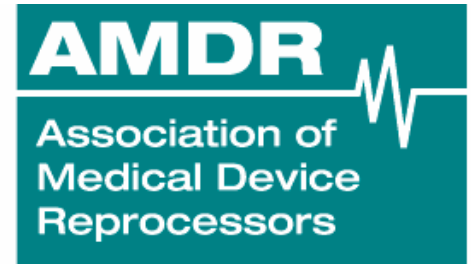


2007 Annual Report ***Reprocessing Industry Update***



2007 has been an exceptionally busy year for the third-party reprocessing (TPR) industry. AMDR was actively involved in the 2007 reauthorization of the federal Medical Device User Fee and Modernization Act (MDUFMA) legislation, fought an unprecedented six OEM-sponsored anti-reprocessing bills, in three states, and, in a first for the industry, the Commonwealth of Virginia considered a pro-reprocessing bill. Below is a brief summary of the major issues faced by the reprocessing industry in 2007.

Federal Legislation

Already dubbed the biggest FDA reform in a decade, the House and Senate overwhelmingly passed the FDA Amendments Act of 2007 in early September. President Bush signed the legislation on September 27. The legislation allows FDA to continue to collect fees from original equipment manufacturers (OEMs) and reprocessors for use by FDA in reviewing premarket submissions for products from industry (reauthorizing the MDUFMA legislation).

While reprocessing certainly was not the focus of the legislation, one provision, added by Rep. Timothy Murphy (R-PA), captured TPR. The Government Accountability Office (GAO) is to investigate several possible causes of hospital-based infections. One possible cause to be investigated is TPR. AMDR believes this issue will be addressed in the forthcoming GAO report (see below), expected for release in January. If not, AMDR believes the GAO will discover what America's top medical institutions already know – that reprocessed medical devices pose no greater risk of infection to patients than original equipment.

Another provision of the legislation mandates that all medical device manufacturers label their products with a unique device identifier (UDI). The goal is to provide hospitals with a universal tracking system for all devices in case of recall, among other things. FDA is to implement UDI, and AMDR anticipates that this will take several years. Of note, unlike OEMs, reprocessed medical devices are already 100 percent traceable.

GAO Report

The long anticipated report from GAO on reprocessing is now scheduled to be released in January, 2008. Requested by House Government Reform Committee Chairman Henry Waxman (D-CA) and ranking member Tom Davis (R-VA), the report is expected to evaluate the safety of reprocessing and adequacy of FDA's oversight. Throughout 2007, AMDR has been cooperating with GAO investigators, including facilitating a tour through one of its member's plants.

CMS

In the summer of 2007, hospital inspection officials from the Massachusetts Department of Public Health (DPH) notified at least one Boston-area hospital that the state would be penalizing the hospital for not obtaining patients' informed consent prior to using reprocessed devices. DPH attempted to enforce an informed consent requirement, relying, apparently, on an "official policy" from the federal Center for Medicare and Medicaid Services (CMS). In fact, no such policy exists. AMDR worked swiftly with both federal and regional CMS and DPH officials to resolve the confusion, and prevent Massachusetts hospitals from taking such action. AMDR suspects these efforts to enforce non-existing regulations were instigated by the OEMs.

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State Legislation

Massachusetts

On September 26, 2007, AMDR testified before the Massachusetts Joint Committee on Public Health in opposition to SB 1338, a bill sponsored by medical device manufacturers in Massachusetts that requires a patient provide his or her informed consent prior to a reprocessed medical device being used during the patient's procedure. Joining AMDR in opposing the legislation, were representatives from the Massachusetts Hospital Association, Lahey Clinic, and Healthcare Without Harm. The Massachusetts Medical Society, Massachusetts Organization of Nurse Executives, and Massachusetts Association of Orthopedic Surgeons also submitted testimony in opposition to the legislation. Medical device manufacturer Smith & Nephew testified in favor of the bill. To advance the legislation, the Committee will need to favorably recommend the bill to the Health Care Finance Committee by March, 2008.

New Jersey

Three anti-reprocessing bills, all promoted by the OEMs, are pending before the New Jersey legislature. Due, in part, to the strong support of the New Jersey Hospital Association, no formal action has been taken to advance any of the bills. The New Jersey legislature's session adjourns the first week of January 2008. If no action is taken on the bills by that date, the legislation will die in committee.

Rhode Island

Rhode Island bill S2607 was yet another state bill proposing to require a patient's informed consent prior to the use of a reprocessed medical device. The bill died August 30, 2007 when the Rhode Island legislature formally adjourned without taking action on the legislation.

Virginia

In January 2007, Virginia State Delegate Mark Sickles introduced HB 2815, a bill to promote and require Virginia health care facilities to consider third-party reprocessed devices, and to restrict anti-reprocessing language from OEM contracts within the state. On January 31, 2007, AMDR testified before the Virginia House Committee on Health, Welfare and Institutions in support of the bill. Ultimately, the bill did not garner enough votes for passage.

AMDR Outreach

Association for Professionals in Infection Control and Epidemiology (APIC)

APIC issued a position statement supporting third-party reprocessing in September, 2007. The statement strongly supports the current standards utilized by AMDR members for the cleaning and sterilization of medical devices, and endorses existing FDA regulation of the practice.

Association of periOperative Registered Nurses (AORN)

AORN approved an AMDR educational program on third-party reprocessing. AMDR hopes to coordinate with AORN to conduct these continuing education credit courses in 2008 and beyond.

Health Care Without Harm & Hospitals for a Healthy Environment (H2E)

Health Care Without Harm, parent organization for H2E, has renewed its support for FDA-regulated third-party reprocessing. Additional information on third-party reprocessing should be available on the environmental groups' websites by January, 2008. Both organizations opposed anti-reprocessing legislation in Massachusetts.