
Study of Proposed Mandatory Health Insurance Coverage for Medical Foods in the Treatment of Inherited Metabolic Diseases

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

Report No. 99-4
January 1999

THE AUDITOR
STATE OF HAWAII

Study of Proposed Mandatory Health Insurance Coverage for Medical Foods in the Treatment of Inherited Metabolic Diseases

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

Submitted by

THE AUDITOR
STATE OF HAWAII

Report No. 99-4
January 1999

Foreword

Sections 23-51 and 23-52, Hawaii Revised Statutes, require the State Auditor to study the social and financial impacts of measures that propose to mandate health insurance benefits. As requested by Senate Concurrent Resolution No. 19, S.D. 1, H.D. 1 of the 1998 legislative session, this report assesses the impacts of mandating health insurance coverage for medical foods in the treatment of inherited metabolic diseases as proposed in Senate Bill No. 2408, S.D. 1 of the 1998 legislative session.

We wish to express our appreciation for the cooperation and assistance of those state agencies, private insurers, and other interested organizations and individuals whom we contacted in the course of this study.

Marion M. Higa
State Auditor

Table of Contents

Chapter 1 Introduction

Background on Mandated Health Insurance	1
Background on Medical Foods in the Treatment of Inherited Metabolic Diseases	3
Current Proposal to Mandate Coverage	6
Mandated Coverage in Other States	7
Objective of the Study	8
Scope and Methodology	8

Chapter 2 Social and Financial Impact of Mandating Health Insurance Coverage for Medical Foods in the Treatment of Inherited Metabolic Diseases

Overview of the Proposed Mandate	11
Social Impact	12
Financial Impact	17
Conclusion	20

Notes	21
--------------------	----

Response of the Affected Agency	23
--	----

Chapter 1

Introduction

Sections 23-51 and 23-52, Hawaii Revised Statutes (HRS), require the Legislature to pass concurrent resolutions requesting the State Auditor to study the social and financial effects of any proposed legislative measure that would mandate health insurance for specific services, diseases, or providers.

The law stems from legislative concern over the increasing number of these proposals in recent years and their impact on the cost and quality of health care. The purpose of the assessment is to provide the Legislature with an independent review of the social and financial consequences of each proposal.

Senate Concurrent Resolution No. 19, Senate Draft 1, House Draft 1 of the 1998 legislative session requests the State Auditor to study the social and financial impacts of requiring all employer group health policies, contracts, plans, or agreements issued on a group or individual basis to provide coverage for foods that are medically necessary for the treatment of inherited metabolic diseases. The resolution states that such coverage would be mandatorily provided for at least 80 percent of the cost of care. Senate Bill No. 2408 was introduced during the 1998 legislative session as the vehicle to mandate health insurance coverage for medical foods in the treatment of inherited metabolic diseases.

Background on Mandated Health Insurance

Since the 1960s, states have enacted a variety of laws mandating the health coverage that insurers must provide. These laws have required insurers to cover specific medical conditions and treatments, particular groups of people, and services of certain health practitioners. Between 1978 and 1992, the number of mandates grew dramatically from 343 to 950. Since 1992, the growth of mandated coverage has slowed, with a total of approximately 1,050 state mandates in 1997.

Arguments for and against mandated health insurance

Mandated health insurance may be appropriate in certain circumstances. However, proponents and opponents disagree about several key issues, such as whether a particular coverage is necessary, whether it is justified by the demand, and whether it will increase costs. Generally, providers and recipients of medical care support mandated health insurance, and employers and insurers oppose it.

Proponents say gaps in existing coverage prevent people from obtaining needed care. They believe the current system is not equitable because it does not cover all providers, medical conditions, or needed treatments and services. Proponents also argue that mandated coverage could increase competition and the number and variety of treatments available. In some instances, mandated coverage could also reduce costs by making preventive care, early treatment, or alternate care more available.

Opponents argue that mandated benefits add to the cost of employment and production and reduce other more vital benefits. They create particular hardship for small businesses that are less able to absorb rising premium costs that result from increased numbers of mandated benefits. Opponents also contend that mandates reduce the freedom of employers, employees, and unions to choose the coverage they want. Insurers state that premium rates may rise beyond what employers and consumers are willing to pay. They argue that mandates create an incentive for employers to adopt self-insurance plans that are exempt from the mandates.

Types of insurance plans affected

Laws mandating health insurance in Hawaii affect three main types of private insurance: (1) Blue Cross and Blue Shield plans (a mutual benefit society in Hawaii) in accordance with Article 432:1, HRS, (2) health maintenance organizations (HMOs) under Chapter 432D, HRS, and (3) commercial insurance plans in accordance with Article 431:10A, HRS. By 1996, approximately 80 percent of Hawaii's civilian population was covered by private insurance plans.

