

Critical Questions Surrounding Rental Equipment

How important is quality when it comes to moveable medical equipment (MME), specialty beds and other rental equipment? Over the past two years, the Food and Drug Administration (FDA) had been considering creating entirely new quality management regulations for medical device service providers. Today, third-party providers are not required to adhere to the same high-level, nationally-recognized quality and patient safety standards as manufacturers — a gap that is shockingly unknown.

Although no additional regulations have been implemented yet, the FDA's heightened focus in this area confirms that the quality of rental equipment — and how they are serviced — is worth monitoring. In fact, while many assume that patient incidents are few and far between, studies show that during a four-year period the FDA received 56,000 reports* of adverse events associated with infusion pumps alone. From a healthcare perspective, it is imperative to take steps to reduce that risk by ensuring that any rental equipment in their facility is maintained according to the same stringent quality standards applied to OEMs. Few MME and bed rental providers voluntarily adhere to these standards, so it's critical to monitor the level of quality being introduced to your hospital.

* 2010 FDA Whitepaper: Infusion Pump Initiative



Protect Your Patients & Your Reputation by Asking Your Rental Provider These Questions



Do you purchase used equipment? If so, do you have a full service and maintenance history of the purchased equipment?



Do you substitute non-OEM replacement parts for your equipment? If so, can you supply evidence that you've validated their compatibility?



Do you follow the OEM instructions and preventive maintenance schedule for all the equipment you provide?



If there is a problem with a substituted non-OEM replacement part (malfunctions, recalls), do you offer traceability back to the serial number of the affected device?



Do you have documentation of ownership and prior service history for any used equipment you rent? Are these records open for inspection?



Are technicians with OEM certifications and two-year associate degrees (minimum) in electronics or medical device fields servicing all used equipment?



Do your technicians receive on-going clinical engineering training for a minimum of 20 hours per year?