

---

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

---

A Report to the  
Governor  
and the  
Legislature of  
the State of  
Hawai'i

Report No. 08-05  
March 2008



**THE AUDITOR**  
STATE OF HAWAI'I

---

## Office of the Auditor

The missions of the Office of the Auditor are assigned by the Hawai'i State Constitution (Article VII, Section 10). The primary mission is to conduct post audits of the transactions, accounts, programs, and performance of public agencies. A supplemental mission is to conduct such other investigations and prepare such additional reports as may be directed by the Legislature.

Under its assigned missions, the office conducts the following types of examinations:

1. *Financial audits* attest to the fairness of the financial statements of agencies. They examine the adequacy of the financial records and accounting and internal controls, and they determine the legality and propriety of expenditures.
2. *Management audits*, which are also referred to as *performance audits*, examine the effectiveness of programs or the efficiency of agencies or both. These audits are also called *program audits*, when they focus on whether programs are attaining the objectives and results expected of them, and *operations audits*, when they examine how well agencies are organized and managed and how efficiently they acquire and utilize resources.
3. *Sunset evaluations* evaluate new professional and occupational licensing programs to determine whether the programs should be terminated, continued, or modified. These evaluations are conducted in accordance with criteria established by statute.
4. *Sunrise analyses* are similar to sunset evaluations, but they apply to proposed rather than existing regulatory programs. Before a new professional and occupational licensing program can be enacted, the statutes require that the measure be analyzed by the Office of the Auditor as to its probable effects.
5. *Health insurance analyses* examine bills that propose to mandate certain health insurance benefits. Such bills cannot be enacted unless they are referred to the Office of the Auditor for an assessment of the social and financial impact of the proposed measure.
6. *Analyses of proposed special funds* and existing *trust and revolving funds* determine if proposals to establish these funds are existing funds meet legislative criteria.
7. *Procurement compliance audits* and other *procurement-related monitoring* assist the Legislature in overseeing government procurement practices.
8. *Fiscal accountability reports* analyze expenditures by the state Department of Education in various areas.
9. *Special studies* respond to requests from both houses of the Legislature. The studies usually address specific problems for which the Legislature is seeking solutions.

Hawai'i's laws provide the Auditor with broad powers to examine all books, records, files, papers, and documents and all financial affairs of every agency. The Auditor also has the authority to summon persons to produce records and to question persons under oath. However, the Office of the Auditor exercises no control function, and its authority is limited to reviewing, evaluating, and reporting on its findings and recommendations to the Legislature and the Governor.



### THE AUDITOR STATE OF HAWAII

Kekuanao'a Building  
465 S. King Street, Room 500  
Honolulu, Hawai'i 96813

# 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.

---

**Marion M. Higa**  
State Auditor  
State of Hawai'i

Office of the Auditor  
465 South King Street, Room 500  
Honolulu, Hawai'i 96813  
(808) 587-0800  
FAX (808) 587-0830

---

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

---

A Report to the  
Governor  
and the  
Legislature of  
the State of  
Hawai'i

Conducted by

The Auditor  
State of Hawai'i  
and  
Millicent Y.H. Kim,  
Consultant

Submitted by

**THE AUDITOR**  
STATE OF HAWAI'I

Report No. 08-05  
March 2008

---

## Foreword

We assessed the social and financial impacts of mandating insurance coverage for the use of intelligent medical vigilance services for patients in acute care hospitals in Hawai'i, pursuant to Sections 23-5 and 23-52, Hawai'i Revised Statutes (HRS). The 2007 Legislature requested this assessment through Senate Concurrent Resolution No. 209, House Draft 1, Conference Draft 1.

Our assessment was conducted by Millicent Y.H. Kim, consultant. We acknowledge and appreciate the cooperation of the Departments of Commerce and Consumer Affairs and Health and other organizations and individuals that we contacted during the course of this assessment.

