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Susan A. Cantrell Explains the Necessity of Pre- and Post-Approval Communications

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The Academy of Managed Care Pharmacy (AMCP) is working with Congress to improve communication both in the pre- and post-approval settings between pharmaceutical companies and payers, according to Susan A. Cantrell, RPh, CAE, CEO of AMCP.

Transcript

Are there any specific policy issues that AMCP would like to see change?

One important issues that AMCP has focused on for the last year is the ability or lack thereof of manufacturers and payers to communicate in 2 specific areas.

One is in the post-approval setting when you have a product on the market that has been approved, and the ability of the manufacturers to share healthcare economic information with formulary entities and other similar groups. In particular, the payer community. That relates to a law that was passed in 1997, Section 114 of the Food and Drug Administration Modernization Act (FDAMA), for which we only recently got guidance from the FDA in January of this year. So expanding and further clarifying FDAMA 114 is very important.

Equally important to AMCP members is the ability of pharmaceutical companies to be able to in a very specific and targeted way share information 12 to 18 months in advance of a product's approval with the payer community. With, of course, appropriate guide rails in place, to ensure there's not broad dissemination. But these conversations are important because health plans are doing forecasting, they're doing budgeting, they're doing rate setting, they're submitting their cost information to CMS well in advance of the beginning of a new plan year, and as we have new innovation coming to market, and in many cases expensive innovation, the plans need to be able to plan for it.

So allowing some very targeted communication in the pre-approval setting, we as an organization and our members feel is very important. So we're working with Congress right now to hopefully craft legislation to make that happen in the near future.