The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

March 9, 2020

Stephen Hahn, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Re: Importation of Prescription Drugs, FDA-2019-N-5711-0001

Dear Commissioner Hahn:

The American College of Obstetricians and Gynecologists (ACOG), representing more than 60,000 physicians and partners in women's health, appreciates the opportunity to provide comments on the Food and Drug Administration (FDA) proposed rule on the importation of prescription drugs. As physicians dedicated to providing quality care to women, ACOG supports efforts to provide relief from rising prescription drug costs.

ACOG appreciates the efforts of the FDA to consider the importation of prescription drug products as a method to potentially lower drug costs and ensure patient safety and product quality, authenticity, and integrity.

ACOG has concerns, however, that the current proposal may not impact patient cost. Indeed, as noted in the FDA's regulatory analysis,[1] estimated impacts on patient savings and the market were not able to be calculated. The analysis indicates that the cost of the program may fall to the "…federal government, importation program sponsors, importers, and manufacturers of imported drugs." If changes to the current system of contracting for prescription drug products, without proper policies in place, pass additional cost to the manufacturers and the market, the disruption may ultimately result in increased costs to patients (e.g., higher premiums).

It is unclear how prescription drug products offered with a new National Drug Code (NDC) will be treated by health plans and offered to insured patients; in particular, how discounts and coupons would be applied. Simultaneous to the FDA proposed rule, CMS issued the proposed Notice of Benefit and Payment Parameters for the 2021 benefit year, which included a plan to limit how insurance companies apply coupons toward an enrollee's cost-sharing in any scenario. Currently, copayments for prescription drugs are applied to the overall out-of-pocket limit. To compete with available drug alternatives, drug manufacturers often offer coupons to reduce the copayment the individual pays for the prescription drug. If the importation of prescription drugs limits coupons and discounts, and CMS finalizes their proposal, patients may not receive the

cost-savings they are due. This outcome is inconsistent with CMS's broader efforts to reduce the costs of prescription drugs.

Patient safety is of the utmost importance, and any proposal for the importation of prescription drugs must ensure quality assurances. This is dually complex, as the necessary processes to ensure drug safety, protect from counterfeiting, and correct labeling may lead to the duplication of efforts by the US and Canada. Any proposal to allow for the importation of prescription drug products into the U.S. must ensure that all drug products are subject to reliable electronic track and trace requirements and meet all other FDA regulatory requirements regarding the authenticity and integrity of the products in question. ACOG requests that all regulatory requirements for product safety, customs and shipping, and tracking is considered in a thorough financial analysis of the proposed rule.

Prior to finalizing the proposed rule, ACOG strongly encourages the FDA to consider all of the possible implications of the rule and conduct thorough market research with a comprehensive financial impact assessment. The FDA should be confident that changes in policy will result in direct savings for patients and maintain the integrity and safety of the drug products.

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Thank you for the opportunity to comment on the Notice of Benefit and Payment Parameters for plan year 2021 proposed rule. We hope you have found our comments useful. Should you have any questions, please contact me a lsatterfield@acog.org.

Sincerely,

Lisa Satterfield, MS, MPH, CAE, CPH
Senior Director, Health Economics & Practice Management

[1] https://www.fda.gov/about-fda/economic-impact-analyses-fda-regulations/importation-prescription-drugs-proposed-rule-regulatory-impact-analysis