The Hawaii Medical Service Association (HMSA) is the Blue Cross and Blue Shield insurer in Hawaii. It offers traditional fee-for-service plans that reimburse physicians and hospitals for services. HMSA also has various HMO plans that offer a package of preventive and treatment services for a fixed fee. With a 1996 membership of 639,400, HMSA covered about 59 percent of Hawaii's civilian population.¹

Health maintenance organizations (HMOs) are certified to provide services in compliance with Chapter 432D, HRS. An HMO undertakes to provide or arrange for the delivery of basic health care services to enrollees on a prepaid basis, except to enrollees responsible for co-payments, deductibles, or both.²

Kaiser Foundation Health Plan is a federally qualified and state-licensed health maintenance organization. In 1996, Kaiser provided insurance coverage for 195,607 people in Hawaii, or about 18 percent of the civilian population.³

As of May 1998, Health Plan Hawaii, Kapi'olani HealthHawaii, Pacific Health Care, and QPH Health (better known as Queen's/HMSA Premier Plan) also operated as state-licensed health maintenance organizations in Hawaii.

The Queen's health plans (which include Queen's Island Care, Queen's Hawaii Care, and Queen's Preferred Plan) provided coverage for 33,734 members in 1996, or approximately three percent of Hawaii's civilian population.⁴

Commercial insurance plans and other insurers, such as University Health Alliance (formerly Hawaii Dental Service Medical) and Straub Care Plus, covered most of the remaining privately insured population.

Mandatory health insurance laws in Hawaii normally affect only private insurers and do not affect public health plans such as Medicaid and Med-QUEST. Self-insured plans are also not subject to mandatory health insurance laws. In addition, each specific state statute pertaining to the different types of private insurers must be amended in order for a new mandated coverage to apply.

Potential legal challenge

Hawaii's Prepaid Health Care Act, enacted in 1974, requires employers to provide a qualified prepaid health care plan to regular employees who work at least 20 hours per week. A qualified plan is one with benefits that are equal to, or are medically reasonable substitutes for, the benefits provided by the plan with the largest number of subscribers in Hawaii.⁵

Federal courts have ruled that the Prepaid Health Care Act is preempted by the federal Employee Retirement Income Security Act (ERISA), which has a provision preempting state laws relating to employment benefit plans. A subsequent congressional amendment exempted Hawaii's Prepaid Health Care Act from ERISA. The exemption, however, applied only to the law as it was enacted in 1974. In effect, this has frozen the law at its original provisions, since ERISA would preempt any subsequent amendments. It is possible, therefore, that in Hawaii any mandated benefit laws passed after 1974 could be viewed, and challenged, as bypassing the limitations placed on the Prepaid Health Care Act.⁶

Background on Medical Foods in the Treatment of Inherited Metabolic Diseases

Inherited metabolic diseases, known sometimes as inborn errors of metabolism, are abnormalities resulting from genetic defects in the body's ability to metabolize (or process) particular nutrients. These diseases are inherited, lifelong conditions that can be detectable through screening programs. Treatment is dependent on the type of metabolic disease. For example, children and adults affected by such metabolic diseases as phenylketonuria (PKU) and maple syrup urine disease are treated

through restricted and monitored diets of special formulas, modified solid foods, and portions of regular foods.

Inherited metabolic diseases

Inherited metabolic diseases affect the body's ability to process amino acids, organic acids, nitrogen, carbohydrates, energy, and fatty acids. Although many of these individual conditions are rare, in the aggregate they are reported as possibly being as frequent as 1 in 5,000 births.

For example, phenylketonuria is a metabolic disorder which occurs when a person is born with impaired phenylalanine hydroxylase activity. Phenylalanine hydroxylase is necessary to metabolize phenylalanine, an amino acid found in proteins. It is one of the most common amino acid disorders; its incidence is estimated at 1 in 10,000 to 15,000 live births. In Hawaii, its incidence rate is 1 in 19,889 live births. The inability to process phenylalanine results in the accumulation of metabolites which become toxic to the body. Without early diagnosis and treatment, phenylketonuria (and other forms of inherited metabolic disorders) can result in irreversible mental retardation, severe health complications, and in some cases death. However, phenylketonuria is detectable, and when diagnosed early, the mental deficiency caused by the disease can be prevented by a restrictive therapeutic diet. Only early treatment—within the first weeks of life—prevents abnormal brain development in infants with this condition.

In 1965, the Legislature first recognized the problems of inherited metabolic diseases by mandating the screening for phenylketonuria in all newborns through Act 19, Session Laws of Hawaii (SLH) 1965 (subsequently codified as Part XXII, Section 321-291, HRS). The State later amended the statute to include screening for congenital hypothyroidism (the inability of the body to produce enough thyroid hormones) and to authorize the Department of Health to adopt administrative rules to screen and track specific diseases in newborn infants.

In 1996, the Legislature amended Section 321-291, HRS. Via Act 259, SLH 1996, it created a newborn screening special fund and required the health department to convene a panel to develop a plan to provide newborn screening services to the community. The Department of Health currently screens for seven disorders (phenylketonuria, congenital hypothyroidism, congenital adrenal hyperplasia, galactosemia, hemoglobin disorders, biotinidase deficiency, and maple syrup urine disease) through its Newborn Screening Program.

