



Supporting Documentation
On Reuse Practices

Illinois halts the reuse of single-use devices

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New law exempts most facilities, however

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Illinois became the latest state in the union to regulate the reuse of single-use devices but exemptions to the law may weaken its impact.

On Jan. 1, 1998, hospitals and other health care facilities will no longer be able to re-

process single-use devices unless they satisfy certain requirements. They must either use federally registered commercial reprocessors or be qualified under specific state licensing measures.

Illinois state Senator Evelyn Bowles (D-Edwardsville) drafted and introduced the bill after reading a story in the *St. Louis Post-Dispatch* on the reuse of single-use medical devices.

"When I saw that they (doctors) were reusing single-use medical devices, I couldn't believe my eyes," Bowles told *Healthcare Purchasing News*. "I immediately phoned the FDA to find out if they were aware of this and they said they were. But to my knowledge, they have yet to establish any regulations on it."

After the state legislature unanimously approved the bill, Gov. Jim Edgar signed it into law on Aug. 15.

"When this thing hit the floor, it hit like a bomb," Bowles said. "The reaction I got from people in the legislature was 'That is crazy!'"

The law specifically prohibits the reuse of certain devices marketed or sold as disposable or single-use items, such as cardiac catheters, angioplasty balloon catheters and arthroscopic knee surgery blades. "No person shall knowingly reuse,

recycle or refurbish for reuse, or provide for reuse of a single-use surgical device," the law stated. The legislature passed the measure "to avoid risk of infection from improper sterilization or risk of mechanical failure posed by subsequent use."

More bark than bite?

But the new law may not have the bite to go along with the bark. That's because it does not apply to those facilities who use commercial or third-party reprocessors registered with the FDA, and those hospitals that are licensed under

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the Illinois Hospital Licensing Act and University of Illinois Hospital Licensing Act.

However, "you cannot run a hospital in the state of Illinois unless you are licensed under the Illinois Hospital Licensing Act," said David Harris, vice president of government relations at the Illinois Hospital and Healthsystems Association, Naperville, IL. The University of Illinois is registered under a separate license.

The two licensing acts cover roughly 98% of Illinois hospitals, except those run by the federal government, according to Harris.

Because nearly every facility in the state is exempt from the law, some industry observers are scratching their heads.

"I'm not so sure that this law will have any effect on the industry," said Janet Schultz, R.N., president of Jan Schultz & Associates, Allison Park, PA. "[Many of] the individual hospitals that are reprocessing single-use devices are exempt."

Bowles told HPN that in order to pass the law, the legislature had to make certain concessions. The intent of the law was to get something on the books that could serve as a blueprint for other states to follow and ultimately stop the practice of reusing single-use items, she added.

In fact, a few states are already pursuing legal action, including Texas, Ohio, New Jersey and the District of Columbia, according to the Washington-based Health Industry Manufacturers Association. One industry observer noted that even if other state laws are enacted, they most likely will fail to change what is becoming a standard practice in hospitals anyway.

"It would be hard to enforce such a

law," said Anne Booth, principal consultant at Barrington, IL-based Booth & Associates. "The doctors are never going to tell you if they're reusing single-use devices, and the manufacturers of single-use devices aren't telling anyone how to reprocess them."

HIMA takes action

Meanwhile, HIMA submitted a citizen petition to the FDA Sept. 5, urging the federal agency to require all commercial reprocessors to comply with FDA policies on medical device manufacturing.

Those policies include premarket notification approval, good manufacturing practices, device labeling and medical device reporting.

"Although FDA has recognized that commercial reprocessors are device manufacturers, the agency currently does not require commercial reprocessors to comply with many of the regulations that apply to original device manufacturers," HIMA stated in its petition.

HIMA pointed out that the FDA's recently published quality system regulations acknowledged that many types of commercial reprocessors, including "servicers" and "refurbishers," fall outside the control of the original equipment manufacturers, but they perform functions that meet the definition of a manufacturer.

The underlying motivation behind HIMA's petition is to protect manufacturers from being unjustly named in lawsuits filed by patients who suffered injuries allegedly from reprocessed devices.

"It is unreasonable for FDA's policy to place the original manufacturer at risk of these types of actions when the manufacturer has no control over the subsequent reprocessing of the device once it is sold to a distributor or end user and when the manufacturer has no assurance that FDA is making sure that the reprocessing is done in a safe and effective manner," HIMA noted. In addition, the manufacturer should not be held liable if a device labeled as single-use only is reprocessed.

Specifically, the FDA should regulate the cleaning and sterilization techniques of commercial reprocessors, according to HIMA. That includes using the right chemicals in the proper manner, tracking the number of reprocessing cycles and setting a limit and identifying when devices deteriorate so they can be discarded. ■