Study of Proposed Mandatory Health Insurance Coverage Regarding Step Therapy Requirements for Stage 2 Through Stage 5 Cancer

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

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OFFICE OF THE AUDITOR
STATE OF HAWAI‘I

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Foreword

Pursuant to Sections 23-51 and 23-52, Hawai‘i Revised Statutes (HRS), we assessed the social and financial impacts of prohibiting health insurers, mutual benefit societies, and health maintenance organizations (collectively referred to as “health insurers”) that cover treatment for stage 2 through stage 5 cancer, from requiring an insured diagnosed with stage 2 through stage 5 cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured’s health care provider, under certain conditions, as proposed in Senate Bill No. 2316 (Reg. Session 2024). Section 23-51, HRS, requires passage of a concurrent resolution requesting an impact assessment by the Auditor before any legislative measure mandating health insurance coverage for a specific health service, disease, or provider can be considered. The 2024 Legislature requested this assessment through House Concurrent Resolution No. 225 (Reg. Session 2024).

We wish to express our appreciation for the cooperation and assistance extended to us by the State’s health insurance providers, the State of Hawai‘i Department of Commerce and Consumer Affairs, Insurance Division, as well as other organizations and individuals we contacted during the course of our work.

Leslie H. Kondo
State Auditor

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Introduction

We assessed the social and financial effects of requiring health insurers to cover drugs recommended and prescribed by an insured's health care provider to treat stage 2 through stage 5 cancer without requiring that the insured undergo step therapy, as proposed in Senate Bill No. 2316 (Reg. Sess. 2024) (SB 2316). "Step therapy" is defined in SB 2316 as a protocol that requires an insured to use a prescription drug, or sequence of prescription drugs, other than the drug recommended and prescribed by the insured's health care provider before the insurer provides coverage for the recommended prescription drug. According to House Concurrent Resolution No. 225 (Reg. Session 2024) (HCR 225), which requested our assessment of the proposed mandate, step therapy is "a type of prior authorization that requires patients to try a certain, less expensive drug on a health insurance plan that has been proven effective before further treatments are authorized."

We determined the mandatory health insurance coverage proposed in SB 2316 will have minimal social or financial impacts on Hawai‘i’s health insurers and their insureds. Of the five major health insurers in Hawai‘i that responded to our survey and whose membership totaled 1,205,883, only one requires “a form of step therapy,” and it explained that its medical providers apply appropriate American Society of Clinical Oncology and National Comprehensive Cancer Network use guidelines, which include sequential and escalating medication recommendations. The insurer, however, said that the guidelines are “very, very infrequently enforced” when a provider does not follow the guidelines’ therapeutic recommendations. That insurer provides health insurance coverage for about 60,000 individuals, 4.1 percent of Hawai‘i residents collectively covered by the five major health insurers that responded to our survey. The other four insurers represented that they do not require step therapy. For that reason, the proposed mandate should have no material social or financial impact on those insurers or their insureds.

Objectives of the Study

In accordance with Section 23-52, Hawai‘i Revised Statutes (HRS), we assessed the social and financial impacts of prohibiting health insurers from requiring their insureds to use a prescription drug or sequence of prescription drugs other than the drug recommended and prescribed by the insured’s health care provider before the insurer provides coverage for the recommended drug.

Scope and Methodology

We surveyed Hawai‘i Medical Service Association (HMSA), Kaiser Permanente Hawai‘i (Kaiser Permanente), Hawai‘i Medical Assurance Association (HMAA), ‘Ohana Health Plan,[1] and the University Health Alliance (UHA) to gain their perspectives about the mandate proposed in SB 2316, including the social and financial impacts that they foresee for themselves and their insureds if the Legislature prohibits the use of step therapy protocols for insureds diagnosed with stage 2 to stage 5 cancer.[2] Collectively, in 2023, those insurers provided health insurance to over 1.2 million residents (about 84 percent of Hawai‘i’s population).

[1] ‘Ohana Health Plan provides only government-sponsored managed care services, primarily through Medicaid (QUEST), Medicare Advantage (Wellcare), and Medicare Prescription Drug Plans in the State.

