THORN RUN PARTNERS
GOVERNMENT RELATIONS

Background Brief: Competitive Acquisition Program for Medicare Part B Drugs

May 10, 2016

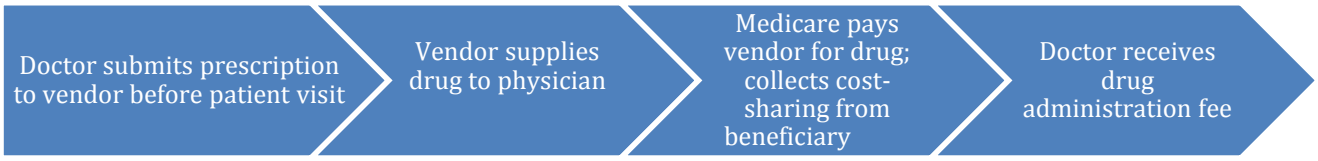
I. EXECUTIVE SUMMARY

This 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, the Center for Medicare and Medicaid Innovation (CMMI) renewed attention on the program by requesting comment on it as part of the Medicare Part B Drug Payment Model proposed rule.[1] The agency cited the possibility of the program's inclusion as a policy alternative in future CMMI reimbursement models. This brief reviews the CAP model's key aspects, lessons learned from its prior iterations, and current policy considerations.

II. BACKGROUND ON THE ORIGINAL CAP

CAP's Initial Iteration

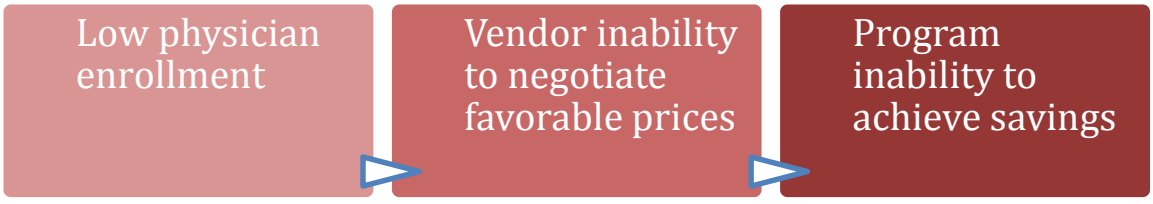
The CAP program was established by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and ran between July 2006 and December 2008.[2] It was voluntary for physicians, with participation renewed annually.[3] Providers obtained drugs through a vendor selected by competitive bidding; BioScrip was the sole vendor. Elements of the process included:



MedPAC slides, March 2016

Key Challenges Faced

During its early 2016 meetings, the Medicare Payment Advisory Commission (MedPAC) highlighted several challenges faced by the CAP.[4] Among them:



For example, the Commission noted that Medicare paid vendors more than Average Sales Price plus six percent.[5]

An earlier report on the CAP program commissioned by CMS found that differences in the program's payment amounts, compared with ASP plus six percent, stemmed from several factors, including:

- Differences in the utilization of drugs compared to the amount expected to be used when the vendor submitted the bid; and
- Use of the Producer Price Index (PPI) to adjust payment amounts to account for the period between bid submission and program start. The report notes, for example, that since the CAP "basket" was different from PPI, it is possible that ASPs for CAP drugs lagged compared to inflation.[6]

Notably, the report found general satisfaction among physicians with the program. It also surmises that the program achieved savings – or at least did not spend more than ASP plus six percent – during the last year of implementation.[7]

A June 2007 MedPAC report chapter includes physicians' "key criticisms of with the program.[8] Following is an excerpt of these findings:

- Vendors can stop supplying drugs for beneficiaries who do not pay their copayments in a timely fashion, leading to interruptions in treatment;
- Offices have to maintain separate inventories for each patient in the CAP program;
- If patients cannot receive treatment on a given day, the office has to return the drug to the vendor instead of using it at the next appointment;
- The program required physicians to appeal all claim denials even if they do not believe the time and effort required to mount the appeal is an effective use of practice resources;
- Physicians with satellite offices in rural areas cannot participate in the program because they often cannot accept drug deliveries and mix drugs in their satellite offices; and
- Urologists pointed out that some of the drugs most important to them are not among those the CAP vendor supplies.[9]

III. CMMI'S REQUEST FOR COMMENTS

In its March 2016 Medicare Part B Drug Payment Model proposed rule, CMMI sought comment on the CAP program, including "whether we should consider implementing an updated version" as part of future rulemaking.[10] It elaborated, "Although we are not proposing to include a CAP-like alternative in this model at this time, we are interested in receiving comments that would help us determine whether sufficient interest in such a program is present for us to consider developing and testing such an alternative as a part of a future model." Furthermore, it notes that there are some concerns about the CAP program that cannot be fixed without legislative changes. These include:

- Uncertainty about the participation of non-pharmacy entities, such as wholesalers, as approved CAP vendors; and
- The requirement for a beneficiary-specific order, which affects the use of a consignment model to facilitate emergency deliveries and to manage inventory through automated dispensing systems in the office.

