AMCP Releases Consensus Recommendations to Improve Sharing of HCEI Used in Pharmaceutical Coverage Decisions

PRESS RELEASE

Alexandria, Va., June 24, 2016 — The Academy of Managed Care Pharmacy (AMCP) today released a set of recommendations that would allow biopharmaceutical companies to more easily share health care economic information (HCEI) with entities that make formulary and coverage decisions, a move that addresses the growing need to determine the "value" of new medicines.

The recommendations address restrictions in the sharing of product information that does not appear on the drug label, a prohibition that hinders decision makers from accessing HCEI on new therapies.

"Effective communication of HCEI is more important than ever, as biopharmaceuticals entering the market today are highly complex and often very expensive," says AMCP Chief Executive Officer Susan A. Cantrell, RPh, CAE. "With the U.S. health care system increasingly focused on the concept of providing value, it is essential that pharmaceutical product value is accurately measured and disseminated. These recommendations are a major step forward in addressing a barrier that has prevented health care decision makers from obtaining such information."

Specifically, the recommendations seek to clarify Section 114 of the 1997 Food and Drug Administration Modernization Act (FDAMA). Section 114 serves as a regulatory safe harbor for the dissemination of HCEI to formulary decision makers, such as pharmacy and therapeutic (P&T) committees. The safe harbor is needed because HCEI typically is not included within the FDA-approved labeling, and the agency prohibits manufacturers from distributing such information unless it is specifically requested from a health care decision maker.

Section 114, however, has been little used because of ambiguity in its wording and lack of implementing guidance from the FDA. The FDA announced that it plans to release guidance this year. To help inform the FDA's current thinking on development of new guidance, AMCP held a diverse stakeholder partnership forum this spring that resulted in a series of consensus suggestions. Among them:

- HCEI includes much more than costs, and should encompass such things as health care utilization (e.g., hospitalizations, emergency department visits), patient benefits, adherence, endpoint extrapolations, quality of life, and adverse events.

- "Competent and reliable scientific evidence" — which will form the basis of HCEI — should be defined as "truthful and non-misleading tests, analyses, research, studies, models, or other evidence."
- HCEI related to a drug in the pipeline should be communicated to appropriate stakeholders 12 to 18 months prior to approval.
- "Other similar entities" that could receive HCEI besides P&T and formulary committees include health plans and integrated delivery systems that make health care decisions for patient populations, and organizations that evaluate HCEI or develop value frameworks and compendia.
- AMCP's Format for Formulary Submissions and the eDossier system is one format well suited to seek HCEI from manufacturers, but other options also exist.

The recommendations are contained in the forum proceedings, published in the July issue of AMCP's Journal of Managed Care & Specialty Pharmacy (JMCP). AMCP now will lead the development of a draft guidance document to share with the FDA. This information also will be shared with Congress as it considers legislative solutions to improve sharing of HCEI. In addition, AMCP will develop educational programing and tools for members to better understand this provision.

AMCP's March 1-2 Partnership Forum, held in Washington, D.C., included participants from managed care organizations, biopharmaceutical companies, academia, health care providers, patient advocacy groups and pharmacoeconomic experts. The event was sponsored by AbbVie, Amgen, Boehringer Ingelheim Pharmaceuticals, Merck & Co., the National Pharmaceutical Council, Pfizer, Pharmaceutical Research and Manufacturers of America, Precision for Value, Takeda Pharmaceuticals and Xcenda.