## Sunrise Analysis of a Proposal to Regulate Certified Professional Midwives

A Report to the Governor and the Legislature of the State of Hawaii

Report No. 99-14 March 1999

THE AUDITOR STATE OF HAWAII

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Submitted by

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### **Foreword**

The Hawaii Regulatory Licensing Reform Act, Chapter 26H, Hawaii Revised Statutes, contains a "sunrise" provision requiring that measures proposing to regulate professions or vocations be referred to the State Auditor for analysis prior to enactment.

This report evaluates the regulation of certified professional midwives that was proposed in House Bill No. 3123, introduced in the Regular Session of 1998. The Legislature requested this study in Senate Concurrent Resolution No. 64, Senate Draft 1, of the 1998 session. The study presents our findings on whether the proposed regulation complies with policies in the licensing reform law and whether there is a reasonable need to regulate certified professional midwives to protect the health, safety, or welfare of the public.

We acknowledge the cooperation of the Department of Commerce and Consumer Affairs, the Department of Health, and other organizations and individuals knowledgeable about the occupation whom we contacted during the course of our analysis.

Marion M. Higa State Auditor

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### Chapter 1

### Introduction

This report responds to a "sunrise" provision of the Hawaii Regulatory Licensing Reform Act—Chapter 26H, Hawaii Revised Statutes (HRS). The provision requires that legislative bills which, if enacted, would regulate previously unregulated professions or vocations, must be referred to the State Auditor for analysis prior to enactment. The Auditor is to assess whether the proposed regulation is necessary to protect the health, safety, or welfare of consumers and is consistent with other regulatory policies stated in the law. The Auditor is to also set forth the probable effects of the proposed regulation and assess alternative forms of regulation.

This report analyzes the regulation of certified professional midwives that was proposed in House Bill (H.B.) No. 3123, introduced in the Regular Session of 1998. Currently, *certified professional midwife* is a title given to certain "lay" (non-nurse) midwives by an organization called the North American Registry of Midwives. The Legislature requested this analysis in Senate Concurrent Resolution (S.C.R.) No. 64, Senate Draft (S.D.) 1 of the 1998 session.

### Background on Midwives

Midwives are nonphysicians who care for women during pregnancy, assist with labor and delivery, and provide aftercare for the mother and child. The specific title given to a midwife depends on such factors as custom, training, credentials, and state laws.

Midwives fall into two broad categories: nurse midwives and non-nurse midwives. Both types of midwives attend to healthy, normal, low-risk women and newborns. In most situations, both types of midwives can conduct deliveries on their own with little medical and technical intervention.

#### Nurse midwives

Nurse midwives are educated in nursing and midwifery and are recognized by law in all states. Typically they hold the credential of *certified nurse-midwife* awarded by the American College of Nurse-Midwives. This credential requires completing a baccalaureate or master's degree program in nursing and a nationally accredited curriculum in midwifery, and passing the American College's national certification examination.

Nurse midwives may limit their practice to pregnancy care or expand their practice to include primary, preconception, gynecological, contraceptive, and infertility care. They may care for women from teenage to childbearing years, mid-life, or old age. They may use both modern medical approaches and measures from older traditions such as acupressure, herbal therapy, homeopathy, healing touch, positioning, and nutritional interventions.

Usually, nurse midwives practice in collaboration with other health care professionals in clients' homes, birth centers, or traditional labor and delivery units in hospitals.

### Non-nurse (lay) midwives

Non-nurse midwives may be trained in midwifery with some medical basis, but they do not need a nursing degree. Their education and training vary widely; some have no formal education.

Depending on their situation, non-nurse midwives may be called *lay*, *direct entry*, *traditional*, or *empirical* midwives. One national organization awards the credential *certified professional midwife* to qualified persons; another awards the credential *certified midwife*. In this report, we will use the term lay midwife to mean any non-nurse midwife.

Lay midwives are more limited in their scope of practice than are nurse midwives. However, like nurse midwives, they conduct deliveries on their own, provide immediate postpartum care of the newborn, provide continued gynecological care to the healthy woman, and may use alternative approaches to care.

Lay midwives usually provide services in the home (including deliveries) or in other out-of-hospital, "natural" settings. In Hawaii, the *pale keiki* (midwife) long predated the arrival of Westernized medicine.

### Professional organizations

The American College of Nurse-Midwives is involved with both nurse midwifery and lay midwifery. The college offers two credentials: certified nurse-midwife (requiring a nursing degree) and certified midwife (requiring a baccalaureate degree or enrollment in an accredited degree program, but not a nursing degree). Both credentials require completion of an educational program that teaches the same core competencies of midwifery. These knowledge and practice expectations are revised at least every five years to reflect changing trends and new developments. The college, which represents more than 6,000 certified nurse midwives from 50 states and 6 certified midwives from New York, has a Hawaii chapter.

The college's Certification Council accredits educational programs that teach the core competencies. Its accreditation program has been recognized by the U.S. Department of Education for 15 years.

Other organizations focus on lay midwifery. The Midwives' Alliance of North America (the local affiliate is the Midwives Alliance of Hawaii) was formed in 1982 to identify core competencies of lay midwifery, which are similar to the core competencies of the American College of Nurse-Midwives. The North American Registry of Midwives awards the credential of *certified professional midwife* to lay midwives who pass its examination in the core competencies and who meet other requirements of experience, knowledge, and skill.

In 1991, the Midwives Education Accreditation Council began accrediting programs that teach the core competencies of lay midwifery. The council accredits various educational routes: apprenticeships, distance learning (off-site learning through electronic communication), certificate programs, degree programs, programs within institutions, and private institutions. The U.S. Department of Education does not recognize the council's accreditation program.

