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HCFA cuts coverage of reprocessed single-use devices

The Health Care Financing Administration (HCFA) has announced that it will no longer cover the use of reprocessed single-use devices under Medicare, the US federal healthplan for the elderly.

The decision, which could throw hospitals and medical device reprocessors into turmoil, was disclosed in a September 8 letter to Josephine Torrente, an attorney for Hyman Phelps & McNamara, who is also the president of the Association of Disposable Medical Device Manufacturers.

Ms Torrente had asked HCFA to clarify its policy following a July 9 FDA letter which declared that third-party reprocessing of devices labelled for single use was unlawful unless those engaged in the practice complied with all regulatory requirements, including filing a 510(k) with the agency.

The FDA said, however, it would exercise regulatory discretion until it comes forward with a new proposal in October covering reprocessing. But HCFA does not have such regulatory flexibility. It requires that devices be approved by the FDA in order to be eligible for coverage under Medicare. In the past HCFA has agreed to cover reprocessed disposables because it assumed they were lawful under FDA statutes, regulations and policy guidelines.

Now the FDA's new statement puts a different light on the matter, Grant Bagley, director of HCFA's coverage and analysis group, acknowledged in the letter to Ms Torrente. If the FDA's current position is that the reprocessing of single-use medical devices is unlawful without premarket notification, these devices will not be covered under Medicare, he told Ms Torrente.

American Hospital Association (AHA) officials readily admit that millions of single-use devices are reprocessed each day in hospitals and clinics as a cost-saving measure. Spokeswoman Dionne Dougall said the organisation is still reviewing HCFA's letter to see what implications it may have for hospitals, particularly as the FDA is poised to issue additional guidance.

Meanwhile, the AHA and the American Society for Healthcare Central Service Professionals (ASHCSP) have announced their support for increased funding for FDA oversight of reused single-use devices. The FDA's budget is contained in the Agriculture Appropriations bill. The Senate's version of the legislation includes an amendment by Senator Richard Durbin which provides the FDA with \$1 million for the premarket review, enforcement and oversight

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of reprocessed disposables. In a September 13 letter to Congress, AHA executive vice-president Rick Pollack and ASHCSP president Jean Hodge said the appropriation will help restore the public's confidence in reuse. Before the AHA's key endorsement, supporters had been uncertain whether House and Senate conferees would retain the Durbin amendment in a final version of the farm bill.

The two hospital groups did call for some minor language modifications in the amendment to clarify that the appropriated funds be used for oversight of reprocessed single-use medical devices, rather than reprocessed products intended for multiple use. The revised language would also permit a device that has not been used on a patient but whose packaging has been opened to be resterilised and not subject to this amendment, the two association heads added.

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