CMS Issues Request for Information on Electronic Prescribing of Controlled Substances

On Aug. 4, CMS issued a request for information (RFI) on implementing the provision of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act that mandates that prescriptions written for Schedule II, III, IV, and V controlled substances in Part D are done electronically starting in 2021, with limited exception. The law gives HHS the authority to enforce and specify appropriate penalties for noncompliance with electronic prescribing requirements as well as to determine any circumstances that may waive electronic prescribing for controlled substances. The RFI asks questions about which stakeholders can provide feedback for the agency. Answers will help the agency best understand how to structure any waivers or penalties for non-compliance.

Read AMCP's summary of the RFI. AMCP will be submitting comments about the RFI. Please send feedback to inform AMCP comments to advocacy@amcp.org by Sep. 25.

Eye on Washington

President Trump Signed Executive Orders on Drug Pricing

Earlier this month, President Trump signed three executive orders (EOs) related to drug pricing. AMCP is monitoring these developments and is working with other stakeholders to advocate for AMCP's preferred policy positions.

- **The first EO** would require HHS to promulgate a rule eliminating the safe harbor of the anti-kickback statute for rebates negotiated between Part D plans and drug manufacturers unless the rebates are passed back at the point-of-sale, aligning with a 2019 withdrawn proposed rule. The EO includes language that requires the Secretary of HHS to confirm that the rule will not increase federal

Advocacy Tip

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

spending, Medicare beneficiary premiums, or patient total out-of-pocket costs. A similar proposed rule that was projected to cost nearly $200 billion was withdrawn last year. It is unclear whether HHS can move forward by issuing a modified final rule of the proposal withdrawn last year, or if the agency will need to start the rulemaking process over from the beginning.

- **A second EO** directs HHS to finalize previous rulemaking allowing for the importation of certain drugs from Canada and for the re-importation of insulin products.

- **A third EO** will require federally qualified health centers (FQHCs) participating in the 340B program to offer insulin and EpiPen products to patients at their acquisition costs.

- **President Trump also discussed a fourth EO** that would implement a drug pricing scheme tying the prices of certain drugs to the prices charged in other, comparable countries. He did not sign this order, instead giving drug manufacturers 30 days to come up with a different plan to limit drug prices.

AMCP Submits Comments on Medicaid Drug Rebate Program Proposed Rule

On July 20, AMCP submitted comments on the proposed rule related to changes to the Medicaid Drug Rebate Program (MDRP) to better account for value-based purchasing (VBP) arrangements between payers and manufacturers. AMCP's comments supported the proposed definition of VBP arrangements as well as the proposed methodology for accounting for VBP arrangements to not reset the best price for purposes of the MDRP based on the outcomes of a few patients. As manufacturers often cite the MDRP best price requirement as a barrier to VBP arrangements, AMCP supports these changes to potentially increase their use.

Read AMCP's comments.

House of Representatives Holds COVID-19 Vaccine and Coronavirus Response Hearings

July 21 Hearing

Executives from AstraZeneca, Johnson & Johnson, Merck, Moderna, and Pfizer appeared before the House Energy and Commerce Subcommittee on Oversight and Investigations to testify on the status of their organization's coronavirus vaccination development and plans for production and distribution. Key takeaways were:

- The vaccine makers stated that the U.S. government should oversee the allocation and distribution of any vaccine.

- Subcommittee Democrats sought commitments from each executive to an affordable vaccine, while subcommittee

Reminder

FDA Issues RFIs on Improving the Orange Book

On June 1, the FDA published two RFIs soliciting comments on how stakeholders and the public use the Orange Book and how it can be improved.

Please send feedback to advocacy@amcp.org

Republicans asked for assurances that vaccine materials and production would not be linked to China.

- None of the manufacturers were concerned that political pressure would influence the timing or approval of a safe, effective vaccine. All agreed that educational outreach to the American people needs to begin immediately.

View the hearing video and prepared witness testimony.

July 31 Hearing

The House Select Subcommittee on the Coronavirus Crisis held a hearing on the national response to the coronavirus with NIH Director Dr. Anthony Fauci, CDC Director Dr. Robert Redfield, and Assistant Secretary for Health at the HHS Admiral Brett Giroir. Key takeaways were:

- Dr. Fauci assured lawmakers about the safety and efficacy of any COVID-19 vaccine made available to the American public, while stating he is "cautiously optimistic" a vaccine will be available in late 2020 or early 2021.
- Drs. Fauci and Redfield highlighted the importance of children returning to school, if possible.
- Dr. Fauci discussed the four components of NIH's COVID-19 strategic plan: (1) the improvement of fundamental knowledge of the virus; (2) diagnostics development; (3) therapeutics testing; and (4) vaccine development and testing.

View the hearing video and prepared witness testimony.

on any provisions included in the request for comments by **Aug. 25**.

AMCP
675 North Washington Street, Suite 220, Alexandria, VA 22314
703.684.2600 | www.amcp.org