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HSCA URGES FDA TO IMPLEMENT QUALITY METRICS TO MONITOR DRUG MANUFACTURING ESTABLISHMENTS, ADVANCE PRODUCT QUALITY, AND MITIGATE DRUG SHORTAGES

HSCA Files Comment Urging Both Foreign and Domestic Facilities to Provide Publicly Available Quality Metrics

Washington, DC (September 30, 2015) – The Healthcare Supply Chain Association (HSCA) announced today that it has commented on the U.S. Food and Drug Administration’s (FDA) draft guidance entitled “Request for Quality Metrics: Guidance for Industry.” The draft guidance lays out quality metrics that establishments involved in the manufacture, preparation, propagation, or processing of human drugs would be required to report to the FDA, to help the agency ensure the safety and availability of all drugs entering U.S. markets. As part of its comment, HSCA urged FDA to:

- Hold all suppliers, foreign and domestic, to the same quality standards;
- Focus on suppliers that have not been inspected or that have a history of compliance problems;
- Implement consequences for any organization manufacturing or distributing products for U.S. markets that chooses not to provide quality metrics; and
- Make quality metrics provided by manufacturers publicly available, after a grace period in which FDA reviews said metrics.

“HSCA supports FDA’s efforts to use quality metrics to monitor establishments involved in the manufacture, preparation, propagation, or processing of human drugs. By leveraging quality metrics to make critical decisions about risk-based scheduling and prediction of drug shortages, FDA will advance product quality and quality manufacturing facilities, and mitigate threats that could put patients, providers, and the broader healthcare market in jeopardy,” said HSCA President and CEO Todd Ebert, R.Ph., in the comment.

HSCA and its member group purchasing organizations (GPO) are crucial cost-savings engines for America's hospitals, clinics, nursing homes, and surgery centers. HSCA and its members are committed to lowering costs and increasing competition and innovation in the healthcare marketplace.

For the full text of HSCA’s comments, [click here](#).

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About the Healthcare Supply Chain Association (HSCA)

The Healthcare Supply Chain Association (HSCA) represents the nation’s leading healthcare group purchasing organizations (GPOs), which are critical cost-savings partners to America’s hospitals, nursing homes, nursing home pharmacies, clinics, home healthcare providers and surgery centers. GPOs deliver billions in savings annually to healthcare providers, Medicare and Medicaid, and taxpayers. HSCA and its member GPOs are committed to delivering the best products at the best value to healthcare providers, to increasing competition and innovation in the market, and to being supply chain leaders in transparency and accountability. For more information, visit www.supplychainassociation.org. Follow HSCA on Twitter [@HSCA](https://twitter.com/HSCA).