



Supreme Court Hears Oral Arguments in *California v. Texas*

On Nov. 10, the Supreme Court heard [oral arguments](#) in *California v. Texas*, a case challenging the constitutionality of the individual mandate in the Patient Protection and Affordable Care Act (ACA). The Court must address three key questions: whether the individual and state plaintiffs have standing to challenge the individual mandate; whether the elimination of the individual mandate penalty in the Tax Cuts and Jobs Act of 2017 rendered the individual mandate unconstitutional; and, if so, whether the individual mandate is severable from the rest of the ACA. Justices Roberts and Kavanaugh appear likely to side with the Court's three liberal justices in finding the mandate severable and preserving many of the provisions in the ACA, based on recent decisions they wrote and statements made during oral arguments. The Court is expected to decide on the case by the end of its term in June 2021.

Read AMCP CEO Susan Cantrell's [statement](#) on *California v. Texas*.



Eye on Washington

AMCP Submits Comments on CMS Third COVID Interim Final Rule

On Nov. 2, AMCP submitted comments on CMS's Third Interim Final Rule responding to the COVID-19 emergency. In our comments, we thanked the agency for granting pharmacists the authority to order COVID-19 diagnostic tests for Medicare beneficiaries but expressed concern about the agency's new guidance limiting COVID-19 diagnostic tests without an order. In the interim final rule, CMS finalized a policy that only one COVID-19

Advocacy Tip

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

diagnostic test and one of each related test may be provided without an order from a physician or other health care practitioner.

[Read the comments.](#)

AMCP Submits Comments on Medicare Coverage of Innovative Technology Proposed Rule

On Nov. 2, AMCP submitted comments on a CMS Medicare Coverage of Innovative Technology proposed rule establishing a national coverage pathway for innovative devices authorized under FDA's Breakthrough Devices Program and clarifying the agency's definition of "reasonable and necessary." AMCP called on CMS to indicate how digital therapeutics (DTx) will fit into Medicare's coverage and payment framework in its Final Rule.

[Read the comments.](#)

Pharmaceutical Supply and Payment Chain Coalition Releases Principles for Safe Access to COVID-19 Vaccine

On Oct. 22, AMCP joined with representative organizations of America's pharmaceutical supply and payment chain in releasing [guiding principles](#) for the safe and efficacious development, distribution, and allocation of vaccine(s) to achieve mass immunization against the coronavirus (COVID-19). The principles call for a transparent and scientifically rigorous vaccine development and approval process, a national strategy for vaccine distribution, removal of financial barriers to promote vaccine affordability and access, an equitable allocation of priority access to vaccines with consistent public engagement regarding the decision-making process, and the development of vaccine deployment strategies that consider worker safety and the readiness of local vaccination infrastructure.

[Read the principles.](#)

HHS Partners with Pharmacies to Distribute COVID-19 Vaccine

On Nov. 12, HHS [announced](#) partnerships with chain and independent community pharmacies — which represent approximately 60% of pharmacies throughout the — United States,



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to distribute the eventual FDA-approved COVID-19 vaccine. The vaccine will be administered at partner pharmacy locations at no cost to patients. HHS Secretary Alex Azar said that partnerships with pharmacy networks, "[are] a critical step toward making sure all Americans have access to safe and effective COVID-19 vaccines" and recognized the vital role pharmacists, interns, and technicians have played throughout the public health emergency.

[Read the announcement.](#)

CMS Releases Fourth COVID-19 Interim Final Rule with Comment Period (IFC-4)

On Oct. 28, CMS released its plan to ensure free COVID-19 vaccines for seniors, the uninsured, and poor Americans. [The rule](#) guarantees free coverage for seniors under Medicare and taps into unused hospital bailout funds within the CARES Act for the uninsured. The rule also requires private insurers to cover vaccines under emergency use authorization for the duration of the public health emergency.

Read CMS' [press release](#) and [fact sheet](#).

Trump Administration Releases Insurance Transparency Final Rule

On Oct. 29, the Trump administration released a [final rule](#) requiring that health insurers provide data on the prices they pay to providers and for prescription drugs by 2022. When the full rule goes into effect in 2024, insurers will be required to provide a patient's bill up front, along with their out-of-pocket costs for medications.

[Read the final rule.](#)

FDA Releases Essential Medicines under 'Buy American' Executive Order

On Oct. 30, the FDA released a [list](#) of 223 essential medicines and medical devices to ensure adequate supplies during public health emergencies, a requirement of President Trump's "Buy American" executive order in August. The FDA must develop strategies to acquire the listed products, including increasing domestic manufacturing and addressing supply chain vulnerabilities.

[Read the release.](#)

Election 2020: A Biden/Harris White House, Slim Democrat House Majority, and Senate Runoff

As of publication, former Vice President Joe Biden has secured 306 electoral college votes, surpassing the necessary 270 to win the presidency. While legal challenges and recounts are underway, none are expected to change the current results. Vice President-elect Kamala Harris will be the first woman, first Black, and first South Asian to hold the position in U.S. history.

Democrats narrowly retained their 218-seat majority in the House of Representatives with Republicans picking up 12 seats and Democrats gaining three. Eight races are outstanding with four forecasted for Democrats, one for Republicans, and three toss ups.

The Senate currently stands at 48 Democrat and 50 Republican seats with two runoff races scheduled for January 5 in Georgia after no candidate secured the required 50% of the vote. Incumbent Republicans Kelly Loeffler and David Perdue will face off against Democrat challengers Raphael Warnock and Jon Ossoff, respectively. Republicans must win one seat to maintain their Senate majority. Democrats must win both seats for the majority, as Vice President-elect Harris will cast the tie-breaking vote.

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