



**MONE**

Massachusetts  
Organization of  
Nurse Executives

**Massachusetts Organization of Nurse Executives  
Testimony in Opposition to House Bill 2233/Senate Bill 1338, An Act  
Relative to a Patient's Right to Know of the Re-Use of Certain Medical  
Devices Manufactured for Single Use  
Submitted to the Joint Committee on Public Health**

**September 26, 2007**

The Massachusetts Organization of Nurse Executives (MONE) wishes to be recorded in opposition to ***House Bill 2233 and Senate Bill 1338, An Act Relative to a Patient's Right to Know of the Re-Use of Certain Medical Devices Manufactured for Single Use.***

The Massachusetts Organization of Nurse Executives (MONE) is a statewide not-for-profit, professional association committed to the advancement of professional nursing, promoting the delivery of quality patient care and influencing the development of health policy. MONE consists of over 640 nurse leaders from various practice settings. Virtually all acute-care hospitals in the Commonwealth are represented along with a growing number of providers from other settings including homecare, long-term care, academia and corrections. Collectively, the membership employs over 50,000 nurses and health-care workers and administers over \$2 billion in operating budgets annually.

As nurse leaders, there is no higher priority than ensuring the safety and quality of care that is delivered to the patients and families that come to our hospitals and health care facilities every day. We are involved in every aspect of patient care delivery from managing the direct care delivered at the bedside to administering facility-wide operations. We actively participate in the selection of medical devices and other products and continuously evaluate the effectiveness of these products.

As nursing professionals, we are proud to support legislation and initiatives that promote and enhance our ability to provide safe, effective and high quality care. As we reviewed House Bill 2233 and Senate Bill 1338, it became clear that the intent of this legislation was not based on clinical or scientific evidence regarding the safety of reprocessed medical devices. We oppose this legislation because once you strip away the rhetoric, economics are the driving force behind this legislation not patient safety or the quality of patient care.

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This legislation represents an attempt by medical device manufacturers to gain market share by limiting the ability of Massachusetts hospitals to access safe and cost-effective reprocessed medical devices. This will significantly increase costs for our hospitals and the medical waste generated by the increased disposal of single use devices will negatively impact our environment with no demonstrated benefit to patient care.

MONE firmly believes there should not be a debate over single use versus reprocessed devices because both are necessary and both devices play a key role in the delivery of safe and effective patient care. For decades, hospitals in Massachusetts and across the country have safely, appropriately and effectively used reprocessed medical devices. These devices are subject to stringent federal regulation by the Food and Drug Administration (FDA) including rigorous, validated protocols, oversight and reporting. Reprocessed devices have a stellar safety record with **no evidence** indicating any increased risk to patients stemming from the use of reprocessed medical devices. Quite simply, the FDA, hospitals, nurses and clinicians would not be recommending and/or using reprocessed devices if they posed any health or safety risk to patients.

Reprocessing medical devices is not only extremely safe, it is also cost effective. The cost savings associated with reprocessing are significant. It is estimated that in Massachusetts, hospitals save nearly \$4 million per year by using reprocessed devices. These cost savings translate into direct patient care benefits such as the ability to hire additional nurses and support staff and upgrade medical technology on our units.

As professional nurses, we are extremely concerned that informed patient consent and a patient's right to know have been injected into the center of this debate. Requiring informed patient consent for the use of reprocessed medical devices would raise unfounded and unnecessary fear and speculation about reprocessed devices. Furthermore, it would undermine and diminish the value that informed consent plays in the delivery of safe, quality patient care. Informed patient consent represents a clinical dialogue and decision-making process that occurs between the patient, their family and their physician/surgeon regarding the diagnosis, treatment options and the clinical risks and benefits associated with those medical recommendations. Since there is no evidence or clinical data that reprocessed devices pose any increased risk to patients, it is completely inappropriate and unnecessary to require or invoke informed consent.

We hope the Committee will carefully consider the concerns that we have raised about this legislation and the unintended consequences and negative impact that it could have on the delivery of safe patient care in Massachusetts.

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We thank you for the opportunity to provide testimony and we respectfully urge the Committee to reject House Bill 2233 and Senate Bill 1338.

Sincerely,

A handwritten signature in cursive script, appearing to read "Marita Prater".

Marita Prater, MS, RN  
President  
Massachusetts Organization of Nurse Executives