March 6, 2012

The Honorable John Carney
United States House of Representatives
1429 Longworth House Office Building
Washington, DC 20515

Dear Congressman Carney:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) wishes to express support for H.R. 3839, the Drug Shortage Prevention Act of 2012.

Your bill would help address the issues leading to shortages of life-saving medications and provide the Food and Drug Administration (FDA) with additional authority and information that will assist in preventing or resolving further shortages in the future. This legislation, particularly when coupled with an improved early warning system for disruptions in the drug supply, would be a significant step in ensuring that members of the supply chain receive useful information related to drug shortages.

The growing number of drug shortages present serious challenges to hospitals and patients. The number of drugs in critically short supply is increasing at an alarming rate and threatens quality of care in hospitals nationwide. Many of these drugs play a critical role in life-saving treatments, including cancer therapies, widely used anesthetics, antimicrobials, nutritional supplements and pain medications. In many cases, therapeutic alternatives are not available or carry increased risk of side effects and drug-to-drug interactions. The potential harm to patient safety is of paramount concern.

The creation of a critical drug list would be useful to identify medically necessary drugs that are susceptible to shortage, allowing the FDA to work with manufacturers, distributors and others in the supply chain to address vulnerabilities. We would urge the FDA to update the list more frequently than semi-annually given frequently changing conditions.
An improved national critical drug shortage list would help establish predictability in the supply chain, especially if additional information about severity, duration, reason for the shortage, and estimated time for resolution were made available to those in the supply chain. The requirement that this list also identify alternative therapies would be useful for clinicians as they evaluate care alternatives to drugs in short supply.

We also support provisions requiring improved communication and coordination between the FDA and the Attorney General regarding increasing production quotas on controlled substances related to drugs in shortage. Such coordination will help prevent or expedite the resolution of shortages of certain drugs.

Thank you for your leadership on this issue. We look forward to working with your office and other stakeholders toward passage of this legislation.

Sincerely,

Rick Pollack
Executive Vice President