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Trump Administration Issues Proposed Rule That Would Allow Importation of Certain Prescription Drugs

On Dec. 18, The White House, along with HHS and FDA, issued a notice of proposed rulemaking (NPRM) that, if finalized, would allow for the importation of certain prescription drugs from Canada. In addition, the Trump administration announced the availability of a new draft guidance that describes procedures drug manufacturers can follow to facilitate importation of pharmaceuticals, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country. The NPRM is the first step in implementing a provision of federal law that would allow for the importation of certain prescription drugs from Canada under specific conditions, namely that importation poses no additional risk to the public's health and safety while achieving a significant reduction in costs to American consumers. The draft guidance describes procedures for a drug manufacturer to submit documentation that demonstrates the product offered for import from any foreign country is, in fact, an FDA-approved drug product, including that it is manufactured in accordance with the FDA-approved application. AMCP staff is reviewing this proposed rule and will subsequently submit comments in response to the Administration's proposal. AMCP staff will focus its review and comments on the AMCP Position Statement on Prescription Drug Importation.

House Passes H.R. 3 Drug Pricing Bill on Party-Line Vote

On Dec. 12, the U.S. House of Representatives passed the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) by a 230 to 192 party-line vote. A central component of H.R. 3 would give HHS broad authority to negotiate drug prices under Medicare for up to 250 commonly used products — including insulin — and extend those negotiated prices to the private market. HHS would use international prices as a reference in negotiations. H.R. 3 also would cap drug costs by forcing drug companies to give rebates to Medicare if they increased prices above the rate of inflation. In addition, H.R.3 would

Advocacy Tip

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redesign the Medicare Part D drug benefit, including capping patients' out-of-pocket costs to $2,000 annually. Although drug pricing has been a key priority for Congress, the bill is unlikely to be taken up in the Senate by the end of the year due to disagreements in the Democratic-controlled House and GOP-controlled Senate. AMCP will continue to monitor action on drug pricing legislation in 2020.

AMCP Submits Letter to House on 21st Century Cures 2.0

AMCP submitted a Dec. 16 letter to Reps. Diana DeGette (D-Colo.) and Fred Upton (R-Mich.) in response to their request for specific considerations in developing a 21st Century Cures 2.0 bill that would move through Congress in 2020. In 2016, AMCP supported the inclusion of Section 3037 in the 21st Century Cures Act, which modernized Section 114 of the FDA Modernization Act (FDAMA114) of 1997. This section took an important step towards creating a value- and outcomes-based health care system that will give patients the medicines they need while ensuring the wise use of health care dollars. AMCP's feedback on Cures 2.0 focused on better access to innovative therapies through codification of existing FDA guidance for the communication of health care economic information (HCEI) in law and digital therapeutics. AMCP looks forward to working with Congress on enabling better and more timely communications between biopharmaceutical manufacturers and population health decision makers as well as assisting efforts to advance digital health for patients.

Regulatory Update

Stephen Hahn, MD, Confirmed as New FDA Commissioner

On Dec. 12, the U.S. Senate voted to confirm Stephen Hahn, M.D., as commissioner of the FDA. Hahn is a radiation oncology expert and most recently served as chief medical executive at the University of Texas MD Anderson Cancer Center. With underage vaping at the forefront of the Trump administration, Hahn said he is prepared to tackle the issue head on stating, "I do not want to see another generation of Americans become addicted to tobacco and nicotine and I believe we need to take aggressive action to stop that." AMCP shares Hahn's passion and commitment to ensuring the FDA drug review process remains both science-driven and patient-focused. AMCP looks forward to working with the new commissioner on many issues, including ways to increase uptake and acceptance of biosimilars and other initiatives to ensure pharmaceuticals are accessible and affordable to all Americans.

FDA Issues Draft Guidance on Interchangeable Insulin

On Nov. 25, the FDA issued draft guidance on Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. The document reverses FDA's early stance that certain comparative clinical studies, including switching studies, are needed to prove interchangeability for insulin products. The draft guidance also reflects consideration of stakeholder feedback provided at the FDA's May 2019 public hearing on this topic in which AMCP provided input on developing biosimilar and interchangeable insulin products. FDA is accepting comments on the draft guidance through

Jan. 28, 2020. AMCP is reviewing the document and plans to submit comments.

AMCP Leg/Reg Update Webinar: Wed., Jan. 22, 2020, 2pm ET

Join AMCP on Wednesday, Jan. 22, 2020, 2pm ET for an important webinar on the latest federal and state legislative/regulatory actions of interest to managed care and specialty pharmacy professionals. The webinar will keep you up to date and prepared for any potential changes that can impact your practice. For more information or to register visit, AMCP Federal and State Legislative/Regulatory Update Webinar.

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