AMCP Signs Joint Statement Fighting Fake Medicines Bought Online

Buying prescription medicine online or through social media may appear cheap and easy, but it's critical for patients to understand the risks associated with illegal online pharmacies. In the past decade, industry experts have estimated that there are 30,000–40,000 active illegal online pharmacies operating at any given time. These pharmacies can expose patients to contaminated or counterfeit medication, while also putting customers at risk for identify theft or computer malware. On Dec. 4, AMCP joined six other pharmacy and health care organizations, in a sign-on letter calling on providers to educate their patients about safely buying medicine online. In the letter, the undersigned organizations urge pharmacists, doctors, nurses, and other healthcare providers to educate their patients on the risks of obtaining substandard and falsified medicine from social media platforms and illegal online pharmacies. The letter also urges providers to advise their patients to verify the legitimacy of a website before they purchase medications from it.

Read the full sign-on letter.

AMCP Comments on Coverage of Over-the-Counter Preventive Services

On Oct. 10, the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services issued a Request for Information (RFI)

to gather public input on the potential benefits and costs of requiring non-grandfathered health plans to cover over-the-counter (OTC) preventive items and services without cost-sharing and without a prescription. On Dec. 1, AMCP responded to the RFI with a comment letter. In the letter, AMCP shares its support for the use of OTC preventive products when medically necessary but opposes broad coverage requirements for medications that do not require a prescription. AMCP also shares concerns around the operational challenges that coverage of OTC preventive services may create, as well as the potential for fraud, waste, and abuse to proliferate when OTC products are not monitored in the same fashion as those required by prescription. AMCP's comments also support standardized communication and education around OTC preventive products.

Read AMCP's comments.

AMCP Comments on Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence

Artificial intelligence (AI) software has the potential to drastically reshape the work of managed care pharmacists, government officials, and other healthcare policy stakeholders nationwide. On Nov. 3, the Office of Management and Budget (OMB) sought public comment on a memorandum entitled "Advancing Governance, Innovation, and Risk Management for Agency Use of Artificial Intelligence (AI)". On Dec. 1, AMCP responded with comments that support OMB's efforts to safely employ and monitor the use of AI in government programs. AMCP's comments acknowledge the potential for AI to improve healthcare decision-making and advocate for the use of AI in a manner that does not contribute to health disparities. Specifically, AMCP urges OMB to require that any dataset used for rights-impacting or safety-impacting medical decisions includes sufficient representation from medically underserved populations.

View the full comment letter.

AMCP Offers Comments on Medication Guides, Patient Medication Information

On May 31, the Food and Drug Administration (FDA) unveiled a proposed rule which would amend the human prescription drug product labeling regulations for Medication Guides. The proposed rule would require applicants to create a new Medication Guide, known as Patient Medication Information (PMI), for prescription drug products, as well as for blood and blood components, used or transfused on an outpatient basis. On Nov. 27, AMCP responded with comments which commend the FDA's efforts to ensure that patients are informed about the prescription drugs and blood or blood components that they will be administered. AMCP's comments also support the FDA's suggestion that authorized providers offer PMI at patients' request in electronic format.

Read AMCP's comments.

AMCP Comments on Biosimilar Labeling Guidance

On Sept. 9, the FDA announced the availability of draft guidance entitled "Labeling for Biosimilar and Interchangeable Biosimilar Products," which outlines the agency's recommendations for biosimilar and interchangeable biosimilar product labeling. AMCP supports the FDA's principle for providing ample clarity and flexibility through the aforementioned draft guidance and responded with comments on Nov. 17. AMCP's comments specifically flag the draft guidance's biosimilarity statement for both biosimilars and interchangeable biosimilars, as well as the use of the interchangeability designation in the United States. AMCP finds that the existence of the interchangeability designation itself may create confusion for providers, especially when there is no meaningful scientific distinction between biosimilars and interchangeable biosimilars. AMCP's comments also request additional guidance on the FDA's intended use of the interchangeable designation in the future.

Read AMCP's Nov. 17 comments.