

Healthcare Regulatory Compliance Perspective on the UCLA ‘Superbug’ Outbreak



From a compliance perspective, watching the events

unfold at UCLA raises several concerns. Although the media seem to be more broadly covering this story now, the issues involved are not new. The difficulties in decontaminating the specific medical device in question – actually a specialized type of endoscope called a duodenoscope, which is used in over half a million medical procedures annually – have been well-known for years. Outbreaks of infections linked to its use have been documented as far back as 2012.

As healthcare regulatory compliance lawyers and consultants, in light of the fact that many of the associated risks were already public knowledge, we are interested in what procedures and safeguards were put into place preemptively by healthcare facilities to ensure the proper disinfecting of this type of endoscope post-procedure. Are healthcare facilities sitting back and assuming that, if the problem were sufficiently serious, the FDA would have issued a warning prior to the one it issued only today? Are users of potentially dangerous medical devices simply waiting for the manufacturer to issue revised instructions on proper sterilization? Or, alternatively, are healthcare providers taking proactive steps to mitigate risk without waiting to rely on governmental or private sector guidance?

The aftermath of the UCLA outbreak will inevitably involve plenty of finger-pointing among private sector parties from manufacturers to public agencies (the FDA and CDC) to healthcare providers themselves. The public is going to be demanding more accountability of all of these players and it will be interesting to see where the public's wrath is most closely directed.

From a takeaway perspective, this incident should underscore to all healthcare providers that they cannot afford to wait reactively for medical device manufacturers or the government to issue marching orders. Getting out in front of potential compliance risks before problems and potential liability arises is a must.

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