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Medicare Part B Drug Payment Model

APRIL 7, 2016

Agenda

Overview

Details

- Included and Excluded Drugs
- Participating Providers
- Geographic Selection
- Phases

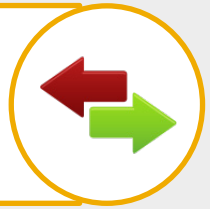
Outlook

Overview of the Proposal

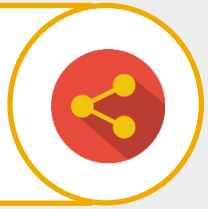
Context

Heightened concern over drug costs and cost increases

Pressure for the Administration to “take action”



Long standing concerns with Part B drug payment formula

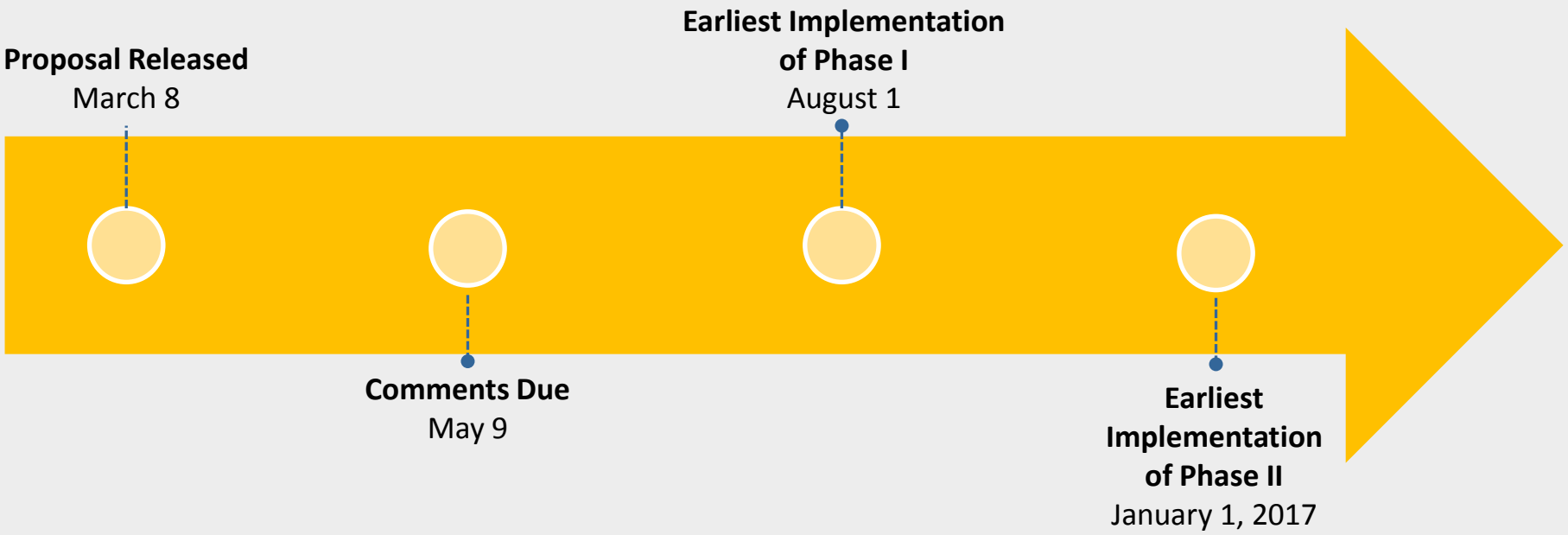


MedPAC attention to issue and recommendations

Authority

- **Section 1115A of the ACA**
- **Center for Medicare and Medicaid Innovation (CMMI)**
- **Very broad authority (several waivers)**
- **No requirement for rulemaking**
- **Limits on judicial review**
- **Precedent for mandatory models**
  - Home Health Value-Based Purchasing (HHVBP) model
  - Comprehensive Care for Joint Replacement Model

Key Turning Points



Five Years – Proposed Model Duration

The Proposal in Detail

Part B Drug Model Includes Most Drugs

Part B drugs generally include:

- Drugs, biologicals and biosimilars furnished incident to physician's service
- Drug provided in hospital outpatient setting
- Drugs administered via a covered item of DME (e.g., intravenous pump, nebulizer)
- Drugs covered under Part B by statute

Most Part B drugs included in model

Few Part B drugs excluded from the model

Part B Model Includes All Providers & Medicare Beneficiaries

Mandatory for all providers / suppliers furnishing Part B drugs

- Physicians, pharmacies, DME suppliers, hospital outpatient departments, ESRD facilities
- Providers / suppliers assigned to control and test arms depending on geographic area

