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AMCP Submits Comments to HHS OIG on Proposed Revisions to Safe Harbors Under Anti-Kickback Statute

AMCP late last month submitted comments to the HHS Office of Inspector General (OIG) on its Oct. 17, 2019 proposed rule to revise safe harbors under the Federal Anti-Kickback Statute (AKS) and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. In the comments letter, AMCP thanked OIG for taking steps to reform the AKS by proposing to modify certain existing safe harbors and add three proposed new safe harbors that foster better coordinated care and patient management.

However, AMCP expressed concerns that the proposed safe harbors will exclude key stakeholders from protection and limit the ability of covered stakeholders to provide meaningful value-based care. Specifically, AMCP is concerned that OIG's proposal "expressly excludes" pharmaceutical manufacturers as value-based enterprise (VBE) participants that could collaborate to achieve value-based purposes and participate in arrangements eligible for safe harbor protection.

AMCP also encouraged OIG to stand by its intent to include pharmacy benefit managers (PBMs) and pharmacists as VBE participants. PBMs should be included in recognition of the important role they play in supporting all value-based purposes described in OIG's proposal. In addition, pharmacists should be included to work with physicians and other health care providers in optimizing medication therapy and providing ideal patient-centered care.

AMCP to Comment on White House Proposal to Allow Drug Importation

AMCP is seeking member feedback for comments to the Trump administration's Dec. 18 notice of proposed rulemaking (NPRM) that would allow for the importation of certain prescription drugs from

Advocacy Tip

Stay up-to-date: Read AMCP's Letters, Statements and Analysis on all legislation and

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 In addition, the Trump administration announced the availability of a new draft guidance that describes procedures drug manufacturers can follow to facilitate importation of pharmaceuticals, including biological products, that are FDA-approved,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. Comments on the NPRM and draft guidance may be submitted to FDA through Feb. 21 and March 9, respectively. AMCP plans to submit comments consistent with the AMCP Position Statement on Prescription Drug Importation and is seeking input from AMCP members. You may provide feedback on the draft guidance by Feb. 7 and NPRM by Feb. 21 to AMCP at advocacy@amcp.org.

FDA Issues Draft Guidance on Interchangeable Insulin

Members are invited to help AMCP craft a response to recent FDA draft guidance on Clinical Immunogenicity Considerations for Biosimilar and Interchangeable Insulin Products. In the document, FDA reversed its 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 at which AMCP provided input on developing biosimilar and interchangeable insulin products. FDA is accepting comments on the draft guidance through Jan. 28. AMCP plans to submit comments and is seeking feedback from AMCP members. You may provide feedback on the draft guidance by Jan. 24 to Afton Wagner, AMCP Director of Government Relations, at awagner@amcp.org.

AMCP Thought Leadership

AMCP Invited to Participate in Pharmaceutical Quality Workshop

AMCP will participate in a Feb. 3 workshop, "Understanding How the Public Perceives and Values Pharmaceutical Quality," sponsored by the Duke Margolis Center for Health Policy, in partnership with the FDA. The workshop, taking place in Washington, D.C., will provide an opportunity to better understand how stakeholders, including patients, providers, pharmacists, drug purchasers, and payers, perceive and value the quality of pharmaceutical products. Participants will include key FDA leaders and staff who will present FDA's current thinking on a range of pharmaceutical quality issues. Topics for discussion include:

- The importance of pharmaceutical quality
- The current state of pharmaceutical quality
- FDA's role in regulating quality
- Stakeholder perceptions of pharmaceutical quality

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

Join AMCP on Wednesday, Jan. 22 at 2pm ET for a free member 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

regulation impacting managed care pharmacy.

register visit, AMCP Federal and State Legislative/Regulatory Update Webinar.

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