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Welcome to "Washington Update," the weekly e-newsletter on the latest health care happenings in the nation's capital that affect APG's members.

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APG Asks CMS to Reconsider or Delay Multiple Proposed Changes to MA

APG submitted its comment letter this week in response to CMS's Medicare Advantage (MA) and Part D proposed rule released last December. The rule, which was followed on Jan. 30 by CMS's separate Advance Notice, is one of several provisions that CMS promulgates annually to make changes in both the MA and Part D programs. CMS noted that the rule was informed by responses to its Request for Information from July 2022, to which APG also responded with comments.

APG's latest comment letter highlighted a number of areas that the agency should—to some degree—revisit or change. Among these were proposals related to prior authorization, utilization management, the Star Ratings, culturally competent care, education to support telehealth use, and behavioral health. CMS now has a month to review the comments and decide whether to amend any provisions in response.

Meanwhile, attention is already shifting to the far more controversial changes contained in the Advance Notice, as reported in last week's *Washington Update*. APG continues to be concerned about a number of implications, including the degree to which they may thwart CMS's own desire to advance both value-based care and health equity. APG continues to seek members' internal data analysis and any other insights or observations for inclusion in its response to CMS, due back on March 3, 2023. Please contact APG Vice President of Federal Policy, Jennifer Podulka, at jpodulka@apg.org. If you are interested in joining APG's outreach to members of Congress, please contact Matt DoBias, APG Vice President of Congressional Affairs, at mdobias@apg.org.

To both inform and gather input from members, APG held two webinars on the proposal on Friday, Feb. 10, and Monday, Feb. 13. The slides that were used during the webinars are available here. The recordings and transcripts of the two webinars are available here and here.

CMMI to Test Three Rx Drug Pricing Models in Medicare and Medicaid

The Center for Medicare and Medicaid Innovation (CMMI) will test three new models in Medicare and Medicaid aimed at keeping costs of prescription medications in check. Announced this week in a report issued by Health and Human Services Secretary Xavier Becerra, the models reflect the White House's pledge to lower the costs of pharmaceuticals and were directed by President Biden's October 2022 executive order.

The three models to be tested include the following:

- The Medicare High-Value Drug List Model would create a list of commonly prescribed generic medications in Part D to treat chronic conditions such as high blood pressure. Going a step beyond provisions of the Inflation Reduction Act, which limited Part D enrollees' out-of-pocket costs for insulin products to just $35 a month, Part D plans participating in this model will cap beneficiary cost-sharing for generic prescriptions at just $2 per month.
- The Cell and Gene Therapy Model would create partnerships among CMS, drug manufacturers, and state Medicaid agencies to test outcomes-based agreements OBA's) for high-cost cellular and gene therapy drugs. Key targets would be therapies for illnesses such as sickle cell disease and cancer. The model builds on so-called "subscription" arrangements that some states have employed to provide hepatitis C therapies to Medicaid beneficiaries. However, instead of state Medicaid agencies negotiating separate agreements with drug manufacturers, states

participating in this model could ask CMS to design and coordinate multi-state OBA's.

- The Accelerating Clinical Evidence Model would adjust Medicare Part B payments amounts for drugs approved under the Food and Drug Administration's accelerated approval process. These payment adjustments would give manufacturers incentives to carry out more extensive clinical trials to confirm the earlier trial results on safety and efficacy. The model is consistent with the "coverage with evidence development" approach that CMS took in 2022 in its National Coverage Decision on the Alzheimer's treatment Aduhelm. In theory, if subsequent trials failed to confirm earlier trial results, Medicare would save money through lower spending on drugs with no confirmed medical benefit.

Although Becerra has directed CMS and CMMI to begin further development of these models this year, at least some, such as the Cell and Gene Therapy model, will not get off the ground for several more years. HHS has also pointed to the need for additional areas of research on new payment models, such as for biosimilars or bundled arrangements to pay for cell and gene therapies in fee-for-service Medicare.

Debt Ceiling Looms Over Congress as Committees Search for Spending Cuts

The Republican House leadership has asked key committees to find billions of dollars of potential Medicare savings as part of a broader deficit reduction exercise tied to the debate over raising the federal debt ceiling. The quest could ensnare hospitals over so-called site-neutral payment policies designed to equalize payments for the same test or procedure regardless of the site of care. Although generally opposed by hospitals, which benefit from so-called facility fees, these policies have long been pursued by both Republican and Democratic administrations, and conceptually endorsed by organizations such as the Medicare Payment Advisory Commission and the Government Accountability Office.

The Republican-led House Ways & Means Committee is now examining policies that would level Medicare reimbursement so that the program pays roughly the same amount for a medical service performed in a hospital as in a doctor's office or ambulatory surgical center. One estimate shows that Medicare could save more than $150 billion depending on how expansively site-neutral policies were enacted. Ways & Means staff appear to be looking to save at least $44 billion in savings from imposing new site-neutral policies for both inpatient and outpatient services.

Site-neutral policies have long been a political, regulatory and legal hot potato, with legislation in 2015 allowing CMS to implement site-neutral payment policies in a limited capacity, a subsequent 2019 payment rule that expanded those policies, and competing legal decisions at the federal and appeals levels that have left the broader policies intact. APG will monitor future developments in

Congress, as well as how site-neutral payment policies may affect the shift to risk-based payment contracts.

Meanwhile, as the impasse over raising the debt ceiling continues, the Congressional Budget Office has projected that the federal government's ability to borrow money will be exhausted sometime between July and September. Congress and the Biden Administration thus have a short timeline of about four months to reach agreement on deficit-reduction measures and a debt ceiling increase.

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