Medicare Part B drug payment policy issues

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MEDPAC

Presentation overview

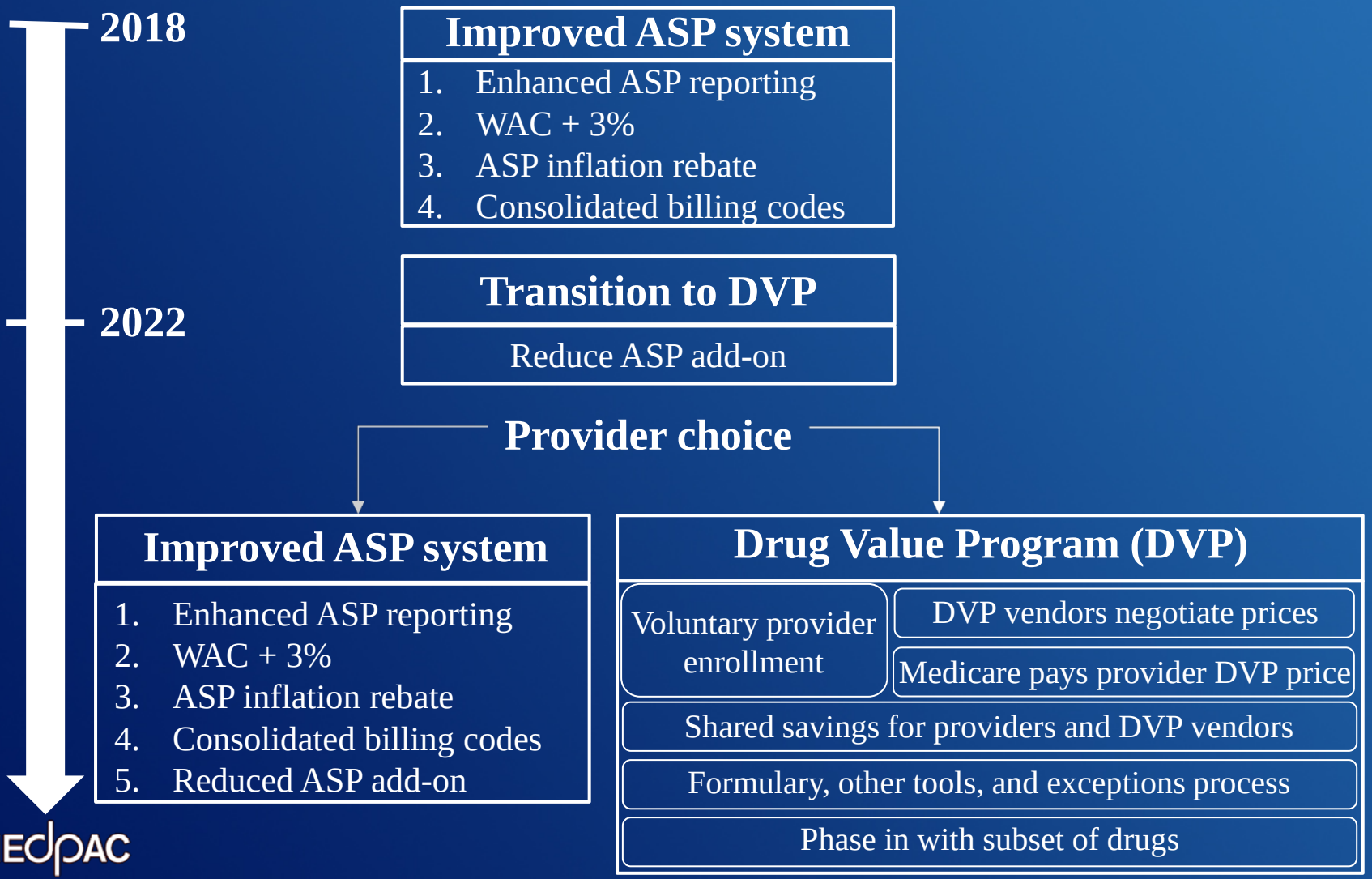
- Background
- Package of potential reforms:
  - Improvements to current average sales price (ASP) system
    - Improved ASP data reporting
    - WAC + 3%
    - ASP inflation rebate
    - Consolidated billing codes
  - Reduce ASP add-on to encourage enrollment in Drug Value Program (DVP)
  - DVP: market-based alternative to ASP payment system

Background

- In 2015, Part B drug spending was $26 billion (up from $23 billion in 2014)
  - $21 billion program spending
  - $5 billion beneficiary spending
- ASP+6 payment system may provide incentive to use higher-priced products
- Part B drug spending has grown 9 percent per year since 2009
  - Half of growth in expenditures accounted for by price growth from 2009 to 2013