Marion M. Higa  
State Auditor

---

# Table of Contents

## **Chapter 1 Introduction and Background**

Introduction .....	1
Background .....	1
Objectives of the Study .....	3
Scope and Methodology .....	3

## **Chapter 2 Assessment of Proposed Mandatory Health Insurance for Intelligent Medical Vigilance**

Summary of Findings .....	5
Social and Financial Impacts Cannot Be Assessed .....	5
Conclusion .....	14

<b>Notes .....</b>	<b>15</b>
--------------------	-----------

<b>Responses of the Affected Agencies .....</b>	<b>17</b>
---	-----------

---

*This page intentionally left blank.*



---

# Chapter 1

## Introduction and Background

---

### Introduction

This report is in response to Senate Concurrent Resolution No. 209, House Draft 1, Conference Draft 1, adopted by the 2007 Legislature requesting the Auditor to prepare and submit a report that assesses both 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). The statute requires passage of a concurrent resolution requesting an impact assessment by the Auditor before any legislative measure mandating health insurance coverage for a specific health service, disease, or provider can be considered. It further provides that the concurrent resolution designate a specific bill that has been introduced in the Legislature and includes, at a minimum, information identifying the:

- Specific health service, disease, or provider that would be covered;
- Extent of the coverage;
- Target groups that would be covered;
- Limits on utilization, if any; and
- Standards of care.

---

### Background

#### ***Senate Bill No. 409, Senate Draft 1***

Senate Bill No. 409, Senate Draft 1, proposes to minimize accidental patient injuries and deaths in hospitals and to ensure that patients in Hawai‘i receive quality health care by requiring health insurance providers to include in their policies, intelligent medical vigilance services or supplies for patients at acute care hospitals. The bill amends Chapters 431 and 432, HRS, to require insurance coverage for health plan subscribers who use intelligent medical vigilance services provided that: “1) the patient is receiving in-patient health care services at an acute care hospital; and 2) the patient’s treating physician recommends the application of medical vigilance services as a precautionary measure due to the nature of the patient’s illness or treatment.”

#### ***Intelligent medical vigilance***

According to the inventors, an intelligent medical vigilance system observes and analyzes, and, only in the event of a clinically significant negative condition, notifies and reports the event to the hospital care staff utilizing the existing nurse call system. The device includes two

components: a *bedside unit* connected to a *pad or coverlet* with a sensor array (placed under the patient) and an existing hospital nurse call system via an interface. Within the physical bedside unit are a signal processor and an alarm processor that measure data and evaluate whether a clinically significant event is occurring. The bedside unit is a wall-mounted unit with a display that becomes active when an alarm condition is enabled. The sensing pad or coverlet is a thin, piezoelectric<sup>1</sup> film, or other similar sensing technology, with an array of sensors sheathed in soft padding and is not directly in contact with the skin of the patient. The sensors measure heart rate, respiration rate and patient movement. The nurse call feature is made up of hardware, software, and cabling to connect to the nurse call system already installed in the hospital or care facility.

Medical monitors to measure a patient's vital signs have been in use for many years. Typically, medical monitors include patient monitors prescribed by a physician in a non-Intensive Care Unit (ICU) setting. Twenty-four hour medical monitors designed to respond to rapidly changing situations are found in ICUs. Outside the intensive care unit, conventional monitors are not usually connected to a remote alarm; and vital signs for an acute care patient are generally monitored every four hours or less based on the physician's orders and the patient's medical condition.

***Hoana Medical, Inc.  
invented technology  
for a new intelligent  
medical vigilance  
system***

In 2004, Hoana Medical, Inc.—a Hawai'i based medical device company—developed and patented technology to passively collect patients' vital signs under the trademark name Passive Sensory Array (PSA). Hoana Medical, Inc. was founded in late 2001, a spin-off from Oceanit Laboratories, established in 1985. Oceanit Laboratories is a Hawai'i based engineering, science, and research company. Hoana's PSA<sup>TM</sup> technology sprang from early development work at Oceanit, funded by grants from the military to develop a medical evacuation ambulatory monitoring platform. Field testing of the initial prototype demonstrated accurate, safe, reliable and convenient measurements of heart and respiration rates, including tests under battlefield conditions, such as the high noise and vibration environment in medical evacuation helicopters.

