

# PART B DRUG COMPETITIVE ACQUISITION PROGRAM

## I. EXECUTIVE SUMMARY

This issue brief provides background information on the Centers for Medicare and Medicaid Services’ (CMS) Medicare Part B Drug and Biological Competitive Acquisition Program (CAP). Although the program is no longer in operation, it has come under renewed attention as a component of the recently-announced *American Patients First: The Trump Administration Blueprint to Reduce Drug Prices and Patient Out-of-Pocket Costs* (Blueprint). After the release of the Blueprint, Secretary Azar said that CMS would be announcing an RFI to “to make new use of an alternative system for buying Part B drugs.” This issue brief reviews the CAP model’s key aspects, lessons learned from its prior iteration, and current policy considerations.

## II. BACKGROUND ON THE COMPETITIVE ACQUISITION PROGRAM

### CAP’s Initial Iteration

The Competitive Acquisition Program (CAP) for Part B drugs was established by Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and ran between July 2006 and December 2008.<sup>1</sup> It was voluntary for physicians, with participation renewed annually. Providers obtained drugs through a vendor selected by competitive bidding. BioScrip was the sole vendor. Elements of the process included:



Subsequently, CMS announced on September 10, 2008, that it would postpone further implementation the CAP as of December 31, 2008. The CAP has not since been reinstated.<sup>2</sup>

### Key Challenges Faced

The Medicare Payment Advisory Commission (MedPAC) highlighted several challenges faced by the CAP.<sup>3</sup> Among them: low physician enrollment; vendor inability to negotiate favorable prices (stemming

<sup>1</sup> <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/CompetitiveAcquisforBios/index.html>

<sup>2</sup> Ibid.

<sup>3</sup> <http://www.medpac.gov/docs/default-source/meeting-materials/april-2016-meeting-presentation-medicare-part-b-drug-and-oncology-payment-policy-issues.pdf?sfvrsn=0>

from low overall enrollment); and, overall inability to achieve savings. The Commission noted that Medicare at times paid the vendor more than Average Sales Price plus six percent.<sup>4</sup>

A June 2007 MedPAC report chapter highlights physicians' "key criticisms of with the program," noting that vendors were able to stop supplying drugs for beneficiaries who did not pay their copayments in a timely fashion, leading to interruptions in treatment. It also highlighted logistical challenges for clinician offices, issues with appeals for claim denials, complexity for patients, and challenges for rural providers.<sup>5</sup>

On the other hand, a CMS contractor-prepared report reviewing the program found general satisfaction among physicians with the program. It also surmised that the program achieved savings – or at least did not spend more than ASP plus six percent – during the last year of implementation.<sup>6</sup>

### **III. RECENT POLICYMAKING CONSIDERATIONS**

#### *CMS 2016 Comment Solicitation*

In March 2016 Medicare Part B Drug Payment Model proposed rulemaking, CMS sought comment on revitalizing the CAP program.<sup>7</sup> In its solicitation CMS noted that there are some concerns about the CAP program due to uncertainty under the statute. These include whether non-pharmacy entities, such as wholesalers, could be approved CAP vendors and concern over the requirement for a beneficiary-specific order, which affects the use of a consignment model to both facilitate emergency deliveries and to manage inventory through automated dispensing systems.<sup>8</sup>

#### *MedPAC June 2017 Report: The Drug Value Program (DVP)*

In its June 2017 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) included a package of proposals to change Medicare Part B drug reimbursement.<sup>9</sup> Under the contemplated recommendations, there would be two tracks for clinicians for Part B drug reimbursement: an option to remain in traditional FFS based on a revised version of the current ASP +6 payment methodology, or participation in a contemplated Drug Value Program (DVP) which is based on the CAP program.

MedPAC notes that the Drug Value Program (DVP) would be a voluntary market-oriented alternative to ASP system. Under the proposal, no later than 2022, clinicians would have a choice to remain in the ASP system or move over to the DVP. Over time, the ASP add-on would be phased down to make DVP participation more attractive to clinicians. See Figure 1 below.

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<sup>4</sup> Ibid.

<sup>5</sup> [http://www.medpac.gov/docs/default-source/reports/Jun07\\_EntireReport.pdf](http://www.medpac.gov/docs/default-source/reports/Jun07_EntireReport.pdf)

<sup>6</sup> [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/CAPPartB\\_Final\\_2010.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/CAPPartB_Final_2010.pdf)

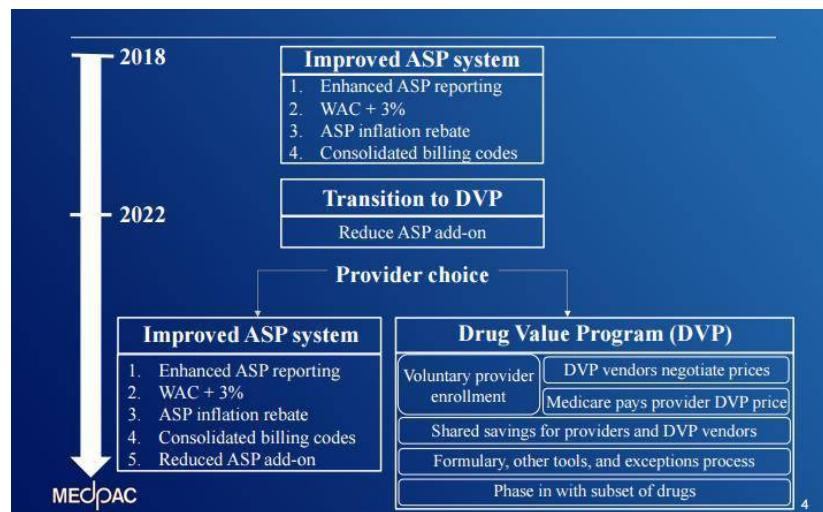
<sup>7</sup> <https://www.federalregister.gov/documents/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model>

<sup>8</sup> Ibid.

<sup>9</sup> <http://www.medpac.gov/-public-meetings-/meeting-details/april-2017-public-meeting>

The DVP program would use private vendors to negotiate prices and offer providers shared savings opportunities. The DVP would include multiple vendors, who would negotiate the prices. Drug prices would not be able to exceed ASP. Vendors would be paid a fixed administrative fee, and would be able to utilize a formulary with an exceptions and appeals process. Further, the recommendation would permit an option for binding arbitration between vendors and manufacturers for certain single source drugs.<sup>10</sup>

**Figure 1: Overview of Part B Reforms<sup>11</sup>**



The President’s Blueprint

On May 11, 2018 President Trump delivered a highly anticipated speech addressing prescription drug pricing. Along with his speech, the Department of Health and Human Services released drug pricing plan, which included a request for public comment on a variety of topics. Among these was a request for input on revisiting the CAP including “What changes would vendors and providers need to see relative to the 2007-2008 implementation of this program in order to successfully participate in the program?”<sup>12</sup>

On May 14, 2018 in a prepared statement for the news media, Secretary Azar said “[i]n short order, we will be issuing a request for proposal to make new use of an alternative system for buying Part B drugs, a Competitive Acquisition Program.”<sup>13</sup>

**IV. CONCLUSION**

We hope you find this information helpful, and please feel free to reach out with any questions.

<sup>10</sup> Ibid.

Slide from MedPAC April 2017 meeting presentation. Available at: <http://www.medpac.gov/docs/default-source/default-document-library/part-b-drug-presentation-april-2017-for-public.pdf?sfvrsn=0>

<sup>12</sup> <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>

<sup>13</sup> <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>