



SWEDISH MEDICAL CENTER

747 Broadway Seattle, WA 98122-4307
(206) 386-6004

I represent Swedish Medical Center in Seattle, Washington, a multi-campus not-for-profit teaching medical center with more than 4,000 employees. Our volume of more than 5,000 infant deliveries and 32,000 surgeries a year requires the support of a very active sterile processing department. Despite all the advantages offered by a large medical center, the current economic constraints placed on us by the Balanced Budget Act, third-party insurance companies, and health care consumers in the United States preclude us from having the resources to develop a 510K premarket validation study for every item and brand for reprocessing. As stated during the teleconference by the representative from ECRI, I believe this is cost prohibitive for the vast majority of medical centers. I propose that a partnership emerge between the FDA; medical centers; and industry promoting the publication of cleaning techniques, functional integrity checks, packaging, sterilization and labeling. If a medical center documents that it is meeting these standards, then patient safety and quality of care with respect to this particular item would be assured. To inspect this process, the FDA can provide education to and partner with JCAHO, state health departments and other inspecting or accrediting agencies teaching them how to more thoroughly inspect sterile processing and central service departments. I understand that the goal of this meeting is to discuss the reprocessing of single-use devices. I must admit that my agenda is larger. I have had the pleasure of inspecting many of the third-party commercial reprocessors in the United States and medical center central service departments. It is my opinion that third-party reprocessors often do a superior job reprocessing "single-use" items than most health care facilities perform on equipment designed to be reused. My goal is improved patient care. I believe promotion of improved published standards and increased inspection can cost effectively raise the standard on the reprocessing of all equipment.

I would caution us all in our proposals to HCFA in regards to reimbursement. The health care industry has been asked to reduce the cost of health care. Sweeping decisions suggesting to HCFA that reimbursement should be denied to a hospital – even if an item is safely reprocessed – because a large volume of paperwork is not submitted by each hospital, is contrary to our national needs. What we need is the cost-effective advancement of scientific data to provide the highest quality, best value patient care.

Presenter:

Will Shelton, M(ASCP), CIC
Manager, Department of Epidemiology
Swedish Medical Center
747 Broadway
Seattle, WA 98122-4307
Work phone (206)386-2054

99N.4491

C 64