Estimates of the number of lay midwives in the United States range from about 2,000 to 3,000.

#### Regulation in Hawaii

Regulation of midwifery in Hawaii began in 1931 when midwives were required to register with the Board of Health and file birth certificates for the births they attended. Eventually regulation was administered by the Maternal and Child Health Branch of the Department of Health. Only registered nurses were eligible for licensure as midwives. Practicing midwifery without a license was illegal.

In 1989, our *Sunset Evaluation Report: Regulation of Midwives*, Report No. 89-21, recommended that regulation be continued, with improvements that included statutory amendments. Subsequently, Act 225, Session Laws of Hawaii (SLH) 1990, established a revised regulatory program under Chapter 321, Part XXXI, HRS.

#### Chapter 321 stated that midwifery means:

the care and management of essentially normal newborns and women before, during, and after pregnancy and childbirth, and includes the provision of normal obstetrical and gynecological services and the rendering, undertaking, or providing of such care, management, or services, regardless of whether compensation or profit is received.

In order to protect the health, safety, and welfare of mothers and infants, Chapter 321 required that no one except physicians could practice midwifery unless licensed by the State as a nurse midwife. Eligibility for licensure required having a license as a registered nurse from the Board of Nursing in the Department of Commerce and Consumer Affairs under Chapter 457, HRS, and being certified by the American College of Nurse-Midwives to practice midwifery. Because practicing midwifery without a nurse-midwife license was a misdemeanor, the practice of lay midwifery apparently was illegal.

As required by Chapter 321, the Department of Health continued to administer the midwifery licensing program (through its Maternal and Child Health Branch). The department adopted detailed rules governing midwifery practice that included:

- Procedures for maintaining a safe and hygienic environment, monitoring the progress of labor and the status of the fetus, recognizing early signs of distress or complications, referring complications to a physician, and preparing an emergency care plan to ensure continuity of medical care throughout labor and delivery and to provide for immediate medical care if an emergency arises;
- Provisions that midwives must practice in accordance with a
  mutually agreed upon written guideline/protocol for clinical
  practice with a physician who specializes in the field of
  gynecology or obstetrics, or a physician or group of physicians
  who have a formal consultative arrangement with a gynecologist
  or obstetrician;
- The allowable scope of midwifery practice regarding the use of equipment, procedures, and medication; and
- Procedures for the issuance and renewal of licenses.

However, Act 279, SLH 1998 repealed the Department of Health's midwifery regulatory program under Chapter 321 as of July 20, 1998. Act 279 also amended Chapter 457, HRS, the nurse licensing law, to require that as of January 31, 1999, the Board of Nursing in the Department of Consumer Affairs must recognize as an *advanced practice registered nurse* any nurse midwife who has current certification from a national certifying body recognized by the Board of Nursing. Act 279 did not establish a nurse-midwife licensing program under the Board of Nursing, nor did it prohibit the practice of midwifery by uncertified nurse midwives or by lay midwives.

Legislative committee reports during the 1998 session suggested that the purpose of Act 279 was to end duplicative regulation of midwives by the Department of Health and the Department of Commerce and Consumer Affairs. Chapter 457 had recognized advanced practice nursing since

1994, so presumably nurse midwives could qualify for advanced practice recognition even before Act 279. But until Act 279, the advanced practice provisions of Chapter 457 did not mention nurse midwives specifically.

### Numbers of midwives and deliveries in Hawaii

The Department of Health reports that about 30 nurse midwives were licensed in Hawaii under Chapter 321 as of 1998. Since 1988, nurse midwives have delivered an estimated 4,000 babies in nine hospitals on the five major islands in the state. In 1995, nurse midwives reportedly delivered over 800 babies in six hospitals.

Information on unlicensed midwives is scarce. Reportedly 20 to 25 lay midwives were active in Hawaii in 1998, of whom some but not all met the requirements of the North American Registry of Midwives. The Department of Health reports that from 1991 through 1996, an average of 171 births occurred at home or in other out-of-hospital settings (less than 1 percent of the annual average of 19,275 total births). Lay midwives probably attended many of the out-of-hospital births, but precise numbers are not available.

### Regulation in other states

Nurse midwives are licensed and regulated in all 50 states.

With regard to lay midwives, state laws run the gamut. About 15 states license them. Legislatures or courts in 8 states have outlawed lay midwives on the ground that they have insufficient training, and 27 states have yet to take a stand on lay midwifery. Physicians in Illinois reportedly are trying to have midwifery classified as a procedure requiring a medical license.

### Current Proposal to Regulate Certified Professional Midwives

The regulatory proposal that we were asked to analyze, H.B. No. 3123 of 1998, would establish a Midwifery Committee in the Department of Commerce and Consumer Affairs with the authority to issue a "certified professional midwifery" license to qualified applicants.

### Legislative findings

H.B. No. 3123 contains 17 legislative findings. These include the following:

 Hawaii needs to improve the cost-effectiveness of the current maternity health care system and to improve the state's poor infant mortality rates;

- The five industrialized nations with the lowest infant mortality rates have 70 percent of all births attended by midwives;
- There is a need to preserve the rights of women to deliver children in out-of-hospital settings and to allow certified professional midwives to serve Hawaii families without fear of criminal prosecution;
- The intent is not to penalize home birth or the practice of midwifery but to remove obstacles to safe out-of-hospital deliveries and encourage cooperation between licensed health care professionals and certified professional midwives, including consultation and transport when appropriate for the well-being of the mother and infant;
- Certified professional midwife credentials are based on widely recognized core competencies for midwifery and represent national midwifery educational and certification standards of practice; and
- The Legislature needs to support a multifaceted, cost-effective approach that includes licensed certified professional midwives providing prenatal, delivery, and necessary follow-up care to lowincome families.

