AMCP Submits Comments to CMS About the Part D Medication Therapy Management Program

On Oct. 5, AMCP submitted comments about the Part D MTM program, specifically in regard to the ability of plan sponsors and MTM vendors to provide annual CMR to individuals other than the beneficiary in certain circumstances in which the beneficiary is unable to participate.

Read the comments.

Eye on Washington

U.S. Supreme Court Hears Arguments in the Rutledge v. Pharmaceutical Care Management Association (PCMA) Case

On Oct. 6, the Supreme Court heard arguments in Rutledge v. PCMA regarding access to affordable medications. At issue is if the state of Arkansas' efforts to regulate what pharmacy benefit managers (PBM) pay independent pharmacists for the medicines they dispense for commercial health plans ran afoul of the Employee Retirement Income Security Act (ERISA), which governs most of the employer insurance market that provides insurance coverage to the majority of Americans.

The Justice Department joined the case to advocate for Arkansas' policy. The Supreme Court appeared divided over whether the state put too much administrative burden on the PBM industry with all the measures included to ensure compliance with the law. AMCP filed an amicus brief in support of the argument that the federal ERISA law — which promotes

Advocacy Tip

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

uniformity and predictability to maximize health care value — preempts the Arkansas law.

Read AMCP CEO Susan Cantrell's opinion on the case in *Morning Consult.*

President Trump's Plan to Deliver $200 Prescription Drug Discount Cards to Seniors is Delayed

The estimated $7.9 billion plan — to be paid out of one of Medicare's trust funds — has been paused after the HHS General Counsel advised officials to seek approval from the Justice Department over concerns that the president's plan violates election law and could lead to legal challenges.

Learn more.

FDA Releases Guidance Regarding COVID-19 Vaccines

The FDA released guidance on the development, authorization, and licensure of vaccines to prevent COVID-19 in advance of an Oct. 22 advisory committee meeting. The guidance requires that vaccine developers monitor half of their clinical trial participants for at least two months following the final dose of vaccine or placebo before they can apply for emergency use authorization. Read more.

FDA Authorizes a Point-of-care Coronavirus Antibody Test

The FDA authorized the first point-of-care coronavirus antibody test, known as a serology test, that can detect antibodies present in a person's immune system after exposure to COVID-19. Emergency use authorization was first granted in July to Assure, the test's manufacturer, for lab-based antibody testing. The point-of-care test allows use of a finger-stick blood sample obtained in a doctor's office, hospital, or urgent care setting. Read more.

Senate Committee Holds Hearing on Federal Response to COVID-19

On Sept. 23, the Senate Committee on Health, Labor, Education, and Pensions (HELP) held a hearing with FDA Commissioner Stephen Hahn, CDC Director Robert Redfield, top NIH expert Anthony Fauci, and Assistant Secretary for Health Brett Giroir, on the federal response to COVID-19, including mitigation measure effectiveness, rapid testing availability, and the development of therapeutics and vaccines. The four witnesses expressed strong confidence in the scientific review process for which the FDA will consider vaccine

candidates for emergency authorization use approval. Drs. Fauci and Redfield said the U.S. could possibly have a vaccine available for health care providers and vulnerable populations by the end of 2020, but late spring or summer 2021 is more realistic.

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