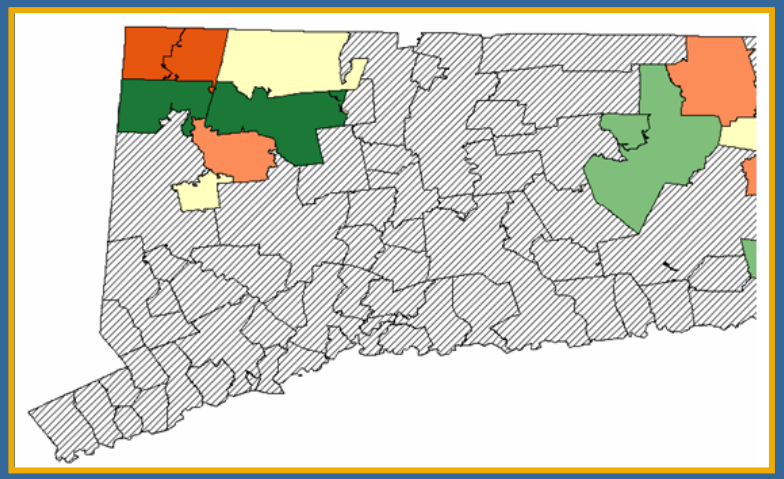
All Medicare beneficiaries including those assigned to other Innovation Center payment model demonstrations

- Medicare Shared Savings Program or other shared savings models (e.g., Next Generation)
- Oncology Care Model
- Intravenous Immune Globulin (IVIG) Demonstration

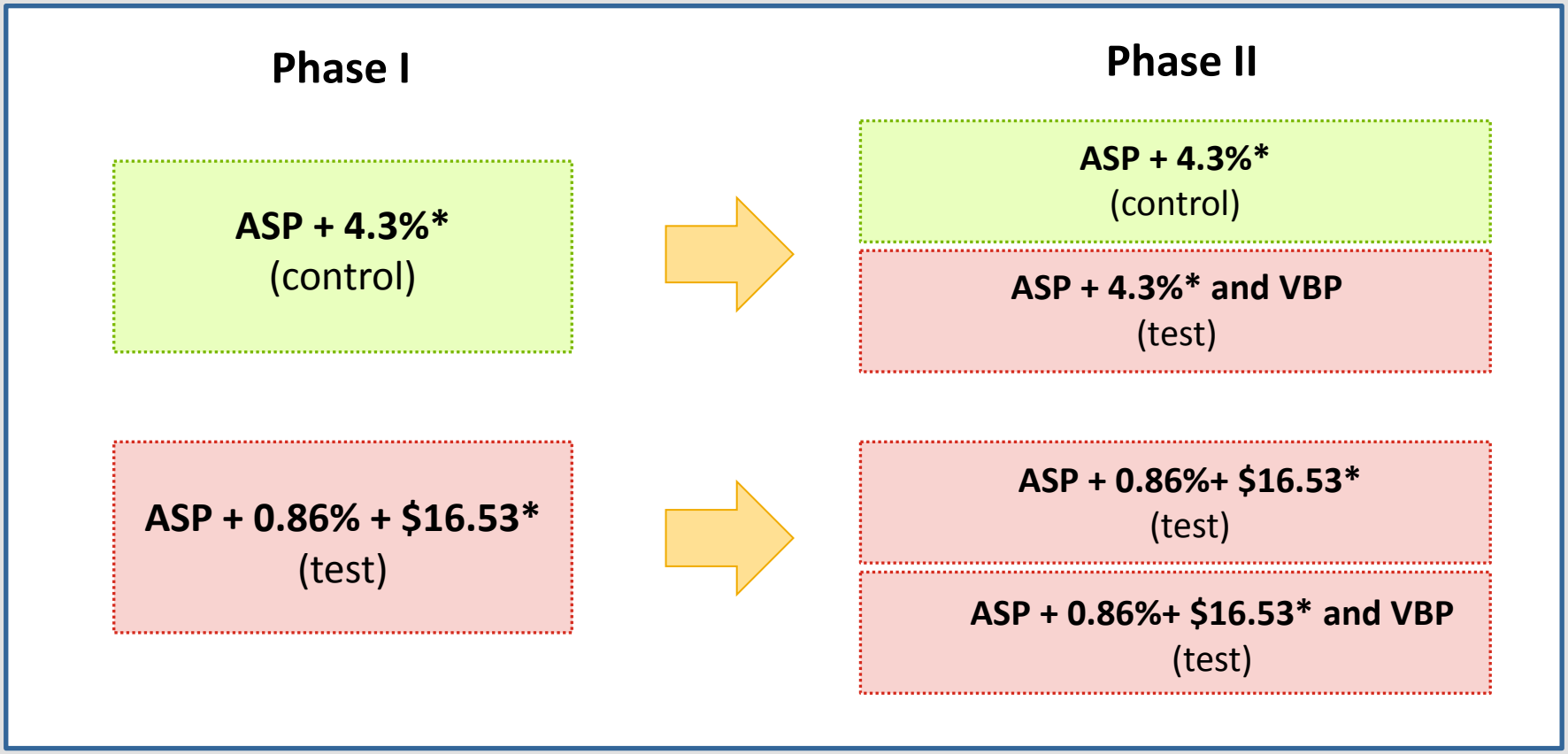
Geographic Unit for Study Design: Primary Care Service Areas

