Click here if you are having trouble viewing this message.

November 23, 2020

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--and the world--continues to face the many challenges presented by COVID-19, we are working to ensure you have the very latest information on the virus and 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.

Valinda Rutledge
Senior Vice President of Federal Affairs
America's Physician Groups

Trump Administration Releases Flurry of Healthcare Regulations
Late Friday, the Department of Health and Human Services (HHS) released a series of regulations covering various healthcare issues, including the anti-kickback statute, physician self-referral, prescription drugs. The release strategy of the rules were timed to come before the informal “midnight regulation” deadline of November 21, 2020 that would make any regulations passed afterward subject to review by the incoming Biden Administration.

The Biden administration is limited in its power to interfere with interim final rules (IFR), such as the Most Favored Nation demonstration IFR, since rules governing this type of regulation requires a more formal process to change them. The final rules that were issued by the Trump administration can only be overruled by another rulemaking process if the incoming Biden administration eventually chooses to do so. Therefore, the eventual finalization of these rules is still in question until we know which a Biden administration could potentially challenge.

Anti-Kickback Final Rule
For its **anti-kickback final rule**, the Centers for Medicare and Medicaid Services (CMS) finalized previously proposed regulatory terminology for three new safe harbor protections surrounding:

- Care coordination arrangements to improve quality, health outcomes, and efficiency
- The value-based arrangements with substantial downside financial risk
- Value-based arrangements with full downside financial risk:

The finalized definitions include:

- A Definition of “Value-Based Arrangement”
- Definition of “Target Population”
- Definition of “Value-Based Entity Participant”
- Change in definition of “substantial downside financial risk”
  - Lowered the bar for meeting the “substantial downside financial risk” safe harbor to “risk equal to at least 30 percent of any loss, where losses are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care.”

Physician Self-Referral (Stark Law) Final Rule
In its **Physician Self-Referral Law**, or “Stark Law”, final rule, the agency finalized exceptions related to value-based payment arrangements, cybersecurity, and electronic health records. Some finalized proposals include:

- Permanent exceptions to the Stark Law for value-based arrangements
  - Physicians and other health care providers may now enter into value-based arrangements violating the Stark Law
- A new exception for donations of cybersecurity technology and related services and eliminates the sunsetting of the exception for electronic health records (EHR) items and services

CMS declined to move forward with a proposal that would have included price transparency requirements for value-based exceptions to the physician self-referral law and also declined to decoupling the Stark Law from the Anti-Kickback Statute.

Removal of Safe Harbor Protection for Rebates to Plans or Pharmaceutical Benefit Managers Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection Final Rule (Rebate Rule)

The "**Removal of Safe Harbor Protection for Rebates to Plans or Pharmaceutical Benefit Managers Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection**" final rule, or "the rebate rule", was also released by HHS creating a new safe harbor for point-of-sale reductions in price for products payable under Medicare Part D or by Medicaid managed care organizations. The final rule also forms a new safe harbor for fixed fees that manufacturers pay to pharmacy benefit managers (PBM) for services rendered to manufacturers. The final rule changed the discount safe harbor to explicitly exclude reductions in price offered by drug manufacturers to PBMs and Part D plans from the safe harbor definition of a discount.

Most Favored Nation CMMI Mandatory Model Interim Final Rule

Finally, CMS released an **interim final rule (IFR)** covering a mandatory Centers for Medicaid and Medicare Innovation (CMMI) "Most Favored Nation" (MFN) model demonstration which begins January 1, 2021. The IFR links Medicare reimbursement for 50 separately payable, single source Part B drugs and biologics to international prices and replaces the current domestic Average Sales Price (ASP) that physician and hospital reimbursement is based on by Medicare Part B with a new MFN Price based on the lowest prices paid by comparable Organization for Economic Co-operation and Development (OECD) countries. The MFN Price would apply to 50 high-cost, brand, physician-administered drugs. The IFR does not apply to certain vaccines, oral drugs, generics, and intravenous immune globulin products. The model will include all providers and suppliers that participate in Medicare with some exceptions such as cancer hospitals. The MFN Price will be phased-in over the first 4 years of the 7-year model, at 25 percent per year for years 1-4, and 100 percent for years 5-7.

APG Urges Congress to Freeze Incentive Payment Thresholds for Advanced APMs

Last week, APG joined 18 other medical groups sent a **letter** to Congress to support legislation freezing the current thresholds for incentive payments to advanced alternative payment model (APM) practices. The bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established incentive payments to attract physicians toward value-based care and away from fee-for-service to help lower healthcare costs and improve quality of care. In today's coalition letter, the groups say that the original thresholds set in MACRA in 2015 are too high. The current 2020 bonus incentives are based on physicians meeting a threshold of 50 percent of payments or 35 percent of

patients in an advanced APM. In 2021, the threshold is scheduled to increase to 75 percent of payments or 50 percent of patients.