MICHIGAN HEALTH & HOSPITAL ASSOCIATION

Advocating for hospitals and the patients they serve.

TO: Members of the Senate Health Policy Committee

FROM: Chris Mitchell, Manager, Government Relations

DATE: June 10, 2009

SUBJECT: Senate Bill 528 – Reuse of Medical Devices Intended for Single-Use

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The Michigan Health & Hospital Association (MHA) supports Senate Bill (SB) 528, which would prohibit a health care professional from reusing medical devices that are intended for single use and would provide for criminal penalties. The legislation also includes a provision to allow hospitals and health care providers to reprocess medical devices that are labeled "single-use only," in accordance with federal regulations set forth by the U.S. Food and Drug Administration (FDA). **Hospitals currently reprocess and reuse over 100 devices labeled for single use within federal guidelines set and tightly regulated by the FDA. These items are effectively re-utilized after cleaning, sterilization and testing which must demonstrate functional performance equivalent to the original device before they can return to the hospital they come from. By properly and safely sterilizing and reprocessing these devices, hospitals can reduce both medical equipment costs and hazardous waste.**

There are thousands of medical devices which are intended for and currently used in hospitals one time and then properly discarded. Throughout the years, more and more manufacturers of medical devices have been labeled "single-use only". It became apparent that the "single-use" label was often motivated by economic objectives as opposed to patient safety concerns. At this time the health care community began to search for avenues to safely and efficiently reprocess some medical devices for reuse.

In 2001, the FDA began regulating the practice of reprocessing and reusing medical devices. Ultimately with assistance from the U.S. Government Accountability Office, the FDA reported that there is no evidence that reprocessed single-use devices create an elevated health risk to patients. In all, the reprocessed devices account for 2 percent of all medical equipment labeled for single use.

The types of devices that are deemed reusable by the FDA but labeled for single-use include Blood Pressure Cuffs, Oxygen Masks, Saw Blades (used to cut hard or soft tissue or bone during surgery), Laparoscopic Scissors/Shears (Used during general and OB/GYN surgery). Every single one of these devices is tested during reprocessing which may create a safer practice as each individual piece of equipment is tested in the process, versus the sampling and spot-checking by new equipment manufacturers.

Please contact Chris Mitchell (cmitchell@mha.org) at (517) 703-8622 at the MHA if you have further questions on this issue.

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