As discussed further in Chapter 2, the monitoring device developed by Hoana Medical, Inc. that includes the PSA<sup>TM</sup> technology is the Lifebed<sup>TM</sup> patient medical vigilance system formerly called the LG1<sup>TM</sup> Intelligent Medical Vigilance System<sup>TM,2</sup>. Hoana's PSA<sup>TM</sup> 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 technology involves a new and improved intelligent medical vigilance system for providing an invisible

“safety net” that observes and analyzes a person’s vital signs. Only in the event of a clinically significant negative condition will the device notify and report the event to a person or nursing staff, via a hospital’s existing nurse call system. In doing so, the technology extends the vigilance capability and reach of the hospital clinical staff so that their resources can be more effectively applied.

---

## Objectives of the Study

1. Assess the social and financial effects of mandating health insurance for the use of intelligent medical vigilance services in acute care hospitals.
2. Make recommendations, as appropriate.

---

## Scope and Methodology

Our assessment examined the social and financial impacts of mandating coverage for the use of intelligent medical vigilance services for in-patients at acute care hospitals in Hawai‘i as required in Senate Concurrent Resolution No. 209, House Draft 1, Conference Draft 1. We surveyed health insurance groups and hospitals statewide with medical-surgical acute care beds. Surveys relating to mandated health insurance coverage for the use of intelligent medical vigilance services were sent to six health insurance companies registered with the state Department of Commerce and Consumer Affairs, Insurance Division. All responded. Surveys relating to intelligent medical vigilance systems in medical-surgical wards were sent to 24 acute care hospitals, of which 15 responded. Interviews were conducted with hospital staff, including risk management and nursing personnel. We reviewed relevant literature relating to other state mandatory health requirements, patient safety initiatives, intelligent medical vigilance systems, nursing protocols, acute care hospital bed procedures, national trends, and healthcare organizations’ research data. Visits to hospitals and nursing programs were also conducted.

Section 23-52, HRS, describes the criteria that we use to assess the social and financial impacts of mandating of health coverage.

## *Social impact*

1. The extent to which the treatment or service is generally utilized by a significant portion of the population;
2. The extent to which such insurance coverage is already generally available;

3. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatment;
4. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment;
5. The level of public demand for the treatment or service;
6. The level of public demand of individual or group insurance coverage of the treatment or service;
7. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts;
8. The impact of providing coverage for the treatment or service (such as morbidity, mortality, quality of care, change in practice patterns, provider competition, or related items); and
9. The impact of any other indirect costs upon the costs and benefits of coverage as may be directed by the legislature or deemed necessary by the auditor in order to carry out the intent of this section.

### ***Financial impact***

1. The extent to which insurance coverage of the kind proposed would increase or decrease the cost of the treatment or service;
2. The extent to which the proposed coverage might increase the use of the treatment or service;
3. The extent to which the mandated treatment or service might serve as an alternative for more expensive treatment or service;
4. The extent to which insurance coverage of the health care service or provider can be reasonably expected to increase or decrease the insurance premium and administrative expenses of policyholders; and
5. The impact of this coverage on the total cost of health care.

We conducted our study from July 2007 to December 2007.

---

# Chapter 2

## Assessment of Proposed Mandatory Health Insurance for Intelligent Medical Vigilance

---

We found that “intelligent medical vigilance” refers to a specific product—a bedside unit and a mattress coverlet embedded with newly patented Passive Sensory Array™ technology developed for use by hospitals to accurately monitor a patient’s heart rate, breath rate and bed movement. As defined in Senate Bill No. 409, Senate Draft 1, the use of an Intelligent Medical Vigilance System™ is not a specific health care service subject to an assessment under Section 23-51, Hawai‘i Revised Statutes.

---

### Summary of Findings

An assessment of the social and financial impacts of requiring health insurers to offer coverage for intelligent medical vigilance services would be inappropriate as it refers to a specific, trademarked, commercial product, rather than specific health care services covered under Section 23-51, HRS.