Government screening and treatment programs

Currently, all 50 states screen for phenylketonuria and congenital hypothyroidism. Furthermore, most states have used existing federal programs to provide treatment services for low income individuals. For example, 43 of the 50 states provide special formulas (medical foods

formulated for dietary treatment of phenylketonuria and other inherited metabolic diseases) for phenylketonuria under the U.S. Department of Agriculture's Women, Infant and Children (WIC) Supplemental Feeding Program. Other states provide special formulas and dietary supervision of eligible individuals through Early and Periodic, Screening, Diagnosis, and Treatment programs. These programs are part of the federal Medicaid program for Medicaid-eligible children, federally administered by the Health Care Financing Administration. Currently, Hawaii provides treatment services for inherited metabolic diseases for eligible individuals under its Medicaid, QUEST, and WIC programs.

Furthermore, some states have passed legislation requiring the state to provide special formula treatment to all individuals with metabolic disorders. For example, North Carolina has established a system whereby individuals with phenylketonuria are provided formula treatment through a collaborative effort between its Genetic Health Care Branch, the University of North Carolina Genetics Program, and the WIC program. North Carolina has not established a financial eligibility scale; therefore, anyone in need is provided this treatment.

Kansas has mandated coverage to provide necessary treatment products for diagnosed cases of phenylketonuria, congenital hypothyroidism, galactosemia, and maple syrup urine disease. Special formulas for the treatment of these diseases in Kansas are provided to families at no cost. Additionally, legislation was passed to provide reimbursement of up to \$1,500 per year for a diagnosed child age 18 or younger for the purchase of medically necessary food treatment products (i.e., modified solid foods). To qualify for reimbursement for modified solid foods, the income of the person or persons responsible for the child cannot exceed 300 percent of the federal poverty level. Neither North Carolina nor Kansas mandate private insurers to provide coverage for medical foods in the treatment of inherited metabolic diseases.

Medical foods

Some metabolic disorders, such as phenylketonuria or maple syrup urine disease, require the afflicted person to consume a special diet throughout their lives. For example, those with phenylketonuria and other metabolic diseases maintain a diet consisting of special formulas, modified low protein food products, and limited amounts of "regular" foods such as fruits and vegetables. Dietary treatment of metabolic diseases utilizing medical foods is the established standard of medical care for individuals with these forms of inherited metabolic disorders.

Medical food is statutorily defined in section 5(b) of the federal Orphan Drug Act as:

food which is formulated to be consumed or administered enterally (of or within the intestine) under the supervision of a physician and which is intended for the specific dietary management of a disease or a condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.⁷

The U.S. Food and Drug Administration (FDA) clarified this statutory definition in its nutrition labeling regulations. The FDA states that medical food:

- (1) Is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral (of or within the intestine) feeding by tube;
- (2) Is intended for the dietary management of a patient who because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuff or certain nutrients, or who has other medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of their normal diet alone;
- (3) Provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;
- (4) Is intended to be used under medical supervision; and
- (5) Is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.⁸

Current Proposal to Mandate Coverage

S.C.R. No. 19, S.D. 1, H.D. 1 of the 1998 legislative session requested the Auditor to study the social and financial impacts of requiring insurers to provide coverage for medical foods in the treatment of inherited metabolic diseases for at least 80 percent of the cost of care. The resolution referred to S.B. No. 2408 of the 1998 legislative session as a legislative vehicle to mandate this coverage; however, the original bill was amended in the Senate Committee on Human Resources and replaced by S.B. No. 2408, S.D. 1, upon which our analysis is based.

Coverage for medical foods

The proposed mandate, S.B. No. 2408, S.D. 1, would amend the Hawaii Revised Statutes to require insurers governed under Articles 431:10A (Accident and Sickness Insurance Contracts) and 432:1 (Mutual Benefit Societies) and Chapter 432D (Health Maintenance Organization Act) to provide coverage for medical foods for the treatment of inherited metabolic diseases. Coverage for medical foods is to be provided not as an option but for at least 80 percent of the cost of medical foods on condition that it is: (1) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases and (2) administered under the supervision of a licensed physician.

Related provisions

The proposed legislation would define inherited metabolic disease and medical foods for the purposes of this legislation. It would define “inherited metabolic disease” as a disease caused by an inherited abnormality of a person’s body chemistry. The proposed legislation would define “medical food” as food formulated to be consumed or administered in or through an enteron (the intestine) under the supervision of a physician, intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, and established by medical evaluations.⁹ Additionally, the proposed mandate would require insurers to provide policyholders with written notice of the coverage by December 31, 1999.

Mandated Coverage in Other States

Private insurance coverage for the treatment of inherited metabolic diseases is currently mandated in at least 21 states (Alaska, Connecticut, Florida, Maine, Maryland, Massachusetts, Minnesota, Missouri, Montana, Nevada, New Hampshire, New Jersey, New York, North Dakota, Oregon, Pennsylvania, South Dakota, Tennessee, Texas, Utah, and Washington). However, the coverage mandated for the treatment of inherited metabolic diseases varies among these states.

Some states, such as Alaska, Minnesota, Montana, South Dakota, Tennessee, and Washington, only cover the treatment of phenylketonuria and do not have provisions for other metabolic diseases. With the exception of Minnesota, these states cover only special formulas for phenylketonuria treatment without provisions for modified solid foods. Connecticut, Florida, Maine, Maryland, New York, and Nevada are a few of the states that mandate coverage for both special formulas and modified solid foods in the treatment of metabolic disease (including phenylketonuria). A number of the states that do provide coverage for modified solid foods include statutory annual limits on the amount of coverage. For example, Maine’s statute requires coverage for low-protein foods of up to \$3,000 annually, while laws of New York and Nevada each provide mandated coverage of up to \$2,500 for low-protein foods.

