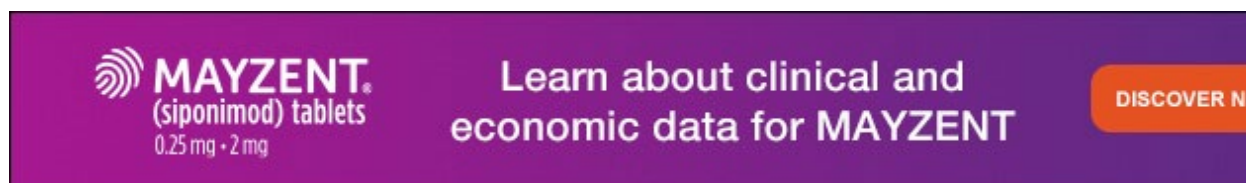




AMCP Virtual Legislative Days 2020

Forty AMCP members met with lawmakers in targeted congressional offices on AMCP's key issues to explain the value of managed care pharmacy in the broader health care system. Discussions centered on pharmaceutical information exchange (PIE) legislation, prior authorization, and advocating to authorize pharmacists to receive reimbursement under Medicare Part B for COVID-19 and flu testing and vaccinations.



Eye on Washington

AMCP Sends Letter to HHS Secretary Azar on Anti-Kickback Rules Concerns

On Sept. 1, AMCP sent a letter to HHS Secretary Alex Azar expressing our concerns with the Executive Order signed by President Trump that would eliminate the safe harbor of the anti-kickback statute for rebates negotiated between Part D plans and drug manufacturers unless the rebates are passed back to individuals at the point-of-sale. In particular, AMCP's letter detailed how implementation of these changes to the anti-kickback statute will lead to increased costs for Medicare beneficiaries and the health care system. AMCP also signed on to a [joint letter](#) to the Secretary on this issue, led by the Better Medicare Alliance.

[Read AMCP's letter.](#)

HHS Authorizes Pharmacists to Administer COVID-19 Vaccine

On Sept. 9, HHS issued guidance authorizing state-licensed pharmacists and registered pharmacy interns working under the

Advocacy Tip

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

supervision of a qualified pharmacist to order and administer COVID-19 vaccines to individuals age three years and older. HHS issued this guidance under its Public Readiness and Emergency Preparedness (PREP) Act authority, preempting any state or local laws that would prohibit or effectively prohibit pharmacists from administering COVID-19 vaccines. In addition to the vaccine needing to be FDA-Approved or authorized, the guidance outlines additional requirements for pharmacists, including practical training approved by the Accreditation Council for Pharmacy Education (ACPE) on vaccine administration, a minimum of two hours of ACPE-approved immunization-related continuing pharmacy education, and compliance with all recordkeeping requirements in their jurisdiction.

[Read the guidance.](#)

AMCP Submits Comments on COVID-19 Vaccine Allocation Framework

On Sept. 4, AMCP submitted comments on the National Academies of Science, Engineering, and Medicine (NASEM) Committee on the Equitable Allocation of Vaccine for the Novel Coronavirus's *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*. This preliminary draft details the Committee's proposal for how a coronavirus vaccine should be distributed and what populations should be prioritized to receive the vaccine, given that initially, supplies will be limited. AMCP's comments focus on two important issues: ensuring that pharmacists are authorized to order and administer any COVID-19 vaccine and that pharmacies are included in the distribution and allocation plans; and that pharmacists are included in the first phase of vaccine administration as frontline health care workers.

AMCP also joined other national pharmacist stakeholders in [sending comments](#) on the preliminary framework that reiterated these same issues and included comments on the need for funding for vaccine and vaccination education.

[Read AMCP's letter.](#)

CMS Issues Proposed Rule Establishing a New Coverage Pathway for Breakthrough Devices

On Sept. 1, CMS published a proposed rule detailing the establishment of a national coverage pathway for new, innovative medical devices approved by the FDA to allow Medicare beneficiaries faster access to these breakthrough technologies. The Medicare Coverage of Innovative Technology (MCIT) pathway will apply to devices that receive market authorization by the FDA through the agency's Breakthrough Devices Program, which has approved market authorization of several digital therapeutics. The proposed rule would shorten the time it takes for an innovative device to receive national Medicare coverage.

[Review a summary](#) of the proposed rule. Please provide

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feedback to advocacy@amcp.org on any provisions included in the proposed rule by Oct. 16.

CMS Issues Rule Limiting Pharmacist-Administered COVID-19 Testing

On Sept. 2, CMS published an Interim Final Rule amending a previous regulation that allows pharmacists to administer COVID-19 tests without a physician's order, by limiting pharmacists to administering one test per Medicare beneficiary. Previously, there were no limits placed on the number of tests for COVID-19 that a pharmacist could order for a patient, but under the new rule, pharmacists would need a physician's order to perform any additional tests for a patient to whom they have already administered a COVID-19 test. Since CMS issued this change as an Interim Final Rule, it went into effect as of Sept. 2. However, there is an opportunity for public stakeholder comments. AMCP is working with a coalition of national pharmacist organizations on this issue.

President Trump Signs Drug Pricing Executive Order

On Sept. 13, President Trump signed an [Executive Order](#) (EO) directing HHS to move forward with rulemaking to test a payment model that would tie the prices of drugs in Medicare Part B and Part D to a "most favored nation" price. This most favored nation price, according to the EO, means the lowest price after adjusting for volume and differences in gross domestic product for a pharmaceutical product sold by the drug manufacturer in an Organization for Economic Co-operation and Development (OECD) member country with a per capita gross domestic product comparable to that of the United States.

AMCP is monitoring this issue.

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