[2] While stages 0 through 4 are well-recognized medical terminology commonly used to describe how much a cancer has spread within the body, “stage 5” is not. One insurer called the term medically inaccurate. Representatives of the American Society of Clinical Oncology said there may be only one pediatric cancer that uses the designation stage 5.

We interviewed and corresponded with representatives of the American Society of Clinical Oncology; the president of the Hawai‘i Society of Clinical Oncology, who is also the division chief in gynecologic oncology at the University of Hawai‘i's John A. Burns School of Medicine and University of Hawai‘i Cancer Center; and the associate director of Cancer Research Education and Training at the University of Hawai‘i Cancer Center, to gain an understanding of step therapy protocols as they relate to cancer drugs.

We met with staff of the State of Hawai‘i Department of Commerce and Consumer Affairs, Insurance Division, to obtain background information regarding Hawai‘i's health insurance laws and with the member of the Hawai‘i State Senate who was the first primary introducer of SB 2316 to understand the public policy concerns regarding step therapy.

We researched the federal Patient Protection and Affordable Care Act to determine whether that law restricts the use of step therapy protocols. To gain an understanding of step therapy, certain other forms of utilization management, and investigational drugs, we reviewed medical journals and other publications by professional and government organizations, including the American Medical Association, National Institutes of Health, American Cancer Society, American Society of Clinical Oncology, U.S. Food & Drug Administration, and U.S. Centers for Medicare & Medicaid Services. We also researched provisions of Hawai‘i's insurance laws relating to cancer treatment and other states' laws that restrict the use of step therapy protocols.

We conducted this study from September 2024 to December 2024 in accordance with Sections 23-51 and 23-52, HRS.

What is Step Therapy?

According to a 2022 *New England Journal of Medicine* article, in the absence of systematic drug-pricing reform in the United States, health insurers frequently employ utilization management strategies to contain their rising prescription drug costs. Step therapy, commonly called "fail-first therapy," is a utilization management strategy that requires an insured to document unsuccessful attempts at treatment with less expensive therapies before insurers cover more expensive treatment options prescribed by the insured's health care provider. More plainly, an insured may be required to try a lower cost prescription drug that treats a given condition before "stepping up" to a similar-acting, but more expensive drug. According to the American Society of Clinical Oncology, proving failure of a drug or series of drugs can take two to three months per drug.

While the bill will prohibit step therapy for insureds diagnosed with stage 2 to stage 5 cancer, SB 2316 will not affect insurers' step therapy protocols in the treatment of other diagnosed medical conditions and diseases.

Ideally, step therapy is designed to help curb unnecessary medical use. The clinical basis supporting an insurer's step therapy protocol is that some conditions can be treated with different but therapeutically equivalent prescription drugs and there is not a good way to predict if

Prior Authorization

Step therapy and other types of prior authorization can delay treatment for days, weeks, or even months.

PRIOR AUTHORIZATION – sometimes called prior approval, precertification, or preauthorization – requires a health care provider to obtain approval from a patient's insurer before prescribing a specific medication, performing a procedure, or initiating a treatment. If prior authorization is required under a patient's policy and is not obtained, the insurer may reject the claim, even if the procedure was medically necessary and would otherwise have been covered.

Prior authorization is one type of utilization management policy used by health insurers to control drug costs.[3] It is intended to ensure that the prescribed drug therapy is appropriate and aligns with evidence-based guidelines before the patient receives it. However, prior authorization requirements can also delay – for days, weeks, or even months – a patient's ability to obtain the treatment, including medication, recommended by the patient's health care provider.[4]

According to a 2023 American Medical Association survey of 1,000 practicing physicians, most work on over 40 prior authorizations each week, which translates into about 12 hours of work for office staff per week.

Step therapy is a form of prior authorization, requiring an insured to use a certain drug or drugs, without success, before the insurer will authorize coverage of the drug recommended by the insured's health care provider.

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[3] Other types of utilization management policies include clinical pathways, restrictive formularies, and specialty tiers.

