LEGISLATIVE GENERAL COUNSEL
₵ Approved for Filing: C.J. Dupont ₵
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S.B. 110

MEDICAL DEVICE NOTIFICATION AND LIABILITY

2005 GENERAL SESSION

STATE OF UTAH

Sponsor: D. Chris Buttars

LONG TITLE

General Description:

This bill makes a reprocessor of a single-use medical device liable for the safety of the reprocessed medical device, and requires health care providers to notify the Health Data Authority if a reprocessed single-use medical device malfunctions and cause patient injury or death.

Highlighted Provisions:

This bill:

- ▸ amends the Judicial Code to:
  - • create a right to sue a reprocessor of a single-use medical device regarding the safety or effectiveness of the reprocessed single-use medical device; and
  - • eliminates the right to sue an original manufacturer of a single-use medical device when that single-use medical device has been reprocessed; and
- ▸ amends the Health Code to require a health care provider to notify the Department of Health's Health Data Committee if a reprocessed single-use medical device malfunctions and causes a patient injury or death.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

ENACTS:

26-33a-115, Utah Code Annotated 1953

78-11-28, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **26-33a-115** is enacted to read:

26-33a-115. Notification of failure of reprocessed single-use medical device.

(1) For purposes of this section:

(a) "Health care provider" shall have the same meaning as defined in Section 78-14-3.

(b) "Reprocessed or reconditioned single-use medical device" shall have the same meaning as defined in Section 78-11-28.

(c) "Reprocessor" shall have the same meaning as defined in Section 78-11-28.

(d) "Single-use medical device" shall have the same meaning as defined in Section 78-11-28.

(2) A health care provider or reprocessor shall submit a report to the committee if the health care provider or reprocessor has knowledge or suspects that a reprocessed or reconditioned single-use medical device:

(a) caused or contributed to a death or serious injury; or

(b) malfunctioned, and the malfunction, if it were to occur again, could cause or contribute to a death or serious injury.

(3) Notwithstanding the provisions of Section 26-33a-106, the committee may report occurrences reported pursuant to this section to the Federal Food and Drug Administration.

Section 2. Section **78-11-28** is enacted to read:

78-11-28. Liability of reprocessor of single-use medical devices.

(1) For purposes of this section:

(a) "Original manufacturer" means any person or entity who designs, manufactures, fabricates, assembles, or processes a single-use medical device which is new and has not been used in a previous medical procedure.

(b) "Reprocessor" includes a person or entity who performs the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development of a reprocessed single-use medical device.

(c) "Reprocessed or reconditioned single-use medical device":

(i) means a single-use medical device that has previously been used on a patient and has been subject to additional processing and manufacturing for the purpose of additional use on a different patient;

(ii) includes a device that meets the definition under Subsection (1)(c)(i), but has been labeled by the reprocessor as "recycled," "refurbished," or "reused"; and

(iii) does not include a disposable or single-use medical device that has been opened but not used on an individual.

(d) "Single-use medical device" means a medical device that is:

(i) intended by the original manufacturer of the device for one use on a single patient during a single procedure; and

(ii) is marked as a "single-use" device by the original manufacturer.

(2) (a) A reprocessor who reconditions or reprocesses a single-use medical device is liable for the safety and effectiveness of the reprocessed single-use medical device.

(b) The original manufacturer of a single-use medical device is not liable for the safety and effectiveness of the single-use medical device once it has been reprocessed or reconditioned.

(c) (i) The liability established in Subsection (2)(a) is in addition to any other liability in state or federal law that may apply.

(ii) The immunity in Subsection (2)(b) is in addition to any other immunity or protection in state or federal law that may apply.

Legislative Review Note
as of 1-3-05 9:04 AM

Based on a limited legal review, this legislation has not been determined to have a high probability of being held unconstitutional.

Office of Legislative Research and General Counsel

State Impact

This bill will add a small amount of work to the Department of Health's workload. The Analyst estimates that it would require approximately 0.05 FTE to handle the additional workload, but the Department should be able to absorb this within existing Departmental resources.

Individual and Business Impact

Reprocessors will be impacted to the extent the additional reporting is required.

Office of the Legislative Fiscal Analyst