A Position Auction Demonstration Project for Lowering Reference + Biosimilar Drug Prices in Medicare Part B

Summary

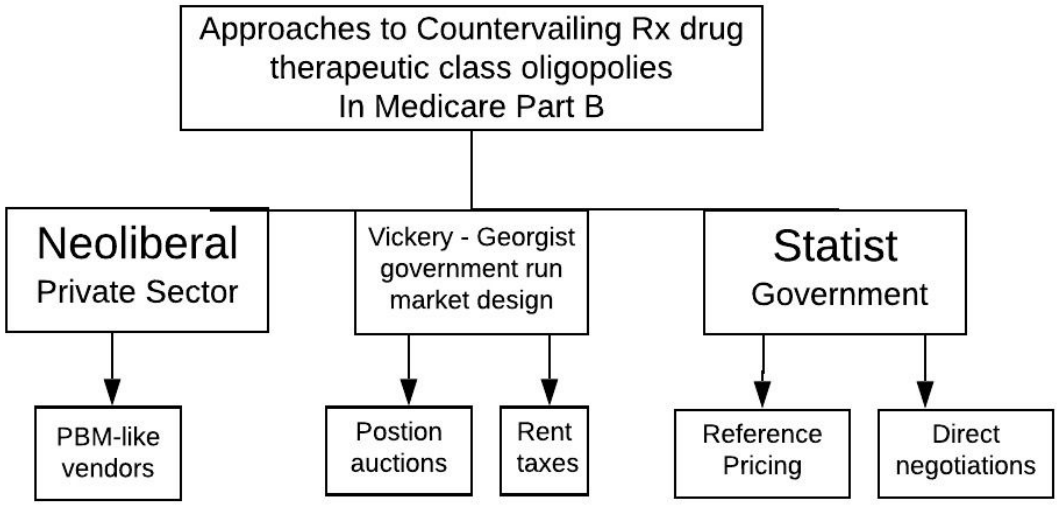
We outline below a proposal for a Center for Medicaid and Medicare Services (CMS) demonstration project involving a position auction overlay to the existing reimbursement system for Medicare Part B.

What is being auctioned off is a yearly "fail first" position in Medicare Part B.

The auction is limited in scope to therapeutic classes where at least one biosimilar has entered the market to compete with the off-patent reference drug. While limited in scope, we present data below indicating that the addressable market for this auction covers 22% of total Part B drug benefit costs in 2017.

We fully expect a minimum of a 50% reduction from current Part B average sales price (ASP) reimbursement formula. It will be a winner-take-all position auction for arguably the largest single physician-administered biologic market in the world.

The Blended Ideology of this Proposal



The ideological roots of this proposal come from the writings of economists David Ricardo in the early 1800s and Henry George in the late 1900s. Unlike labor or capital, they argued that land did not earn its return, which Ricardo called rent.

Rather, land rent was derived fortuitously from its location or position to reap the external benefits of government social welfare projects such as roads or water resource projects or economic growth in general. George argued that funding government through a tax on land rent would be both efficient and equitable.

George's ideas were picked up late in life by the economist, and Nobel Prize winner, William Vickery who championed auctions and congestion pricing as a blending of the command economy ideology of the 1930s with innovative rent-capturing market designs.

The application here of Vickery - Georgist ideas is not an isolated event. Our awareness that Vickery was a Georgist comes from reading the 2018 book by Eric Posner and Glen Weyl called Radical Markets, who outline a number of innovative market designs aimed at solving some of today's toughest problems.

Our contribution to this thread is two-fold.

One has been our 2005 conceptualization of a prescription (Rx) drug benefit formulary as a set of therapeutic class markets with varying degrees of substitutability and hence, competitive choice: monopolistic, oligopolistic, and competitive.

What this does is expand the opportunities for Vickery - Georgist rent-capturing market designs beyond traditional industrial or post-industrial oligopolies. The Rx drug industry's sales in 2018 was $344 Billion of which about $100 Billion came from Medicare Part D and another $30 Billion came from Mediare Part B.

Our other contribution has been an awareness of economist George Stigler's 1954 criticism of economist John Kenneth Galbraith's romantic belief that intermediate market countervailing powers would pass-on all rent captured from sell-side oligopolies to downstream consumers.

Stigler was right, based on our sixteen year analysis of the conflicted business model of pharmacy benefit managers (PBMs), and the complete failure by plans and insurance companies that hire PBMs to see through their deception. Galbraith in the 1950s had no clue how creative private sector healthcare intermediaries like PBMs and insurance companies can be at devising opaque business models.

Today PBMs have such a bad reputation that the authors of a MedPac proposal for a private-sector solution to lowering drug prices in Part B vaguely refer to their entities as "vendors". There is little support in Congress for any private-sector solution to Part B problems. Current CMS initiatives are all varying degrees of reference pricing or direct negotiations with arbitrary penalties for not accepting a government offer.

As bad as PBMs are, doing away with them without a replacement rent-capturing market design is worse. It is ludricious to presume that Pharma would voluntarily lower list prices to net prices after rebates in the absense of some countervailing power.

