

OVERVIEW

Study of the Social and Financial Impacts of Mandatory Health Insurance Coverage for Use of Intelligent Medical Vigilance Services in Acute Care Hospitals

Report No. 08-05, March 2008

Summary

In Senate Concurrent Resolution No. 209, House Draft 1, Conference Draft 1, the 2007 Legislature requested the Auditor to assess the social and financial impacts of mandating health insurance coverage for the use of intelligent medical vigilance services for patients in acute care hospitals in Hawai'i. We conducted the work pursuant to Sections 23-51 and 23-52, Hawai'i Revised Statutes (HRS).

According to the inventors, an intelligent medical vigilance system observes, analyzes, and, only in the event of a clinically significant negative condition, notifies and reports the event to the hospital care staff via an existing nurse call system. Intelligent medical vigilance refers to a system or device with two components: a *bedside unit* connected to a *pad or coverlet* with embedded Passive Sensory Array (PSA™) technology. Within the bedside unit are a signal processor and an alarm processor that measure data and evaluate whether a clinically significant event is occurring. The array of sensors within the coverlet is sheathed in soft padding and is not directly in contact with the skin of the patient. The sensors monitor a patient's heart rate, respiration rate and bed movement.

The use of the term, intelligent medical vigilance system, more aptly identifies a specific product rather than services or intangible activities performed by a person to benefit another. As defined by the U.S. Patent and Trademark Office, trademarks are used by their owners to identify goods, that is, physical commodities, which may be natural, manufactured, or produced, which are sold, transported or distributed via interstate commerce. Service marks are used by their owners to identify services, that is, intangible activities, which are performed by one person for the benefit of another person or persons.

In 2004, Hoana Medical, Inc.—founded in late 2001 as a spin-off from Oceanit Laboratories, a Hawai'i based engineering, science, and research company—developed and patented the PSA™ technology. Hoana's PSA™ technology accurately, transparently, and continuously measures basic physiology (heart rate and breath rate) passively, without the use of electrodes, leads, or cuffs, 24 hours a day, seven days a week. The PSA™ technology is embedded in the mattress coverlet of Hoana's LG1™ Intelligent Medical Vigilance System™. In February 2006, Hoana received "US [Food and Drug Administration] 501(k) clearance to begin marketing its flagship product, the LG1™ Intelligent Medical Vigilance System™." The LG1™ system is a wireless device designed to monitor a patient's heart rate, breath rate, and bed movement using a coverlet on a mattress pad which is electronically hooked up to a display screen (bedside unit) in the patient's room and at the nursing station. Hoana's target market for the LifeBed™ (formerly



called the LG1™) is the medical-surgical unit of an estimated 6000 acute care hospitals in the United States. Besides the Queen's Medical Center, eight medical centers across the mainland have installed the LG1™ or Lifebed™ for use in medical-surgical wards.

Senate Bill No. 409, Senate Draft 1, defines intelligent medical vigilance as “the use of an automated, wireless, early alert system that is authorized by the Federal Food and Drug Administration and provides accurate and continuous observation of heart and respiratory rates and patient mobility.” We found that the only early alert system with intelligent medical vigilance technology that meets the definition of the bill refers to a specific, trademarked, commercial product, rather than a specific health care service as required for analysis according to Section 23-51, HRS. We also found that the lack of adequate information in the proposed bill as required by Section 23-51, HRS, made an assessment difficult. Therefore, an assessment of the social and financial impacts of requiring health insurers to offer coverage for the use of intelligent medical vigilance services was not feasible.

Recommendations and Response

We do not make any recommendations. Both the Departments of Commerce and Consumer Affairs and Health opted not to provide responses.

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