Objective of the Study

The objective of this study was to describe the social and financial effects of mandating health insurance coverage for medical foods in the treatment of inherited metabolic diseases.

Scope and Methodology

Pursuant to Sections 23-51 and 23-52, HRS, we assessed both the social and financial effects of the proposed coverage.

Scope

We examined the impact of mandatory health insurance coverage for medical foods in the treatment of inherited metabolic diseases and the cost of such services as proposed in Senate Bill No. 2408, S.D. 1. To the extent feasible, we considered the following issues set forth in Section 23-52, HRS.

Social impact

1. Extent to which medical foods in the treatment of inherited metabolic diseases are generally utilized by a significant portion of Hawaii's population.
2. Extent to which insurance coverage for medical foods in the treatment of inherited metabolic diseases is already generally available.
3. Extent to which the lack of coverage results in persons being unable to obtain necessary treatment.
4. Extent to which the lack of coverage results in unreasonable financial hardship on persons needing treatment.
5. Level of public demand for medical foods in the treatment of inherited metabolic diseases.
6. Level of public demand for individual or group insurance coverage for medical foods in the treatment of inherited metabolic diseases.
7. Level of interest of collective bargaining organizations in negotiating privately for this coverage.
8. Impact of providing coverage for medical foods in the treatment of inherited metabolic diseases on the health status, quality of care, practice patterns, provider competition, or other related items.
9. Impact of indirect costs upon the costs and benefits of coverage.

Financial impact

1. Extent to which insurance coverage would increase or decrease the cost of medical foods in the treatment of inherited metabolic diseases.
2. Extent to which this proposed coverage might increase the use of medical foods in the treatment of inherited metabolic diseases.
3. Extent to which mandated medical foods in the treatment of inherited metabolic diseases might serve as an alternative to more expensive treatment or services.
4. Extent to which insurance coverage for medical foods in the treatment of inherited metabolic diseases might increase or decrease the insurance premiums or administrative expenses of policyholders.
5. Impact of insurance coverage for medical foods in the treatment of inherited metabolic diseases on the total cost of health care.

Methodology

We reviewed relevant literature and reports on the social and financial aspects of medical foods in the treatment of inherited metabolic diseases. Applicable federal and state laws and regulations and the proposed legislation were also reviewed and assessed. We surveyed and obtained information from private insurers, employer groups, unions, professional associations, and other local organizations and entities, including the Department of Health and other affected agencies. We conducted follow-up interviews with surveyed entities as necessary.

We contacted and obtained information from national organizations including the Blue Cross and Blue Shield Association, the National Association of Insurance Commissioners, and federal government agencies. To the extent that information was available, we reviewed and documented coverage for medical foods in the treatment of inherited metabolic diseases adopted in other states.

Our work was performed from July 1998 to December 1998 in accordance with generally accepted government auditing standards.

Chapter 2

Social and Financial Impact of Mandating Health Insurance Coverage for Medical Foods in the Treatment of Inherited Metabolic Diseases

This chapter summarizes our assessment of the potential social and financial impacts of mandating health insurance coverage for medical foods in the treatment of inherited metabolic diseases. To the extent feasible, and based on available information, we addressed the social and financial issues set forth in Section 23-52, Hawaii Revised Statutes (HRS).

Medical foods are used in the dietary treatment of some forms of inherited metabolic diseases such as phenylketonuria and maple syrup urine disease. Treatment through medical foods is considered the established standard of care for individuals with some forms of inherited metabolic diseases. Currently, at least 21 states have passed legislation mandating private insurance coverage for dietary products (special formulas and/or modified solid foods) in the treatment of inherited metabolic diseases. Other states that do not mandate private health insurance coverage have created a system to provide treatment services (particularly special formulas) to those in need at no cost to affected individuals. Hawaii does not currently mandate coverage. As a result, coverage is variable, with some receiving coverage and others not.

Overview of the Proposed Mandate

As outlined in Chapter 1, Senate Bill No. 2408, S.D. 1 proposes to mandate private health insurance coverage for medical foods in the treatment of inherited metabolic diseases. The bill would require commercial insurers, mutual benefit societies, and health maintenance organizations governed under Articles 431:10A, 432:1 and Chapter 432D, HRS to provide this coverage.

The proposed legislation would define inherited metabolic disease as a disease caused by an inherited abnormality of a person's body chemistry. Medical food is defined as food formulated to be consumed or administered in or through the enteron (or intestine) under the supervision of a physician. It is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.¹

The proposed legislation would require that at least 80 percent of the cost of medical foods be covered provided that they are: (1) prescribed as

medically necessary for the therapeutic treatment of inherited metabolic diseases and (2) administered under the supervision of a physician. This proposed legislation would also require all insurers covered under the mandate to provide policyholders with written notice of the coverage by December 31, 1999.

Social Impact

1. Extent to which medical foods in the treatment of inherited metabolic diseases are generally utilized by a significant portion of Hawaii's population.