Data are preliminary and subject to change

Overview of potential reforms



Policy: Improving ASP data reporting

- Only Part B drug manufacturers with Medicaid drug rebate agreements currently required to submit ASP data
- This policy would:
  - Require manufacturers to report ASP data for all Part B drugs
  - Increase penalties for non-reporting
  - Give the Secretary authority to exempt repackagers

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

- Wholesale acquisition cost (WAC) is a manufacturer's undiscounted price to wholesalers or direct purchasers
- Analysis of subset of new, high-expenditure drugs – modest discounts (0.7% to 2.7%) common
  - Because discounts are not incorporated into WAC, Medicare pays more for the same drug when WAC-priced vs. ASP-priced
- This policy would:
  - Reduce payment rate for WAC-priced drugs by 3 percentage points (i.e., WAC + 3%)
  - Reduce WAC add-on further if ASP add-on is reduced to maintain parity between WAC-priced and ASP-priced drugs

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Policy: ASP inflation rebate

- Medicare's payment rates under the ASP payment system are driven by manufacturer pricing decisions
- No limit on how much Medicare's ASP+6 payment rate for an individual drug can increase over time
- Between January 2010 and January 2017, 9 of the top 20 highest-expenditure drugs had annual ASP growth of 5 percent or more

Policy: ASP inflation rebate

- This policy would require manufacturers to pay Medicare a rebate when the ASP for their product exceeds an inflation benchmark, and tie beneficiary cost-sharing and the ASP add-on to the inflation-adjusted ASP
- Could exempt low-cost drugs and avoid duplicate discounts
- Inflation benchmark: CPI-U or alternative

Policy: Consolidated billing codes

- To maximize price competition:
  - 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 reference biologics and for single-source drugs with similar health effects do not maximize price competition
- The Commission has held that Medicare should pay similar rates for similar care

Policy: Consolidated billing codes

- This policy would require the Secretary to use a common billing code to pay for a reference biologic and its biosimilars
  - The Secretary would rely on FDA approval process to group reference biologic and biosimilars
  - The Secretary could consider implementing a limited payment exception process
- The Secretary could study the use of a consolidated billing code more broadly for groups of products with similar health effects

Policy: Drug Value Program (DVP)

- This policy would give the Secretary authority to create a Part B DVP that would use private vendors to negotiate prices and offer providers shared savings opportunities
- Informed by lessons learned from the Competitive Acquisition Program (CAP) for Part B drugs
- Structured differently to increase vendors' negotiating leverage and encourage provider enrollment

Policy: Drug Value Program – key design elements

- DVP would be voluntary for physicians and hospitals
- Reduce ASP add-on to encourage DVP enrollment
- Small number of DVP vendors
- Vendors negotiate prices but do not ship product
- Providers buy drugs in marketplace at the DVP price
- Medicare pays providers for drugs at DVP price and for drug administration services at PFS or OPPS rate
- Providers would have shared savings opportunities
- Beneficiaries would save through lower cost-sharing
- Vendors would be paid an administrative fee, and potentially shared savings
- Medicare would share in savings

Policy: Drug Value Program – key design elements

- Tools to increase DVP vendors' negotiating leverage
  - Formulary (with exceptions process)
  - Limit prices under DVP to no more than 100% of ASP
  - Additional tools such as step-therapy and prior authorization
  - Binding arbitration could be used in the DVP for expensive drugs without close substitutes
- DVP prices would be excluded from ASP
- Phase in DVP beginning with a subset of drug classes

ASP add-on

- The policy would reduce the ASP add-on to encourage enrollment in the DVP

- Analysis of proprietary IMS data for 34 Part B drugs in our June 2016 report found:
  - For two-thirds of the drugs, at least 75% of the volume was sold to clinics at an invoice price less than 102% of ASP in first quarter 2015
  - Manufacturers appear to have modified their pricing in a way that mitigated the effect of the sequester on some providers

Hypothetical example of how DVP would work for the provider and beneficiary

- DVP negotiates price of $400 for drug with ASP of $500
- Provider buys drug at DVP price of $400 for Medicare patients
- Provider payment rate:
  - Drug payment=$400
  - Additional payment for drug administration under PFS or OPPS
  - Provider opportunity for shared savings (share in $100 savings)
- Beneficiary cost-sharing reflects lower negotiated prices
- Retroactive true-up of price paid by provider to distributor to reflect volume furnished to Medicare and other patients

Overview of potential reforms