Sec. 300.500 Reuse of Medical Disposable Devices (CPG 7124.16)

BACKGROUND:

Investigations by the Food and Drug Administration (FDA) and other Federal agencies have disclosed that a number of health care institutions have engaged in the practice of reusing single use sterile disposable medical devices. Such devices may not be amendable to resterilization and/or reuse. The FDA is not aware of any data which would establish conditions for the safe and effective cleaning and subsequent resterilization and/or reuse of any disposable medical devices.

In January of 1975, the Bureau of Health Insurance of the Social Security Administration issued State Agency Letter No. 29 concerning the Reuse of Disposable Guidewires and Catheters. The letter stated that such devices were not to be reused. Since that time, the FDA has received a number of inquiries relative to the economics of the policy as related to issues concerning protection of the public health, and has been requested to reconsider and reevaluate the position it has taken.

The FDA, in recognition of the validity of the concerns expressed by all parties involved in this matter, has reviewed its position on this issue, but finds that there is a lack of data to support the general reuse of disposable medical devices, including disposable guidewires and catheters. The fact that devices are labeled disposable is indicative of this lack of data. In order for a device to be considered "reusable," it must be capable of withstanding necessary cleaning, and resterilization techniques and methods, and continue to be safe and reliable for its intended use.

The FDA has concluded, therefore, that the institution or practitioner who reuses a disposable medical device should be able to demonstrate: (1) that the device can be adequately cleaned and sterilized, (2) that the physical characteristics or quality of the device will not be adversely affected, and (3) that the device remains safe and effective for its intended use. Moreover, since disposable devices are not intended by the manufacturer or distributor for reuse, any institution or practitioner who resterilizes and/or reuses a disposable medical device must bear full responsibility for its safety and effectiveness.

POLICY:

The reuse of disposable devices represents a practice which could affect both the safety and effectiveness of the device. Information developed regarding this practice should be referred to the *Center for Devices and Radiological Health* for review and evaluation.

Material between asterisks is new or revised

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