assess a reallocation of funding for buy and bill drugs is at the drug level rather than the book of business level. But doing so ignores the cumulative revenue impact of the flat fee.**

Letters 1, 2, and 3, but not letter 4, appear to anchor much of the concerns around whether particular drugs might in some cases have higher acquisition costs than reimbursement rates for some providers, rather than looking at payment overall for drugs overall. As Medicare has noted, the two alternative payment formulas are intended to be budget neutral. This is achieved in the pilot formula by counter-balancing a lower percentage based add-on with a flat fee payment per treatment. The math is intended to lead doctors to earn the same total amount under either arrangement if their prescribing patterns are the average. But by definition they will not earn the same amount on each drug under the two formula – they will earn more for lower priced drugs (under \$480 per treatment), less for higher priced ones (over \$480 per treatment). The concern from Members of Congress about some drugs being underwater seems to ignore the fact that the structure of the reimbursement formula is specifically to have the total revenues from flat fees collectively make-up for any particular shortfalls within the Medicare book of business for doctors.

**Assuming rural doctors will go ‘under water’ assumes those doctors face higher acquisition prices**

Letters 1 and 3 also delve into the question of whether doctors in rural settings are particularly vulnerable to facing higher than reimbursed acquisition prices. We are unaware of any data on differences in acquisition prices for Part B drugs in rural or urban settings.







MEDPAC’s analysis examining the impact of payment changes in hospitals, not doctor’s offices, separate rural from urban but projected the same degree of change in both settings. These analyses did not include data on acquisition prices either.

Therefore the only way we have to gauge whether rural physicians would be particularly harmed by the cuts is to look at the problem indirectly, examining whether the decline in reimbursement rates due to sequestration affected

2012 Medicare Providers Enrollment Status as of 2016 by Urbanicity -- Hematology, Heme/Onc & Oncology P-value for comparison =0.8987			
	Still Enrolled	Disenrolled	Total
Rural	2259 (92%)	201 (8%)	2460
Urban	6949 (92%)	625 (8%)	7574
Total	9208	826	10034
Frequency Missing = 564			

rural and urban oncologists differently. The hypothesis here is that if rural oncologists were facing higher acquisition prices than urban providers, then the decline in reimbursement margin from sequestration would have had a disproportionately negative impact on rural providers, and as a consequence would stop participating in Medicare more frequently. Yet from 2012 to 2016 (a time period that bridges the 2013 sequestration) we found the same proportion of cancer doctors in rural and urban settings, 8%, stopped participating in the Medicare program. Analyses not shown include an examination whether population density as a continuous variable predicted disenrollment (it didn’t), or if other specialties less affected by Part B drug reimbursement (gastroenterology and rehabilitation medicine) disenrolled at different rates than oncologists (they didn’t, and they did not differ by rural/urban status either).

**Domain #2: Patients will be sent to hospital outpatient departments from doctor’s offices**

Letters 1, 2 and 3 raised concerns that the payment formula might lead doctors to send their patients to hospital outpatient departments, which Members of Congress characterized as less convenient and more expensive.

**Assuming some doctors will send patients to the hospital outpatient department from their offices requires that a budget neutral reimbursement change alters finances so severely that they forego revenue generating business:**

While the finances of private practice offices are not public, this particular concern was raised before, under the specter of an actual reimbursement cut that was not reimbursed, so observing

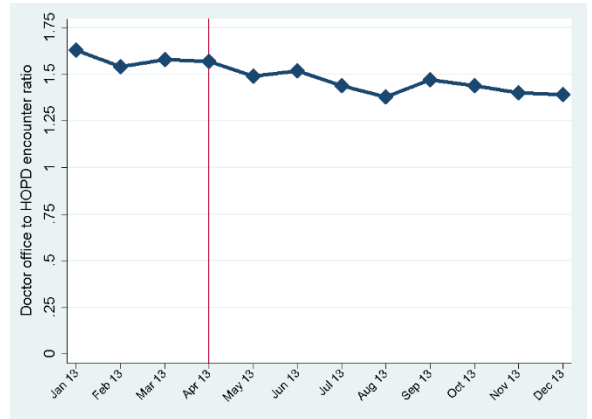




whether doctors followed through on transferring care to hospitals can provide indirect guidance on the possible impact of the payment formula change. Specifically, in 2013 the Community Oncology Alliance, a lobbying group for cancer doctors, [warned](#) that the sequestration cut would force 72% of practices to stop treating new Medicare patients, and also stated that [community doctors would 'split' care of patients](#) into the hospital outpatient department for drugs where community practices were 'under water'. Given this prediction, we analyzed 2013 Medicare claims to see if this occurred after budgetary sequestration:

