

The Battle Over Drug Pricing: First Shot Targets Pharmacy Benefit Managers

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On July 18, 2018, the federal Department of Health and Human Services (HHS) sent a [proposed rule](#) to the Office of Management and Budget (OMB) for review and clearance. While the substance of the proposed rule is not yet published (or leaked), the title of the rule itself is rather transparent:

Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of a New Safe Harbor Protection (Proposed Rule).^[1]

Pharmacy Benefit Managers (PBMs) act as connectors between prescription benefit plans (largely employer-sponsored plans), pharmaceutical manufacturers and pharmacies. Their role is to help plans manage cost and drug utilization by negotiating with manufacturers and pharmacies to facilitate beneficiary access to appropriate medications, while managing the costs to the plan.

Currently, there is an Anti-Kickback Statute (AKS) safe harbor that allows drug manufacturers to pay rebates to PBMs with protection against enforcement actions when the conditions set forth in the safe harbor are met. This safe harbor has been relied upon, for example, to permit the PBM to exclusively cover the manufacturer's product or favor such products through prescription benefit plan design, such as inclusion of the drug on the plan formulary or lower co-pays to plan beneficiaries.^[2] Groups like [America's Health Insurance Plans](#) believe that such rebates are beneficial for consumers.^[3] Conversely, the [American Patients First](#) blueprint, which was issued in May 2018 by the Department of Health & Human Services and is subtitled "The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," states: "What had been a hidden negotiation and wealth transfer between drug manufacturers and PBMs is now a direct increase on consumer out-of-pocket spending that likely decreases drug adherence and health outcomes."^[4]

Food and Drug Administration commissioner [Scott Gottlieb](#) has been vocal regarding PBM rebates as a component of drug pricing controls, stating "One of the dynamics I've talked about before that's driving higher and higher list prices, is the system of rebates between payers and manufacturers . . . what if we took on this system directly, by having the federal government reexamine the current safe harbor for drug rebates under the [AKS]?"^[5]

The Proposed Rule was sent to OMB just two days after the close of public comments in response to the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information (RFI).^[6] The timing and apparent aim of the Proposed Rule has the PBM industry understandably concerned. The Pharmaceutical Care Management Association (PCMA) offered the following in response to the administration's proposed rule just days after the organization submitted comments in response to the RFI:

"While we will await the Administration's expected proposal to re-examine the Anti-Kickback and Medicare Part D statutes as they relate to rebates and safe harbors, we are immediately faced with several troubling questions. Before proceeding further with any proposed changes to the longstanding safe harbor protection for manufacturer rebates to [PBMs], we would encourage the Administration to review the extensive public comments PCMA and other payer-oriented groups submitted just a few days ago in response to HHS's [RFI] on



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this very issue.”^[7]

Despite the difference in opinion regarding the role of PBMs in rising drug costs, removal of the safe harbor would dramatically affect the PBM market, as it would curtail its ability to collect rebates from drug manufacturers under the AKS safe harbor protection.^[8] OMB review could take up to several months, and until that point the proposed rule is not made public.^[9] However, companies operating throughout the pharmaceutical manufacturing, wholesale, insurance, PBM and pharmacy markets should follow developments closely.

Olivia King contributed to this post.

[1] Office of Mgmt. & Budget, Exec. Office of the President, RIN No. 0936-AA08, Removal of Safe Harbor Protection for Rebates to Plans or PBMs involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection (July 18, 2018). https://www.reginfo.gov/public/do/eoDetails?rrid=128288&utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top.

[2] See <http://www.modernhealthcare.com/article/20180719/NEWS/180719882>.

[3] <https://www.fiercehealthcare.com/regulatory/pharmacy-benefit-managers-safe-harbors-drug-price-hhs-omb>

[4] <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> (p. 17).

[5] <http://www.modernhealthcare.com/article/20180719/NEWS/180719882>.

[6] See Office of Mgmt. & Budget, Exec. Office of the President, RIN No. 0936-AA08, Removal of Safe Harbor Protection for Rebates to Plans or PBMs involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection (July 18, 2018); 83 Fed. Reg. 22692 (May 16, 2018).

[7] Pharmaceutical Care Management Association, *PCMA Statement on the Administration's RX Rebates Proposal*, available at: <https://www.pcmanet.org/pcma-statement-on-the-administrations-rx-rebates-proposal/> (July 19, 2018).

[8] Washington Analysis, LLC.

[9] Washington Analysis, LLC.

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