- Approximately 7,048 Primary Care Service Areas (excludes 96 PCSAs in Maryland)
- Represents service areas for office-based primary health care based on Medicare Part B primary care utilization patterns

Example:
PCSAs for Connecticut



Two Phases: Phase II Augments Phase I with VBP Tools



** POST-Sequestration*

Value-Based Pricing

For some drugs or drug classes as "appropriate"

Specific drugs and specific tools:

- Proposed publicly
- 30 day comment period (comments due May 9)
- At least 45 days notice prior to implementation

Pre-appeals payment exceptions review process

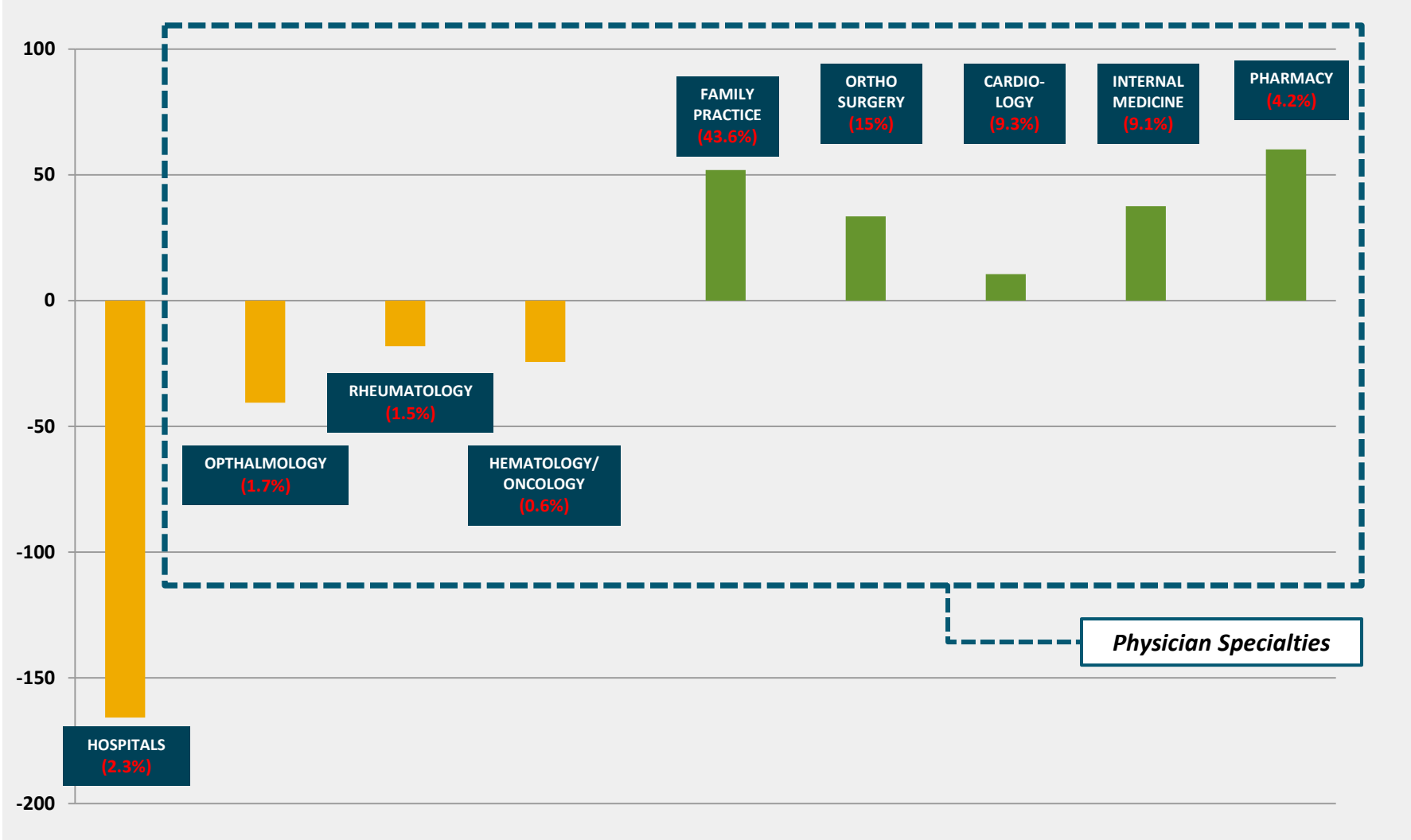
- Available to provider, supplier, or beneficiary
- Appeal to contractor for exemption for specific drug for specific beneficiary
- Standard
  - ✓ "payment exception is appropriate, given the beneficiary's circumstances" (proposed rule)
  - ✓ "and explain why the price provided under the Phase II pricing policy does not provide accurate compensation for the prescribed drug" (preface explanation)
- 5 business days to provide decision

