

Senator D. Chris Butters proposes the following substitute bill:

**MEDICAL DEVICE NOTIFICATION AND
LIABILITY**

2005 GENERAL SESSION

STATE OF UTAH

Sponsor: D. Chris Butters

LONG TITLE

General Description:

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

Highlighted Provisions:

This bill:

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



26 Section 1. Section **78-11-28** is enacted to read:

27 **78-11-28. Liability of reprocessor of single-use medical devices.**

28 (1) For purposes of this section:

29 (a) "Critical single use medical device" means a medical device that:

30 (i) is marked as a "single-use" device by the original manufacturer; and

31 (ii) is intended to directly contact normally sterile tissue or body spaces during use, or
32 is physically connected to a device intended to contact normally sterile tissue or body spaces
33 during use.

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

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

40 (d) "Reconditioned or reprocessed critical single-use medical device" means a critical
41 single use medical device that:

42 (i) has previously been used on a patient and has been subject to additional processing
43 and manufacturing for the purpose of additional use on a different patient;

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

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

48 (2) A reprocessor who reconditions or reprocesses a critical single-use medical device
49 assumes the liability:

50 (a) of the original manufacturer of the critical single use medical device; and

51 (b) for the safety and effectiveness of the reconditioned or reprocessed critical
52 single-use medical device.

Fiscal Note
Bill Number SB0110S02

Medical Device Notification and Liability

28-Jan-05

11:05 AM

State Impact

No fiscal impact.

Individual and Business Impact

This bill shifts legal and financial liability from one entity to another.

Office of the Legislative Fiscal Analyst