Inherited metabolic diseases are relatively rare and the number of persons being treated for this class of diseases in Hawaii is very small. As of December 1998 the Department of Health reported knowledge of 22 individuals (19 children and 3 adults) in Hawaii with inherited metabolic diseases that require treatment through medical foods. The department also reports that based upon the 1990 census population of 1,108,229, the prevalence rate in Hawaii of individuals requiring medical food treatment is approximately .02 per 1,000 (or 20 individuals per million). Further, the department stated that since metabolic diseases are inherited, the population of individuals in need of medical foods in the treatment of their metabolic disease is expected to remain constant.

2. Extent to which insurance coverage for medical foods in the treatment of inherited metabolic diseases is already generally available.

Medical foods can be classified into two general categories: special formulas and modified solid foods. Special formulas are formulated to address the specific metabolic deficiency of the affected person. Modified solid foods are specially formulated solid food products such as breads and pastas that address the deficiency. The extent of insurance coverage available in Hawaii varies considerably not only for medical foods in general, but also between the categories of special formulas and modified solid foods.

Currently, 5 of the 22 individuals known and identified by the Department of Health as needing medical foods are denied insurance coverage for special formulas. The remaining 17 individuals are provided insurance coverage for special formulas, either through private or public health plans.

The Hawaii Medical Service Association (HMSA) currently provides coverage for medical foods (special formulas) to four individuals. HMSA states that this coverage or benefit is not generally provided by the

association but is available as a substitution benefit through its Integrated Case Management Service program after a case-by-case evaluation. HMSA stated that no individual is currently being covered for modified solid foods since it has not received any demand for this coverage. However, HMSA stated that modified solid foods would also be covered if these products are determined by a physician to be medically necessary and upon approval of HMSA's medical director.

The health department reports that individuals in need of medical foods have not been able to obtain insurance coverage for modified solid foods such as low-protein foods. While special formulas in the treatment of inherited metabolic diseases are classified as medical foods, it is unclear whether modified solid foods are also medical foods. Modified solid foods are items such as breads and pastas that have been specially formulated to contain little or no amounts of substances that the affected individual cannot metabolize, such as low-protein foods. Advocates for Senate Concurrent Resolution No. 19, S.D. 1, H.D. 1 and Senate Bill No. 2408, S.D. 1 who were instrumental in the introduction of the measures, testified for mandatory health insurance coverage for both special formulas and modified solid foods. Connecticut, Florida, Maine, Maryland, Massachusetts, New York, and Nevada all have mandated coverage for both special formulas and modified solid foods. The statutory definition provided in Hawaii's proposed measure does not clearly state whether both products are covered. A nutritionist with the Department of Health stated that a strict definition of medical foods would only encompass special formulas. Therefore, if legislators intend to provide mandatory health insurance coverage for both special formulas and modified solid foods, they should explicitly state so within the legislation.

University Health Alliance offers coverage for "medically necessary food supplements" (special formulas) for the treatment of inherited metabolic diseases for its members, but has no members utilizing this service. However, as a third party administrator for two self-funded union plans that do not provide coverage for medical foods, University Health Alliance reports that three children, under the self-funded union plans, require "dietary supplements" (i.e., medical foods) for inherited metabolic diseases.

A University Health Alliance representative stated that self-funded union plans are not affected by mandatory health insurance requirements because they are exempt under the provisions of the federal Employee Retirement Income Security Act. The insurance division of the Department of Commerce and Consumer Affairs confirmed that self-insured/self-funded health plans are not regulated by the division and are not affected by passage of state legislation mandating coverage. University Health Alliance did note that coverage under these union health plans can be obtained through an approval of the board of trustees of the respective unions.

Kaiser Foundation Health Plan, Inc. (Kaiser) and Queen's Health Management (Queen's) do not provide coverage for medical foods (neither special formulas nor modified solid foods). Kaiser contends that medical foods are available as over-the-counter products, i.e., non-prescription. Over-the-counter products are not covered under Kaiser's HMO plan.

Modified solid foods, such as low-protein foods, are products that can be obtained without a prescription. However, there is dispute regarding whether special formulas are also over-the-counter products. The Department of Health testified that these substances are not considered to be dietary supplements and implied that they were not over-the-counter products. A local pharmacist stated that special formulas are prescription items, while other local pharmacists in the state have indicated that these special formulas are products that can be obtained without a prescription. Whether these products are prescription or non-prescription, they are not readily available. Individuals and families obtain modified solid foods from mainland corporations through the mail and necessary special formulas from pharmacies. Pharmacies that provide special formulas generally special order these products for individuals since most do not normally carry them. Additionally, under the proposed health insurance mandate, coverage is provided only if it is prescribed as medically necessary for the treatment of inherited metabolic diseases and administered under the supervision of a physician.

3. Extent to which the lack of coverage results in persons being unable to obtain necessary treatment.

Normally, the lack of coverage for medical foods does not prevent affected persons from obtaining necessary treatment. Since lack of treatment through medical foods has dire consequences, such as mental retardation and even death, families without insurance coverage pay for treatment products out-of-pocket.

Of the families we surveyed, those that do have coverage for special formulas report not having coverage for modified solid foods. They pay out-of-pocket for these special foods. The Department of Health reports that the lack of coverage for modified solid foods has contributed to poor scholastic achievement in three Hawaii children with metabolic diseases, requiring the need for special education services and eligibility evaluations for special education services.

