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## Pharma, MCOs, HCPs Unite to Recommend Expanding FDAMA Inclusion

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Health care stakeholders participating in the Academy of Managed Care Pharmacy (AMCP) Partnership Forum agreed on new recommendations aimed to increase utilization of Section 114 of the FDA Modernization Act of 1997 (FDAMA).

FDAMA was designed to encourage companies to share health care economic information (HCEI) to those who need it for formulary decision making. However, lack of clarity and guidance from the FDA has resulted in its underutilization.

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Forum participants, which included pharmaceutical companies, managed care organizations, academia, health care providers, and patient advocates, recommended the following to the FDA for inclusion in guidance on FDAMA Section 114.

- Dissemination of information under Section 114 should be expanded to health care decision makers beyond health plan formulary committees, including those making coverage decisions in accountable care organizations and integrated delivery networks, as well as organizations that evaluate pharmacoeconomic information or develop value frameworks and compendia.
- HCEI must be truthful and non-misleading, and be based on the expertise of professionals in the relevant area. The HCEI also must be derived and disclosed in a transparent, reproducible and accurate manner. This recommendation stems from a Section 114 requirement that a company support HCEI with "competent and reliable scientific evidence," not the stricter "substantial evidence" standard required for drug approval. The lower standard has never been fully defined.

Proceedings from the forum will be published in the July 2016 issue of *Journal of Managed Care & Specialty Pharmacy*, as well as presented to the FDA as it develops expected regulations on FDAMA 114 later this year. AMCP also hopes to share these recommendations with Members of Congress as potential legislative solutions involving pharmacoeconomic information sharing are discussed.

Susan Dentzer, incoming President and CEO of the Network for Excellence in Health Innovation, moderated the forum, which was held March 1-2 in Washington, DC.

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