In the request for comments, CMS specifically asked for stakeholders' input on:

- Whether there is a role for a CAP-like alternative to the ASP (i.e., buy-and-bill) process for obtaining drugs; and
- Updated perspectives on issues such as:
  - Smaller geographic areas;
  - Smaller scope of drugs included in the program;
  - Role of wholesalers and consignment in the program;
  - Drug ordering process;
  - Risk-sharing, and the impact on physician-negotiated volume discounts when CAP would be used for Medicare patients; and
  - How these issues could be addressed if the agency were to consider developing and testing a phase of this model in the future that is based on the CAP.

Potential Policies for CAP Revamp

MedPAC discussed potential CAP policies in early 2016. Notably, some of these proposals would eliminate the ASP add-on payment for non-CAP participants. They would seek to encourage more doctors to participate in the program, including through:

- Shared savings for doctors;
- Elimination of the ASP add-on in traditional Medicare;
- Restructuring of CAP to be a stock replacement model; and
- Provision of shared savings for vendor.

Additionally, Medicare's 2010 proposed Physician Fee Schedule regulation would have implemented the following changes to the then-suspended CAP, as highlighted in MedPAC's 2009 comment letter on those proposals:[11]

- Eliminate automatic payment increases that led to drugs being paid at higher than ASP+6;
- Ease restrictions on physicians transporting CAP drugs subject to voluntary agreements between vendors and physicians;
- Allow CAP vendors to maintain ownership of a quantity of drugs stored at physicians' offices. When a physician administers a drug from this stock, they would notify the vendor electronically and the vendor would bill Medicare and the beneficiary. Under then-current rules, physicians had to order drugs for each patient as needed and store them separately from the rest of their inventory; and

- Limit CAP-provided drugs to high cost, high volume products to ease the administrative burden of tracking and billing for all drugs.

IV. ADDITIONAL CONSIDERATIONS

In their recent discussions, MedPAC commissioners generally appeared skeptical about a restructured CAP program, which may not bar CMS from testing a version as a demonstration. However, since the Part B Drug Payment Model proposal borrows heavily from Commission work, it seems unlikely CMS would implement a restructured CAP without Commission input.[12]

At the March 2016 MedPAC meeting, Commissioner Warner Thomas said, "CAP is a challenge," suggesting the Commission deal with easier policies to address Part B drug spending before considering CAP.[13] During that meeting, Commissioner Kathy Buto added that she was skeptical of the program, and said it might work better under a system with a restructured ASP.[14] Commissioner Jack Hoadley was skeptical during the meeting as well. Commissioner Bill Hall said the program was "almost too exquisite a design" and cited concerns about inventory management and provider burden in billing. For proposed policy changes that include shared savings, Commissioner Hall said he was concerned that the voluntary nature of the program would encourage only the most efficient providers to participate.[15]

During the April 2016 meeting, some commissioners reiterated these concerns, with Commissioner Hoadley saying he was "still skeptical" and with Commissioner Buto noting the critical need to have more vendors in the program.[16]

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[1] CMMI, Part B Drug Payment Model Proposed Rule, March 11, 2016, available here.
[2] SSA 1847B(a), available here.
[3] CMS website, accessed May 6, 2016, available here.
[4] MedPAC slides, March 2016; MedPAC slides, April 2016.
[5] *Ibid*.
[6] RTI International, December 2009, available here; RTI International, April 2009, available here.
[7] *Ibid*.
[8] MedPAC Report to Congress, June 2007, available here.
[9] *Ibid*.
[10] CMMI proposed rule, March 11, 2016.
[11] MedPAC comments, August 2009, available here.
[12] TRP notes, March 2016.
[13] *Ibid*.
[14] *Ibid*.
[15] *Ibid*.
[16] TRP notes, April 2016.