



Advising the Congress on Medicare issues

Medicare Part B drug payment policy issues

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Policy options

- Options that seek to increase price competition and address Part B drug price growth
 - Consolidated billing codes
 - Average sales price (ASP) inflation limit
 - Restructured drug acquisition program
- Options that seek to improve the current payment formula and data
 - Modifying the ASP add-on formula
 - Modifying the payment formula for drugs paid wholesale acquisition cost (WAC) plus 6 percent
 - Strengthening manufacturer reporting requirements for ASP data

Background

- In 2014, Part B drug spending was \$22 billion (\$18B program and \$4B beneficiary cost-sharing)
- Part B drug spending has grown over 8 percent per year in the last 5 years
- Medicare pays physicians and HOPDs for most Part B drugs at 106% of the average sales price (ASP)
 - ASP = average price realized by manufacturer for sales to all purchasers (with exceptions) net of rebates and discounts
 - The prices individual providers pay for a drug may differ from ASP for a variety of reasons (e.g., price variation across purchasers, 2-quarter lag in ASP payment rates, prompt pay discounts)

Policy option: Consolidated billing codes

- Most single-source drugs and biologics have their own billing code with two exceptions:
 - Generic drugs and their associated brand drug are paid under one billing code
 - All biosimilar products associated with the same reference biologic are grouped in one billing code
- Separate billing codes for products with similar health effects do not promote price competition
- The Commission has held that Medicare should pay similar rates for similar care

Policy option: Consolidated billing codes

- Option: Give the Secretary the authority to:
 - Group a reference biologic and its biosimilars in a common billing code
 - Group drugs with similar health effects in a common billing code and group biologics with similar health effects in a common billing code

Policy option: Consolidated billing codes

- Implications:
 - Putting products with similar health effects in the same billing code and paying them the same rate would be expected to generate price competition relative to separate codes
 - Consolidated billing codes would be expected to generate savings for beneficiaries and taxpayers
- Issues:
 - The Secretary could rely on FDA approval process to group biosimilars and reference biologic; for other drugs and biologics, the Secretary would need a process to identify products with similar health effects
 - Some stakeholders assert effect on R&D and innovation and effect on beneficiary access to care

Policy option: ASP inflation limit

- No limit on how much Medicare's ASP+6 payment rate for an individual drug can increase over time
- Median ASP growth for the 20 highest-expenditure drugs was slower than inflation from 2005 to 2010, but has exceeded inflation since then
- Between October 2015 and 2016, 10 out of the 20 highest-expenditure drugs had an ASP increase of 5 percent or more

Policy option: ASP inflation limit

- Option: Place a statutory limit on how much Medicare's ASP+6 payment can grow over time by:
 - Requiring manufacturer rebates when ASP growth exceeds an inflation benchmark (e.g., similar to Medicaid inflation rebate)
 - Sharing rebates with beneficiaries by basing cost-sharing on the lower inflation-adjusted ASP
- Question of whether provider add-on payments should be unaffected by inflation limit or based on the lower inflation-adjusted ASP

Policy option: ASP inflation limit

- Implications:
 - Generate savings for beneficiaries and program
 - Simulated rebates under a hypothetical policy with baseline period of 1st quarter 2013 and CPI-U as inflation benchmark
 - Estimated rebates would have been \$750M in 2014 and more than \$1.25B in 2015, with 20% of those rebates used to lower cost-sharing
- Issues:
 - Some stakeholders assert that policy could spur manufacturers to increase launch prices for new drugs

Data are preliminary and subject to change

Policy option: Restructured Competitive Acquisition Program (CAP)

- Voluntary CAP Program (2006-2008) where physicians who enrolled obtained Part B drugs through a competitively selected vendor
 - Vendor supplied drug to physician
 - Medicare paid vendor for drug and paid physician for administering drug
 - Vendor collected drug cost-sharing from beneficiary
- Unsuccessful because low physician enrollment and vendor had little price leverage with manufacturers
- Option: Give Secretary authority to implement an improved CAP

Policy option: Restructured CAP

- Design questions for new CAP structure
 - Mandatory or voluntary with incentives
 - Physicians only or physicians and hospitals
 - Extent of formulary authority or management tools
 - All or a subset of drugs
 - Number and scope of CAP vendors
 - Stock replacement model or GPO model

