SUMMARY OF CMS' REQUEST FOR INFORMATION ON COMPETITIVE ACQUISITION PROGRAM FOR MEDICARE PART B DRUGS

Within its calendar year (CY) 2019 hospital outpatient prospective payment system proposed rule, the Centers for Medicare and Medicaid Services (CMS) includes a Request for Information (RFI) on how to structure a Competitive Acquisition Program (CAP)-type model for Part B drugs through the Center for Medicare and Medicaid Innovation (CMMI).[1] The agency asks numerous questions about design considerations for a CAP-like model, such as drugs and biologics that could be included, what role private-sector vendors should play, the appropriate scope of a demonstration, and other issues.[2]

Below, we summarize what CMS is considering and where it is seeking stakeholder input. Comments are due by **Sept. 24, 2018**.

I. WHAT CMS IS CONSIDERING IMPLEMENTING

CMS says it may use its wide-ranging demonstration authority through CMMI for pursuing a CAP-like model that would "build on lessons learned from CMS' previous experience with CAP," which was in place between 2006 and 2008 and faced challenges with low physician enrollment and other issues.[3] Under a new demonstration, CMS notes that:

- Private-sector model vendors would "enter into and administer value-based arrangements with manufacturers of separately payable Medicare Part B drugs and biologicals."[4]
- Part B providers would acquire drugs from these competitively selected private-sector vendors.
- Vendor-administered payment arrangements may be required to include a range of value-based payment approaches, such as outcomes-based agreements; indication-based pricing; payment over time; shared savings; performance-based payments based on the impact on total cost of care; and reduced beneficiary cost-sharing.

CMS adds that reductions in beneficiary cost-sharing under the model could more "closely tie the Medicare payment and beneficiary cost-sharing for an included drug or biological to the value of such therapy."[5]

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[1] *See*: https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-15958.pdf?utm_campaign=pi%20subscription%20mailing%20list&utm_source=federalregister.gov&utm_medium=email

[2] *Ibid.* at p. 653.

[3] *Ibid.* at p. 650.

[4] *Ibid.* at p. 653.

[5] *Ibid.* at p. 654.

CMS suggests that vendor-administered arrangements could start with a "subset of therapies" and be broadened to include more medications over time.[6]

Title to and Possession of Drugs and Biologics

CMS notes that a "potential benefit of a CAP-like model of this nature would be eliminating the financial risk to providers and suppliers of taking title to very high-cost drugs and biologicals."[7] The agency indicates that it is considering approaches under which the CAP vendor both would take title to drugs and biologics (as in the original CAP) or would not take title (as in the MedPAC Drug Value Program's reliance on pricing arrangements). CMS suggests that it could test different approaches for key types of drugs, such as applying one particularly for high-cost therapies and single-source drugs and specific drug classes.[8]

If model vendors do take title to included medications, the agency is weighing whether vendors also should take possession of those drugs and biologics or whether "existing distribution channels" would remain in place for direct distribution to providers and suppliers.[9]

Custodial Arrangements

The agency also discusses the potential role of custodial agreements between providers and suppliers and model vendors. For example, CMS says it is exploring how custodial agreements could help enable the provider and supplier to continue to collect beneficiary cost-sharing, obviating the need to transmit billing data to vendors.[10] The agency is also examining the potential for custodial arrangements to "address concerns with existing CAP [statutory] requirements that CAP drugs could only be delivered upon receipt of a prescription, with limited exceptions."

