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 regarding the impact of Phase 1 of the pilot that might be helpful, focusing on those predictions 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 neutrals. Our prior analyses, and those from others including Avalere and MEDPAC suggest that the flat fee should be higher than originally proposed for some specialties such as oncology, and lower for others such as internal medicine.

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. We found no evidence of rural providers facing higher acquisition prices for drugs.

2) Predictions regarding the payment formula causing a shift in care of cancer patients from doctor’s offices to hospital outpatient departments seem unsupportable. We base this on the observation that in 2013, cancer doctors warned that due to budget sequestration, there would be massive shifting 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 and making acquiring physician offices very slightly less, but certainly not more, attractive to hospitals.
### Domains of Concern

<table>
<thead>
<tr>
<th>Domain #1: Access will be limited from drugs going ‘under water’</th>
<th>Domain #2: Patients will be sent to hospital outpatient departments from doctor’s offices</th>
<th>Domain #3: Payment change will accelerate consolidation of doctors’ offices into hospitals</th>
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<tbody>
<tr>
<td>1. <strong>Letter from Senate:</strong> 4/27/16</td>
<td>2. <strong>Letter from Senate:</strong> 4/28/16</td>
<td>3. <strong>Letter from House:</strong> 5/2/16</td>
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<tr>
<td>4. <strong>Letter from House:</strong> 5/9/16</td>
<td>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.</td>
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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 I … 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.

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).

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. Within this domain, the key assumptions appear to be that:

1) The average acquisition price for physician practices, as expressed by the ASP, is not an adequate representation of the acquisition price for all practices. Rather, some practices (postulated by some Members to be those that are small or rural) pay a meaningfully higher amount than the average acquisition price. Based on this assumption, if the proportional mark-up is reduced from current levels (6%, 4.3% under sequestration) to the pilot formula level (2.5%, or 0.9% including sequestration), then some drugs for some practices will be reimbursed below the acquisition price even if the payment exceeds the average acquisition price. Several predictions depend on the assumption that the mismatch, if present, between acquisition price and reimbursement level will not change if payment policy changes.

2) That the proper way to evaluate this payment policy is each drug separately in the buy and bill program and not factoring in potential counterbalancing impact of other aspects of the pilot payment formula, including the flat fee payment that will be added to every drug administration and thus raises total reimbursement.
Conclusion regarding Domain #1 Concerns: Predicting the impact of the formula change depends on an expectation 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).

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. 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.
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 as well. 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 accommodated 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 (right), the upper range of acquisition prices, as shown by the 75th 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.

**Conclusion regarding Domain #1 concerns: Predicting the impact on rural providers may not comport with the limited data available**
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 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, 7%, 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).

**Conclusion regarding Domain #1 concerns: concerns about drugs being ‘under water’ seem to ignore the cumulative positive impact of the flat fee add-on included in the pilot formula, and seems to focus on individual drugs rather than a doctors’ Medicare book of business:**

Letters 1, 2, and 3, but not letter 4, appear to anchor much of the concerns about the pilot around whether particular drugs might in some cases focus on the acquisition cost for particular drugs 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.

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. The concern that doctors send their patients to the hospital outpatient department due to reduced reimbursement on drugs has not been examined empirically, but neither is it a new concern. In fact 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 the importance of the question on whether community cancer doctors WILL shift care to hospital outpatient departments under a shift in payment formula that is budget neutral or can be made to be budget neutral examining if community cancer doctors DID send patients to hospital outpatient departments in 2013 when reimbursement was actually reduced by 2%.

Because there are several different versions of what it might mean for community doctors to send their patients to hospitals due to reduced reimbursement, we analyzed 2013 events to address 3 slightly different questions (methods in appendix):
a) 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 number of patients receiving care in both settings was very small (around 1 in 200 patients) 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.

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 the trend of such consolidation is strong, that is distinct from knowing how the new payment formula would affect consolidation.

That question can be addressed under the assumption that it is the arbitrage opportunity made available to hospitals specifically around the use of Part B drugs that is driving consolidation. As highlighted in our first report, 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 who do not obtain those discounts. Thus the gross profits for these hospitals are far higher on these drugs, meaning they can make larger margins if they own doctors offices than can the doctors themselves.

The pilot formula would be projected to accelerate this trend were it to widen this arbitrage opportunity between hospitals and doctors. But as detailed in our first report, hospitals actually see larger revenue declines than doctors’ offices under the pilot formula because of how the flat fee will be applied. Hospitals will not receive it when patients receive inexpensive drugs, while doctors’ offices will. The net impact can be seen in the table to the right (for methods see appendix).

<table>
<thead>
<tr>
<th>Change to reimbursement with pilot formula in cancer care</th>
<th>Doctor’s office</th>
<th>Hospital outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark-up/profit only</td>
<td>-24.2%</td>
<td>-60.5%</td>
</tr>
<tr>
<td>Total drug reimbursement</td>
<td>-1.0%</td>
<td>-2.8%</td>
</tr>
<tr>
<td>Drug and infusion fee</td>
<td>-0.9%</td>
<td>-2.6%</td>
</tr>
</tbody>
</table>

**Conclusion regarding Domain #3 concerns:** Under the proposed formula the gap between the profits doctors make compared to hospitals is slightly narrowed. This means that the change in payment formula would not be predicted to accelerate consolidation and may at the margin very slightly slow it. The prediction would be the same if Medicare raises the flat fee to a level that keeps doctors revenue neutral.
Appendix:

Methods

A. Site-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. Rural/urban analysis

Provider enrollment data was obtained from the CMS publicly available Medicare Fee-For-Service Public Provider Enrollment Data for 2012\(^1\) and 2016\(^2\). 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\(^3\). Zip code tabulation areas are used by the US Census to generally represent USPS zip code service areas.\(^4\) Providers in zip codes with no matching ZCTA had unknown population density and were excluded from the analysis. To keep in line with the Census Bureau’s

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\(^1\) 2012 data available at https://data.cms.gov/Medicare/Medicare-Providers-2012/2hst-cj54
definition of an urbanized area⁵, 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. Net impact of payment formula

Data Sources
This analysis used data from CMS’s October 2014 ASP file⁶ and Summary Data for 2014 MPFS Drug Codes used in the Part B Drug Payment Model⁷. 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.

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

\[
\text{Units per Encounter} = \frac{\# \text{ Units}}{\# \text{ Encounters}}
\]

\[
\text{Dose per encounter} = \text{Units per Encounter} \times \text{HCPCS code dosage}
\]

Payment per encounter:

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

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

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

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

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.

\[
ASP \times 0.06 = ASP \times 0.025 + 16.8
\]
Examining Congressional comments regarding Part B payment proposal

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

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 (\(\text{ASP} + 0.9\%\)) + \$16.46 per encounter, we determined which drugs on a per encounter basis that doctors will be above/below the current sequestration \(\text{ASP} + 4.3\%\) 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:

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

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

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

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.