Policy option: Restructured CAP

- Illustrative structure for CAP model
 - Voluntary but encourage participation
 - offer shared savings opportunities in CAP
 - reduce or eliminate ASP add-on in buy-and-bill system
 - Include physicians and hospitals
 - Permit vendor to operate a formulary
 - Focus on a subset of drugs
 - Multiple regional CAP vendors
 - Stock replacement model

Policy option: Restructured CAP

- Implications:
 - A redesigned CAP could lead to savings for beneficiaries and Medicare program
 - Amount of savings would depend on many factors (e.g., which drugs included, amount of provider enrollment, how much ASP add-on is reduced, extent of formulary authority)
- Issues:
 - Some providers express concern about administrative burden
 - The Secretary would need to develop and oversee CAP

Policy option: Modifying ASP add-on

- The 6% add-on may incentivize use of higher-priced drugs, although few studies have examined this issue
- Our analysis of proprietary IMS data for 34 Part B drugs found that for two-thirds of those drugs at least 75% of the volume was sold to clinics at an invoice price less than 102% ASP in first quarter 2015
- In the June 2016 report, we modeled a hybrid option: 103.5% ASP + \$5 per drug per day
 - Add-on payments increase for drugs with an ASP per administration less than \$200 and decrease for other drugs
 - Estimated to save 1.3% (assuming no utilization changes)

Policy option: Modifying ASP add-on

- In response to Commissioners' feedback, we have modeled additional options:
 - 103.5% ASP + \$5 per drug per day (hybrid)
 - Lesser of hybrid or 150% ASP (modified hybrid)
 - 105% ASP (lower percentage add-on)
- Implications:
 - Generate savings for beneficiaries and Medicare program
 - Revenue effect by type of provider varies across options
 - Lessens difference in add-on payments across high- and low-cost drugs
- Issues:
 - Some stakeholders assert policy could contribute to the trend toward more hospital-based care

Policy option: Modifying ASP add-on

	Lower percentage add- on: 105% ASP	Hybrid: 103.5% ASP + \$5 per drug per day	Modified hybrid: Lesser of hybrid or 150% ASP
Savings estimates			
Medicare program	\$150M	\$215M	\$285M
Beneficiaries	\$40M	\$55M	\$70M
Change in Part B drug revenues			
All providers	-0.9%	-1.3%	-1.7%
Physicians	-0.9	-1.0	-1.6
Oncology	-0.9	-1.5	-1.9
Ophthalmology	-0.9	-2.0	-2.0
Rheumatology	-0.9	-1.8	-2.0
Primary Care	-0.9	1.5	-0.7
Hospitals	-0.9	-2.1	-2.1
Suppliers	-0.9	-0.4	-0.6

Source: MedPAC estimates based on 2014 Medicare claims data.

Data are preliminary and subject to change

Policy option: Modifying payment rate for drugs paid at WAC + 6%

- Wholesale acquisition cost (WAC) is a manufacturer's undiscounted price to wholesalers or direct purchasers

- Types of drugs paid at WAC + 6%
 - New single-source drugs (until ASP available)
 - Other drugs without ASP data

Policy option: Modifying payment rate for drugs paid at WAC + 6%

- Analysis of new, high expenditure Part B drugs
 - 7 of 8 drugs' prices dropped going from WAC to ASP; 1 drug's price remained flat
 - Changes ranged from -0.7% to -2.7%
 - Suggests discounts were present when drugs were paid at WAC + 6%
- Option:
 - Require Secretary to reduce payment rate for WAC-priced drugs by 2 percentage points (i.e., WAC + 4%)

Policy option: Improving ASP data reporting

- Only Part B drug manufacturers with Medicaid drug rebate agreements required to submit ASP
- Option:
 - Require manufacturers report ASP data for all Part B drugs and give Secretary authority to enforce requirement
- Implications:
 - Improve data accuracy
 - Complements other policies (e.g., inflation limit)

Discussion

- Clarifications
- Feedback on policy options
 - ASP inflation limit
 - Competitive acquisition program
 - Modifying ASP add-on
 - WAC + 6 drugs
 - ASP data reporting
 - Consolidated billing codes