

LEGISLATIVE & REGULATORY BRIEFING

RECENT DEVELOPMENTS ON THE
LEGISLATIVE AND REGULATORY FRONTS



December 2020

AMCP Signs Letter to Congressional Leaders Urging Funds for COVID Vaccine Administration

On Dec. 11, AMCP signed a Pharmaceutical Supply and Payment Chain Coalition (PSPCC) [letter](#) supporting the CDC's request for supplemental appropriations to cover operations related to the cost of planning, preparing for, distributing, and facilitating administration of COVID-19 vaccines. This funding will allow the CDC to support state and local governments and other stakeholders as they collectively prepare to rapidly provide broad-based distribution and access to FDA-approved vaccines. The PSPCC letter also urges Congress to advance federal funding for a robust, multiprong outreach and communication effort to build public trust in the COVID-19 vaccine(s), encourage Americans to be vaccinated, as well as a strategy to ensure equitable distribution and allocation across the country.

[Read the Letter.](#)

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Eye on Washington

FDA Recommends EUA for Pfizer-BioNTech COVID-19 Vaccine

On Dec. 10, the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) voted 17 to 4 to recommend granting an Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine for people 16 and older. The vote came after a public hearing with presentations by Pfizer, FDA officials and patient advocacy groups. On Dec. 11, FDA granted an EUA implementing VRBPAC's recommendations. The first vaccinations were administered to high-risk health care workers on Monday, Dec. 14. HHS will distribute roughly 2.9 million doses this week to sites across the country, divided among the states based on population. According to Gen. Gustave F. Perna, the chief operating officer of the federal effort to develop a vaccine, 145 sites are set to receive the vaccine on Monday, 425 on Tuesday and 66 on Wednesday. On Dec. 14, AMCP signed onto a statement with other pharmacy organizations welcoming the FDA's authorization.

[Read the full statement.](#)

CDC Advisory Committee Releases Interim Recommendations for Allocating Initial COVID-

Advocacy Tip

Stay up-to-date: Read AMCP's [Letters, Statements and Analysis](#) on all legislation and regulation impacting managed care pharmacy.

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19 Vaccine

On Dec. 3, the CDC's Advisory Committee on Immunization Practices (ACIP) [released](#) interim guidance for federal, state, and local jurisdictions on the allocation of initial doses of COVID-19 vaccine. ACIP recommended that health care personnel and residents of long-term care facilities be offered vaccination in the initial phase of the COVID-19 vaccination program. The committee considered scientific evidence of SARS-CoV-2 epidemiology, vaccination program implementation, and ethical principles while developing these guidelines. This guidance may be updated as ACIP receives more safety and efficacy data from clinical trials and the conditions of FDA's EUA.

[Read the guidance.](#)

Supreme Court Issues Ruling on *Rutledge v. PCMA*

On Dec. 10, the Supreme Court [held](#) 8-0 that the Employee Retirement Income Security Act (ERISA), which governs most of the employer insurance market, does not preempt an Arkansas law (Act 900) which required Pharmacy Benefit Managers (PBMs) to reimburse pharmacies at or above the pharmacy's acquisition cost for covered drugs. The Court found that Act 900 1) does not have an impermissible connection with an ERISA plan, and 2) does not "refer to" ERISA. AMCP said in a [statement](#) that the Court's ruling, "could make it challenging, if not impossible, for managed care professionals to efficiently apply proven tools and practices that provide millions of patients the best possible benefits for their prescribed medications at the lowest possible costs."

[Read the full statement.](#)

AMCP Summary of Medicare Part B Most Favored Nation Model

On Nov. 20, HHS released an [Interim Final Rule with Comment Period](#) (IFC) establishing a Most Favored Nation (MFN) Model for Medicare Part B drugs. The MFN Model will calculate the payment rate for included drugs based on a price that reflects the lowest per capita GDP-adjusted price among a group of OECD countries, with an additional flat payment based on the average payment for MFN Model drugs in 2019 adjusted quarterly for inflation. The MFN Model is slated to begin on Jan. 1, 2021 and will be mandatory for all providers and suppliers that participate in the Medicare program nationwide. Read AMCP's [summary](#) of the MFN Model IFC.

AMCP is following legal challenges to the MFN Model filed by [BIO](#) and [PhRMA](#), both of which seek declaratory and injunctive relief, while alleging that the administration violated the Administrative Procedure Act and the Affordable Care Act. Implementation of the Model could be delayed if the courts grant injunctive relief.

AMCP Summary of Medicare Part D Rebate Rule

On Nov. 20, HHS released a [Final Rule](#) that amends the discount safe harbor regulation to eliminate protections for price concessions offered by pharmaceutical manufacturers to plan sponsors and pharmacy benefit managers (PBMs) under contract with plan sponsors starting Jan. 1, 2022. The regulation also creates two new safe harbors that would protect certain point-of-sale (POS) reductions in price offered by manufacturers and certain PBM service fees. In Aug., AMCP [signed](#) a Better Medicare Alliance letter in opposing the

administration's Rebate Rule, and submitted its own [comments](#) separately to Secretary Azar.

[Read the letter.](#)

AMCP Comments on CMS Draft Guidance for CY 2022 Medicare Advantage Capitation Rates, Part C and Part D Payment Policies — Part II

On Nov. 30, AMCP submitted [comments](#) on CMS draft guidance for Calendar Year (CY) 2022 Medicare Advantage capitation rate and Part C and Part D payment policies. AMCP responded to CMS's proposed introduction of a COVID-19 measure for the 2023 Part C and Part D performance measure display page and in the Star Ratings program. AMCP suggested CMS consider number of critical factors and unintended consequences that could impact plan performance with a future COVID-19 vaccine measure. AMCP also recommended close collaboration between CMS, measure developers and interested stakeholders to develop and implement new measures that are aligned with equitable access to COVID-19 vaccines.

[Read the comments.](#)

Electoral College Formally Designates Joe Biden President-Elect

On Dec. 14, the Electoral College officially named Joe Biden President-Elect by a vote of 306-232. Electors gathered in their respective states and signed certificates indicating their vote, and then the governor of each state signed a certificate verifying the state's vote total. The results are sent to Congress, which begin its 117th Session on Jan. 3. On Jan. 6, Congress will hold a Joint Session to officially count the votes and publicly declare the results.