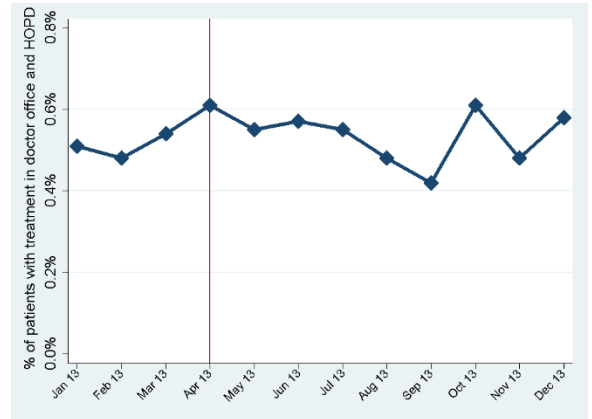
Did the migration of care to the hospital outpatient department from the doctor office accelerate as a result of sequestration?

a. Answer: **NO**, the pace of migration appeared to proceed at the same pace before and after sequestration. The figure shows the ratio of encounters for cancer treatment that were in doctors' offices and hospital outpatient departments.



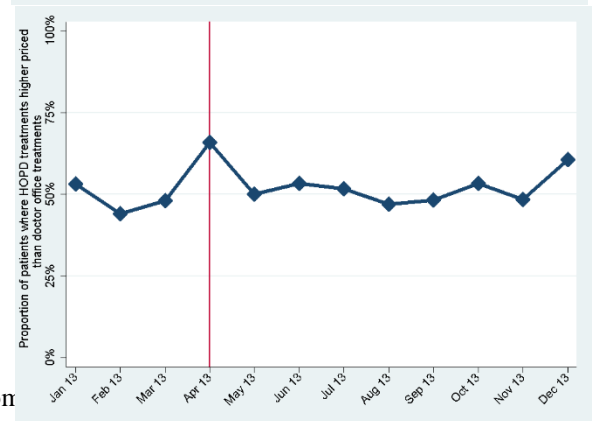
b) Did the fraction of patients getting care in both settings rise, fall, or remain unchanged as a result of sequestration?

Answer: **NO**, the percent of patients receiving care in both settings was very small (around 0.5%, or 1 in 200) and unchanged over the year.



c) Did patients receiving care in both settings tend to get more expensive drugs in the hospital outpatient department than in the doctor office?

a. Answer: **NO**, over the year there was an even split of in which setting patients received more expensive treatments.







**Conclusions regarding Domain #2 concerns:**

There is no evidence that the reimbursement formula change that Medicare proposes implementing will lead community cancer doctors to send patients to hospital outpatient departments. We base this on the observation that warnings that this would occur from budget sequestration in 2013 did not come to fruition, and sequestration was an actual cut in reimbursement while the payment formula modification is not (assuming appropriate flat fee at implementation).

**Domain #3: Payment change will accelerate consolidation of doctors’ offices into hospitals**

Letters 2 and 3 expressed concern that the payment formula change would accelerate consolidation of doctor office practices into hospital systems. While that trend is strong, that is distinct from knowing how the new payment formula will alter it.

**Assuming the payment formula will accelerate consolidation means assuming that physician offices will become more attractive acquisitions to hospitals under the new formula:**

As highlighted in our first report, a major driver of consolidation is that a sub-category of hospitals under the 340B program can obtain deep discounts when they acquire Part B drugs but still obtain identical reimbursement from Medicare as hospitals and doctors that do not obtain those discounts. This creates an arbitrage opportunity – the doctors’ offices are more valuable to 340B hospitals than to the doctors. But as detailed in our first report, hospitals actually see larger revenue declines than doctors’ offices under the pilot formula (Table, right).