"Use of contractor. One or more contractors will be utilized to implement CMS approved VBP tools."

Value-Based Pricing Tools

- Reference Pricing
- Pricing based on safety and cost-effectiveness for different indications
- Outcomes-based risk-sharing agreements
- Discounting or elimination of patient coinsurance amounts
- Clinical decision support (CDS) tools for appropriate drug use and safe prescribing
- Competitive Acquisition Program
- Bundled or episode payments for Part B drugs

Winners and Losers (according to the rule)



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Market Behavior

Providers

- One certain thing: providers will change practices
- Potential site of service shifting
- Incentive for consolidation
- Increased incentive for using 340B
- Shift to Part D

Manufacturers

- "Plus" portion of formula maintained
- Unlikely to impact pricing decisions in Phase I
- Phase II is the big game – chilling effect?

Stakeholder Reactions

- Winners are diffuse and not organized
- Losers/opponents are concentrated and highly motivated
- Medical professional groups strongly opposed and already active
- Bio/pharma companies and trade groups energized
- AARP expresses support
- Patient group opposition could be critical

Outlook

Phase I Regulatory Options

Two factors potentially modified: different payment rate and fewer regions

CMS has given itself the ability to pay an amount in between the proposed amount of ASP+ 2.5% +16.80 and the current payment rate

- Different percentages (e.g., 3 percent)
- Combinations of percentage and flat fee add-ons across several tiers of drugs defined base on cost
- Add-on payments across groups of drugs with common features such as cold handling or other special cost considerations
- Could use one of MedPAC's three policy options

Could finalize any of these approaches or one suggested in comments

Likely pull back to fewer regions and perhaps even a higher rate

Phase II – CMS direction is far less clear

Soliciting comments on a variety of approaches but did not propose a specific approach

- CMS likely not sure which direction it will go but has given itself plenty of options that could be finalized

Final policy likely to include one arm with Phase I payment rate

Second test arm likely include VBP, but in fewer areas (a pilot) and unclear which VBP option

- Options very different outcomes (e.g., reduced coinsurance vs. reference pricing) and some would take a great deal of work to implement (e.g., outcomes-based risk-sharing agreements)

Comments and data submitted will have a significant effect on the final decisions; CMS will want to pursue strategy with support

- Comments that are most likely to influence the direction of the final rule will be those that articulate why a particular approach would achieve CMS' goals and benefit patients

Phase II – CMS direction is far less clear

New President can suspend any rule that has not taken effect

- Major rules (over 100 million in impact) have 60 days effective date
- Final rule must be issued by mid-November to avoid suspension

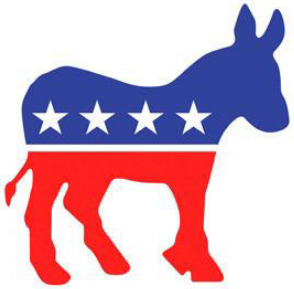
Congress can overturn a rule within 60 legislative days

- Republican President with a majority in Congress could overturn rule not final by May /June 2016 (exact date depends on how long chambers are in session in the fall)

Even if rule does take effect new President could use CMMI authority to issue another rule/demonstration

Obama Administration may finalize Phase II in the rule, but new Administration can – and likely will – alter

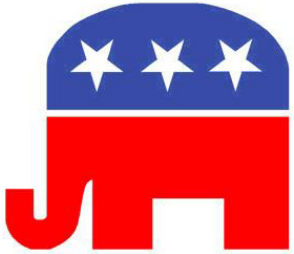
Thus, Phase II different no matter who wins the election



D wins: **Likely delays Phase II to allow more testing time, but may still use CMMI authority to pursue VBP**

Probably will want more time to:

- Investigate the impacts of Phase I
- Hear from stakeholders about best approaches for Phase II
- Have more time to implement



R wins: **Won't want to use waiver authority to implement, may let Congress decide the formula**

- Administration will be evaluating CMMI as a whole; much less likely to use CMMI authority to address drug pricing, especially right away
- Assuming Republicans also control both Chambers, may defer to Congress to determine if/how to address

Thank You!

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