One parent reports that she is able to feed her child special formulas but not modified solid foods. Her public health plan covers only the special formulas, and she cannot afford to purchase modified solid foods on a regular basis. Her child is now being evaluated for special education classes, which she contends is a result of her inability to regularly obtain modified solid foods for her child.

The proposed legislation would only affect private insurers governed under Articles 431:10A (Accident and Sickness Insurance Contracts) and 432:1 (Mutual Benefit Societies) and Chapter 432D (Health Maintenance Organization Act) of the Hawaii Revised Statutes. Individuals obtaining coverage from public health insurance programs and private plans not governed by the amended laws will not be affected by the proposed insurance mandate.

4. Extent to which the lack of coverage results in unreasonable financial hardship on persons needing treatment.

Medical foods (both special formulas and/or modified solid foods) are expensive and can create unreasonable financial hardship on families requiring these products. A 1997 California report entitled *Cost and Availability of Dietary Treatment of Phenylketonuria* concluded that feeding a child affected with phenylketonuria is more expensive than feeding an unaffected child. This report found that it costs 1.1 times more to feed an infant with phenylketonuria than an unaffected infant. The cost differential increases with age. The report projects that by the time a child reaches school age, it will cost three times more to feed an affected than an unaffected child.

The cost of medical foods treatment depends on the individual's disorder, age, and physical and clinical condition. One Hawaii family with two children in need of medical foods and no medical insurance coverage for the products estimates that monthly out-of-pocket costs are \$810 per month for special formulas and \$150 per month for modified solid food products. This results in annual out-of-pocket expenses of approximately \$11,520. Another Hawaii family with one child suffering from an inherited metabolic disease without coverage for medical foods estimates an annual cost of \$10,800. Since inherited metabolic diseases are life-long diseases, the cost for dietary treatment and monitoring of individuals will be incurred throughout their lives.

5. Level of public demand for medical foods in the treatment of inherited metabolic diseases.

The overall public demand for medical foods in the treatment of inherited metabolic diseases is low because the number of occurrences of inherited metabolic diseases requiring this treatment is rare. However, there is life long demand for medical foods from affected individuals as well as from health professionals and provider organizations that treat metabolic diseases.

6. Level of public demand for individual or group insurance coverage for medical foods in the treatment of inherited metabolic diseases.

Similarly, the overall public demand for insurance coverage for medical foods in the treatment of inherited metabolic diseases is also low. Demand comes largely from those affected by the diseases and from professionals and other health care providers. Employer organizations report that this treatment has not been a health coverage issue of their member companies.

Nationally, however, the American Academy of Pediatrics published a policy statement in 1994 regarding its position that special medical foods in the treatment of various metabolic diseases are medical expenses that should be reimbursed by health insurers. The Hawaii Dietetic Association stated that this position was endorsed by representatives of the American Dietetic Association, the U.S. Department of Agriculture, the Centers for Disease Control & Prevention, and other organizations. Additionally, we found at least 21 states that have passed laws mandating private health insurance coverage for this treatment (special formulas and/or modified solid foods).

7. Level of interest of collective bargaining organizations in negotiating privately for this coverage.

We found collective bargaining organizations were either disinterested or showed little interest in negotiating privately for this coverage. University Health Alliance, the administrator of two separate self-funded union health plans, stated that based on its experience, the level of interest of collective bargaining organizations to negotiate privately for this coverage is low. Additionally, employer organizations reported that coverage for this treatment has not been demanded by labor unions when negotiating with their member companies.

The unions we surveyed were unable to provide us with much information. However, the United Public Workers did express concern regarding the financial hardship on low- to moderate-income families who are generally not reimbursed by health insurers for medical foods.

8. Impact of providing coverage for medical foods in the treatment of inherited metabolic diseases on the health status, quality of care, practice patterns, provider competition, or other related items.

Coverage for medical foods would improve the health status and quality of care of affected individuals. The Department of Health reported that accessibility to special formulas and modified solid foods would contribute

to optimal medical management and cognitive and social development in affected individuals. The department and other respondents reported that coverage would lead to fewer emergency room visits and less frequent hospitalizations for affected individuals.

Some insurers stated that the overall impact of coverage would be minimal and would affect only those in need of medical foods. Kaiser expressed concern that additional diets requiring nutritional monitoring would either fall within the present legislation or be mandatory in the future. Kaiser stated that it would be unreasonable to expect health plans to provide coverage for over-the-counter-foods for all diseases that would benefit from careful nutritional management.

9. Impact of indirect costs upon the costs and benefits of coverage.

Insurers and other respondents were not able to provide much impact data regarding indirect costs on the costs and benefits of coverage. However, Queen's identified the need to develop policies and procedures to limit coverage of medical foods to meet statutory requirements and the need to monitor the development and production of new foods as indirect costs that would impact the costs and benefits of coverage.

Financial Impact

1. Extent to which insurance coverage would increase or decrease the cost of medical foods in the treatment of inherited metabolic diseases.

The impact on the cost of medical foods in the treatment of inherited metabolic diseases is expected to be small or non-existent since few individuals require this treatment. The health department and the Hawaii Dietetic Association both stated that insurance coverage would not affect the cost of these products since they are set by manufacturers. The Department of Health further reported that the cost of medical foods during the past four to five years has remained stable.