But, that is exactly what Health and Human Services Secretary Alex Azar, along with patient advocate groups and popular bloggers, assumed when he advocated ending the safe harbour for drug rebates in Part D. Thankfully, the Congressional Budget Office's (CBO) score for this proposal came up with an estimated 10 year cost to the Federal government of $177 Billion. The "world without rebates" initiative was killed shortly thereafter.

The Debate Over How to Reduce Rx Drug Prices in Medicare Part B

Medicare Part B covers outpatient healthcare costs including most Rx drugs administered in physicians' offices and outpatient facilities. Currently, the only government controls on drug prices in Part B has been the imposition of a mild reference price calculated as the average sales price (ASP) in the private sector.

This is in dramatic contrast to Medicare Part D which covers drugs taken or injected by seniors at home. Here, seniors can choose from a variety of private plans managed by "middlemen" called pharmacy benefit managers (PBMs) who try to hold down costs with the primary tool being rebates paid by Pharma for inclusion in a formulary -- a list of covered drugs grouped into 60-80 therapeutic classes and subclasses.

Medicare Part D was hailed initially as a shining example of a private-sector, market-based approach to controlling Rx drug costs. However, since 2015 PBMs have come under increasing scrutiny as the driver of rising drug list prices due to their conflicted reseller business model dependent on retained rebates.

On May 11, 2018 President Trump announced publicly that "one of my greatest priorities is to reduce the price of prescription drugs."

This has sparked a great debate about how the Federal government can best lower drug prices, beginning with Medicare Part B. The debate and related proposals for Part B can be divided into two groups with readable blog posts conveniently aggregated by *Health Affairs*:

1. Proposals for direct government intervention which we label statist:

    a. Bach et al, Part 1 Part 2, and a followup build the case for abandoning biosimilars as a competitive force and regulating the biologics drugs after patent expiration as "natural monopolies";
    b. Conti and Kluetghen analyze pending legislation for direct government negotiations;
    c. Sachs analyzes a CMS demonstration project involving imposition of an international reference pricing index.

2. Proposals advocating private-sector market-based initiatives which we label neolibertal:

    a. Brill and Ipolitto's present a rebuttal and a followup to Bach's claims of lack price competition within biologic therapeutic classes upon entry of biosimilars;
    b. Ginsberg et. al and Antos et. al advocate going forward with a CMS demonstration project involving intermediaries sounding a lot like PBMs.

Within that debate, there is growing recognition that there is no "one-size fits all" solution.

This is due to the fact that the market designs or negotiation strategies available to countervailing powers depend critically on drug "substitutability" -- the number of drugs which are close substitutes -- called therapeutic equivalents or biosimilars -- and the number of drugs which are perfect molecule-for-molecule substitutes called generics.

In theory, private-sector PBMs or government run auctions can be an effective rent-capturing countervailing power in therapeutic class oligopolies. But, in cases where there are no substitutes -- the monopolistic therapeutic classes -- bilateral bargaining under conditions of information asymmetry about other party's willingness to pay theoretically is indeterminate per the Myerson - Satterwaith Impossibility Theorem.

There needs to be some addional rule to the bilateral bargaining game to produce an efficient outcome. This includes something like a Nash bargaining solution involving assumptions about knowledge about other party's willingness to pay (one party cuts the pie, the other has first choice on piece) or a Rubenstein game play clock where some

draconian penalty like "march-in" rights kicks in if Pharma doesn't accept the government's offer in a timely manner.

In cases of monopolistic therapeutic classes, Vickery auctions can't be used. An alternative to statist approaches could be a Georgist rent tax, but even that seems statist compared to our position auction proposal.

A Position Auction Demonstration Project

We outline below a CMS demonstration project involving a position auction overlay to the existing reimbursement system for Medicare Part B.

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Obviously, this constriction of health care options, even between a reference drug and its biosimilars, is open to legal challenges as a possible violation of a Part B rule that insures coverage for all " reasonable and necessary" treatments.

But, unlike other CMS demonstration project proposals, we believe this auction will work without any legislative changes. Specifically, we have designed the auction with the idea of making no changes to the existing ASP reimbursement formula.

Position auctions are a subclass of auctions studied by economists. The most famous is the Google ad position auction designed by Google chief economist Hal Varian and Google co-founder Larry Page.

Access to markets with reduced competition is a position that has value and can be sold by intermediaries. If members of an oligopoly want access, the intermediary improves consumer welfare by transferring oligopolistic rent to the intermediary which is more or less passed on to downstream consumers with "more or less" the heart of the Galbraith - Stigler debate of the 1950s on intermediate market countervailing power.

What to name the money transfer in this auction will be debated. For now, we use the neutral term “proceeds”. It is not a “price” which is usually associated with competitive markets. We do not think it should be called a “discount” or a “rebate” as, unlike PBMs, the government is not purchasing or taking title to anything.

Actually, it would be entirely appropriate economics, and astute in pitching this to the current administration, to call the auction proceeds a “tariff.”

This auction become an **overlay** to the existing ASP-based reimbursement formulas.