#### **Definitions**

The bill defines a certified professional midwife as an independent practitioner who has met the standards for certification set by the North American Registry of Midwives and who is qualified to provide the "midwifery model of care" as follows:

- 1. Monitoring the physical, psychological, and social well-being of the mother through the childbearing cycle;
- 2. Providing the mother with individualized education, counseling, prenatal care, continuous hands-on assistance during labor and delivery, and postpartum support;
- 3. Minimizing technological interventions; and
- 4. Identifying and referring women who require obstetrical attention.

"Midwifery services" is defined as antepartum (before childbirth or labor), intrapartum (during childbirth or delivery), and postpartum (after childbirth or delivery) care for essentially healthy women. Services include newborn assessment, care of newborns, gynecological care for healthy women during the intraconceptual period, and related pharmacology.

### Licensing committee

The Midwifery Committee would consist of three certified professional midwives, one certified nurse-midwife, one allied health professional, and two members of the public. The governor would appoint all the members from nominations submitted by the Midwives Alliance of Hawaii. Committee members would be reimbursed for expenses but receive no other compensation.

The duties of the committee would include adopting rules, examining and licensing applicants, disciplining licensees, and requiring that licensees undergo "uniform or random peer review" to ensure quality of care.

### Scope of practice; licensing requirements

Licensed certified professional midwives would be authorized to:

- Give necessary supervision, health care, and education to women during pregnancy, labor, and the postpartum period;
- Conduct deliveries on their own; and
- Provide immediate postpartum care of the newborn and continued gynecological care to the healthy woman during the interconceptual period.

The practice of midwifery would include taking preventive measures; identifying the physical, social, and emotional needs of the woman and newborn; arranging for consultation, referral, and continued involvement when the care required extends beyond the abilities of the midwife; and executing emergency measures in the absence of medical assistance.

A licensed midwife would have to be trained to use—and could use and order—equipment, procedures, diagnostic laboratory tests, and medications necessary for the safe and skillful management of pregnancy, labor, and postpartum care consistent with national standards of midwifery care.

License applicants would have to hold certification as a certified professional midwife from the North American Registry of Midwives. Licensure would require extensive and varied clinical experience, including out-of-hospital settings with emphasis on early detection and response to abnormal conditions. Also required would be graduation from any Midwifery Education Accreditation Council program "according to national midwifery educational and certification standards of practice."

Licenses would have to be renewed every three years, contingent upon maintaining certification as a certified professional midwife and completing 30 continuing education units "according to national midwifery educational and certification standards of practice."

### Reimbursement and liability

H.B. No. 3123 states that licensed midwives shall be entitled to receive third-party reimbursement for performance of all midwifery services that would be reimbursable if performed by a physician, nurse, or certified nurse-midwife.

Any physician, certified nurse-midwife, or hospital providing medical care or treatment to a woman or infant due to an emergency arising during childbirth as a consequence of the care received by a licensed midwife could not be held liable for any civil damage as a result of such medical care or treatment. The exception would be when "the damages result from [the physician, nurse midwife, or hospital, presumably] providing or failing to provide care or treatment under circumstances demonstrating reckless disregard for the consequences so as to affect the life or health of another."

### Request for analysis

S.C.R. No. 64, S.D. 1, asks the Auditor to perform a sunrise analysis of H.B. No. 3123. The Auditor is to assess the probable effects of the proposed regulation—including the cost impact on the agency and the regulated group—and make recommendations on how midwives could be regulated, alternative forms of regulation, and which state agency would be best suited to implement regulation.

### Objectives of the Analysis

- 1. Determine whether regulation of certified professional midwives is warranted.
- 2. Assess the probable effects of regulation.
- 3. Assess the appropriateness of alternative forms of regulation.
- 4. Make recommendations based on our findings.

### Scope and Methodology

In assessing the need to regulate certified professional midwives as proposed in House Bill No. 3123, we applied the regulation criteria set forth in Section 26H-2, HRS, of the Hawaii Regulatory Licensing Reform Act.

The Legislature established policies in Section 26H-2 to ensure that regulation of an occupation takes place only for the right reason: to protect consumers. Regulation is an exercise of the State's police power and should not be taken lightly. Consumers rarely initiate regulation; more often, practitioners themselves request regulation for benefits that go beyond consumer protection. Practitioners often equate licensure with

professional status in seeking respect for their occupation. Regulation may also provide access to third-party reimbursements for services and help control entry into the field.

The policies set forth in Section 26H-2, amended by Act 45, SLH 1996, continue to reinforce the primary purpose of consumer protection:

- The State should regulate professions and vocations only where reasonably necessary to protect consumers;
- Regulation should protect the public health, safety, and welfare and not the profession;
- Evidence of abuses by providers of the service should be given great weight in determining whether a reasonable need for regulation exists;
- Regulation should be avoided if it artificially increases the costs
  of goods and services to the consumer unless the cost is exceeded
  by the potential danger to the consumer;
- Regulation should be eliminated when it has no further benefits to consumers:
- Regulation should not unreasonably restrict qualified persons from entering the profession; and
- Aggregate fees for regulation and licensure must not be less than the full costs of administering the program.

We were also guided by the 1994 edition of *Questions A Legislator Should Ask* by Benjamin Shimberg and Doug Roederer (published by the national Council on Licensure, Enforcement and Regulation in Lexington, Kentucky). The primary guiding principle for legislators, according to this publication, is whether the unregulated profession presents a clear and present danger to the public's health, safety, and welfare. If it does, regulation may be necessary; if not, regulation is unnecessary and wastes taxpayers' money.

