



Advising the Congress on Medicare issues

Medicare Part B drug payment policy issues

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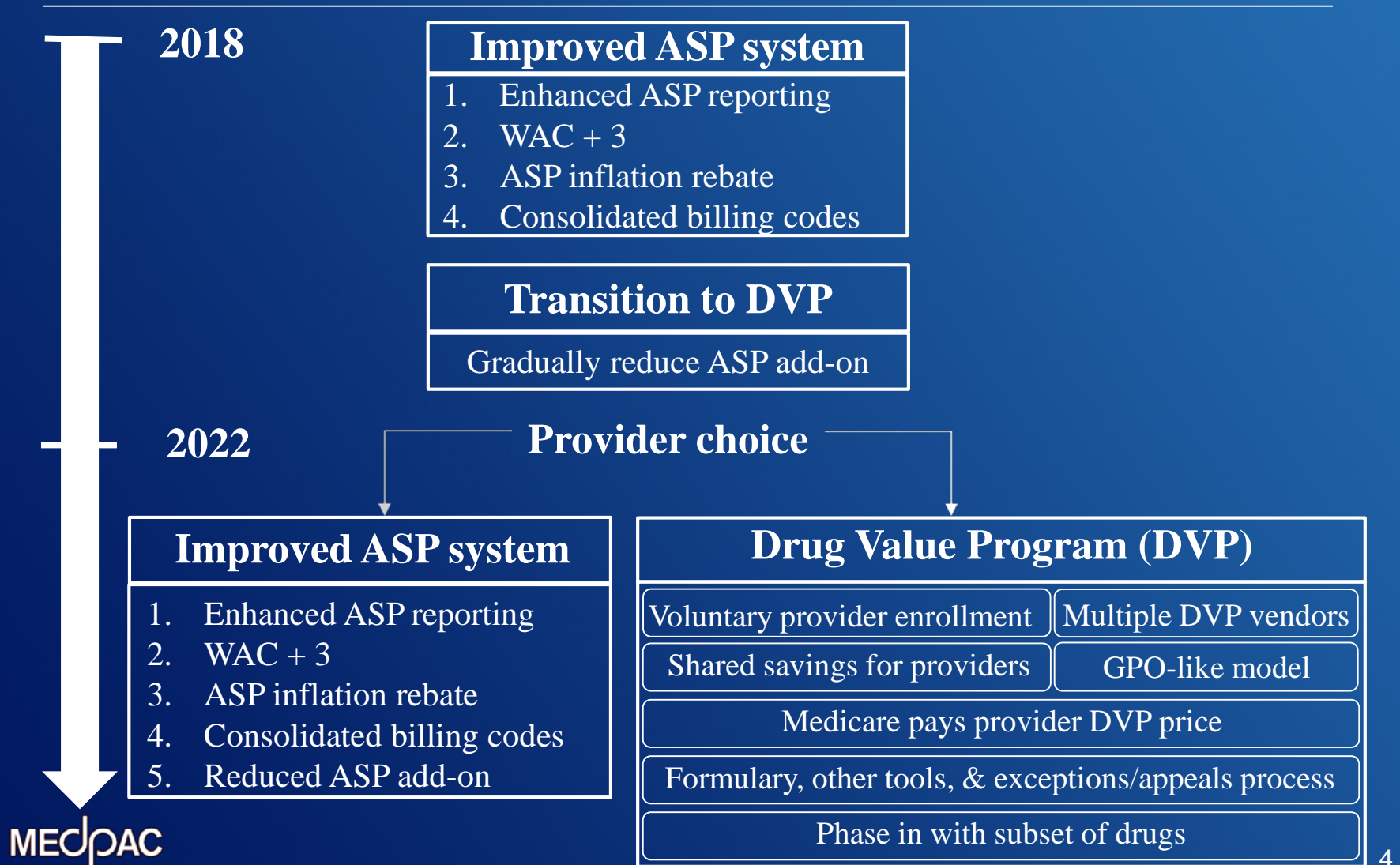
Presentation overview

- 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
 - Gradually reduce ASP add-on to encourage enrollment in Drug Value Program
 - Drug Value Program (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
- Part B drug spending has grown 9 percent per year since 2009
- Medicare pays physicians and HOPDs for most Part B drugs at 106% of 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, etc.)