---

### Social and Financial Impacts Cannot Be Assessed

Our findings on the social and financial impacts of mandating insurance coverage for the use of intelligent medical vigilance services as a product, rather than a health care service, are gleaned primarily from literature obtained, and responses to surveys sent to health insurers and hospitals. We surveyed six health insurance companies registered with the Health Insurance Division of the state Department of Commerce and Consumer Affairs, all of whom responded. Twenty-four public and private hospitals in the state were surveyed and 15 (62.5 percent) responded. Serious questions were raised regarding the proposed mandated health insurance coverage on the basis that “intelligent medical vigilance” refers to a device or product whose use should be market driven. Intelligent medical vigilance refers to a device in a field that is rapidly changing. According to hospitals we surveyed, it is not a direct patient care service, so it would not be or should not be included as part of any hospital bed reimbursement plan. Most of the hospitals we surveyed indicated that the conventional patient safety and monitoring systems currently in use are satisfactory.

***The LG1™ meets the definition of intelligent medical vigilance***

We found the only early alert system on the market with intelligent medical vigilance technology and Food and Drug Administration (FDA) authorization is the LG1™ Intelligent Medical Vigilance System™ (LG1™). In February 2006, Hoana Medical, Inc. announced its receipt of “US FDA 501(k) clearance to begin marketing its flagship product, the LG1™ Intelligent Medical Vigilance System™.”

Intelligent medical vigilance is defined in Senate Bill No. 409, Senate Draft 1, as “the use of an automated, wireless, early alert system that is authorized by the Federal [FDA] and provides accurate and continuous observation of heart and respiratory rates and patient mobility.” Senate Concurrent Resolution No. 209, House Draft 1, Conference Draft 1, states that:

A medical vigilance service is an automated early alert system that identifies at-risk patients with an invisible, non-contact, “Star Trek-like” device that provides accurate and continuous observation of heart and respiratory rates—the two most critical vital signs—while the patient is in bed, and immediately notifies nursing staff upon detecting a life-threatening condition.

Intelligent Medical Vigilance System™ is the trademark phrase associated with patient safety technology developed and patented by Hoana Medical, Inc. 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. We searched past health insurance studies for examples of specific health care services covered under Section 23-51, HRS. In 2004 we assessed the social and financial impacts of mandating insurance coverage for cognitive rehabilitation services. Cognitive rehabilitation refers to a variety of strategies or techniques performed by physicians or psychologists to help patients with traumatic brain injury reduce, manage, or cope with cognitive defects.<sup>1</sup>

The United States Patent and Trademark Office defines trademark as a:

Word, phrase, symbol or design, or a combination of words, phrases, symbols or designs, that identifies and distinguishes the source of the goods of one party from those of others. A service mark is the same as a trademark, except that it identifies and distinguishes the source of a service rather than a product.

Trademarks are used by their owners to identify goods, that is, physical commodities, which may be natural, manufactured, or produced, and which are sold or otherwise transported or distributed via interstate commerce. On the other hand, service marks are used by their owners to identify services, that is, intangible activities, which are performed by one person for the benefit of a person or persons other than himself.

Since the term intelligent medical vigilance system is identified with a specific trademarked product, an assessment of the social and financial impacts is inappropriate as it does not refer to specific health care services covered under Section 23-51, HRS.

***LG1™ Intelligent Medical Vigilance System™ monitors certain vital signs***

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 or a fully equipped bed, which is electronically hooked up to a display screen (bedside unit) in the patient's room and at the nursing station. Unlike traditional telemetry patient alert systems, where a patient in distress is required to self-activate the vigilance system by pressing a call button should help be required between regularly scheduled patient bed checks by nurses or health care personnel, the LG1™ is an electrically generated alert system.

According to hospital staff we surveyed, an intelligent medical vigilance system monitors only three of six generally measured vital signs: heart rate, respiratory measurements, and bed movement. Vital signs are clinical measurements that indicate the state of a patient's essential body functions: temperature, blood pressure, heart rate, pulse, respiration, and patient movement. The standard of care for monitoring vital signs depends on the individual patient care plan based on the physician's and registered nurse's assessment of the patient's condition and what is required to stabilize the patient and enhance improvement. Vital sign monitoring devices vary from different types of electronic equipment to different levels of intensity depending on the patient care plan, physician plan, and nurse's patient care plan.

