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SUMMARY

AMCP Summary: ***MedPAC June 2016 Report to the Congress: Medicare and the Health Care Delivery System***

Released*: June 15, 2016*

On June 15, 2016, the Medicare Payment Advisory Commission (MedPAC)[1] released its June 2016 *Report to the Congress: Medicare and the Health Care Delivery System*[2]. Of the 347-page report, three chapters focus on examining policy issues related to prescription drugs, with a particular focus around "rapid growth in drug prices, which can affect beneficiary access to needed medications, as well as the financial sustainability of the Medicare program." While MedPAC recommendations are not binding, they are highly influential and provide insight into potential future legislative and regulatory changes that will impact the Medicare program.

The following recommendations are areas of specific importance to AMCP:

- Medicare Part B:
  - Change the current ASP +106% payment model to ASP + a flat fee such as 103.5% of ASP + $5 per drug administered per day.
  - Group single-source drugs and biologics with similar health effects under the same billing code to encourage price competition among similar products.
  - Group biosimilar and reference products under a single billing code to encourage price competition.
  - Reduce dispensing and supplying fees for certain drugs furnished by suppliers and covered under Medicare Part B to rates similar to those paid by Medicare Part D and Medicaid.

- Medicare Part D:
  - Transition Medicare's individual reinsurance subsidy from 80% to 20% while maintaining Medicare's overall 74.5% subsidy of basic benefits.
  - Exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.
  - Eliminate enrollee cost sharing above the out-of-pocket threshold.
  - Remove antidepressants and immunosupressants for transplant rejection as protected classes.

Detailed information on the key AMCP issues contained in the MedPAC report is outlined in the summary below.

[1] The Medicare Payment Advisory Commission (MedPAC) is an independent congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program. The Commission's statutory mandate is quite broad: In addition to advising the Congress on payments to private health plans participating in Medicare and providers in Medicare's traditional fee-for-service program, MedPAC is also tasked with analyzing access to care, quality of care, and other issues affecting Medicare. Two reports—issued in March and June each year—are the primary outlet for Commission recommendations. Website: http://www.medpac.gov/.

[2] Available at: http://medpac.gov/documents/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0. Accessed June 28, 2016.

Chapter 4 – Medicare Drug Spending in its Broader Context (page 109)

In this chapter, MedPAC summarizes the current landscape of Medicare drug expenditures to inform its thinking and recommendations in Chapter 5 and Chapter 6. MedPAC remains concerned about the rapid growth in drug prices because that growth can affect beneficiary access to needed medications, as well as the financial sustainability of the Medicare program. In 2013, drugs and pharmacy services made up 19% of Medicare program spending.

Medicare does not purchase drugs directly. Instead, it makes payments to drug plans, physicians, and health care facilities, which in turn negotiate rates with drug manufacturers, both directly and indirectly. Because Medicare does not purchase drugs from manufacturers, its ability to influence drug prices is indirect. External factors, including the FDA approval process and patent law, can also affect the prices Medicare pays for prescription drugs. MedPAC will continue to recommend changes to Medicare policies intended to promote drug price competition and improve incentives for providers and beneficiaries to seek better value when they purchase drugs.

Chapter 5 – Medicare Part B Drug and Oncology Payment Policy Issues (page 117)

In this chapter, MedPAC focuses on potential modifications to the current payment structure for drugs under Medicare Part B, with a particular focus on oncology drugs because they account for more than 50% of Medicare Part B drug spending. Of note, the MedPAC report makes no mention of the Center for Medicare and Medicaid Innovation (CMMI) proposed rule titled "Medicare Program; Part B Drug Payment Model (CMS-1670-P)[3]" which would implement drastic changes to the current payment model under Medicare Part B and contains many of the same themes considered by MedPAC. AMCP released a detailed summary of the proposed rule and submitted comprehensive comments to CMMI on the proposed rule in May 2016.

MedPAC considers three questions in this chapter:

- 1. Is there a better way to structure the current 6% add-on payment to ASP?
    - MedPAC notes that the current 6% add-on to ASP has garnered attention because of concerns that it may create incentives for use of higher priced drugs when lower priced alternatives exist, although it is difficult to determine whether these concerns are valid as few studies have looked at this issue.
    - MedPAC concludes that the current 6% add-on may be too high because at least 75% of Part B drugs were purchased at 102% of ASP or less.
    - MedPAC recommends considering ASP + a flat fee such as 103.5% of ASP + $5 per drug administered per day. This payment model would increase add-on payments for drugs with an ASP per administration of less than $200 and reduce add-on payments for higher priced drugs. This payment model is estimated to save about 1.3% of the $21 billion in annual Part B drug spending.
    - MedPAC cautions that while data demonstrates that a majority of Part B providers can purchase drugs at 102% of ASP or less, small providers may have difficulty purchasing drugs at these rates. Therefore, considerations would have to be taken into account for small provider groups as well as the potential shift towards more hospital-based care.

- 2. Are there payment policies that could be considered to promote more price competition among Part B drugs and put downward pressure on ASP?
    - MedPAC notes that in addition to concerns over financial incentives associated with the 6% add-on, there are also concerns about the overall price of drugs in Medicare Part B, of which ASP is the largest component. Therefore, MedPAC states exploring payment policies that create more incentives for price competition among drugs and place downward pressure on ASP are warranted. MedPAC examines three policy options.

[3] Available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-05459.pdf. Accessed June 28, 2016.

