Massachusetts Hospital
Association

testimony

SB1338/HB2233/HB2209

Joint Committee on Public Health

September 26, 2007

The Massachusetts Hospital Association (MHA), on behalf of our member hospitals and health systems, appreciates this opportunity to offer comments on **SB1338, HB2233** and **HB2209.**

MHA strongly opposes **SB1338** and **HB2233.** These bills would improperly limit the use of safe, federally approved re-processed medical devices. In addition to altering liability standards, these bills would require all providers to obtain separate informed consent prior to using any re-processed medical device. Original manufacturers can currently place a "single-use only" sticker on any product they choose. Because this decision can be made on a profit-basis instead of in the best interests of patient care, the federal Food and Drug Administration (FDA) has approved the reprocessing of certain medical devices whether they are labeled "single-use" or not. Hospitals only reprocess those devices that are federally approved and monitored.

MHA is unaware of any substantiated evidence-based study that documents safety or quality concerns with federally approved re-processed single use devices. Requiring separate notice that a health care provider "may" use a re-processed device and that there "may" be a risk implies that these products are of lesser quality or pose an increased risk of harm, when, in fact, there is no scientific evidence to support this notion. For this reason, requiring specific informed consent prior to the use of federally approved re-processed medical devices would undermine and diminish the value that informed consent plays in the delivery of safe, quality patient care.

SB1338 and **HB2233** also fail to reflect that there is already a strict federal criterion that regulates the re-processing of medical devices. The federal regulations specifically take into consideration the quality and safety of patient care in determining if a device is appropriate for re-processing. These regulations also mandate specific notice and pre-market certification prior to the re-processing of any medical device. In addition, unlike most original equipment, every individual re-processed device is rigorously tested for safety prior to use. While hospitals and clinicians sometimes have concerns with the quality of *original*-manufactured medical devices, they often prefer re-processed devices because of the more stringent quality control mandates that are in place.

The use of federally approved re-processed medical devices by medical professionals is simply an example of safe and efficient quality patient care. Since re-processed devices already meet strict federal criteria for re-use and have been proven safe for patient care, these bills serve only to pose administrative and economic burdens that would have no impact on the quality of patient care. As the overwhelming majority of Massachusetts hospitals currently use re-processed devices on a daily basis, this legislation poses an economic danger to many providers who are operating on the narrowest of margins. The use of these devices saves significant money for hospitals (reducing health insurance premiums for everyone), benefits the environment by eliminating tens of thousands of pounds of unnecessary medical waste every year, and benefits patients by reducing the overall cost of health care services through the reduced purchase of equipment and materials. In contrast to the

provisions of these bills, and in furtherance of the goals of health care reform, MHA believes that the use of re-processed medical devices should be further encouraged and enhanced.

At the federal level, Congress and the FDA have repeatedly rejected the provisions put forward by these bills because there is simply no substantiated scientific evidence that documents safety or quality concerns with federally approved re-processed devices. We urge this committee to do the same. MHA respectfully requests that the committee issue **SB1338** and **HB2233** an unfavorable report.

HB2209 addresses an important issue that is causing confusion and concern for health care providers in Massachusetts. Effective January 1, 2007, the Department of Public Health (DPH), pursuant to new requirements issued by the U.S. Centers for Disease Control and Prevention (CDC), required all providers to start reporting the names of individuals who test positive for HIV infection. However, under the Massachusetts General Laws (Chap. 111, sec. 70F) providers are prevented from releasing such data without express written informed consent. In the interest of public health, MHA believes that this apparent conflict between confidentiality and reporting requirements must be addressed by DPH or the legislature. We look forward to working with the committee to identify a solution that is in the best interests of all patients.

Thank you for the opportunity to offer testimony on these important matters. If you have any questions regarding this testimony, or require further information, please contact Michael Sroczynski, MHA's Senior Director of Government Advocacy, at (617) 367-9667.