***Hoana Medical, Inc. markets the LG1™ or LifeBed™ in Hawai'i and other states***

Hoana's target market for the LifeBed™ patient vigilance system (formerly called the LG1™) is the medical-surgical unit of an estimated 6000 acute care hospitals in the United States. Besides Hawai'i, eight medical centers in Indiana, Massachusetts, Texas, Florida, California, Iowa and Florida have installed the LG1™ or LifeBed™ for use in medical-surgical wards. The medical-surgical wards represent the bulk of non-critical care beds in hospitals. The number of vigilance systems installed range from 15 to 53 units per hospital. Hoana markets its product through its website [www.hoana.com](http://www.hoana.com), printed collateral materials, trade shows, presentation to hospitals, and maintaining a database.

***Intelligent Medical Vigilance System™ installed at the Queen's Medical Center***

To date, Queen's Medical Center is the only acute care bed medical facility to install the LG1™ or LifeBed™ system in the state. In June 2006, Queen's installed the coverlet devices in 24 acute care beds of its

oncology ward. As of October 2007, a total of 1,834 in-patients at Queen's have occupied beds installed with the LG1™ or LifeBed™ technology.

### **Costs for supplies, training, and installation**

The cost to Queen's is \$15 per day per unit that includes a supply of replacement coverlets during the contract period, software upgrades, and technical support. Another \$2 is charged for the cost of other services such as staff-servicing, data reports, and equipment maintenance. The cost of installation and training is separate. Daily cost of training and installation is \$1,500 per person plus any travel costs. Training and installation is dependent upon the number of LG1™ or LifeBed™ devices to be installed and employees to be trained. Approximate time to install one unit (up to 30 beds) is four to eight days. The number of installation days depends upon the number of floors/units to be installed, the number of beds on each unit, the type of nurse call system, and the method for bracket installation. Installation time and associated costs can be reduced relative to the amount of assistance provided by a hospital's bio-medical facilities department. Pricing is negotiable for wider installation, dependent upon the hospital's commitment to assign its own employees to assist in the installation.

### **Use of intelligent medical vigilance provides satisfactory results**

A project team of oncology staff at Queen's measured the results of a patient surveillance system in an attempt to improve fall data, address failure-to-rescue rates and improve patient and nurse satisfaction. While not specifically identified as the LG1™ or LifeBed™, the system was described as a "wireless mattress coverlet and a wall unit that measures heart rate, respiratory rate and the patient's presence in bed." Fall rates decreased from 7.4 in July 2006 to 1.4, 0.0, and 1.5 over the next three months respectively.

In December 2006 the Queen's intelligent medical vigilance system was upgraded and the staff re-trained. This resulted in zero fall rates for the next two months. According to the abstract from the Queen's surveillance report:

RN satisfaction scores showed an increase in [eight] out of the [nine] areas, including task, RN-RN interaction, decision making, autonomy, and job enjoyment. The patient satisfaction tool is divided into sections that specifically relate to nursing care. The data results used to monitor patient satisfaction were "response to call lights" and the "overall nursing care" score. The [scores] for both areas have increased following [installation] of the automated [patient] surveillance system . . . . This project demonstrated the positive impact



that technology can have for both patients and nurses. It was also shown to give the nurses an extra sense of security and has received positive feedback from the [patients] as well . . . .

The Queen’s patient safety surveillance report did not include economic data.

