

Providing Services for Janssen, the Pharmaceutical Companies of Johnson & Johnson

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Update Regarding CMS Proposed Rule on Medicare Part B Drug Payment Model

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Model Overview

Model Arm (1/4 assigned to each arm)	Phase 1 No earlier than 60 days after the Final Rule (Fall 2016)	Phase 2 No earlier than January 1, 2017
1 (control)	106% of Average Sales Price (ASP)	106% of ASP
2 (test)		106% of ASP with value-based purchasing tools
3	102.5% of ASP + \$16.80 flat fee per drug per day	102.5% of ASP + flat fee
(test) 4 (test)		102.5% of ASP + flat fee with value-based purchasing tools

For additional information, please see:

https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-03-08.html https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html

Reference: CMS, Medicare Program; Part B Drug Payment Model, Proposed Rule, 81 Fed. Reg. 13,230, 13,233

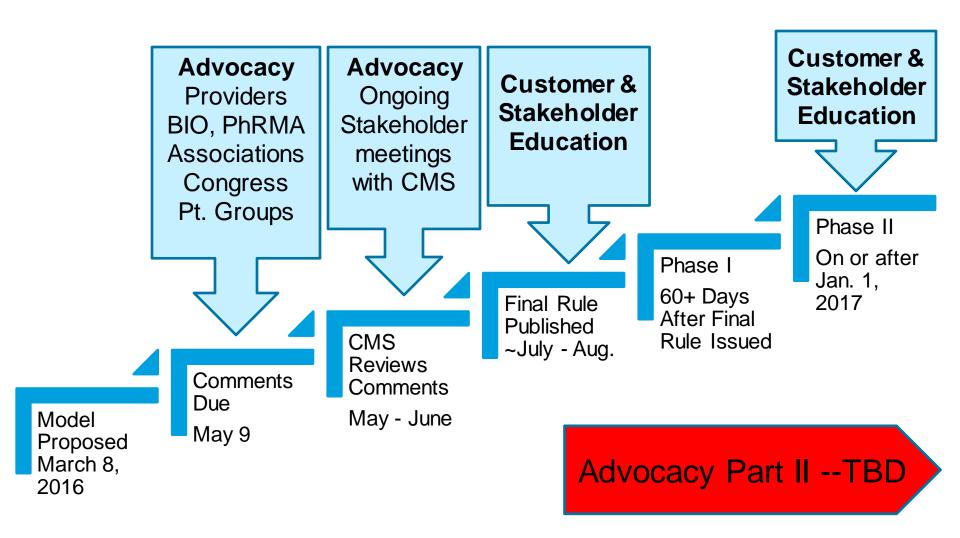
(tbl.1) (Mar. 11, 2016)

Proposed Value Based Purchasing Tools

- **Discounting or eliminating patient cost-sharing.** Decrease or eliminate cost sharing to improve beneficiaries' access and appropriate use of effective drugs.
- Feedback on prescribing patterns and online decision support tools. Create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications (e.g., best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends).
- **Indications-based pricing.** Vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time.
- **Reference pricing.** This proposed model would test the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products.
- Risk-sharing agreements based on outcomes. This proposed test would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

Reference: CMS, Fact Sheet, CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries (Mar. 8, 2016)

Timeline



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Potential Downside Implications

- May lead to diminished Medicare access
 - Rural & underserved areas may be at particular risk
- May contribute to multi-tier healthcare system
- Potential loss of physician choice and shared decision making
- Unintended Consequences
 - Potential shift in site of care
 - Clinically inappropriate shift to Part D or biosimilar
- Could result in confusion amongst providers and patients

Avenues for Comment

- Comment to CMS at: https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-paymentmodel#open-comment
- If you have concerns, they can be expressed to:
 - Professional societies (state & national)
 - Members of Congress:
 - U.S. Capitol operator: (202) 224-3121
 - U.S. Senate:
 - http://www.senate.gov/general/contact_information/senators_cfm.cfm?State
 - U.S. House of Representatives:
 - http://www.house.gov/representatives/find/

The End