AMERICA'S PHYSICIAN GROUPS = HEALTHCARE ON THE HILL

April 15, 2022

Welcome to America's Physician Groups' "Healthcare on the Hill," where you can get the latest on healthcare happenings in our nation's capital--and with a special focus on the value-based care movement.

As our nation continues to face many challenges, we are working to ensure you have the very latest information on our rapidly changing healthcare landscape.

Think someone else may enjoy "Healthcare on the Hill?" Forward this email and have them click here to be added to our subscription list. And remember, you can always visit our website for more news and resources.

Garrett Eberhardt
Director of Federal Affairs
America's Physician Groups

HHS Extends Public Health Emergency

Yesterday, Department of Health and Human Services (HHS) Secretary Xavier Becerra announced an extension of the COVID-19 public health emergency (PHE) for an additional 90 days. The Centers for Medicare & Medicaid Services (CMS) has continually stated its intention to give stakeholders a 60-day notice before ending the PHE. The next extension will go into effect on Saturday, April 16th, and will extend COVID-19 waivers and flexibilities such as continuous enrollment requirements and waivers of telehealth restrictions. APG continues to advocate in Washington for making the telehealth waivers, such as audio-only telehealth support, permanent as Congress seeks to develop legislation in support of this effort.

CMS Issues Medicare Advantage Parts A & B Out-of-Pocket Limit, Cost Sharing Final Rule

Last week, CMS issued a final rule covering Medicare Advantage (MA) policies for Parts A and B services out-of-pocket (OOP) and monthly cost sharing limits. Three separate OOP limits were set as well as corresponding cost sharing limits based on classifications related to coinsurance percentages and emergency care cost OOP limits. In addition, CMS used the final rule to limit OOP costs by requiring that MA cost sharing cannot exceed Medicare fee-for-service (FFS) rates for durable medical equipment (DME), home health services, and Part B drugs. The final rule

implements MA changes that were part of the 21st Century Cures Act and the Families First Coronavirus Response Act.

CMS will set OOP limits for 2022 and in the future with the provisions in the final rule beginning in 2023. CMS will transition ESRD costs into OOP methodology, with the agency proposing safeguards against excessive changes in OOP limits during the transition of ESRD patients into MA. CMS is also adopting a provision requiring annual guidance surrounding OOP and cost sharing limits and imposing a ten percent cap on OOP limit increases from year to year on mandatory and lower OOP limits when calculating total catastrophic limits.

For cost sharing limits, CMS is implementing ranges for three new OOP categories:

- *Lower Limit*: Plans with an in-network OOP limit between $0 and $3,650 and are considered lower limit OOP plans (24.9 percent of plans)
- *Intermediate Limit:* Plans with an in-network OOP amount between $3,651 and $6,000 (36.9 percent of plans)
- *Mandatory Limit* — An in-network OOP rate between $6,001 and $7,550 (38.2 percent of plans)

CMS finalized existing policy that beneficiary cost sharing over 50 percent of MA's total plan liability for Parts A and B is considered discriminatory. CMS is revising its policy limiting cost sharing for many services to 50 percent coinsurance for lower OOP limits, 40 percent for intermediate OOP limits, and 30 percent for mandatory OOP limits. The OOP limit for emergency care was also raised in the final rule from $90 to $115 for the mandatory OOP limit, from $120 to $150 for the lower OOP limit, and a $130 limit for the intermediate OOP limit.

Linking MA to FFS — CMS is also referencing Medicare FFS in its adjustment of MA rates by adopting a requirement that MA cost sharing cannot exceed FFS cost sharing for: (1) home health services; (2) DME for plans with a mandatory OOP limit; and (3) Part B drugs, excluding chemotherapy. Additionally, transitions from 2022 to 2023 cost sharing standards may not exceed any of the cost sharing limits imposed in this FC. Also, cost sharing limits calculations for seven inpatient length-of-stay scenarios will set based on estimated FFS cost sharing and will include ESRD costs, due to the inclusion of ESRD patients in MA

CMS Rules Alzheimer's Drug to be Covered Under Medicare

CMS announced its final national coverage determination (NCD) for Aduhelm, a drug approved by the Food and Drug Administration (FDA) last year to treat early Alzheimer's. The agency is approving coverage of the drug, and all future FDA approved monoclonal antibody treatments directed against amyloid for the treatment of Alzheimer's disease, for patients who have a clinical diagnosis of mild cognitive impairment due to Alzheimer's disease or mild Alzheimer's disease dementia. CMS' coverage determination stipulates that a Medicare beneficiary must be enrolled in a randomized, controlled clinical trial conducted by either the National Institutes of Health (NIH) or the FDA in order for the drug to be covered under the program as it was approved under the accelerated approval process. In the event that Aduhelm, or other specified drugs included in the NCD, are not covered by Medicare Part B under the terms of the NCD, CMS plans to consider them Part D drugs.

MedPAC Holds April Public Meeting

The Medicare Payment Advisory Commission held its April public meeting last week covering topics including Part B drug pricing and streamlining alternative payment models (APM) under Medicare. Staff members presented three different options for regulating Part B drug prices. Medicare currently pays physician practices the average sales price for most Part B drugs in addition to a six percent administrative fee, which MedPAC principal policy analyst Nancy Ray argued give providers

incentive to prescribe higher-priced drugs. She and principal policy analyst Kim Neuman listed three options for commissioners to consider:

1. Requiring coverage with evidence development for new first-in-class drugs with high prices at launch and limited evidence of effectiveness. The drug would only be covered under Medicare if the patient is enrolled in a clinical trial with a payment cap based on an analysis of the drug's cost-effectiveness.

2. Reference pricing, where a drug is paid for by factoring in its competitors' prices, could take effect for drugs that already have therapeutic alternative. The reference price could be set based on:
    a. the lowest-cost product in the group
    b. the volume-weighted average sales price of all the products in the group
    c. using the minimum volume-weighted average sales price (ASP) of all the products in the group

3. For the ASP plus six percent reimbursement formula three possible alternatives were offered:
    a. Capping the administrative payment at the lower number between six percent or $175
    b. Capping the administrative fee at three percent plus $21
    c. Paying the lower amount between six percent, three percent + $21, or $175

Ms. Neuman stated that the first alternative would most affect the highest-priced drugs, the second lower and mid-priced drugs, and the third mid and higher-priced drugs. The presentation on APMs highlighted the topics that will be included in its June 2022 Report to Congress. MedPAC staff suggested harmonizing accountable care organizations (ACOs) and episode-based payment models (EPMs). Support was shown for possibly reducing the number of ACO tracks and eliminating the rebasing of benchmarks by basing them on historical spending instead. The operation of a national EPM concurrently with ACOs for certain types of episodes was also mentioned.

CMS Adds Calendar to ACO REACH Materials Website

Following questions from stakeholders regarding timing and key deadlines for ACO REACH model performance year 2023 participation, CMS is publishing a calendar to the ACO REACH Model website. CMS is planning to align key dates with the Medicare Shared Savings Program, including:

- **August 4, 2022: the deadline to add providers to a REACH ACO and deadline to add ACO participant TINs to a Shared Savings Program ACO**
- **September 9, 2022: the deadline to drop providers from a REACH ACO and deadline to drop ACO participant TINs from a Shared Savings Program ACO**

The agency notes that these dates are subject to change.