To: AMDR Members
From: Daniel J. Vukelich, Esq., President
Re: Informed Consent – State Legislative Update
Date: September 1, 2010

No state requires hospitals to obtain a patient's informed consent when using reprocessed medical devices. As you are no doubt aware, over the last several years, some original equipment manufacturers (OEMs) orchestrated a number of bills at the state legislative level proposing to require hospitals to obtain a patient's informed consent (among other things) prior to use of a reprocessed device. To date, every state that has considered such legislation promoted by the OEMs has rejected it.

Recently, AMDR has received reports from its member-companies of false information disseminated by OEM sales representatives to hospital personnel on the subject of medical device reprocessing and state informed consent legislation. The sheer number and consistency of these reports indicates to AMDR that, yet again, there is likely some concerted effort on the part of OEMs and/or OEM sales reps to discourage the use of reprocessed devices (and therefore promote the use of OEM equipment). Specifically, these OEM sales reps may attempt to instill fear and doubt about medical device reprocessing by disseminating false and/or misleading information about alleged state-level informed consent (among other) requirements for reprocessed devices. As always, the medical device reprocessing industry is confident that, when presented with the facts, hospitals will continue to choose safe, FDA-regulated, reprocessed medical devices over the rumor, innuendo and unsubstantiated fear campaign espoused by the OEMs.

The informed consent process is defined by FDA regulation (21 CFR Part 50) as a means of informing patients of the use of investigational and/or experimental devices. Under the federal Food, Drug and Cosmetics Act (FDCA), reprocessed devices are subject to FDA's premarket clearance or approval requirements (FDA Guidance of 2000) (among other requirements) and, once cleared or approved, reprocessed devices therefore are NOT investigational or experimental nor is informed consent required under FDA regulations. Reprocessed devices are "substantially equivalent" to new devices.

Because reprocessors are held to the same requirements as all other device manufacturers (FDA Guidance of 2000) and FDA has stated that it believes reprocessed devices to be "as safe and effective as [a] new device," (Testimony of Dr. Daniel Schultz, Director, CDRH, FDA (September 26, 2006)) AMDR believes that the OEM "patient consent" campaign is nothing more than a marketing ploy by OEMs to discourage the use of reprocessed devices (and therefore bolster sales of original equipment). Patient consent for devices that have been cleared or approved by FDA would only serve to confuse patients by inappropriately implying that reprocessed devices are less safe than original equipment.

We do not foresee any changes to informed consent requirements for reprocessed devices.

Please feel free to make this information available to your field teams and to your hospital customers that have encountered OEM sales reps with "updates" on alleged state legislation. AMDR encourages hospitals to take strong measures to reprimand and/or bar any sales representatives who disseminate false or misleading information about lawful, FDA-regulated reprocessed products. If AMDR can be of any additional assistance on these matters, please do not hesitate to contact me at DVukelich@AMDR.org or at 202.518.6796. Thank you.