



Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

AMCP Joins Patient and Provider Groups in Urging the Supreme Court to Preserve FDA Authority

On Jan. 30, AMCP and 24 other patient and provider organizations filed an amicus brief urging the Supreme Court to reverse the Fifth Circuit's decisions in *Alliance for Hippocratic Medicine et al. v FDA et al.* because it threatens Americans' ability to rely on FDA decisions about drug safety. The FDA is the ultimate authority for decisions on drug safety and effectiveness in the United States, but the Fifth Circuit's decision could set a dangerous precedent that jeopardizes patients' access to FDA approved treatments. If upheld, the ruling would undermine the decisions of FDA experts in favor of court rulings. AMCP and the filing organizations urge the Supreme Court to act in the interest of patients and preserve the authority of the FDA by striking down this ruling.

View the full [amicus brief](#).

View the [press release](#).



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AMCP Highlights Pathways to Expand Access to Cell and Gene Therapies

On Dec. 5, Senate Health, Education, Labor, & Pensions (HELP) Committee Ranking Member Bill Cassidy (R-LA) released a Request for Information on “Improving Americans’ Access to Gene Therapies.” On Jan. 22, AMCP responded with [comments](#) that position the Medicaid VBPs for Patients (MVP) Act ([H.R. 2666](#)) as a pathway for improving America’s most vulnerable patients’ access to emerging cell and gene therapies while also protecting Medicaid Programs from paying for expensive treatments that are not effective. AMCP’s comments follow a Jan. 18 blog post from AMCP CEO Susan Cantrell, who also highlights the role the MVP Act may play in expanding access to emerging, high-cost therapies, including those utilizing the CRISPR genome editing technology. “Value-based agreements represent the most likely way that underserved and vulnerable populations...will be able to access these potentially life-saving treatments,” Cantrell states. “AMCP is proud to be a champion for steps like the MVP Act that will enable patients to have affordable access to the life-altering therapies they deserve.”

Read the full [blog post](#).

Pharmacy Organizations Raise Concerns About Florida’s Drug Importation Program

On Jan. 5, the FDA authorized Florida’s Agency for Health Care Administration’s drug importation program, which allows the state to import certain prescription drugs from Canada. On Jan. 17, AMCP joined dozens of other pharmacy organizations in a letter that raises concerns around Florida’s importation program, which may allow harmful and counterfeit drugs to enter the nation’s supply with little evidence to support increased cost savings for patients. State importation programs introduce opportunities for mix-ups, mishandling, and mislabeling that would put vulnerable patient communities at risk. The undersigning organizations remain committed to working with the FDA to lower the high cost of prescription drugs without compromising patient safety.


Read the full [letter](#).

AMCP, Health Care Organizations Urge CMS to Maintain Stability in the Medicare Advantage Program



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On Jan. 11, AMCP and 65 other health care organizations submitted a joint letter urging the Biden administration to implement policies that would stabilize and support a strong, sustainable Medicare Advantage program for its beneficiaries. The Medicare Advantage program currently serves over 31 million beneficiaries, representing 51% of the Medicare population. The undersigning organizations applaud CMS' ongoing commitment to preserving and strengthening the Medicare Advantage program and align with the recently released CY 2025 Medicare Advantage and Part D Proposed Rule's goals to advance health equity, improve access to mental and behavioral health care, and support beneficiaries in making informed choices regarding their care. The letter also emphasizes the need for continued stability and clarification regarding the implementation of programmatic changes, including the CY 2024 Rate Announcement.

View the [sign-on letter](#).

Stay Up to Date with AMCP's Regulatory NEWSBREAKs

AMCP delivers Regulatory NewsBREAKs directly to member inboxes in response to newly enacted federal regulations and guidance. This month, AMCP released Regulatory NewsBREAKs on HHS' Final Rule on Medications for the Treatment of Opioid Use Disorder, CMS' 2025 Advanced Notice and Draft Part D Redesign Program Instructions, and CMS' Final Rule on Interoperability. Last month, AMCP sent NewsBREAKs regarding ONC's Final Rule on Health Data, Technology, and Interoperability, CMS' Guidance on Prescription Oral Antivirals for COVID-19, FDA's Authorization of the Florida Drug Importation Program, OCR's Final Rule on Safeguarding the Rights of Conscience, and HHS' Guidance on Contraceptive Care Coverage. With additional guidance on the Inflation Reduction Act expected to be released this year, stay in the loop by monitoring AMCP's Regulatory NewsBREAKs.

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