***Hospitals apply a diagnosis related group basis for vital sign monitoring devices***

Health insurance companies compute hospital coverage costs through per diem rates negotiated with hospitals. Hospitals are paid on a diagnosis related group (DRG) basis for monitoring vital signs. A DRG is a patient classification system that standardizes prospective payment to hospitals and encourages cost containment initiatives. In general, a DRG payment covers all charges associated with an in-patient stay from the time of admission to discharge. The DRG also includes any services performed by an outside provider as directed by the supervising physician. The monitoring of vital signs is a cost that is incorporated into the DRG with hospitals left to make decisions regarding what monitoring method is appropriate. Since the DRG is based on the type of health condition being treated, patient safety may not be considered a direct health condition cost. Survey responses cited this as a “hospital decision” as far as the level and types of monitoring devices used in individual patient care plans prepared by physicians and hospital staff.

***Senate Bill No. 409, Senate Draft 1, is problematic***

Senate Bill No. 409, Senate Draft 1, mandates health coverage for the use of intelligent medical vigilance services for patients in acute care hospitals. However, we found that the use of intelligent medical vigilance monitoring devices refers to a product, that is, the LG1™ or LifeBed™—an automated early alert system with two components, a bedside unit and a mattress coverlet—rather than to specific health care services.

We found other problems with Senate Bill No. 409, Senate Draft 1, that made an assessment of proposed mandatory health insurance for intelligent medical vigilance services difficult. The bill does not provide adequate information required by Section 23-51, HRS. The areas not identified in the bill include:

- the extent of the coverage, such as length of use, level of service, provider, conditions to initiate or terminate service;
- limits on utilization, if any, that is, limited to certain types of patients, conditions, frequency; and
- standards of care to be followed for accident prevention, and how this relates to a specific health service, disease, or provider.

The bill needs to accurately identify the target groups that would be covered. The bill identifies the target group to be covered as “patients receiving in-patient health care services at an acute care hospital.” The target market for the LG1™ or LifeBed™ system should include the 24 public and private acute care hospitals with an estimated 2,285 medical-surgical acute care beds in the state.

### ***Social impact***

**1. The extent to which the treatment or service is generally utilized by a significant portion of the population.**

The population that utilizes the LG1™ or LifeBed™ is very small. It is in use in 24 out of a possible 2,285 acute care beds in Hawai‘i. Except for the Queen’s Medical Center, none of the hospitals we surveyed had plans or intentions to install the LG1™ or LifeBed™ in the near future. It is reported to be highly satisfactory at the Queen’s oncology ward, contributing to reductions in unattended falls down to zero after six months of use.

**2. The extent to which such insurance coverage is already generally available.**

Health insurance coverage for the LG1™ or LifeBed™ system is not presently available.

**3. If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatment.**

The lack of coverage for the LG1™ or LifeBed™ system would not prevent persons admitted in acute care hospitals from obtaining necessary health care treatment. The LG1™ or LifeBed™ system functions within the nexus of other patient safety devices presently used by hospitals to monitor and alert hospital staff of patient care problems. All hospitals provide vital sign monitoring as part of the patient care plan for an acute care bed in a medical-surgical ward and bed movement monitoring when necessary. According to survey results, without health insurance coverage of the LG1™ or LifeBed™, acute care hospitals are satisfied with the present vital sign monitoring systems that are being used in the medical-surgical wards.

**4. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.**

This is unknown. Financial hardship resulting from the lack of coverage for a safety device such as an LG1™ or LifeBed™ would occur if its absence caused an unattended accident or injury to the patient, creating additional health care costs by a return to the ICU, treatment for injury unrelated to the patient's admission condition, or impairment of income earning capacity. The same would be true for "failure to rescue" or "unattended fall" using other patient safety devices and programs. However, data regarding the frequency of such an occurrence is unavailable. Recent initiatives have been taken by hospital risk management and quality care programs to regularly collect data relating to unattended falls, injuries and other accidents not related to a patient's condition at admission but occurring on the hospital grounds. The data are relatively new and kept in different types of categories to serve different purposes, and not sorted specifically to acute care beds.

**5. The level of public demand for the treatment or service.**

There is no public demand. The LG1™ or LifeBed™ system is a relatively new device recently installed in hospitals from 2006 to 2007. It is an industrial device that would be known to specialists in the field rather than of interest to the "general consumer public." The level of "public demand" would depend on the nature of Hoana's marketing plan in various types of hospital settings. Hoana's marketing plans are directed at hospitals and other institutional users and not the public at large.