        - ASP inflation limit (page 131) → MedPAC considers placing a limit on ASP growth year over year by either 1) implementing a rebate system if ASP grows faster than a specified threshold (similar to the inflation portion of the Medicaid rebate) or 2) by allowing CMS to pay the lesser of actual ASP + 6% or an inflation-adjusted ASP +6% (to be adjusted quarterly). MedPAC cautions that exceptions to the policy, such as drugs in shortage, would have to be considered.
        - Consolidated billing codes for Medicare Part B drug and biologic payments (page 133) → MedPAC considers grouping single-source drugs and biologics with similar health effects under the same billing code at the same payment rate to encourage price competition among similar products. MedPAC further considers grouping biosimilar and reference products under a single billing code to encourage price competition, contrary to CMS's biosimilar payment policy finalized in November 2015.[4] MedPAC cautions that prior to implementation, a key issue that must be addressed with consolidated billing codes is how CMS would determine when products should be grouped together and what constitutes comparable clinical outcomes.
        - Restructuring the Part B drug competitive acquisition program (page 135) → MedPAC considers restructuring the competitive acquisition program (CAP) which was implemented in 2006 to eliminate financial incentives for prescribing drugs, but was suspended in 2008. MedPAC explores several options to restructure the CAP to encourage physician enrollment by offering shared savings to physicians, reducing or eliminating the ASP add-on payment in the traditional buy-and-bill system, and giving physicians more options for how they obtain drugs under the program. Furthermore, to enhance the vendor's negotiating leverage, MedPAC considers permitting the vendor to establish a formulary.
    - MedPAC recommends the dispensing and supplying fees for certain drugs furnished by suppliers (inhalation, immunosuppressants, oral anticancer agents, and oral antiemetic drugs) are lowered to rates similar to those paid by Medicare Part D and Medicaid. Reducing the Part B dispensing and supplying fees for these drugs would decrease federal program spending by $50 million and $250 million over one year and would also result in savings to beneficiaries through lower cost-sharing.

- 3. How can the quality and efficiency of oncology care be improved in fee-for-service Medicare?
    - MedPAC examines four approaches designed to improve the efficiency of oncology care in Medicare, which accounts for about 55% of the nearly $21 billion spent on Part B drugs.
        - Risk-sharing agreements → Agreements made between product manufacturers and payers to link payment for a drug to patient outcomes, such as a clinical measure (laboratory value) or an event (inpatient hospital admission).
        - Oncology clinical pathways → Evidence-based treatment protocols adopted by payers and providers to standardize drug treatment, reduce unnecessary variation, improve quality of care, and reduce costs. While generally consistent with clinical guidelines, pathways differ in that they narrow treatment options and suggest when these options are appropriate, may be more prescriptive, and may provide specific guidance on the sequencing of care steps and the time line of interventions.
        - Oncology medical homes →Built on the concept of patient-centered care, the expectation is that enhanced services, such as team-based care, will expand patient access and education and that clinical practices will improve health outcomes and reduce cost.
        - Bundling Part B oncology drug with non-oncology services → Holds providers accountable for the total cost of services across an episode of care.

[4] CMS final rule, "Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016." Published in the Federal Register November 16, 2015. Available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-28005.pdf. Accessed June 29, 2016.

Chapter 6 – Improving the Medicare Part D Prescription Drug Program (page 157)

In this chapter, MedPAC focuses on potential modifications to Medicare Part D to better ensure financial stability because of concerns with sizable increases in program expenditures for high-cost enrollees and costly medications in the development pipeline. To address these concerns, MedPAC recommends three major policy changes to Medicare Part D to increase incentives and tools for private plans to manage drug costs. The first recommendation shifts more financial risk to plans and would give sponsors greater financial incentives and stronger tools to manage the benefits of high-cost enrollees. The second and third recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true out-of-pocket spending, while providing greater insurance protection by eliminating beneficiary cost sharing above the catastrophic cap. The recommendations would also allow plans to send greater price signals to low-income beneficiaries to use generic drugs and would allow plans to use selected tools to manage specialty drug benefits.

MedPAC notes that under the combined recommendations, Part D's risk adjusters would become more important as a tool for counterbalancing plan incentives for selection, and CMS would need to take steps to recalibrate the risk-adjustment system. Similarly, because plans would have greater flexibility to use formulary tools to manage benefits, CMS would need to continue monitoring plan operations to ensure appropriate beneficiary access. CMS would also need to ensure that the exceptions and appeals process under Part D functions effectively.

MedPAC's three recommendations for changes to Part D are:

- The Congress should change Part D to:
  - Transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits;
  - Exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending; and
  - Eliminate enrollee cost sharing above the out-of-pocket threshold.

- The Congress should change Part D's low-income subsidy to:
  - Modify copayments for Medicare beneficiaries with incomes at or below 135 percent of poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes;
  - Direct the Secretary to reduce or eliminate cost sharing for generic drugs, preferred multisource drugs, and biosimilars; and
  - Direct the Secretary to determine appropriate therapeutic classifications for the purposes of implementing this policy and review the therapeutic classes at least every three years.

- The Secretary should change Part D to:
  - Remove antidepressants and immunosupressants for transplant rejection from the classes of clinical concern;
  - Streamline the process for formulary changes;
  - Require prescribers to provide standardized supporting justifications with more clinical rigor when applying for exceptions; and
  - Permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.