We also used additional criteria for this analysis, including whether:

- The incidence or severity of harm based on documented evidence is sufficiently real or serious to warrant regulation;
- The cause of harm is the practitioner's insufficient skill or incompetence;

- The occupational skill needed to prevent harm can be defined in law and measured;
- No alternatives provide sufficient protection to consumers (for example, federal programs, other state laws, marketplace constraints, private action, or supervision); and
- Most other states regulate the occupation for the same reasons.

We also assessed the specific regulatory proposal—H.B. No. 3123—as to whether:

- The scope of practice to be regulated is clearly defined and enforceable;
- The licensing requirements are constitutional and legal (for example, no residency or citizenship requirements);
- Licensing requirements, such as experience or continuing education, are directly related to preventing harm;
- Provisions are not unduly restrictive and do not violate federal competition laws;
- Prohibited practices are directly related to protecting the public;
   and
- · Disciplinary provisions are appropriate.

In assessing the need for regulation and the specific regulatory proposal, we took the position that the burden of proof is on those in the occupation to justify their request for regulation and defend their proposed legislation. We evaluated their arguments and data against the criteria stated above.

We examined the regulatory proposal and determined whether practitioners and their professional associations had made a strong enough case for regulation. It is not enough that regulation *may* have *some* benefits. (We recommend regulation only if it is *demonstrably* necessary to protect the public.) We also scrutinized the language of the regulatory proposal for appropriateness.

In examining the type of regulation being proposed, we determined whether it was one of three approaches to occupational regulation:

Licensing. A licensing law gives persons who meet certain qualifications the legal right to deliver services, that is, to practice the profession (for example, social work). Penalties may be imposed on those who practice without a license. To institute and monitor minimum standards of

practice, licensing laws usually authorize a board that includes members of the profession to establish and implement rules and standards of practice.

Certification. A certification law restricts the use of certain titles (for example, social worker) to persons who meet certain qualifications, but does not bar others who do not use the title from offering such services. This is sometimes called *title protection*. (This government certification should not be confused with professional certification, or credentialing, by private organizations. For example, social workers may receive certification from the National Association of Social Workers.)

Registration. A registration law simply involves practitioners signing up with the State so that a roster or registry will exist to inform the public of the nature of their services and to enable the State to keep track of them. Registration may be mandatory or voluntary.

In addition to considering whether regulation of certified professional midwives is warranted and whether the approach proposed in H.B. No. 3123 is appropriate, we also considered the appropriateness of other regulatory alternatives. We assessed which state agency would be best suited to implement any regulation and the cost impact on the agency and the regulated group.

To accomplish the objectives of our analysis, we also reviewed literature on midwives, their regulation, competencies, and standards of care, including standard texts and information from other states and countries. We also contacted members of various health professions, two state regulatory agencies, and three emergency rooms for complaints and other evidence of harm to consumers.

We contacted staff of the Department of Commerce and Consumer Affairs, the Department of Health, and other government agencies as appropriate. This included contacts to assist us in identifying costs related to regulation. In determining the probable effects of regulation on consumers, the regulating agency, and the regulated group, we contacted representatives of related health professions and health facilities to obtain any available information on the demand for midwifery services, the likelihood of utilization of these services if regulated, and the identification of costs related to insurance reimbursements for these services.

Our work was performed from July 1998 through February 1999 in accordance with generally accepted government auditing standards.

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### Chapter 2

# Regulation of Certified Professional Midwives and Other Lay Midwives Is Warranted But Would Be Premature

This chapter presents the findings of our analysis of the regulation of certified professional midwives proposed in House Bill (H.B.) No. 3123 of the 1998 Regular Session. We concluded that the bill should not be enacted.

As explained in Chapter 1, certified professional midwife is a designation given by the North American Registry of Midwives to persons who meet the registry's certification requirements. Our analysis included an examination of the desirability of regulating a broader group—lay midwives—of which certified professional midwives are a type. We did not assess the need to regulate nurse midwives, although our report does include some discussion of that group.

### Summary of Findings

- 1. The regulation of certified professional midwives and other lay midwives is warranted. Regulation could help protect consumers from harm, and other public benefits are possible.
- H.B. No. 3123, which proposes regulation of certified professional midwives, raises concerns that must be addressed before any regulation is enacted. These concerns include fragmented regulation and a lack of agreement about qualifications and practice standards for lay midwifery.
- 3. Either the Department of Commerce and Consumer Affairs or the Department of Health could administer the regulation of lay midwives. Each has advantages and disadvantages.

Regulation of Certified Professional Midwives and Other Lay Midwives Is Warranted

Section 26H-2 of the Hawaii Regulatory Licensing Reform Act states that professions and vocations should be regulated only when necessary to protect the health, safety, or welfare of consumers. Because of the harm that incompetent practice can cause, we find that regulation of certified professional midwives and other lay (non-nurse) midwives is warranted. Also, other reasons for regulation may have merit, such as improving availability of midwives.

## Regulation could help protect consumers from incompetent practice

As we stated in our 1989 Sunset Evaluation Report: Regulation of Midwives, Report No. 89-21, the practice of midwifery poses a clear and significant potential for harm to the health and safety of the public. Regulation can help reduce the risk of harm.

Our 1989 report focused on nurse midwifery and found that the practice of nurse midwifery may injure the mother or newborn. We stated that during the maternity cycle, a patient may be exposed to a number of harmful conditions and situations if the practitioner is incompetent or negligent. Medication may be given by the wrong route or in the wrong dosage; an infant may fall during delivery and sustain a fractured skull; a nurse midwife may fail to consult with a physician when needed; or an abnormal pregnancy may go undetected.

