AMCP Joins Pharmaceutical Supply Chain Stakeholders to Support Access to Medications

AMCP signed on to a letter to Vice President Pence and congressional leadership detailing the joint efforts of various pharmacy, manufacturer, health plan, and pharmaceutical distribution stakeholders to ensure that patients have access to needed medications. The group also established a set of principles for ensuring adequate medication supply and keeping the pharmaceutical supply chain working. These principles include ensuring that:

- The public and private sectors work together to sustain access to care for patients and to help mitigate disruptions and shortages.
- Pharmaceutical supply and payment chain stakeholders have access to information on any disruptions and shortages.
- Policymakers prioritize patient needs by balancing clinically appropriate drug supplies; efforts to prevent inappropriate stockpiling, substitution and therapeutic interchangeability if shortages occur; and the need to manage drug shortages and future drug shortage risks.
- A closely connected, diverse, and resilient global supply chain is the best means to ensure a consistent and affordable supply of medicines for patients.

Read the letter.

Eye on Washington

AMCP Comments on COVID-19 Changes to Medicare Program

On June 1, AMCP submitted comments on a CMS interim final rule implementing many of the Medicare program waivers the agency has issued in its efforts to address the ongoing COVID-19 public health emergency. AMCP’s comments focused on the additional flexibilities that CMS is implementing for telehealth providers, arguing that pharmacists should be included as eligible telehealth providers in the Medicare program. Pharmacists are already active telehealth users and vital members of patient care teams and, as such, should be included as providers in the Medicare program. As CMS issued this regulation as an interim final rule within the comment period, its
provisions went into effect as of March 31, though a comment period was included for the submission of stakeholder comments. Read AMCP’s comments.

FDA Issues RFI on Improving the Orange Book

On June 1, the FDA published two requests for information (RFI) soliciting comments on how stakeholders and the public use the Orange Book and how it can be improved. The Orange Book identifies FDA approved drug products and includes information such as therapeutic equivalence evaluations for multisource drugs and patent information on each listed drug. The first RFI is more general and includes several questions aimed at understanding who utilizes the information contained in the Orange Book and what they use the information for, as well as specific questions about the usefulness of the therapeutic equivalence information. The second RFI solicits comments on the listing of patent information in the Orange Book, including the types of patents currently listed and changes to current patent listing practices that may impact drug product development. Read summaries of the two RFIs. Please send any feedback on provisions in the RFIs to advocacy@amcp.org by Aug. 14.

CMS Issues Final Medicare Part C and Part D Policy, Technical Rule

On May 22, CMS published Part 1 of the Contract Year 2021 Policy and Technical Changes final rule. In departure from previous years, CMS chose to finalize certain provisions of the rule in this publication, notably those sections related to Medicare Advantage and Part D plan bids and benefits for CY 2021, for which bid submissions were due in early June. The agency also removed “CY 2022” from the title of the rule. The provisions on which AMCP submitted comments — permitting a second specialty drug tier in Part D, the required implementation of a beneficiary real time benefit tool, and implementation of various SUPPORT Act provisions — will be included in Part 2 of the final rule, which CMS states will be published “later in 2020.” AMCP will update its membership when Part 2 is published.