

Department of Legislative Services  
Maryland General Assembly  
2000 Session

**FISCAL NOTE**

Senate Bill 28 (Senator Bromwell)

Finance

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**Health - Reused Single-Use Medical Devices -  
Patient Consent Required**

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This bill prohibits a hospital from re-using a medical device designated as disposable or for single-use on an individual without written consent. Upon admission or registration, a hospital must provide each patient with a written notice describing its practices regarding the re-use of single-use medical devices. The hospital must give the patient an opportunity to provide or refuse consent on a separate, plain-language document with a signature line which is to become part of the patient's permanent medical record. The Department of Health and Mental Hygiene (DHMH) must approve the consent document and adopt regulations implementing the bill's requirements. The bill includes measures to facilitate a patient's comprehension of the notice through the use of verbal communication or an interpreter. A hospital violating the bill's requirements is subject to a maximum fine of \$10,000 for each violation.

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**Fiscal Summary**

**State Effect:** None. The bill's requirements could be handled with existing resources. The potential impact on general fund revenues resulting from the bill's administrative penalty provision cannot be reliably estimated at this time. DHMH facilities do not re-use single-use medical devices.

**Local Effect:** None.

**Small Business Effect:** None.

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**Analysis**

**Current Law:** The re-use of single-use medical devices is not addressed in current statute.

**Background:** The issue of the re-use of single-use medical devices in a health care setting focuses on the risk of cross-infection to the patient. Outbreaks of infectious diseases have been caused by the re-use of components packaged as single-use medical devices used in dialysis and catheterization procedures. Effective disinfection of single-use medical devices reduces the risk of cross-infection, but may damage or weaken the device. Economic and environmental concerns have prompted some facilities to re-use sterilized single-use devices or to contract out the sterilization process to reprocessing firms.

**State Fiscal Effect:** The increased workload and costs for DHMH to approve a patient consent form, and to develop and enforce regulations, could be handled by the department using existing budgeted resources. It is assumed that revenues from the fines for violations of the bill's requirements will be deposited in the general fund, but the amount depends upon the magnitude of any administrative penalties imposed by DHMH.

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### **Additional Information**

**Prior Introductions:** None.

**Cross File:** None.

**Information Source(s):** Department of Health and Mental Hygiene, Department of Legislative Services

**Fiscal Note History:** First Reader - January 24, 2000  
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Analysis by: Louise Hanson

Direct Inquiries to:  
John Rixey, Coordinating Analyst  
(410) 946-5510  
(301) 970-5510