[4] According to the American Society of Clinical Oncology, 56 percent of physicians feel that prior authorization, including step therapy, "always or often delays necessary care."

a particular drug will be more or less effective for any one individual. In those cases, it is more cost-effective to start with a "step 1" drug – a generic drug or lower-cost or preferred brand-name drug – before trying a more expensive or non-preferred drug. Step 1 drugs are likely on a lower tier of an insurer's prescription drug formulary[5], so the insured likely pays a lower copay.

An article published in the *New England Journal of Medicine*, "Step Therapy's Balancing Act – Protecting Patients while Addressing High Drug Prices," notes that step therapy protocols "may also promote improved quality of care when it's used to steer patients to evidence-based care, which it can do when steps are modeled on consensus treatment guidelines." Step therapy's actual contribution to improved quality, though, "appears to be limited." The authors reported that "a recent study examining commercial insurers' use of step therapy for specialty drugs found that only about one-third of protocols aligned with clinical guidelines."

Critics of step therapy contend that all too often its use compromises patient care and well-being; the process can interfere with the patient-provider relationship and limit a health care provider's ability to tailor care to the individual patient's needs based on the provider's clinical assessment and knowledge of the patient's medical condition. These critics contend that step therapy can be detrimental for patients if the lower-cost drug doesn't work for them, prolonging ineffective treatments and delaying access to the right treatment.

According to an article published on the National Institutes of Health website, of the 10 diseases most often subjected to step therapy, insurers applied step therapy in almost 40 percent of their drug coverage policies.[6] Of those step therapy protocols, the study reported "34.0 percent were consistent with corresponding clinical guidelines, 55.6 percent were more stringent, and 6.1 percent were less stringent. Trials of alternatives not included in the clinical guidelines were required in 4.2 percent of protocols, and the consistency of protocols varied within and across plans."

According to the article's authors, "These findings raise questions about potentially overly restrictive step therapy protocols, as well as concerns that variability across health plans makes protocols onerous for patients

[5] A prescription drug formulary is a list of prescription drugs covered by an insurer's prescription drug plan or an insurance plan offering prescription drug benefits. Insurers establish their own formularies, and modifications are routinely made.

[6] The diseases included in the study were chronic migraine, Crohn's disease, psoriasis, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, polyarticular juvenile idiopathy arthritis, multiple sclerosis, and hepatitis C.

and practitioners alike. The findings thus suggest the need for state and federal legislative initiatives to help ensure appropriate prescription drug use."

It should be noted that while SB 2316 will limit insurers' ability to utilize step therapy in covering cancer drugs, other forms of prior authorization would not be affected by the bill.

Senate Bill No. 2316: Proposed Mandatory Health Insurance Coverage

SB 2316 proposes to amend Chapters 431, 432, and 432D, HRS (collectively, Hawai'i's health insurance laws), to prohibit health insurers that cover treatment of stage 2 to stage 5 cancer from requiring an insured diagnosed with stage 2 to stage 5 cancer to undergo step therapy prior to covering the drug recommended and prescribed by the insured's health care provider. The proposed coverage requires the prescribed drug to be either: (1) an investigational new drug; or (2) a prescription drug approved by the U.S. Food and Drug Administration (FDA) that is consistent with best practices for treatment of cancer in its respective stage and included in the insurer's prescription drug formulary.

SB 2316 defines step therapy as "a protocol that requires an insured to use a prescription drug or sequence of prescription drugs, other than the drug that the insured's health care provider recommends for the insured's treatment, before the insurer provides coverage for the recommended prescription drug."

Investigational new drug is defined to have "the same meaning as provided under 21 Code of Federal Regulations Section 312.3." That section of the Code of Federal Regulations defines an investigational new drug as "a new drug or biological drug that is used in a clinical investigation," which means "any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects." That section defines experiment as "any use of a drug except for the use of a marketed drug in the course of medical practice."

According to HCR 225, "step therapy may limit full access to effective treatment options at early stages of illness" and the proposed mandate will override any "step therapy" policy that requires an insured to first try cancer drugs other than those prescribed by an insured's health care provider before those drugs are covered by the insurer. "Whereas, the Legislature believes that prohibiting health insurers that cover treatment for stage two through five cancer from requiring an insured to undergo step therapy before covering the drug prescribed to the insured by the insured's health care provider will increase the likelihood of proactive treatment and save lives."