2. Extent to which this proposed coverage might increase the use of medical foods in the treatment of inherited metabolic diseases.

The proposed coverage may slightly increase the use of medical foods. The utilization of special formulas would probably not increase since those in need are already using these products; however, if the proposed coverage includes modified solid foods, use of these items could increase. According to the Department of Health, no individual in need of medical foods is currently receiving insurance coverage for modified solid foods

such as low protein products. However, since so few individuals with inherited metabolic disease need medical foods, any increase in usage would be slight.

3. Extent to which mandated medical foods in the treatment of inherited metabolic diseases might serve as an alternative to more expensive treatment or services.

Treatment by medical foods is less expensive than other forms of treatment for these individuals suffering from inherited metabolic diseases. Extensive and severe health conditions such as seizures, comas, irreversible brain damage, and in some cases even death can occur due to lack of treatment. HMSA stated that it was compelled to provide coverage for its members diagnosed with these needs since it recognized that the alternatives would be more expensive. For example, such services as extensive physician supervision, emergency room admissions, and other forms of hospitalization may be required without treatment. Additionally, the Department of Health listed other possible alternative services that are more costly than medical foods such as special education services, care home placements, and day program and training support services.

Furthermore, the department also provided cost comparison data illustrating the annual cost differential between a successfully treated child and an untreated adult both suffering from phenylketonuria, a metabolic disease requiring early treatment with medical foods. The annual cost of treating the adult, including care home placement, day program and training support services is reported to be \$46,657; the annual cost for a successfully treated child (basically consisting of medical foods) is \$8,707.

4. Extent to which insurance coverage for medical foods in the treatment of inherited metabolic diseases might increase or decrease the insurance premiums or administrative expenses of policyholders.

Mandating coverage for medical foods for the treatment of inherited metabolic diseases would probably have little effect on the cost of insurance premiums or administrative expenses of policyholders since so few individuals require this treatment.

The Hawaii Dietetic Association and the Department of Health anticipate that the mandate will have very little cost impact on policyholders from increases in insurance premiums or administrative expenses since very few individuals require treatment through medical foods. Some mixed information was obtained from insurers. University Health Alliance

reported that the mandate will have no effect on its premiums since medical foods are already a covered benefit. HMSA stated that it could not calculate the impact on policyholders; Queen's and Kaiser do anticipate increases in their premiums or benefit costs, which may affect policyholders. Kaiser stated that any additional mandates will create additional costs that can be passed on to policyholders but that the overall effect on premiums would be small since few individuals need medical foods.

5. Impact of insurance coverage for medical foods in the treatment of inherited metabolic diseases on the total cost of health care.

Mandating coverage for medical foods in the treatment of inherited metabolic diseases could have minimal impact on the total cost of health care. Coverage could greatly impact the lives of individuals in need of medical foods since accessibility to these items would improve health status of individuals and medical management of these diseases; however, the impact on the total cost of health care would probably be minimal because so few individuals are affected. Both HMSA and Kaiser expect negligible or little impact on the total cost of health care, while University Health Alliance warned that the smaller health insurance carriers would be impacted negatively.

Some respondents opposed legislation to mandate coverage for medical foods even if it could have minimal effect on the total cost of health care. They raised concerns regarding mandating health insurance benefits in general. For instance, HMSA stated that a mandate would be unnecessary since it currently provides coverage on a case-by-case basis. It warned that mandates would potentially limit its ability to review and determine appropriate care for its members (essentially restricting its flexibility) which it indicates is an important element of managing health care costs. Kaiser raised concerns that this mandate would set a precedent regarding other diseases that have dietary management components to treatment. Queen's is also against the mandate. It expressed concern that such a mandate would enter into the area of custodial care and social support. Queen's also stated that a social service agency is better equipped to provide these services to those in need.

Employer organizations were also against this mandate even if the financial impact could be minimal. The Hawaii Employers Council stated that this mandate is unwarranted when businesses in Hawaii are struggling. Additionally, the Hawaii Business League stated that individuals prefer to have choices in their coverage and that mandates reduce their flexibility.

Conclusion

We found very few individuals in the state—currently 22 as identified by the Department of Health—in need of medical foods for the treatment of their inherited metabolic diseases. The demand for this treatment and for insurance coverage comes from those few individuals and their families in need of medical foods and from health professionals and provider organizations. We found no indication that employers and unions are interested in these services or would demand coverage for them. We expect minimal financial impact caused by passage of this legislation since so few individuals in the state require this form of treatment. However, employer organizations and insurers oppose coverage even though the financial impact due to coverage is expected to be minimal.

Dietary treatment of those suffering from some forms of inherited metabolic diseases includes both special formulas and modified solid foods, such as low-protein foods. Some individuals with insurance coverage, either through public or private health plans, do receive coverage for special formulas but none receive coverage for modified solid foods. A strict application of the definition of medical foods would encompass only special formulas. If the intent of the legislation is to provide coverage for both these items, this intent should be clearly stated within the proposed legislation. States such as Connecticut, Florida, Maine, Maryland, Massachusetts, New York, and Nevada that have passed legislation to provide coverage for both special formulas and modified solid foods have clear language in their statutes providing coverage for both of these products.