There will be three accounting flows with the new auction flow virtually independent of the other two:

1. The auction proceeds would flow directly to the Federal government reducing overall government plan costs. We strongly recommend that the copayment of auctioned drugs be changed to a percentage of net costs. This might even spur bidding.

2. No changes are required to ASP-based reimbursement formulas. With a position auction overlay, government ASP reimbursements becomes a temporary accounting outlay later netted significantly by auction proceeds a quarter later due to the lengthy time to settle claims.

3. Provider and distributor margins should remain the same. This demonstration project is focused on extracting oligopoly excess profits or economic rent and not on the relatively minor issue of provider profits.

4. We do admit to a potential indirect effect as the very success in this government auction could lead to reduced rebate offers in the commercial sector leading to higher ASPs and lower Medicaid “best prices.”

Some Specifics

The auction would be a first price sealed bid, reverse auction with the winning low bid calculated as current ASP minus unit bid. We expect that the bidding to be competitive and comfortable with having no reserve -- i.e. winning bid could be ASP minus 0.

The specific winning bid amount should never be revealed, but the government should be allowed to make qualitative assessments. And like Medicare Part D rebates, the bid data should never be used in calculating ASPs or Medicaid "best prices".

Addressable Market

We target five reference drugs (see chart below) each with one to two biosimilars for this demonstration project.

Addressable Market - Medicare Part B Position Auction

(HCPCS Code)	Dosage	Brand Name	Generic Name	Rank	Calendar Year 2017 Part B Spend	Ave.Total Spend Per Beneficiary	ASP+6% **
J9299	100 mg	Rituxan	Rituximab	2	$1,753,455,037	$24,906.32	$831.90
J1745	6 mg	Neulasta	Pegfilgrastim	4	$1,400,100,685	$15,346.43	$4,219.14
J0897	10 mg	Remicade	Infliximab	5	$1,341,011,663	$23,764.58	$85.17
J2778	10 mg	Avastin	Bevacizumab	7	$1,066,675,107	$4,859.30	$74.34
J0129	10 mg	Herceptin	Trastuzumab	10	$782,404,051	$38,093.58	$95.86

2019 Biosimilar Competitors	
Ruxience * #	Truxima * #
Fulphila	Udenyca
Inflectra	Renflexis
Mvasi	
Kanjinti	Trazimera

* not yet launched

did not seek approval for all indications per agreement with reference company

Data Source: CMS, Part B Drug Spend Dashboard

Auction Total	**$6,343,646,544**
Part B Total	**$29,481,723,485**
Auction % of Total	**22%**

** ASP (2017 Average quarterly payment listed on ASP files for most recent year including 6% and other applicable add-ons

Based on publicly available data downloadable from the CMS Medicare Part B Drug Spending Dashboard, these biologics drugs comprise only about 2% of drug J-codes covered under Part B, but their 2017 total spend, including patient copayments, represents 22% of total spend.

The 5 reference drugs are just beginning to face biosimilar competition and represent 5 of the 10 highest ranking drugs by total Part B spending.

According to a chart kept by consultant Stanton Mehr, there are 5 other biosimilars not listed below that have been approved by the FDA, but not yet marketed. So, by next year, with the exception of Avastin, there could be at least three bidders in each auction.

We left out Neulasta and its two biosimilars as the combination of declining quantities and ASPs have progressed to the point that these drugs barely made it into the top 100 ranking drugs.

With the exception of startup Coherus with its Udencya biosimilar to Neulasta, these five auctions shape up be match-ups among the titans of the pharmaceutical industry. There is no need to water-down winner-take-all auctions for these titans.

Three of the five auctions feature bitter rivals in the patent and antitrust courtrooms, but will that translate into spirited competition in the bid room?

Both Amgen and Pfizer potentially will be bidding in 3 of the 5 auctions. Indications from Amgen and Pfizer that they are open to competing in this arena could be key in making this demonstration project happen.

Expectations

We fully expect a minimum of a 50% reduction from current ASP-based reimbursements for a winner-take-all position auction for arguably the largest single physician-administered biologic market in the world.

Winning the Medicare Part B position auction would be would be bigger than winning the exclusivity on the formularies of the largest medical drug benefit payers in the commercial space. It would represent more business that winning any European tender (procurement). With a few more bidders, say four, the winning bid could even be best the Medicaid “best price”

We see two major deterrents to meeting our expectations. One, of course, is lack of bidders. The difference between two and four seems huge to us. The second is that, unlike large generic drug manufacturers, brand-oriented drug companies aren’t used to competing on price. They might not like the fact that the biosimilars market, like the generics market, becomes a high gross profit dollars, but low margin percentage business because that dilutes their consolidated P&Ls.

Expansion

If successful, position auctions could be expanded:

1. Position auctions could be expanded to 340(b) and Medicaid with the stipulation that the auction reserve is set to the Medicaid “best price”.

2. Home injectable biologics are covered by Medicare Part D. By 2023 (hopefully), the patent thicket for top selling injectable biologics Humira and Enbrel will be cleared and position auctions for these reference drugs and their biosimilars could begin. That is, of course, assumes that the Part D protected class clause is modified to allow for a few winner-take-all position auctions.

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