Overview of potential reforms



Policy: Improving ASP data reporting

- Only Part B drug manufacturers with Medicaid drug rebate agreements currently required to submit ASP
- This policy would:
 - Require manufacturers report ASP data for all Part B drugs
 - Increase penalties for non-reporting
- Repackagers could be exempted from policy

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
- New, single-source drugs and first biosimilar to a reference biologic paid at WAC + 6% for up to three quarters
- Analysis of subset of new, high-expenditure drugs – modest discounts (0.7% to 2.7%) common

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

- 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
 - E.g., If ASP add-on reduced from 6% to 5%, WAC add-on could be reduced by an equal amount (3% to 2%)

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
- This policy would require that Medicare collect rebates from manufacturers when ASP growth exceeds an inflation benchmark

Policy: ASP inflation rebate – key design elements

- Manufacturer could be required to pay a rebate when ASP for its drug exceeds the inflation-adjusted ASP for the billing code
- Base beneficiary cost-sharing and provider add-on payments on lower inflation-adjusted ASP
- Exempt low-cost drugs (e.g., drugs with annual cost per user less than \$100)
- Avoid duplicate discounts
 - ASP inflation rebate would not be applicable to Medicare utilization subject to 340B discounts or Medicaid rebate
- 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 single-source products with similar health effects do not promote price competition
- The Commission has held that Medicare should pay similar rates for similar care

Policy: Consolidated billing codes

- This policy would 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
- 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

Policy: Consolidated billing codes

- Medical exception process could be considered:
 - Clinician could be required to provide medical justification to Medicare Administrative Contractor
 - Appeals could be coupled with existing process for other Medicare Parts A and B services
 - Payment could be set at the higher-cost product's ASP without an add-on payment and beneficiary 20 percent coinsurance could be based on the coinsurance of the consolidated billing code payment rate

Policy: Reduce ASP add-on

- Six percent add-on may make buy-and-bill system attractive to providers over DVP
- This policy would gradually reduce the ASP add-on in the buy-and-bill system to encourage DVP enrollment

Policy: Drug Value Program (DVP)

- Intent: Develop a market-based alternative to the ASP system to create more incentives for provider efficiency and obtain lower prices from manufacturers
- 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

- Voluntary provider enrollment
 - Providers would decide annually whether to enroll
 - Providers not enrolling would remain in ASP system with reduced add-on
- Multiple DVP vendors
- GPO-like model
 - Vendors negotiate rates but do not ship product
 - Providers buy drugs for Medicare beneficiaries at DVP rate and Medicare pays providers DVP rate
- Providers have shared savings opportunities
- Beneficiaries save through lower cost-sharing
- Vendors would be paid an administrative fee, and potentially shared savings

