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April 11, 2000

Documents Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
Room 1061 (HFA-305)
5630 Fishers Lane
Rockville Maryland 20852

Re: Docket No. 00D-0053

Dear Sir/Madam:

The Healthcare Association of New York State (HANYS) appreciates the opportunity, on behalf of our 500 health care facility members, to comment on the Food and Drug Administration's (FDA) Guidance on the Reuse of Single-Use Devices (SUDs). We believe that the FDA's proposed guidelines represent a thoughtful approach to a complex issue; they both echo and further the goals of patient safety, which we share.

The potential for device malfunctions, patient injuries, or infections related to the reuse, reesterilization, and reprocessing of SUDs is a matter of great concern to hospitals and health systems, whose primary function and focus is the provision of safe and effective care. HANYS, along with the American Hospital Association (AHA), strongly supports the FDA's plan to develop a research program to help bridge the "data gap" between the perceived and actual safety risks associated with reuse of SUDs. HANYS suggests that such research should be directed first at the more critical and complex high-risk devices. The outcome of such research should be to provide device-specific scientific evidence regarding patient safety.

ENFORCEMENT PRIORITIES FOR SINGLE-USE DEVICES REPROCESSED BY HOSPITALS AND THIRD PARTIES

Quality and Safety Oversight of Hospitals

As part of ongoing quality improvement, patient safety, and risk management strategies, health care providers are always searching for opportunities for improvement. Hospitals are subject to significant regulatory and accreditation oversight and recommendations. Entities such as the Health Care Financing Administration (HCFA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), state licensing authorities, the Centers for Disease Control and Prevention (CDC), and other agencies have regulations and recommendations related to patient safety and quality of care. For

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example, JCAHO, during its announced and unannounced surveys, focuses heavily on patient safety. In addition to visiting patient care and reprocessing areas to observe infection control practices, JCAHO reviews the minutes of the infection control committee, the medical staff executive committee, the performance improvement oversight committee, and the governing body. The inspectors look for evidence of sufficient reporting of performance improvement information and for action on performance improvement recommendations. Failure to adequately demonstrate compliance in these areas results in substantial findings of non-compliance for the facility. Additionally, in New York State, hospitals are required to report adverse patient events to the State Department of Health under the New York Patient Occurrence Reporting Tracking System (NYPORTS). Hospitals are required to report any equipment malfunction problems, defective products, and post-operative wound infections through the NYPORTS system.

Hospital reprocessing activities are marked by a high degree of physician involvement, supervision, and control. Reprocessing standards, policies, and procedures, in conjunction with the quality improvement program, are designed specifically to protect the well-being of hospital patients. In many cases, a multi-disciplinary committee, such as the infection control committee, consisting of clinical staff (physicians and nurses) and operational staff (sterile processing, risk management, and materials management), oversees the reprocessing activities of health care facilities. This committee monitors reprocessing quality assurance and improvement activities, recommends strategies for improving performance, and reports such findings and recommendations to the facility's performance improvement oversight committee, medical staff, and governing body. This type of multi-disciplinary committee, through its membership, responsibilities, and accountabilities, meets the requirements of numerous JCAHO standards, including those for infection control, surveillance, and prevention.

Scope of Enforcement Guidance

HANYS questions why the proposed enforcement activities apply only to hospitals and third-party reprocessors. Reuse and reprocessing activities take place in numerous health care locations that also include ambulatory surgery centers, diagnostic and treatment centers, free standing urgent care centers, clinics, community health centers, group practices, and physicians' offices. Exempting non-hospital locations and facilities that are involved in reprocessing is counterproductive to the FDA's belief that "the agency's regulatory activities should be implemented in accordance with the degree of risk involved." In fact, it is highly probable that many of these other locations do not have the resources or protocols to provide for safe and effective reprocessing of SUDs, nor are they subject to the same critical regulatory and accreditation oversight activities as hospitals.

Exclusion of Open-but-Unused SUDs

Many SUDs are routinely opened prior to use and assembled as part of customized procedure trays that contain several devices. Sterile processing professionals assemble, wrap, and sterilize these trays, which may consist of a mixture of single-use and disposable items. It is essential that hospitals be permitted to open single-use devices, combine them with other devices as needed for each medical procedure, and resterilize the entire tray. HANYS is pleased to note that the FDA has excluded such SUDs from regulation in this guidance document.

Low-Risk SUDs

HANYS is pleased that the FDA intends "to continue to exercise its discretion not to enforce premarket requirements" for two years from the date of the final SUD Enforcement guidance. As stated in the FDA's Statement of Purpose, "The enforcement priorities for premarket priorities are based on the degree of risk associated with reprocessing SUDs as categorized by an FDA proposed risk scheme." Devices that pose little or no public health risk or are not invasive to patients or users should not require this level of regulation, including Quality Systems regulation.