**6. The level of public demand for individual or group insurance coverage of the treatment or service.**

There is no public demand for the same reasons as provided in item 5.

**7. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.**

This is unknown. Public collective bargaining units no longer negotiate separate health insurance programs but have combined their employee/employer contributions with one broker for benefits for unit membership. Private unions each negotiate separate and independent contracts which include health benefits with individual employers. Only the Hawaii State Teachers Association (HSTA) continues to negotiate a dollar amount with the State for health benefits. Responsibility for negotiating benefits with individual health care insurance carriers rests with the HSTA VEBA Trust.

Presently, HSTA is served by Hawaii Medical Service Association and Kaiser HMO. HSTA responded that patient safety devices are very important to include in health plans.

**8. The impact of providing coverage for the treatment or service (such as morbidity, mortality, quality of care, change in practice patterns, provider competition, or related items).**

This is unknown. While preliminary results show significant decline in unattended falls, survey respondents felt the LG1™ or LifeBed™ would not significantly impact patient safety because current patient safety devices are considered satisfactory. Overall improvements in risk management record keeping and rapid response programs as a whole are considered to be more significant factors in changing practice patterns and improving quality care. Such a device would further advance patient safety in acute care beds, but it is not known how significant a portion of the general categories of “unattended injuries” or “failure to rescue” occur in medical-surgical acute care bed settings.

**9. The impact of any other indirect costs upon the costs and benefits of coverage as may be directed by the legislature or deemed necessary by the auditor in order to carry out the intent of this section.**

This impact cannot be assessed since the LG1™ or LifeBed™ system is not a specific health care service covered under Section 23-51, HRS.

***Financial impact***

**1. The extent to which insurance coverage would increase or decrease the cost of the treatment or service.**

This is unknown as data are unavailable on whether insurance coverage or lack of it would increase or increase the cost of the Intelligent Medical Vigilance System™.

**2. The extent to which insurance coverage might increase the use of the treatment or service by acute care hospitals.**

This is unknown as data are unavailable regarding a projected increase in the use of the Intelligent Medical Vigilance System™ if covered by health insurance. Hospitals decide whether it is worth the cost of purchase and installation of the LG1™ or LifeBed™, and how much of this cost would be offset by insurance reimbursements

for its use. The hospital would negotiate hospital acute care per day reimbursements with health insurers in its decision on whether it is worth the cost to install the device.

**3. The extent to which mandated coverage might serve as an alternative for more expensive service.**

There is no alternative to an LG1™ as defined in Senate Bill No. 409, Senate Draft 1. Its function as a vital sign monitoring device is inapplicable since not all vital signs are monitored. Conventional patient bed safety devices are already in use, including attached bed alarms and bed guards. These features are also less expensive to install and operate.

**4. The extent to which insurance coverage of the health care service or provider can be reasonably expected to increase or decrease the insurance premium and administrative expenses of policyholders.**

All insurers and hospitals responded that to mandate specific types or brands of devices such as the LG1™ or LifeBed™ system as part of the diagnosis related group (DRG) based on daily hospital bed reimbursement cost would increase the cost of health care. Coverage of medical vigilance services as described in Senate Concurrent Resolution No. 209, House Draft 1, Conference Draft 1, would ultimately increase whatever the present cost might be should the DRG include requirements for patient safety monitoring. Typically, hospital coverage is provided for whatever services are necessary or required depending on the patient's medical condition upon admission, as long as the medical condition resulting in admission is covered by benefits.

Mandated coverage for the use of intelligent medical vigilance would involve installation, staff training, and maintenance expenses added to the capital and operating costs of acute care hospitals. These costs would ultimately be passed on to patients in the form of higher health insurance premiums. Presently, there is no known separate charge for similar monitoring devices to the policy holder in an acute care setting since this cost is included in the universal DRG fee paid to the facility. If it is counted at all, it is likely in a hospital's charges for administration and overhead. Mandating health insurance carriers to cover the cost of the LG1™ or LifeBed™ system would not guarantee that hospitals would provide for the use of the LG1™ Intelligent Medical Vigilance System™ or LifeBed™ as it may not be required or appropriate in certain instances depending on the patient care plan.