The lack of coverage has not prevented affected individuals from obtaining overall treatment since consequences for lack of treatment are often dire (i.e., mental retardation, coma, seizure, and even death). Dietary treatment for inherited metabolic diseases is expensive. Families who have been refused insurance coverage have annual out-of-pocket expenses of over \$10,000 for treatment through medical foods. However, if these individuals are members of self-funded health plans, passage of the proposed mandate may not affect their insurance coverage. The insurance division of the Department of Commerce and Consumer Affairs does not regulate those plans. The division stated that legislation mandating coverage would not affect self-funded health plans. Therefore, even if this mandate is passed, the financial burdens on these individuals and their families may not be eased.

Additionally, the proposed legislation would also be ineffective for individuals receiving health insurance coverage through public health plans such as Medicaid and QUEST. The proposed legislation amends only statutes governing private health insurers under Articles 431:10A (Accident and Sickness Insurance Contracts), 432:1 (Mutual Benefit Societies) and Chapter 432D (Health Maintenance Organization Act), HRS.

Notes

Chapter 1

1. Hawaii, Department of Business, Economic Development and Tourism, *Data Book*, 1997, p. 404.
2. Section 432D-1, HRS.
3. Hawaii, Department of Business, Economic Development and Tourism, *Data Book*, 1997, p. 404.
4. Ibid.
5. Section 393-7, HRS.
6. National Governors' Association, *Roadblock to Reform, ERISA Implications for State Health Care Initiatives*, 1994, pp. 6, 46, 49, and 50.
7. 21 U.S.C. 360ee (b) (3).
8. 21 C.F.R. 101.9 (j) (8).
9. Senate Standing Committee Report No. 2053 on Senate Bill No. 2408, S.D. 1, Regular Session of 1998.

Chapter 2

1. Senate Standing Committee Report No. 2053 on Senate Bill No. 2408, S.D. 1, Regular Session of 1998.

Response of the Affected Agency

Comments on Agency Response

We transmitted a draft of this report to the Department of Health on January 4, 1999. A copy of the transmittal letter to the department is included as Attachment 1. The response from the department is included as Attachment 2.

The Department of Health provided us with a few technical and editorial suggestions for purposes of clarification which were incorporated in the study. The department also reported that it was informed of changes being made to the proposed legislation to clarify an issue raised in our study regarding the extent of food products being covered.

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

January 4, 1999

COPY

The Honorable Bruce Anderson
Director of Health
Department of Health
Kinau Hale
1250 Punchbowl Street
Honolulu, Hawaii 96813

Dear Dr. Anderson:

Enclosed for your information are three copies, numbered 6 to 8 of our draft report, *Study of Proposed Mandatory Health Insurance Coverage for Medical Foods in the Treatment of Inherited Metabolic Diseases*. We ask that you telephone us by Wednesday, January 6, 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, January 13, 1999.

The 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

Enclosures

BENJAMIN J. CAYETANO
GOVERNOR OF HAWAII



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

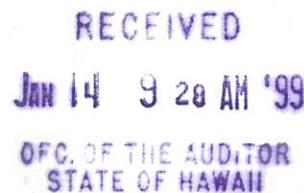
STATE OF HAWAII
DEPARTMENT OF HEALTH

P.O. BOX 3378
HONOLULU, HI 96801

January 12, 1999

In reply, please refer to:
File:

Ms. Marion M. Higa
State Auditor
Office of the Auditor
465 South King Street, Room 500
Honolulu, Hawaii 96813-2917



Dear Ms. Higa:

We have reviewed the draft report *Study of Proposed Mandatory Health Insurance Coverage for Medical Foods in the Treatment of Inherited Metabolic Diseases*. The following are comments from DOH regarding this report and its recommendations:

Page 4: **Inherited metabolic diseases, 2nd paragraph**

1st sentence: Revise to "For example, phenylketonuria is a metabolic disorder which occurs when a person is born [without] with impaired phenylalanine hydroxylase activity. Phenylalanine hydroxylase is necessary to metabolize phenylalanine, an amino acid found in protein."

4th sentence: Revise to "The inability to process phenylalanine [hydroxylase] results in the accumulation of [it] metabolites which become toxic to the body."

Page 12: **Social Impact, 1st paragraph:** The number of individuals with inherited metabolic diseases who required medical foods for the treatment of their disease increased from 17 at the time of our initial response to your survey, to 22 (2 newborns and 1 child diagnosed, 2 moved here from the mainland). This will result in a change in the prevalence rate.

Ms. Marion M. Higa
January 12, 1999
Page 2

3rd sentence: Revise to "The department also reports that based upon the 1990 census population of 1,108,229, the prevalence rate in Hawaii of individuals requiring medical food treatment is approximately [.015] .02 per 1,000 (or [15] 20 per million)."

Page 20: **Conclusion, 2nd paragraph:** Department of Health has been informed that changes are being made to the proposed legislation to clarify that required coverage includes both medical foods (formulas) and low protein modified food products.

Thank you for the opportunity to review and respond to this report.

Sincerely,



Bruce S. Anderson, Ph.D., M.P.H.
Director of Health