In the present study, we focused on lay (non-nurse) midwifery and identified similar concerns. If incompetently practiced, lay midwifery can harm the mother or newborn and even result in death. Lay midwives must have sufficient education and experience to enable them to determine the needs of their patients and to follow appropriate standards of care. They must be knowledgeable enough to know that physicians can confirm whether the pregnancy is a low or high risk through an office visit during the early and late stages of pregnancy. Lay midwives must also be able to arrange for consultation and refer their patients to physicians when the required care exceeds their abilities. They must be trained and able to take emergency measures in the absence of medical assistance. Without these and other minimum competencies, midwives are less able to ensure patient safety.

Health care professionals in Hawaii have noted a possible lack of competency in some out-of-hospital deliveries. The incidents are anecdotal and unrecorded, and it is not clear whether lay midwives were involved. However, the reports suggest potentially serious problems.

Our informal survey of three neighbor island emergency rooms indicated that home-birth transfers to those emergency rooms occurred about once a year for each facility. An official of one hospital described births which took place in the ocean that resulted in complications and transfers to the hospital. In other interviews, lay and nurse midwives and obstetricians in the state told us of incidents of harm and fetal death that might have been prevented had proper precautions been taken at home births. Breech births (feet-first rather than the normal head-first presentation) and fetal distress (cardiac or respiratory failure) are conditions that nurses and physicians told us should be attended by a physician in a hospital setting with proper equipment. Interviewees also described post-delivery complications due to incompetent care that endangered a mother.

We did not find complete agreement on whether regulation of lay midwives is necessary. Nevertheless, we believe that the severity of potential harm to the mother and newborn resulting from incompetent practice is sufficient to warrant regulation of lay midwives. With regulation, the State could examine whether persons wishing to practice lay midwifery have the necessary basic competencies and could establish standards of care.

Although the Department of Health is notified of home births through birth certificate applications that are supposed to identify who attended the birth, the department's efforts to investigate births attended by lay midwives have sometimes been thwarted by uncooperative parents. The required information is often unreported or misreported. Regulation of the occupation could improve home-birth reporting and thus contribute to the public health.

The limited available data suggest that enough births are attended by lay midwives in Hawaii to justify government attention. Similar to the rest of the nation, home births and other out-of-hospital births account for about 1 percent of total births in the state (an average of 171 out-of-hospital births each year). Many of these births are probably attended by lay midwives.

Regulation could have other benefits for the public

H.B. No. 3123 lists several reasons for regulating certified professional midwives. Reducing infant mortality rates, protecting certified professional midwives from criminal prosecution, and supporting a cost-effective approach to maternity care that includes certified professional midwives providing prenatal, delivery, and follow-up care to low-income families are described. While these results could occur, they would not necessarily result from the passage of H.B. No. 3123.

#### Potential advantages

It is possible that regulation would help achieve the ends described in the bill. Considerable data indicate that results from home births attended by competent lay midwives are at least as good as from hospital births. Some data also indicate that the lowest infant mortality rates occur in countries with high accessibility to lay midwives. Regulation might improve maternal and child health care by ensuring that current or future lay midwives meet minimum standards, thus reducing potential harm. Other improvements could result from legitimizing lay midwifery as a noncriminal activity with adequate reimbursement, thus possibly encouraging greater availability of midwives and their utilization by families that might otherwise receive little or no care.

Some testimony during the 1998 legislative session supported H.B. No. 3123 on the grounds that it would foster setting safety standards for a recognized underground practice and promote serving consumers who remain at home due to geographical distances from health care facilities. These testifiers were primarily from rural areas on the islands of Hawaii, Maui, and Kauai.

Home births can have cost advantages for consumers. Licensed midwives charge less than physicians for their services. In 1992, midwives in the state of Washington charged \$1,900 for comprehensive maternity care, while physicians averaged \$2,500. In Hawaii, nurse midwives charge around \$1,000. Also, substantial savings are achieved by eliminating hospital costs. Midwifery care uses fewer resources such as intravenous fluids, anesthesia, and analgesia.

Insurance coverage for nurse midwifery services is available in Hawaii under Medicaid, QUEST, HMSA, Aetna, CHAMPUS, and others. However, insurance coverage for lay midwifery service is limited. According to February 1998 information from the Midwives' Alliance of North America, eight states reimburse direct entry (lay) midwives for Medicaid services. Hawaii's proposed legislation, H.B. No. 3123, provides for licensed midwives to be entitled to receive third-party reimbursement for performance of all midwifery services that would be reimbursable if performed by a physician, nurse, or certified nurse-midwife.

#### Advantages uncertain

Despite these potential benefits, we concluded that there is no guarantee that regulation of certified professional midwives would achieve the purposes listed in H.B. No. 3123. For example:

- The precise impact of midwifery regulation is uncertain. Health care utilization and health status are affected by complex variables.
- Because Act 279, SLH 1998, repealed Chapter 321, Part XXXI, HRS, which restricted the practice of midwifery to only physicians and nurse midwives, lay midwifery is now apparently legal even if regulation is not enacted.
- Regulation could encourage acceptance of a practice—lay midwifery—that some observers believe poses an inherent danger to consumers.
- Regulation does not ensure that licensed lay midwives will receive third-party reimbursement for their services. For example, the impact of placing reimbursement requirements in a licensing

law—not in an insurance law where they would normally be located—is uncertain. Furthermore, such a state law would not govern reimbursement by federal payers such as Medicaid.

#### Concern about regulatory costs

H.B. No. 3123 would place the regulation of certified professional midwives under the Department of Commerce and Consumer Affairs. Under Hawaii law, licensure fees must meet the full costs that the department would incur in administering the regulatory program. These costs include, for example, program start-up, board administration, examination development, licensee application review, and enforcement activities. Because licensees must absorb the costs of these fees or pass the costs on to consumers, the costs could become barriers to lay midwives entering or staying in the profession and to consumers seeking these midwives' services.