Inclusion of Other Payers

Given its flexibility to structure a CMMI demo unconstrained by the CAP statute, CMS contemplates the inclusion of other payers such as Medicare Advantage organizations, state Medicaid agencies, and Medicaid managed care organizations. CMS mentions the possibility of giving such other payers access to the "same or similar" value-based vendor-administered payment arrangements available through the potential CMMI-led CAP, including "paying for included drugs and biologicals for their enrollees through model vendors."[11]

II. WHERE CMS IS SEEKING COMMENTS

While the agency already has sought comments on how to leverage its existing authority for CAP – through both the withdrawn Part B Payment Model proposed rule during the Obama Administration and the Drug Pricing Blueprint by the Trump Administration – CMS now seeks additional feedback on key design

[6] *Ibid.* at p. 654.
[7] *Ibid.* at p. 653-654.
[8] *Ibid.* at p. 655.
[9] *Ibid.* at p. 655.
[10] *Ibid.* at p. 655.
[11] *Ibid.* at p. 656.

considerations. CMS specifically seeks comment on the design issues discussed above and "how to best initially test and then broaden the scope of a potential CAP-like model."

The agency also asks a series of detailed questions regarding the potential CAP-like model.[12] Below are selected highlights in each of the thematic categories into which questions are grouped:

- **Included Providers and Suppliers** – CMS asks whether types of Part B providers and suppliers should be included or excluded, and why. The agency seeks input on whether (and if so, how) a model should address concerns about certain specialties experiencing a reduction in revenue. CMS seeks input on incentives for provider participation in a CAP-like model.

- **Included Drugs and Biologicals** – CMS asks if there are "certain separately payable Part B drugs and biologicals or drug classes that should be excluded, and if so, why?"[13] CMS asks which drug classes would be appropriate to include, and which ones should be included initially. The agency specifically asks whether Part B mental health and substance abuse drugs should be included.

  CMS asks which "specific drugs, drug classes, groups of drugs, or indications" would be appropriate for inclusion in a CAP-like model or in specific types of value-based purchasing and for which drugs reduced beneficiary cost-sharing should be considered. CMS asks what other value-based purchasing strategies it should consider and how to ensure site-neutrality. The agency asks what aspects (e.g., quality measures or targets) outcomes-based agreements should include.

- **Beneficiary cost-sharing, protections, and fiscal considerations** – CMS asks how a CAP-like model can be structured to improve beneficiary access and how value can be shared with beneficiaries. The agency asks about considerations related to "beneficiary cost-sharing, experience of care, choice of health care provider and drug or biological, and access to care."[14]

- **Model vendors** – CMS seeks input on how to avoid challenges for vendors and what types of organizations should be considered for the role. Comments are sought on selection criteria for a competitive selection process, how to determine the geographic areas serviced by vendors, and whether there should be one or more vendor per region. CMS asks about using a consignment approach. CMS asks about which (if any) "formulary and/or utilization management strategies, such as step therapy, should model vendors be allowed to include in their value-based payment arrangements with manufacturers."[15]

- **Regulatory barriers and transparency issues** – CMS asks about barriers to value-based purchasing and how to address them. The agency asks about what "specific engagement strategies, information sharing, and transparency" would be needed for value-based vendor-administered

[12] *Ibid*. at p. 657-664.
[13] *Ibid*. at p. 657.
[14] *Ibid*. at p. 659.
[15] *Ibid*. at p. 662.

payment arrangements with manufacturers to drive participation and allow for informed decision-making.[16]

- **Manufacturer participation** – CMS asks how to incentivize manufacturers to participate in vendor-administered payment arrangements and whether manufacturer participation should be mandatory. CMS also asks, "How would drug prices and manufacturer price reporting for included drugs and biologicals be impacted by the potential CAP-like model test?"[17]

- **Model scope** – CMS asks about how "geographically broad" a CAP-like model should be and whether certain states or localities should be excluded.[18] The agency asks about how the model could be structured to allow the participation of other payers and under what circumstances such payers' payment for included drugs and biologicals through a vendor-administered arrangement would not be appropriate.

III. CONCLUSION

We hope this is a helpful overview of the key areas addressed in CMS' CAP RFI. Comments are due by **Sept. 24, 2018**. We are happy to discuss any questions you may have.

[16] *Ibid*. at p. 662.
[17] *Ibid*. at p. 663.
[18] *Ibid*. at p. 664.