

Statement by Blair Childs, senior vice president of Public Affairs, on legislation to require implementation of Unique Device Identification

Members of the Premier alliance applaud Senators Jeff Merkley (D-OR), Michael Bennett (D-CO), Charles Grassley (R-IA) and Herb Kohl (D-WI) for introducing legislation that would require implementation of a Unique Device Identification (UDI) system for medical devices.

UDI is the missing link to protect patient safety. Enabling healthcare providers to track medical devices electronically in the supply chain will improve the speed and accuracy of product recalls, as well as adverse event reporting. In addition to these important safety benefits, automating the now manual process of tracking of medical devices is projected to save the healthcare industry approximately \$16 billion each year from greatly improved efficiencies.

Although the law requiring UDI was passed nearly five years ago with broad support from hospitals, doctors, consumer groups and patient advocates, it has been awaiting approval from the Office of Management and Budget (OMB) for more than six months. Despite urging from industry requesting that UDI be fast-tracked in the approval process, no action has been taken. While OMB delays, patients continue to face the real risks of a flawed recall or an adverse event even though a better system exists and is ready for implementation today.

It is essential that UDI regulations move out of the OMB and into implementation immediately. Electronic tracking systems are commonplace in other industries, and have been in place since the 1970s. Today, we can recall tainted dog food using standardized bar codes faster than we can medical devices, including those that are implanted in patients. It's time for healthcare to join the 21st Century with a fully functioning UDI system.