**5. The impact of this coverage on the total cost of health care.**

As new technology is used by hospitals, insurance coverage for intelligent medical vigilance is expected to raise hospital overhead, which historically has resulted in the hospitals' demand for higher reimbursement from payers. Higher reimbursements to hospitals will likely cause premiums to increase, which increases the cost to businesses, policyholders, and their dependents. If the cost is more than the cost of the current technology, then it would increase premiums in the beginning. If this helps to prevent unnecessary stays or reduces medical errors, then this could save in premiums. However, per day rates for telemetry units that are equipped with monitoring levels similar to the LG1™ or LifeBed™ used for cardiac patients are at least 30 percent higher than general medical-surgical per day rates.

---

**Conclusion**

An assessment of the social and financial impacts of mandating insurance coverage for intelligent medical vigilance as identified and defined in Senate Bill 409, Senate Draft 1, was not feasible since it refers to a product, that is, the LG1™ system, instead of a specific health care service covered under Section 23-51, HRS. Our evaluation is also hampered by the lack of identifying information in the bill. Therefore, we make no recommendations.

---

## Notes

### Chapter 1

1. Piezoelectricity is the ability of crystals and certain ceramic materials to generate a voltage in response to applied mechanical stress.  
En.wikipedia.org/wiki/Piezoelectric
2. Joshua L. Jacobs, Nathaniel Apatov, Matthew Gleib, “Increasing vigilance on the medical/surgical floor to improve patient safety,” *Journal of Advanced Nursing* 57(5), October 2006, p. 472-481.

### Chapter 2

1. Hawai‘i, The Auditor, *Assessment of Proposed Mandatory Health Insurance for Cognitive Rehabilitation*, Report No. 04-11, Honolulu, November 2004.

*This page intentionally left blank.*



---

## Responses of the Affected Agencies

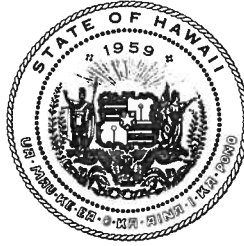
### **Comments on Agency Responses**

We submitted a draft copy of this report to the Departments of Commerce and Consumer Affairs and Health on February 25, 2008. A copy of the transmittal letter to the Department of Health is included as Attachment 1. A similar letter was sent to the Department of Commerce and Consumer Affairs.

Both the Departments of Commerce and Consumer Affairs and Health opted not to provide responses.

ATTACHMENT 1

STATE OF HAWAII  
OFFICE OF THE AUDITOR  
465 S. King Street, Room 500  
Honolulu, Hawaii 96813-2917



MARION M. HIGA  
State Auditor

(808) 587-0800  
FAX: (808) 587-0830

February 25, 2008

**COPY**

The Honorable Chiyome L. Fukino  
Director of Health  
Department of Health  
Kinau Hale  
1250 Punchbowl Street  
Honolulu, Hawaii 96813

Dear Dr. Fukino:

Enclosed for your information are three copies, numbered 6 to 8, of our confidential draft report, *Study of the Social and Financial Impacts of Mandatory Health Insurance Coverage for Use of Intelligent Medical Vigilance Services in Acute Care Hospitals*. We ask that you telephone us by Wednesday, February 27, 2008, on whether or not you intend to comment on our recommendations. If you wish your comments to be included in the report, please submit them no later than Monday, March 3, 2008.

The Department of Commerce and Consumer Affairs, Governor, and presiding officers of the two houses of the Legislature have also been provided copies of this confidential draft report.

Since this report is not in final form and changes may be made to it, access to the report should be restricted to those assisting you in preparing your response. Public release of the report will be made solely by our office and only after the report is published in its final form.

Sincerely,

A handwritten signature in cursive script, reading "Marion M. Higa".

Marion M. Higa  
State Auditor

Enclosures