Labeling

Original equipment manufacturers (OEMs) have little incentive to label devices as reusable and, in fact, have financial incentives to designate devices as “single use.” Currently, there are no required standards or guidelines related to the labeling of devices as “single use only.” Manufacturers appear to use the term “single use only” as part of their labeling without justifying whether, in fact, the device can be safely reprocessed for subsequent use. Our members have told us of numerous occasions where they have observed products that had historically been labeled as reusable, suddenly arriving with a new “single use only” label and without observable change in the product. HANYS urges the FDA to set uniform standards for OEMs in applying the “single use only” label.

HANYS’ RECOMMENDATIONS

1. Since hospitals are already subject to significant regulation from a variety of state and federal agencies, (including JCAHO, CDC, State Department of Health, Health Care Financing Administration, etc), HANYS recommends that the FDA provide guidance or assistance related to reprocessing to these agencies.
2. To ensure and enhance patient safety at all levels and areas, the FDA should phase in enforcement of its guidelines consistently and concurrently for all health care facilities and locations that reprocess SUDs, not just hospitals. Not enforcing guidelines consistently undermines the FDA’s efforts to ensure and enhance patient safety associated with the reuse of SUDs.
3. To further enhance patient safety and address infection control and safety and effectiveness factors, HANYS recommends that the FDA require OEMs to provide instructions related to appropriate, validated sterilization and/or resterilization methods for devices whose sterility may be compromised. Any performance standards that may be compromised through sterilization procedures for open-but-unused devices should also be provide by the OEM.
4. HANYS recommends that low-risk devices be excluded from FDA premarket notification requirements. We suggest that the FDA consider the development of best practice or community practice guidelines, with input from those involved in reprocessing, including infection control and sterile processing professionals, physician specialty associations, device manufacturers, and reprocessing organizations. We would be very interested in working with FDA and other professional associations in developing such consensus guidelines for safe and effective reprocessing of SUDs.
5. HANYS strongly recommends that the FDA regulate the use of the “single use only” label and require OEMs to both justify labeling a device as “single use” and provide valid scientific evidence specifying any resterilization or reprocessing techniques that could compromise the integrity, safety, or effectiveness of the device. OEMs have data on the performance standards and functional specifications of their devices and know the most about the ability of their devices to tolerate repeated cleanings and resterilization procedures. They should share that information with those who use the devices, and be actively involved in developing consensus standards. Further, the device label should clearly indicate the number of times a device will perform without failure as validated by the OEM.

REPROCESSING AND REUSE OF SINGLE-USE DEVICES: REVIEW PRIORITIZATION SCHEME

General Comments

In general, HANYS agrees with the FDA’s risk-based categorization scheme. The scheme addresses the two most critical factors to be evaluated in consideration of reprocessing and patient safety: risk of infection and device performance.

HANYS' RECOMMENDATIONS

Determining Risk Categories

HANYS recommends that this document be widely published and distributed so all stakeholders — OEMs, health care facilities and locations, third-party reprocessors, and the public — have access to the same information and can gain a better understanding of the decision-making process when considering reuse and reprocessing of SUDs. In addition, HANYS suggests that a multi-disciplinary panel of professionals be convened by the FDA to determine the final list of SUDs and each SUD's risk category. Further, this panel could advise the FDA about adding or removing new devices to the Frequently Reprocessed Devices List (Appendix B) as well as a periodic review of the risk categorization.

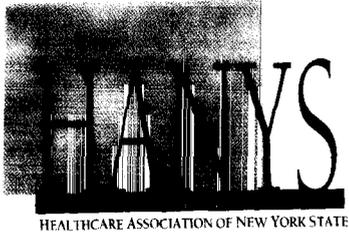
CONCLUSION

Patient safety is the first and foremost concern of all hospitals and health systems. HANYS believes that the FDA's proposed strategy on the reuse of SUDs represents a thoughtful approach to a complex issue, and we are pleased that the FDA has been consulting with front-line caregivers and other experts in its effort to make the standards even more meaningful. This is an important step towards the goal of assuring patient safety. HANYS has consulted with its members and has discovered that many of our facilities use third-party reprocessors for reprocessing of most devices (with the exception of low-risk, non-critical devices), because they felt it enhanced their patient safety objectives. We believe that additional legislation is unnecessary at this time and would only undermine the progress that FDA has already made towards developing a balanced and reasonable regulatory structure. We welcome the opportunity to work with the FDA to ensure best practices are universally used.

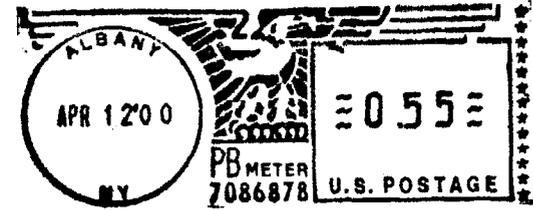
Sincerely,

A handwritten signature in cursive script, reading "Patricia S. McBreen".

Patricia S. McBreen, Director
Quality and Research Initiatives



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