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**Therapeutic Goods (Charges) Amendment Bill
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I N F O R M A T I O N A N D R E S E A R C H S E R V I C E S

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Therapeutic Goods (Charges) Amendment Bill 2001

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7 June 2001

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Therapeutic Goods (Charges) Amendment Bill 2001

Date Introduced: 29 March 2001

House: House of Representatives

Portfolio: Health and Aged Care

Commencement: When Schedule 1 of the *Therapeutic Goods Amendment (Medical Devices) Act 2001* commences

Purpose

To amend the *Therapeutic Goods (Charges) Act 1989* to allow annual charges to be levied in respect of the inclusion of medical devices on the Australian Register of Therapeutic Goods (the Register).

Background

The background to this Bill is explained in detail in the [Bills Digest](#) for the Therapeutic Goods Amendment (Medical Devices) Bill 2001.

Main Provisions

Currently, under the *Therapeutic Goods (Charges) Act 1989*, annual charges are payable in respect of the 'listing' or 'registration' of therapeutic goods. If the Therapeutic Goods Amendment (Medical Devices) Bill 2001 is passed, medical devices will be 'included' on the Register rather than 'listed' or 'registered'.

Item 3 of Schedule 1 of the Bill amends the *Therapeutic Goods (Charges) Act 1989* so that annual charges will be payable also for medical devices that are 'included' on the Register. Under **item 5**, this extends to medical devices which are 'included' on the Register pursuant to a corresponding State law.

Warning:

This Digest was prepared for debate. It reflects the legislation as introduced and does not canvass subsequent amendments.

This Digest does not have any official legal status. Other sources should be consulted to determine the subsequent official status of the Bill.

Charges will be payable even if a particular medical device or class of medical devices is suspended from the Register (**item 2**).

The regulations may prescribe different charges for different classes of therapeutic goods, including different classes of medical devices (**item 7**). The exemption from annual charges for low volume manufacturers of therapeutic goods is also extended to medical devices (**items 8 and 9**).

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