Medicare Part B drug payment policy issues

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MEDPAC

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.

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