Investigational New Drugs

INVESTIGATIONAL NEW DRUGS, also referred to as "investigational drugs," are primarily accessed through participation in clinical trials. Those trials are part of clinical research studies designed to learn more about how people with specific diagnoses respond to potential new medicines or treatments. However, even with scientifically reasonable hypotheses and well-controlled studies, most investigational drugs do not achieve regulatory approval.

Individuals with a serious or life-threatening disease, who have tried all approved treatment options and who are ineligible or unable to participate in a clinical trial, may be able to receive investigational drugs outside of clinical trials through expanded access (sometimes referred to as compassionate use) or "right-to-try" laws.[7]

An individual seeking investigational drugs through the expanded access pathway must obtain FDA approval. However, the drug manufacturer also must agree to make the product available, often based on a combination of business and regulatory factors.

The FDA allows companies to charge patients or their insurers for the "direct costs" of an investigational drug provided through an expanded access program, which costs, according to the FDA, are often not covered by insurance or Medicare. Those costs include the cost per unit to manufacture the drug and shipping costs, but do not include research and development costs. However, according to an article in the *New England Journal of Medicine*, "Practical, Legal, and Ethical Issues in Expanded Access to Investigational Drugs," the FDA reports that most manufacturers do not charge for their investigational drugs.

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[7] Since 2018, at least 40 states as well as the federal government have passed "right-to-try" laws that permit individuals with a terminal diagnosis who have tried all approved treatment options the opportunity to seek access to investigational drugs without FDA approval or formal involvement. However, the manufacturer of the investigational drug ultimately decides whether to make the drug available to individuals who qualify under right-to-try laws. Hawai‘i has not enacted a right-to-try law.

Step Therapy Legislation in Other States and Congress

As of 2024, at least 38 states have enacted statutes limiting health insurers, pharmacy benefits managers, and other entities' use of step therapy or other forms of utilization management policies to limit or restrict coverage for drugs to treat cancer and other conditions.[8] We reviewed statutes limiting the use of step therapy from 25 of those states.

None of the states' statutes we reviewed prohibit the use of step therapy; rather, the statutes restrict an insurer's use of step therapy protocols under certain circumstances. Although states have different approaches to limit the use of step therapy, there are several provisions that appear in a majority of the statutes. For instance, at least 23 states require insurers who use step therapy protocols to provide a process for their insureds to seek exceptions or exemptions from those protocols. At least 21 of the 38 aforementioned states require insurers to grant exceptions or exemptions from applicable step therapy protocols under circumstances such as the prescription drug required under the step therapy protocol being contraindicated, ineffective, or expected to be ineffective.

Additionally, nine of the 25 states require that step therapy protocols be evidence-based, meaning: (1) founded on clinical practice guidelines developed and/or endorsed by a multidisciplinary or interdisciplinary panel, (2) based on high-quality studies, research, and medical practice or, (3) supported by peer-review publications.[9] Two states define step therapy to include protocols that meet the definition of step therapy, regardless of whether the insurer calls it step therapy.

Fifteen states permit insurers to require insureds use generic-equivalent drugs before requiring the insurer to cover other drugs.

