HAWAII HEALTH SYSTEMS CORPORATION *"Quality Healthcare For All"* **POLICY**	**Department:** Quality	**Policy No.:** **EOC 0003A**
		Revision No.: 1
	Issued by: Kathleen Libao-Laygo, Director of Quality	**Effective Date:** February 20, 2014
Subject: ***Single Use Devices***	**Approved by:** Carol A. VanCamp HHSC Board of Directors By: Carol A. VanCamp Its: Secretary/Treasurer	**Supersedes Policy:** May 1, 2001
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Last Review: 12/12/13; Next Review: 12/12/16

I. **PURPOSE:** To meet standards for reprocessing and utilization of single-use medical devices (SUDs). The U.S. Food and Drug Administration (FDA) imposes the same requirements on a SUD reprocessor as those imposed upon the original equipment manufacturer. This policy:

A. Provides guidelines for the safe and efficacious processing and reuse of devices designated by the manufacturer as single use.

B. Defines HHSC expectations of third party reprocessors.

C. Requires compliance with all applicable laws and regulations governing the reprocessing and reuse of SUDs.

II. **POLICY:** If an HHSC facility chooses to permit or support reprocessing and reuse of single-use devices (SUDs), it will maintain high quality standards through compliance with applicable laws, FDA rules, regulations, and guidelines.

A. With the exception of opened-but-unused devices, HHSC facilities shall not reprocess any SUDs internally. An opened-but-unused device is a single-use, disposable device whose sterility has been breached or compromised because its sterile package was opened, but which has not been used on a patient and has not been in contact with blood or bodily fluids

B. HHSC facilities shall only contract with third party reprocessors of single-use devices that demonstrate to the satisfaction of HHSC that:

1. They are registered with the FDA as a reprocessor of single-use devices;

2. They are in full compliance with current FDA guidance on the practice of reprocessing and reusing SUDs including the "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," and with any and all applicable requirements of the Federal Food, Drug, and Cosmetic Act; and

3. Will provide full indemnification and warranty on reprocessed products.

C. In connection with reprocessing, HHSC facilities will:

1. Provide manufacturers' information as necessary for labeling and handling of SUDs for reprocessing;

2. Confine SUDs for reprocessing to appropriate containers and package them appropriately.

D. HHSC facilities will:

1. Limit use of reprocessed SUDs to those cleared by the FDA for reprocessing;

2. Educate and train staff and physicians on the usage and handling of SUDs for specific procedures; and

3. Establish reporting mechanisms for all adverse events involving reprocessed SUDs per FDA requirements.

III. **APPLICABILITY:** All HHSC facilities.

IV. **AUTHORITY:** FDA Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (2000); Federal Food, Drug, and Cosmetic Act, as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997; Medical Device User Fee and Modernization Act (2002); 21 Code of Federal Regulations Parts 807 and 814; also see current CMS survey updates pertinent to facility.

V. **ATTACHMENTS:** None.