The costs and fees of regulating Hawaii's lay midwives would depend on the nature, extent, and complexity of regulation. However, one thing seems clear: the number of licensees would be small. An official of the Midwives Alliance of Hawaii estimates that about 20 to 25 persons could initially qualify for licensing under H.B. No. 3123, with an additional 4 to 6 persons qualifying in each subsequent year. Therefore, the fees that each licensee would incur (and either absorb or pass on to consumers) would tend to be higher than if there were a larger number of licensees.

Our previous reports on other professions suggest the costs and fees that could occur with regulation. An example is our *Sunrise Analysis of a Proposal to Regulate Marriage and Family Therapists*, Report No. 95-26. Like H.B. No. 3123 on certified professional midwives, the proposal to regulate marriage and family therapists would have created a regulatory board. We estimated that 75 therapists might initially obtain licenses, and perhaps 30 therapists would apply in each subsequent year. The Department of Commerce and Consumer Affairs estimated it would charge each initial applicant an initial fee of \$2,670 to cover costs. Examination fees could make the fee even higher.

### Unresolved Issues Make Regulation Premature

The proposed legislation, H.B. No. 3123, raises several concerns that need attention before any regulation of lay (non-nurse) midwives (including those called certified professional midwives) is enacted. The concerns include fragmented regulation and the difficulty of establishing qualifications and practice standards for lay midwives. Until these problems are resolved, regulation would be premature.

### Fragmented regulation of midwives is a danger

Under H.B. No. 3123, fragmented regulation would occur in several ways:

First, the bill paradoxically would start regulating a type of lay midwife at a time when, because of Act 279 of 1998, nurse midwives are no longer being regulated, at least in the traditional sense (Act 279 simply authorizes state recognition of nurse midwives as advanced practice nurses but does not require them to be licensed as nurse midwives). This split approach would undermine consistency in state policy and make it more difficult to set standards for the profession of midwifery as a whole.

Second, the bill would regulate only one type of lay midwives: those designated as *certified professional midwives* by the North American Registry of Midwives. Other lay midwives, such as those designated as *certified midwives* by the American College of Nurse-Midwives, would not be included. This inconsistently treats one private organization differently from others, and could be confusing to consumers, health care institutions, and state regulators. For example, while authorizing licensed certified professional midwives to carry out certain activities, the bill does not clarify whether other types of lay midwives would be prohibited from carrying out these or similar activities.

Third, the State's issuance of a license titled *certified professional midwife* (as the bill authorizes) might mislead the public into believing that the word "professional" by itself means higher prestige, standards, or skills. This would further fragment regulation and add to confusion. Nurse midwives have more education than lay midwives but do not use "professional" as part of their title. "Professional" is not generally used by other states in regulating lay midwives or by other occupations regulated by the State of Hawaii, such as physicians and attorneys.

Fourth, the bill would establish a licensing committee with inappropriately narrow representation. The committee would have seven members: three certified professional midwives, one certified nurse-midwife, one allied health professional, and two members of the public. The governor would appoint these members from lists of nominees submitted by the Midwives Alliance of Hawaii.

This approach to the committee's membership does not ensure broad representation for all persons licensed to provide maternal and newborn care in setting competencies and standards that protect the consumer. Broader representation of medical professionals is needed. Furthermore, consumers themselves would not make up a sufficient proportion of the committee to prevent its domination by medical professionals. Finally, it is inappropriate to limit the governor's choices to persons nominated by a particular professional group, the Midwives Alliance.

### Qualifications for lay midwives lack consensus

For licensing purposes, an applicant's basic competency is normally determined by assessing his or her education and experience, and through tests. However, we found no consensus on how to apply these factors when licensing lay midwives.

H.B. No. 3123 requires license applicants to hold certification from the North American Registry of Midwives, but the requirements imposed on lay midwives by the American College of Nurse-Midwives—which are not mentioned in the bill—differ. The bill also requires license applicants to have graduated from any Midwifery Education Accreditation Council program, yet the council's accreditation process is not recognized by the U.S. Department of Education.

The lack of consensus on the regulation of lay midwives is reflected in a wide variety of licensing laws in other states. States differ, for example, on the number of live births that license applicants must have attended and on which license examination to use (states may use the examination of the North American Registry of Midwives, a state-constructed examination, or none).

Regulation in other states has varied. It may have been permissive or strict. In the mid-1980s, for example, Mississippi and Tennessee permitted any individual to initiate a home birth practice without registration or licensure. Texas required simple registration and imposed certain restrictions on practice, such as attending only normal childbirth, not administering drugs, and not using surgical implements. Licensure standards in Alaska, Arizona, New Mexico, and South Carolina were relatively rigorous.

Differences also existed in the scope of permitted practice. For example, New Mexico allowed midwives to cut emergency episiotomies and to suture small tears and administer antihemorrhagic drugs with physician approval. Arizona did not allow these practices, but acknowledged midwives as independent practitioners who do not require physician supervision.

Lack of consensus also undermines H.B. No. 3123's license renewal requirement to complete 30 continuing education credits. There is little agreement nationally as to the value of continuing education. While it can be argued that continuing education in some medical and allied health professions is appropriate for keeping skills current with changing technology, the need to require continuing education for lay midwives, whose practice is based on a demedicalized natural birth procedure, is questionable. A consensus on the competencies required for lay midwives may be more important than continuing education.

Medically related concerns have not been addressed

H.B. No. 3123 does not sufficiently describe the proper roles and relationships of midwives and other medical professionals in the continuum of maternal and child care. As with licensing qualifications, this omission also reflects a lack of consensus in the field.

