LEGISLATIVE GENERAL COUNSEL
₵ Approved for Filing: C.J. Dupont ₵
₵ 01-20-05 12:21 PM ₵

S.B. 110
1st Sub. (Green)

Senator D. Chris Buttars proposes the following substitute bill:

MEDICAL DEVICE NOTIFICATION AND LIABILITY

2005 GENERAL SESSION

STATE OF UTAH

Sponsor: D. Chris Buttars

LONG TITLE

General Description:

This bill requires a reprocessor of a single-use medical device to assume the liability associated with the original manufacturing and the reprocessing of the medical device.

Highlighted Provisions:

This bill:

- amends the Judicial Code to establish that a reprocessor of a single-use medical device assumes all liability related to the original manufacturing and reprocessing of the single-use medical device.

Monies Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

ENACTS:

78-11-28, Utah Code Annotated 1953

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

Section 1. 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 reprocessor who reconditions or reprocesses a single-use medical device assumes the liability:

(a) of the original manufacturer of the medical device; and

(b) for the safety and effectiveness of the reprocessed single-use medical device.