

## AMCP Praises FDA's Guidance on Communications Between Biopharmaceutical Companies and Population Health Decision Makers

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**Alexandria, Va., January 18, 2017** — The Academy of Managed Care Pharmacy (AMCP) commends the Food and Drug Administration (FDA) for its release today of draft guidance clarifying how biopharmaceutical companies and population health decision makers can proactively share clinical and economic information on both FDA approved products as well as emerging therapies awaiting FDA approval.

The draft guidance largely mirrors consensus recommendations that AMCP developed during two multi-stakeholder meetings last year on the topic. The following statement is from AMCP CEO Susan A. Cantrell, RPh, CAE:

*“We are very pleased with the FDA’s long-awaited draft guidance that gives biopharmaceutical companies clarity on how they can proactively communicate important information with entities that make health care coverage decisions for millions of Americans. Absent this guidance, existing laws had made it difficult for manufacturers to initiate sharing of any information beyond their FDA-approved labeling.*

*This guidance goes a long way toward providing clarity. It also provides assurances around the proactive exchange of information on products prior to FDA approval. Having access to information on both marketed and pipeline products will help population health decision makers design benefits that ensure patients receive the most effective and appropriate medications possible.*

*AMCP is proud to have led on this issue. Last year we hosted two multi-stakeholder meetings that resulted in consensus recommendations on the sharing of information on marketed products and on pipeline products, which we called preapproval information exchange (PIE). We are pleased that the FDA’s draft guidance largely aligns with those recommendations.”*

The FDA draft guidance, “Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers,” is available <http://bit.ly/2jnFU1O>. AMCP’s consensus recommendations were published in AMCP’s *Journal of Managed Care & Specialty Pharmacy* (JMCP). To read the recommendations on marketed products, visit <http://bit.ly/2jzMUef>, and on PIE, visit <http://bit.ly/2jjkHv>.