#### Midwife's role unclear

The role of the midwife is without clear legal guidelines. As a result, the risk to patients may increase due to variations in lay midwifery practice. For example, reportedly the decision to deliver breech births at home or to transfer to a medical facility varies. Some midwives stay in the home setting despite the signs of negative (high risk) delivery, such as delivery beyond the due date. Other midwives initiate a medical transfer in such cases. If not specified in law, midwives may disagree as to what are considered low and high risk conditions due to their individual experiences. They may also disagree on the conditions that warrant physician services such as verifying a healthy low risk pregnancy or attending an emergency birth.

#### Professional relationships vague

The relationship of midwives to other medical professionals is likewise vague. The bill authorizes certain midwifery services without specifying the necessary medical support: identification and referral of women who require obstetrical attention, prescription drug dispensing authority, training and use of equipment, diagnostic laboratory tests, consultation and referral when the care required extends beyond the abilities of the midwife, and executing emergency measures in the absence of medical assistance. These tasks require the assessing, prescribing, or admitting services of a physician or nurse, but this requirement is not clearly established in the bill. The bill broadly describes "arranging for consultation" without stating when and how consultation occurs. Without specific or written assurances of consultation for physician services at perhaps initial and trimester exams and facility support for emergency conditions, consumers may suffer physical injury and financial harm.

The bill's lack of specificity for physician and other medical support creates uncertainty. Lay midwives do not have hospital admitting privileges and they deliver babies primarily in homes, doing so without commonly prescribed guidelines. They may or may not have referral protocols with obstetricians or authority to administer drugs. If hospital arrangements are needed, lay midwives may inform parents to make their own. They may or may not accompany their patients to the hospital, depending on the circumstances. They may or may not see themselves within the health care system or continuum of patient care. Ultimately, the consumer may be deprived of necessary medical support if regulation does not address these conditions sufficiently.

Physician support for midwifery practice is an ongoing controversy. A nationally known certified professional midwife says that lay midwives need medical relationships in order to perform physical examinations and process laboratory work. Liaison between home practice and hospital facilities is also necessary. However, like minimum competencies and licensing requirements, requirements for physician back-up and facility support differ among regulating states. State laws may or may not specify conditions for hospital transfer, administering of antihemorrhagic drugs, minor suturing of lacerations, and informed consent agreements between midwife and client.

According to a Honolulu obstetrician who utilizes nurse midwives in his practice, common parameters of practice for all certified midwives should be established. If certified midwives are allowed to attend home births, they should have sufficient tools, common guidelines, and competencies to do the job reasonably well. An informed consent agreement between clients and midwives would be needed. This agreement, like those used in hospitals, would spell out the parents' responsibilities and would provide for a midwife's complete and timely response to patient needs.

As recently as 1994, numerous physician organizations have clearly stated their opposition to home births. The result has been regulation, liability, and reimbursement barriers to those wishing to provide such services. Reasons for the lack of support from the medical community and the malpractice insurance industry include perceived safety issues, lack of practitioner experience in normal birthing, and prevailing attitudes of society.

In Hawaii, physician malpractice insurance is a contributing problem to midwifery regulation. The physician-owned Honolulu-based malpractice insurer, the Hawaii Association of Physicians for Indemnification (HAPI), does not cover physicians for supervising other practitioners. Insurance companies give obstetricians the highest risk rating, and some pay annual premiums of \$85,000. Other insurers add a surcharge of several thousand dollars to the annual malpractice premium of a physician who backs up even a nurse midwife.

Consensus among states is lacking in their approach to lay midwifery. Some states have established criteria for home-birth settings: (1) attendance by a qualified health professional, (2) strict adherence to stringent screening and transfer criteria, (3) an immediately available transport system, and (4) an immediately accessible backup physician and hospital arrangements. Other states have not established criteria.

Medical and physician support are unresolved issues that affect midwifery regulation. These issues are not sufficiently addressed in the proposed legislation.

# Two State Agencies Are Suitable to Administer Regulation

The Legislature asked us to examine which state agency would be best suited to implement regulation of lay midwives in Hawaii. We found that either the Department of Commerce and Consumer Affairs (as proposed under H.B. No. 3123) or the Department of Health is suitable.

According to a 1994 report, the 13 states that regulated direct entry (lay) midwives used one of four types of regulatory agency, as follows:

#### Types of Regulatory Agencies

- Maternal and child health programs and health agencies
- Occupational, professional licensing agencies
- · Medical examiner boards
- Nursing boards

#### States

- Arizona, New Mexico, South Carolina, Texas, Washington
- Alaska, Florida, Montana, Pennsylvania
- · Louisiana, Minnesota, New Jersey
- · North Carolina

In Hawaii, the Department of Health, through its Maternal and Child Health Division, has many years of experience in regulating midwifery under Chapter 321, HRS, with a focus on nurse midwives. While the Chapter 321 program was recently repealed, the department's expertise in midwifery, incidents of harm, maternal and child health, public health in general, and health care systems would be valuable to any regulatory program for lay midwives. Administering the regulation of lay midwives would also enable the department to more closely monitor home births.

On the other hand, placing regulation of lay midwives in the Department of Commerce and Consumer Affairs would take advantage of the department's wide experience in the complexities of occupational licensing and bring nurse midwives and lay midwives under the same agency umbrella. Otherwise, state involvement in midwifery would be split between the health department and the consumer affairs department, which is now responsible for administering advanced-practice provisions for nurse midwives through the Board of Nursing.

