

Legislative & Regulatory Briefing

RECENT DEVELOPMENTS FROM YOUR STATE AND FEDERAL GOVERNMENTS

JANUARY 2022

Register for the 2022 Policy Outlook Webinar Today!

On Jan. 26, AMCP staff and the policy and government relations experts at Tiber Creek will discuss in a webinar the key legislative and regulatory issues facing the Biden administration and Congress this year. They will share the latest news on the Build Back Better Act, provide insight on the key players concerning PDUFA and BsUFA reauthorization, and review the must-pass legislation Congress needs to consider before the midterms this fall.

Register for the webinar.



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Advocacy Tip

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Letters, Statements and Analysis on all legislation and

Eye On Washington

Ask Congress to Support Cures 2.0

The Cures 2.0 Act (H.R. 6000) is an important follow-up to the 2016 21st Century Cures Act (P.L. 114-255). Cures 2.0 proposes many strong policy ideas that AMCP supports, including improving strategies to expand use of cell and gene therapies, strengthening the collection of confirmatory data for accelerated approval drugs, and expanding access to innovative medical technologies, including digital therapeutics. The bill would also create the Advanced Research Projects Agency for Health (ARPA-H) to focus on developing new treatments. We also support the inclusion of additional provisions to strengthen the bill's efforts. Please use our <u>Action Center</u> to encourage your Representatives to co-sponsor and vote for this important piece of legislation.

Read more about AMCP's suggestions in our Cures 2.0 issue brief.

AMCP Releases State Model Legislation

On Jan. 14, AMCP unveiled state model legislation promoting value-based contracts and electronic prescription tools. The <u>Value in Pharmacy Act</u> would support the growth of value-based and outcomes-based contracts by directing state health departments to establish common metrics and guidelines for these contracts. The legislation would also authorize state Medicaid agencies to enter into these agreements. AMCP's <u>Electronic Prescription Tools</u> model would grow the use of electronic systems for prescribing and reviewing prior authorization claims by requiring most providers to adopt electronic prescribing tools and establishing standards for implementing a fair and reasonable electronic prior authorization framework.

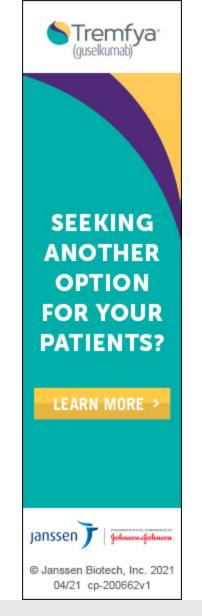
CMS Actions on Alzheimer's Drugs and 2023 Part D Rule

On Jan. 6, CMS released the 2023 Medicare Advantage and Part D <u>Proposed Rule</u>, which would require Part D plans to apply all price concessions they receive from network pharmacies at the point of sale, strengthen programs to ensure beneficiaries receive accurate and accessible information about Medicare coverage, and create new bases for CMS to deny a new application or a service area expansion application. Additionally, on Jan. 11 CMS released a proposed <u>National Coverage Determination</u> memorandum for monoclonal antibodies that target amyloid for the treatment of Alzheimer's Disease. Under the proposed framework, CMS would only cover such treatments for beneficiaries that are enrolled in clinical trials that meet specific criteria.

Request for Medicare Payment Advisory Commission (MedPAC) Nominations

The General Accountability Office (GAO) is now accepting nominations for MedPAC appointments that will be effective starting May 2022. Letters of nomination and resumes should be submitted no later than Feb. 11, 2022. There are no pharmacists currently serving on the Commission, which among other issues advises Congress on the Medicare prescription drug program.

If you are interested in applying to MedPAC, please send your nomination letter and resume to <u>MedPACappointments@gao.gov</u> by Feb. 11.



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