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FDA Releases Guidance Documents on Communicating Clinical and Economic Information

Wednesday, January 18, 2017



The Food and Drug Administration (FDA) this week has released a series of draft guidance documents that clarify how and when different types of [clinical and economic information may be communicated](#).

“There are times when we need to answer important health, safety and efficacy questions about biopharmaceutical products, but the existing regulations are ambiguous,” said National Pharmaceutical Council Vice President for Comparative Effectiveness Research Jennifer Graff, PharmD. “The draft guidance released this week broaden the types of truthful and non-misleading information that industry can share to inform payers as they budget, make coverage decisions, and select drugs for a large number of patients. These population health decision-makers need timely clinical, and economic information to improve our health care system and patient outcomes.

“Whether this guidance will result in significant changes to biopharmaceutical communications remains to be seen. But given the need for high-quality evidence that meets good research practices, meaningful economic and clinical information that can make a difference for health care decision-making should be broadly communicated by all stakeholders,” she said.

The National Pharmaceutical Council (NPC) [has long been engaged in this issue](#), conducting peer-reviewed research and hosting conferences to identify [illustrative examples of the challenges](#) in exchanging certain types of information. In addition, NPC has been an active contributor [in identifying good research practices](#) for conducting observational and modeling studies. More recently, NPC [participated in two forums](#) hosted by the Academy of Managed Care Pharmacy that resulted in recommendations to foster the exchange of health care economic information and pre-approval information between payers and the biopharmaceutical industry.

NPC is reviewing the released guidance documents in greater detail and plans to submit comments during the FDA’s 90-day public comment period.

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