HOUSE RESEARCH

Bill Summary

FILE NUMBER: H.F. 3422 **DATE:** March 23, 2006

Version: As introduced

Authors: Cornish

Subject: Recalled Implantable Device Financial Responsibility

Analyst: Janelle Taylor, 651-296-5808

Overview

This bill would require manufacturers of certain recalled implantable devices to be financially responsible for medical costs associated with removing and replacing the recalled device.

Section

1 **Recall of implantable medical device.** Adds § 604.111.

Subd. 1. Definitions. Defines the following terms:

- "implantable device" as a medical device implanted in the human body, including a pacemaker, defibrillator, heart valve, hearing device, or joint replacement;
- "manufacturer" as a manufacturer of an implantable device sold in the state;
- "patient" as a resident of the state who has a recalled device removed in the state;
- "provider" as a hospital, health care facility, or health care provider performing services for payment to remove and replace an implantable device; and
- "recall" as a Food and Drug Administration Class I or Class II recall. (A Class I recall is the most serious type of recall and refers to recalls where there is a reasonable chance that the product will cause serious health problems or death. A Class II recall is usually less severe, and refers to recalls where there is either a possibility that the device will cause temporary or reversible health problems, or

Section

there is a remote chance that the device will cause serious health problems.)

Subd. 2. Costs; responsibility of manufacturer. Requires manufacturers of implantable devices that are recalled to be financially responsible for all costs incurred by a patient having such a device removed and replaced, including: (1) the cost of the replacement device; (2) the cost of procedures to remove, replace and dispose of the device; (3) any other medical costs directly associated with the removal and replacement of the device; and (4) health complication costs associated with the removal or replacement up to $100,000.

Subd. 3. Payment; binding arbitration. Paragraph (a) requires that a provider submit payment requests for the charges listed in subdivision 2 directly to the manufacturer and reflect any rates or discounts available in the absence of this section.

Paragraph (b) requires providers and manufacturers that are unable to reach agreement on the financial responsibility for the charges to submit the matter to binding arbitration. Requires that either payment be submitted by the manufacturer within 60 days or binding arbitration occur.

Effective date. States that the section is effective for recalled implantable device removals and replacements performed on or after the day following final enactment.