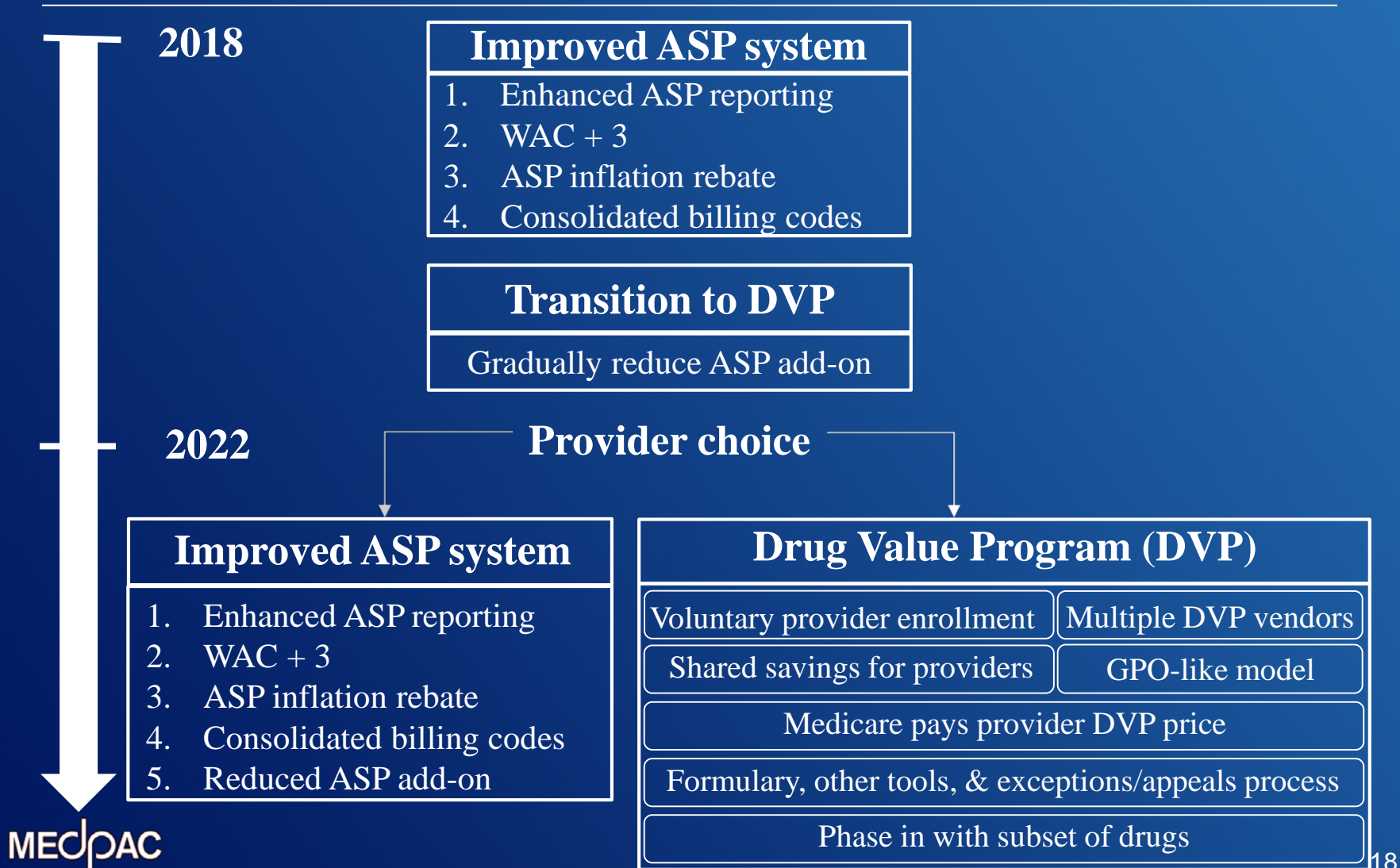
Policy: Drug Value Program – key design elements

- Tools to increase DVP vendors' negotiating leverage
 - DVP vendors would utilize a formulary, with an exceptions and appeals process
 - Limit prices under DVP to no more than 100% of ASP
 - Other tools vendors might use include step-therapy, prior authorization, or innovative purchasing approaches like risk-based contracts or indication-specific pricing
 - Arbitration could also be considered for use in the DVP to facilitate negotiations between DVP vendors and manufacturers for drugs without close substitutes

Policy: Drug Value Program – Key design elements

- DVP prices would be excluded from ASP
- Phase in DVP beginning with a subset of drug classes

Overview of potential reforms



Discussion

- Clarifications
- Feedback on package of potential reforms
 - Improve ASP system
 - Improved ASP data reporting
 - WAC+3%
 - ASP inflation rebate
 - Consolidated billing codes
 - Gradual reduction of ASP add-on to transition to DVP
 - Develop and implement Drug Value Program as voluntary alternative to ASP system