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April 27 1998

Dockets Management Branch (HFA-305)  
Food & Drug Administration, Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20857

Re: **Docket Number 97N-0477**

Dear Sirs,

The Food and Drug Administration has announced its intention to review and, as necessary, to revise or to amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices and the persons who refurbish, recondition, rebuild, service, or remarket such devices.

In the Advance Notice of Proposed Rulemaking published in the Federal Register Volume 62, Number 246, responses are requested to four questions. This response is submitted by the Michigan Society for Clinical Engineering (MSCE). We are a statewide, non-profit organization, whose purposes include promoting the professional development of its members and advancing the development of excellence in hospital and related health care facilities. We currently represent approximately three hundred members in sixty six hospitals in the southeast Michigan and Northern Ohio areas.

We wish to make a clear and emphatic distinction between remarketers and servicers. Remarketers are businesses involved in acquiring and reselling devices. Servicers are either in-house staff or outside staff that maintain equipment in active clinical use for an equipment owner.

The members of MSCE are technicians and engineers involved in servicing medical devices. They have from two to six years of formal education in addition to many years of experience in the field. Many are certified by the International Certification Commission. They exhibit a high degree of professionalism, exercise high ethical standards and are exceeding aware of the risks and consequences involved in the application of medical devices on patients. They take their work very seriously and understand the obligation to provide services that ensure patient safety. Their cautious and conservative approach to repair and inspections, if anything, errs on the side of over testing for safety.

97N-0477

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It is important that high visibility, singular events with extreme drama and impact, such as the 1993 fatal fire in a New York hospital not be used as a justification for triggering regulation, especially since no medical devices or device servicing issues were involved in this tragic event.

The implementation of the Safe Medical Device Act of 1990 has given us first hand experience with new governmental regulations. Those regulations have imposed a significant administrative and financial burden for healthcare institutions and the FDA with little demonstrated benefit. A sampling technique requiring less resources is being developed to collect device problem reports. This process will be of higher quality and less of a burden than the current universal participation.

Specific Questions :

- (1) Has the FDA appropriately defined the terms “refurbisher”, “as is”, “remarketers”, and “servicers”? If not, what changes to those definitions should be made?

The MSCE declines to suggest revisions for most of the definitions, however, the MSCE suggests a definition for servicers as follows:

Persons who repair a device to return it to a published fitness for use specification, and perform scheduled maintenance. Servicers do not significantly change the device’s performance or safety specifications or intended use, and do not perform services for the purpose of resale or redistribution.

Under this definition, servicers are not involved in remarketing activities.

- (2) What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of remarketing? Specific examples should be submitted.

The MSCE ad hoc committee that drafted this response consisted of nine people with a total of 154 years of experience in the field of clinical engineering. We have not previously tracked injuries caused by remarketed devices per se. We also have no evidence of actual problems related to their safety and/or performance that would suggest we ought to track them.

**We requested information from our members and hospitals. From the service records of eight institutions with a total of 4,249 patient beds and 89,351 medical devices, we found that over the last two full years we completed a total of 159, 221 service events. We found no instances where servicer error resulted in any patient incident, and there were no instances of patient injury or death related to servicer error.**

The FDA has been collecting results from the SMDA reports for many years. We suggest a careful review of the SMDA data for examples of injuries caused by servicing events and report the results to the medical equipment community so that we may address any underlying issues.

(3) What is the appropriate level of regulatory controls that should be applied to persons who remarket devices?

We believe that two levels of regulatory controls are appropriate.

- We suggest that **refurbishers, rebuilders, and reconditioners** should comply with the minimum list of regulations described in section V. of the ANPR. They should also be required to notify the original equipment manufacturer, if available, of the new owner at the time of sale. If the OEM is unavailable or unknown, the “As is” remarketer should notify the FDA
- We suggest "**As is**" **remarketers** should be required to notify the original equipment manufacturer, if available, of the new owner at the time of sale. If the OEM is unavailable or unknown, the “As is” remarketer should notify the FDA. This will allow the OEM to comply with notification and recall provisions of Section 518.

(4) Should refurbishers, “as is” remarketers, and servicers be subject to the same or different regulatory requirements?

As explained in the response to question 3 above, there need to be different regulatory requirements for different groups. Because **servicers** do not remarket devices, we suggest that no regulatory controls are justified or needed. Instead, the widely respected and universally accepted voluntary accreditation standards such as JCAHO, AOA, or ISO 9000 can be utilized for servicers of medical devices.

**In conclusion, the Michigan Society for Clinical Engineering wishes to emphasize several points:**

There is no evidence that servicers of medical equipment contribute to the risk of injury to patients. However, there is universal agreement that operator error is the most significant contribution to patient injury.

Servicers are not remarketers and should be treated much differently because of their significantly different role in medical device support.

Most healthcare institutions are accredited by complying with voluntary standards promulgated by the JCAHO, the AOA, and others. These standards require quality processes, continuous performance improvement, and measured performance indicators. JCAHO also requires evidence of competency of all employees, servicers and users. Compliance with voluntary standards is a highly effective motivational tool for healthcare institutions since it is publicly available and used by insurers, Medicare, Medicaid, and other Healthcare Financing Administration programs for reimbursement. All entities providing service to medical devices are required by the healthcare institution to comply with the standard.

There is no evidence that additional regulation of servicers will contribute to improved patient safety or patient outcomes. We expect that an analysis required by the GAO and the OMB of the economic impact of any proposed regulations will validate our recommendations.

We welcome the opportunity to provide technical input and additional information for the FDA as this process continues.

Sincerely yours,

A handwritten signature in cursive script that reads "Nicholas Mason".

Nicholas Mason, President  
Michigan Society for Clinical Engineering

T. Bauld

Draft 2/19/98