



## The 117<sup>th</sup> Congress and Biden Administration — Health Care Legislative and Regulatory Outlook

### Tuesday, Feb. 2, 2021, 2-3pm ET

The 2020 election season culminated in a challenging year. Democrats won the White House and a 50+1 majority in the Senate, while retaining a slim 11-seat majority in the House of Representatives. Please join AMCP for a webinar on the health care policy landscape under the 117<sup>th</sup> Congress and Biden Administration. AMCP will host policy experts Alix Burns and Andrew McKechnie of Tiber Creek Group to examine the Biden administration's health care policy priorities, health appointees, and potential regulatory actions, along with health legislation under the new Congress. *Please note: This webinar is for AMCP members only.*

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## Eye On Washington

### AMCP Letter to President-Elect Joseph R. Biden

In a Jan. 15 [letter](#) to President-elect Biden, AMCP shared its priority issues related to the COVID-19 pandemic and managed care pharmacy. Specifically, AMCP outlined its position on the COVID-19 vaccine distribution process and vaccine awareness and education efforts. The letter highlighted AMCP's support for addressing the rising cost of pharmaceuticals using managed care pharmacy tools and strategies as well as increasing drug pricing transparency for patients. AMCP also registered its opposition to the Most Favored Nation (MFN) Model and rebate rule, while urging support of legislation codifying current regulatory safe harbors for Pre-Approval Information Exchange (PIE).

[Read the full letter.](#)

### President-elect Biden Releases COVID-19 Rescue Package

On Jan. 14, President-elect Biden [released](#) the American Rescue Plan, a \$1.9 trillion package which will deliver direct relief to families and small businesses, launch a comprehensive COVID-19 response plan, and provide resources to safely reopen schools. President-elect Biden's COVID-19 response plan includes more than \$400 billion to combat the pandemic. The Biden administration's plan will mount a national vaccination program, scale up coronavirus testing and contact tracing efforts, and provide \$170 billion for

### Advocacy Tip

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

school reopening preparation. The American Rescue Plan must be approved by Congress.

[Learn more.](#)

## President-elect Biden Releases COVID-19 Vaccine Plan

On Jan. 15, President-elect Biden [released](#) an outline of his administration's COVID-19 vaccine plan. The plan encourages states to open vaccine eligibility to essential workers and anyone ages 65 and older and calls for partnerships with community health centers to reach marginalized communities. The Biden administration will work to ramp up the number of vaccination sites, including building on the Trump administration's efforts to increase capacity at chain and independent pharmacies. Mr. Biden's plan calls for releasing "the vast majority" of vaccines when they are available and using federal government authority to maximize vaccine manufacturing capacity. The federal government will launch a program to build public trust through an education campaign and transparency. Last fall, AMCP joined a coalition of national pharmacy stakeholders to release the [guiding principles](#) for the COVID-19 vaccine program.

Read President-elect Biden's [full vaccine plan](#).

## Presidential Transition Means Potential Changes to Recent Regulatory Actions

The newly sworn-in Biden administration and Democratic Party control of both chambers of congress has created the opportunity to make significant changes to many of the regulatory actions taken at the end of the Trump administration. Congress can use its authority under the Congressional Review Act (CRA) to pass joint resolutions of disapproval to overturn final rules published within a 60-day "lookback" period. In addition, it is a common practice for incoming administrations to issue a memorandum to federal agencies on Inauguration Day to pause ongoing rulemaking and to delay the effective date of published rules that have not yet gone into effect. Recent final rules subject to potential CRA disapproval and/or delayed implementation include the rule eliminating the safe harbor for manufacturer rebates, the Most Favored Nation Model, the prescription drug importation final rule, and the Medicaid Drug Rebate Program value-based pricing final rule.

[Learn more.](#)


## Lawsuit Brought to Block Implementation of the Rebate Rule

On Jan. 12, the Pharmaceutical Care Management Association (PCMA) filed a lawsuit challenging the rebate rule issued in November that would eliminate the safe harbor protections of the Anti-Kickback Statute for pharmaceutical manufacturer rebates to payers and PBMs. PCMA's lawsuit contends that the Trump Administration circumvented the proper rulemaking process by publishing this final rule, failed to consider the significant cost impact to beneficiaries and the Medicare program, and that the timeline for the effective date of the rule is unreasonable.

Read AMCP's [press release](#) in support of PCMA's lawsuit.



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