



# Managed Care Pharmacy Perspectives on Recent Legislative, Regulatory Changes

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A session at the Academy of Managed Care Pharmacy (AMCP) 2017 Nexus meeting discussed the implications of recent legislative and regulatory changes in healthcare at the federal and state levels.

Speakers Regina Grayson Benjamin, JD, BS, director of legislative affairs, and Mary Jo Carden, RPh, JD, vice president of government and pharmacy affairs, both of AMCP, acknowledged that it had been a busy year full of regulatory updates and turbulent legislative efforts. They aimed to highlight some of the most important developments and help the audience understand AMCP's positions on the issues.

Carden began by summarizing the unsuccessful efforts to repeal and replace the Affordable Care Act (ACA) and discussing President Donald Trump's recent executive orders to eliminate cost-sharing reduction subsidies to insurers and to enable the expansion of association health plans, as well as the administration's move to scale back the ACA's contraceptive mandate.

Nonetheless, HHS' draft strategic plan for 2018 to 2022 indicates that the agency will still emphasize physician-led care, promote preventive interventions, and encourage the adoption of voluntary value-based reimbursement and alternative payment models. AMCP supports these objectives, Carden said, particularly in that "we do like the idea of value-based initiatives."

Benjamin then took the podium to provide a brief refresher on the status of federal bills impacting healthcare and pharmaceuticals. The current session of Congress will draw to a close at the end of the year, so Benjamin did not anticipate the passage of many acts before then, but she highlighted several that could have a better shot in the next session, as well as some that have stalled.

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, for instance, would stimulate drug competition by facilitating the entry of new generics and biosimilars onto the market. CREATES is supported by the Campaign for Sustainable Rx Pricing, which has 37 members including AMCP, and Benjamin foresees it passing in the next session.

On the other hand, the Pharmacy & Medically Underserved Areas Enhancement Act, which would

allow pharmacists to be considered providers under Medicare Part B in underserved areas, enjoys bipartisan support but has not moved because it has not received a score from the Congressional Budget Office.

Benjamin discussed several other acts that had been introduced in the House but lack a Senate companion, such as the Lower Drug Costs Through Competition Act, which would award a priority review voucher for new generics. She finally mentioned the Medicare for All Act, which would establish a single-payer healthcare system.

“This is not expected to go anywhere,” she said to the chuckling audience. “I know, that’s a surprise.”

The next topic, presented by Carden, was the FDA regulations surrounding communications between payers and pharmaceutical companies, which she said is “becoming increasingly important.” Guidance documents released this year provided suggestions on how pharmaceutical companies can responsibly disseminate healthcare economic information (HCEI) to insurers and other decision makers.

However, AMCP had recommended that the guidance extend further to unapproved indications with intent to file, not just new molecules. According to Carden, a more open exchange of HCEI is necessary so payers can better forecast their expenses and budget their resources by understanding which populations could be affected by new therapies. She used the example of high-priced hepatitis C therapies that “took everyone by surprise” when they entered the market. Stakeholders, she argued, could have been better prepared if they had received more thorough HCEI.

After highlighting more of AMCP’s responses to various CMS requests for information on prospective rules, Carden turned to the topic of biosimilars, which she predicted “will continue to be discussed for decades.” She discussed the Supreme Court case *Amgen v Sandoz*, which settled questions on the “patent dance” and exclusivity timelines, but said several regulatory hurdles remain, especially surrounding interchangeability.

AMCP would like non-US-based switching studies to be accepted as evidence supporting interchangeability, but it supports pharmacovigilance and postmarketing surveillance. It also seeks more clarity on the naming of biosimilars, their billing and codes, and how biosimilars to proteins or hormones like insulin will be treated.

Benjamin noted that states are actually ahead of the federal government in the realm of biosimilar regulation, as they had begun legislating the drugs in 2013. She raised concerns about some states’ requirements that pharmacists must notify providers when substituting for biosimilars, which not only

consumes the pharmacist's time but could undermine trust in the safety and comparability of biosimilars.

Finally, she provided updates on the multitude of various state legislative proposals debated or passed this year, from prior authorization requirements to drug price transparency efforts to opioid prescribing regulations. "You never want to see either sausage or laws being made," she joked, but she advised the audience members to utilize resources like AMCP's website to help them better understand the complex and sometimes messy landscape of healthcare legislation and regulation.