DATE: January 17, 2014
TO: State Wholesale Drug Distributor Licensing Authorities
CC: NABP and FDA
FROM: HDMA State Government Affairs Department
SUBJECT: H.R. 3204, The Drug Quality and Security Act

HDMA and its primary pharmaceutical distributor members applaud Congress and the President for recently enacting H.R. 3204, The Drug Quality and Security Act, which establishes a national, uniform solution to ensure a safer and more secure pharmaceutical supply chain. The President signed H.R. 3204 on November 27, 2013, becoming Public Law 113-54.

For nearly a decade, primary pharmaceutical distributors have advocated for a single, federal framework to trace prescription medicines throughout the supply chain. The previous 50-state patchwork of rules and regulations is now replaced with one federal traceability solution that will ensure regulatory clarity and consistency, help prevent counterfeits, discourage gray market activities, and further enhance the safety and efficiency of the supply chain for all Americans.

Upon enactment of H.R. 3204 state pedigree requirements are preempted and current federal Prescription Drug Marketing Act (PDMA) requirements remain in effect until January 1, 2015. Specifically, PDMA requires distributors who are not authorized by the manufacturer to handle and sell their products to pass pedigrees that include information regarding transactions going back to either the manufacturer or the last authorized distributor of record that handled the drugs. In 2015, the legislation’s enhanced product tracing requirements begin, eventually resulting in one set of federal electronic unit level product tracing standards in ten years.

In addition to the traceability requirements, HDMA has supported the enhanced licensing provisions contained in H.R. 3204 in the almost 30 state bills and regulations that have been enacted throughout the country over the last ten years. Having strong, consistent distributor licensing is a critical component in ensuring that criminals do not infiltrate the supply chain and gain access to prescription medicines. These include, among others:

- Storage, handling and facility requirements;
- Surety bonds;
- Background checks for key personnel; and,
- Stronger penalties for felons, repeat violations, etc.
Until these new federal licensure standards are promulgated by FDA, the status quo will be maintained with respect to existing state wholesale distributor licensure requirements. HDMA distributor members have made significant changes in the last ten years and are devoted to a business model that maintains the safety and integrity of the prescription drug products that patients depend on for their health and well-being.

Again, HDMA and our distributor members are committed to a secure prescription drug supply chain and we look forward to working with both the individual states and FDA as we go through the federal and state regulatory process in the next two years.

If you have any additional questions or would like more information, please contact Daniel Bellingham at 703-885-0236 or dbellingham@hdmanet.org.