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%

**Conclusion regarding Domain #3 concerns:**

Under the proposed formula the gap between the profits doctors make compared to hospitals is slightly narrowed, which would slow consolidation slightly.





## Appendix:

### Methods

#### **A. Domain 1: Shift-of-care analysis**

A 5% random sample of 2013 Medicare Part B claims was used to identify the site of care for chemotherapy drugs (HCPCS J8521-J9999). Claims from the Carrier file were classified as doctor office and claims from the Outpatient file were classified as HOPD.

For each calendar month in 2013 we calculated and graphed (1) the ratio of chemotherapy days in doctor offices versus HOPD, (2) the proportion of patients who received chemotherapy in both doctor office and HOPD and, (3) of the patients receiving treatment in both doctor office and HOPD, the proportion whose treatments were higher priced in HOPD than doctor office. A reference line is included on the graphs signifying the date under sequester (April 1, 2013) when a 2% reduction in Medicare payment began.

For the calculation of Medicare payments in (3) we excluded drugs that receive no additional payment in HOPD, as payment is rolled into the APC.

#### **B. Domain 2: Rural/urban analysis**

Provider enrollment data was obtained from the CMS publicly available Medicare Fee-For-Service Public Provider Enrollment Data for 2012<sup>1</sup> and 2016<sup>2</sup>. All providers with a specialty code of 82(Hematology), 83(Hem/Onc), or 90(Medical Oncology) were categorized as hematology, hem/onc & oncology providers for the sake of this analysis. Rural/Urban status was determined by population density. Population density by zip code was based on population counts from 2010 census data and square footage by Census-defined zip code tabulation areas (ZCTA) from the 2013 US Gazetteer File<sup>3</sup>. Zip code tabulation areas are used by the US Census to generally represent USPS zip code service areas.<sup>4</sup> Providers in zip codes with no matching ZCTA had unknown population density and were excluded from the analysis. To keep in line

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<sup>1</sup> 2012 data available at <https://data.cms.gov/Medicare/Medicare-Providers-2012/2hst-cj54>

<sup>2</sup> 2016 data available at <https://data.cms.gov/public-provider-enrollment>

<sup>3</sup> Bittner, Jon. 2014. The Splitwise Blog. "2010 US Population Density, by Zip Code." Accessed on May 11, 2016 at <https://blog.splitwise.com/2014/01/06/free-us-population-density-and-unemployment-rate-by-zip-code/>.

<sup>4</sup> US Census Bureau. "Zip Code Tabulation Areas (ZCTAs)." Accessed on May 11, 2016 at <https://www.census.gov/geo/reference/zctas.html>.





with the Census Bureau's definition of an urbanized area<sup>5</sup>, zip codes with a population density of at least 1,000 people per square mile were considered urban. All other zip codes with a known population density less than 1,000 per square mile were considered rural. Disenrollment was defined as providers present in the 2012 Medicare provider file who were not present in the 2016 provider file. Providers were identified across the two datasets by NPI. A chi-square test was used to determine the association between urban/rural status and provider disenrollment from 2012 to 2016.

### C. Domain 3: Net impact of payment formula

#### Data Sources

This analysis used data from CMS's October 2014 ASP file<sup>6</sup> and Summary Data for 2014 MPFS Drug Codes used in the Part B Drug Payment Model<sup>7</sup>. 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

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<sup>5</sup> Rural Information Center. USDA, National Agricultural Library. "Define Rural for Health Programs." Accessed on May 11, 2016 at <https://ric.nal.usda.gov/what-rural>.

<sup>6</sup> ASP October 2014 (<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2014ASPFiles.html>)

<sup>7</sup> Medicare Part B Drugs Payment Model (<https://innovation.cms.gov/initiatives/part-b-drugs>; <https://innovation.cms.gov/Files/x/partb-impactdatasummary.pdf>)





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:

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

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

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

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

## 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:

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

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

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:

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

### 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:

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

Note: For calculation of impact on profit/revenue, administration fees were included. Fees were collected from 5% sample of 2013 Medicare claims, and were added to the denominator of each formula. HCPCS for chemotherapy administration included the following: 96401, 96402, 96405, 96406, 96409, 96411, 96413, 96415, 96416, 96417, 96420, 96422, 96423, 96425, 96440, 96445, 96450, 96542, and 96549.

