AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Transparency, Informed Consent, and Reprocessed Devices

Overview

No state requires hospitals to obtain a patient's informed consent when using FDA-regulated reprocessed single-use medical devices. As you may be aware, in recent 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.

Background

AMDR has received reports of false information disseminated by some OEM sales representatives to hospital personnel on the subject of single-use device reprocessing and state informed consent legislation. 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 some 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 are deemed to be "substantially equivalent" to new devices. Thus, reprocessed devices are NOT investigational or experimental and informed consent is NOT required under FDA regulations.

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)). 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.

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.

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