Options within the Department of Commerce and Consumer Affairs include (1) establishing a new midwifery licensing board as the regulatory authority; (2) establishing a lay midwifery advisory committee, with the director of commerce and consumer affairs as the licensing authority; or (3) using an existing board—such as the Board of Nursing, Board of Medical Examiners (which regulates physicians), Board of Osteopathic Examiners, or Board of Examiners in Naturopathy—as the licensing authority.

The licensing board approach would involve practitioners and consumers in the process of making policy and of adjudicating violations in the profession. However, boards require extensive administrative support by agency staff during both their formation and their ongoing work. Also, boards are sometimes accused of protecting practitioners and not the public, and of setting licensing requirements designed to control the number of new practitioners entering the profession.

An advisory committee could be easier and less costly to administer, and would have less power to protect professional interests, since the director of commerce and consumer affairs would set policy and make disciplinary decisions. However, some might argue that this approach could be detrimental in that decisions would not be made by experts in midwifery.

Placing regulation of lay midwives under an existing licensing board—for example, the Board of Nursing or the Board of Medical Examiners—could have advantages, including lower administrative costs by not establishing a new board, and fostering closer ties between lay midwives and other practitioners such as physicians with whom collaborative working relationships are desirable.

The disadvantages of using existing boards are several. For example, the Board of Nursing or the Board of Medical Examiners may have interests quite distinct from—even opposed to—the interests of lay midwives. Also, these boards would have to become familiar with education, examination, and practice standards and other issues involving lay midwives that are different from those to which the boards are accustomed.

There may be a natural affinity between lay midwives and the Board of Osteopathic Examiners or the Board of Examiners in Naturopathy, since these boards regulate professionals who favor a more natural approach to medicine, similar to the orientation of lay midwives. But, again, these boards' interests may differ from those of lay midwives. Furthermore, the scope of practice of naturopathic physicians does not include maternal and newborn care.

### Conclusion

Regulation of certified professional midwives and other lay (non-nurse) midwives is warranted in order to protect consumers by helping ensure that practitioners have the basic skills—and follow appropriate standards—for consumer protection. Regulation may have other benefits for consumers and the health care system. Either the Department of Commerce and Consumer Affairs or the Department of Health could administer the regulatory program and various administrative structures for regulation are available.

However, we conclude that regulation would be premature until key issues are resolved concerning the scope and nature of regulation and the weaknesses of H.B. No. 3123. These include a lack of consensus in the field that could lead to fragmented regulation and to the establishment of inappropriate or insufficient qualifications and practice standards for the occupation.

### Recommendation

House Bill No. 3123 should not be enacted.

### Responses of the Affected Agencies

## Comments on Agency Responses

We transmitted drafts of this report to the Department of Commerce and Consumer Affairs and the Department of Health on March 1, 1999. A copy of the transmittal letter to the Department of Commerce and Consumer Affairs is included as Attachment 1. A similar letter was sent to the Department of Health. The response from the Department of Health is included as Attachment 2. The Department of Commerce and Consumer Affairs did not submit a response.

The Department of Health commented that our report is comprehensive and thorough and that it raises points about which the department has also had concerns. Agreeing that legislation at this time is premature, the department supports a comprehensive approach that includes establishing qualifications and standards of practice for lay midwives. The department's response discusses other issues including categories of midwives, membership of an advisory board, and the possible involvement of the department's Maternal and Child Health Branch in further study and analysis.

### 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

March 1, 1999

COPY

The Honorable Kathryn S. Matayoshi, Director Department of Commerce and Consumer Affairs Kamamalu Building 1010 Richards Street Honolulu, Hawaii 96813

Dear Ms. Matayoshi:

Enclosed for your information are three copies, numbered 6 to 8 of our draft report, *Sunrise Analysis of a Proposal to Regulate Certified Professional Midwives*. We ask that you telephone us by Wednesday, March 3, 1999, 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 Wednesday, March 10, 1999.

The Department of Health, Governor, and presiding officers of the two houses of the Legislature have also been provided copies of this 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,

Marion M. Higa State Auditor

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Enclosures

BENJAMIN J. CAYETANO GOVERNOR OF HAWAII



BRUCE S. ANDERSON, Ph.D., M.P.H.
DIRECTOR OF HEALTH

In reply, please refer to: File

March 9, 1999

HONOLULU, HAWAII 96801

Ms. Marion M. Higa State Auditor Office of the Auditor 465 South King Street, Room 500 Honolulu, HI 96813-2917 MAR 10 8 47 AM '99

OFC. OF THE AUDITOR STATE OF HAWAII

Dear Ms. Higa:

We commend your office in the *Sunrise Analysis of a Proposal to Regulate Certified Professional Midwives*. The report is both comprehensive and thorough. It brings out salient points which we have also had concerns.

We agree that legislation at this time is premature and that we need to develop a comprehensive approach which would include establishing qualifications and standards of practice for lay midwives. One concern that we have is that the report combines certified and credentialed midwives with non certified/credentialed midwives under the category of lay midwife. We think that there should be a distinction between those midwives who have met nationally or professionally recognized standards through an accepted training program. Good points are raised about a Board for this program and we agree that an Advisory Committee with broad representation would provide a thorough approach in developing qualifications and standards of practice. We recommend that this study include guidelines for home births.

The Department of Health's Maternal and Child Health Branch has the expertise and experience in this field and would be willing to do the study but it should be in concert with the Department of Commerce and Consumer Affairs. However, given the staff shortages that the Branch faces at this time, we would not be able to do the study without funding for staff for this Advisory Committee and the production of this report. We estimate that the study and analysis by staff and an Advisory Committee would take 12-18 months.

Thank you for the opportunity to comment on the draft report.

Sincerely,

BRUCE S. ANDERSON, Ph.D., M.P.H.

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Director of Health