



Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

APRIL 2023

AMCP Statement on Federal Court Decisions Regarding FDA Approvals

AMCP released the following statement in response to conflicting federal court rulings regarding Food & Drug Administration (FDA) drug approval (including Alliance for *Hippocratic Medicine v. FDA*, a related decision by the 5th Circuit Court of Appeals, and *State of Washington v. FDA*). While one ruling overturned longstanding FDA approval of a therapy, another explicitly upheld it.

“AMCP is deeply concerned by recent federal court rulings regarding approval status and dispensing guidelines for a therapy repeatedly deemed safe and effective by FDA. Drug approval and related dispensing policies should be the domain of relevant scientific review bodies, such as the FDA, not the courts. Undermining the FDA approval process denies health payers the certainty they need to develop coverage strategies for medication therapies and threatens patient access to and confidence in the care they receive.

AMCP is closely monitoring the situation for further developments.”

[View AMCP's statement.](#)

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Eye On Washington

AMCP Submits Comments on the Medicare Drug Price Negotiation Program

On March 17, CMS announced an opportunity for the public to comment on the agency's initial guidance for the Medicare Drug Price Negotiation Program, as required by the Inflation Reduction Act. Given the anticipated impact of the Drug Price Negotiation program on the practice of managed care pharmacy in the United States, AMCP took the opportunity to submit comments on several provisions outlined in CMS' guidance. AMCP's comments cover subject areas such as access to the Maximum Fair Price, manufacturer-specific data required for negotiation, evidence about therapeutic alternatives for the selected drug, CMS' methodology for developing an initial offer, the removal of a drug from the selected drug list, and Part D formulary inclusion of the selected drug.

[Read AMCP's full comment letter.](#)

The Equitable Community Access to Pharmacist Services Act is Reintroduced in Congress

Advocacy Tip

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

On March 24, AMCP welcomed the reintroduction of the Equitable Community Access to Pharmacist Services (ECAPS) Act of 2023 (H.R. 1770) in the House of Representatives. The bipartisan bill, introduced by Rep. Adrian Smith (R-NE), included the following original cosponsors: Brad Schneider (D-IL), Larry Bucshon, M.D (R-IN), Doris Matsui (D-CA), Brian Fitzpatrick (R-PA), Scott Peters (D-CA), Buddy Carter (R-GA), Gus Bilirakis (R-FL), Earl Blumenauer (D-OR), Diana Harshbarger (R-TN), and Terri Sewell (D-AL). In a press release, AMCP CEO Susan Cantrell explains the timeliness of this legislation. “With the COVID-19 public health emergency (PHE) declaration ending in May, millions of patients across the United States risk losing access to essential care administered by pharmacists,” Cantrell states. “This bill will create and extend coverage for pharmacists providing this care, which is so important to seniors and other vulnerable patient groups, including rural communities.” Along with extending certain provisions during the COVID-19 PHE, the ECAPS Act would establish Medicare Part B coverage and reimbursement for these pharmacist services.

[View the full press release.](#)

AMCP Comments on Preventive Services Under the ACA

On Feb. 2, the Internal Revenue Service, Employee Benefits Security Administration, and CMS jointly released a proposed rule on the coverage of certain preventative services under the Affordable Care Act (ACA). In a comment letter submitted on March 31, AMCP offers support for the Departments’ proposal to remove the moral exemption to the contraceptive requirement. AMCP’s comments also urge the Departments to replace exclusionary language used throughout the proposed rule with intentionally inclusive language. Specifically, AMCP calls on the Departments to update such regulatory language to reflect the reality of gender diversity.

[Read AMCP’s comment letter.](#)

AMCP, Pharmacy Organizations Send Joint Request for Telehealth Prescribing of Buprenorphine

In the United States, patient demand for substance use disorder treatments such as buprenorphine significantly exceeds the current provider capacity. Given this constraint, AMCP joined 10 other pharmacy organizations in a joint letter to Anne Milgram, Administrator of the Drug Enforcement Agency (DEA). In the joint letter, the signing organizations request the DEA extend flexibilities for telehealth prescribing of buprenorphine using the opioids-related public health emergency. Previous flexibility in telehealth prescribing was outlined in the COVID-19 public health emergency, which is set to expire on May 11.

[View the joint letter.](#)

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