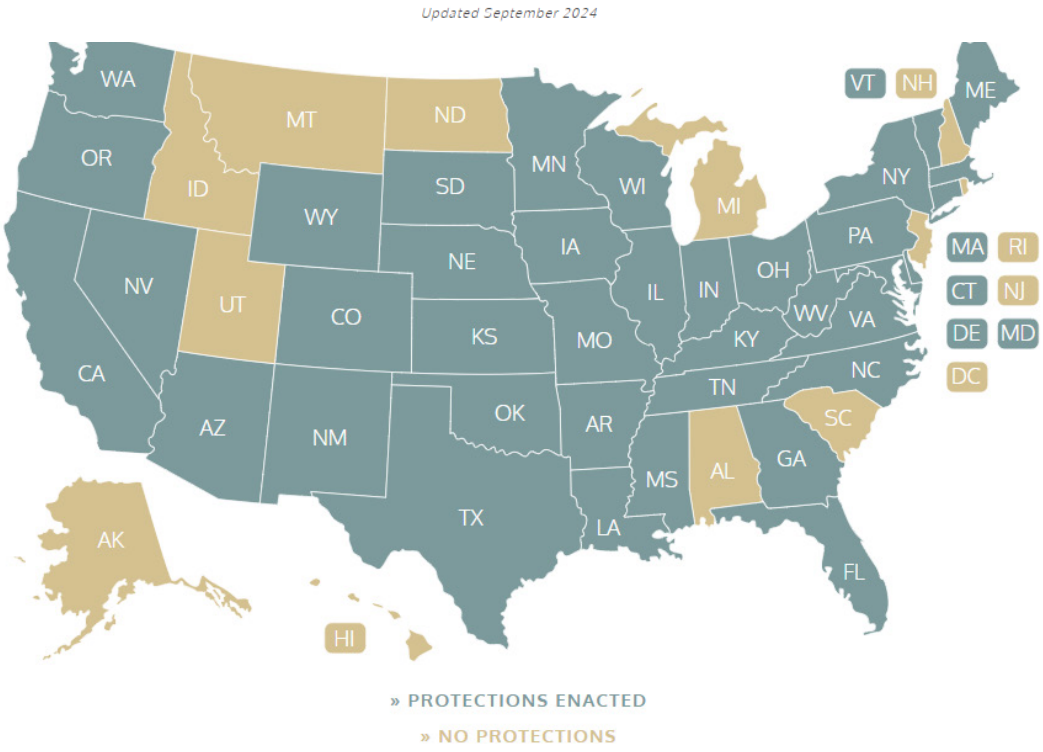
None of the 25 states whose statutes restrict step therapy protocols that we reviewed includes coverage of experimental or investigational drugs.

[8] Kansas' step therapy statute only applies to Medicaid insureds.

[9] Under Washington's statutes, "prescription drug utilization management" includes step therapy protocols.

Step Therapy Protections by State

This map shows states that have step therapy protections and ones that do not.



Source: National Psoriasis Foundation

According to the American Society of Clinical Oncology, there are no differences in the average insurance premiums in states with and without step therapy reform laws.

The U.S. Congress has also considered legislation to restrict insurers' use of step therapy. Legislation introduced in 2023, called the Safe Step Act, aimed to reform step therapy protocols in health plans by requiring group plans to provide exceptions for any medication step therapy protocols. The exceptions included when:

- An otherwise required treatment has been ineffective;
- Such treatment is expected to be ineffective and delaying effective treatment would lead to irreversible consequences;
- Such treatment will cause or is likely to cause an adverse reaction to the individual;
- Such treatment is expected to prevent the individual from performing daily activities or occupational responsibilities;

- The individual is stable based on the prescription drugs already selected; and
- There are other circumstances as determined by the Employee Benefits Security Administration.

Congress has yet to vote on either the version included by the Senate Committee on Health, Education, Labor, and Pensions as an amendment to the Pharmacy Benefit Manager Reform Act or the House version of the legislation.

Social and Financial Impact of Senate Bill No. 2316

How We Construed the Proposed Mandate

Section 23-51, HRS, requires the Auditor to assess "any legislative measure that ***mandates health insurance coverage*** for specific health services, specific diseases, or certain providers of health care services." (Emphasis added.) SB 2316 proposes to ***prohibit*** health insurers from requiring an insured diagnosed with stage 2 to stage 5 cancer to undergo step therapy prior to covering the drug prescribed by the insured's health care provider; the bill is not phrased as mandating coverage for services, diseases, or providers of services. The intent of the bill, however, can be restated in the form of a mandate, which we have done for the purposes of our review. Specifically, we have construed SB 2316 to require coverage of an investigational new drug or FDA-approved drug that is recommended and prescribed by the insured's health care provider as treatment for stage 2 to stage 5 cancer. The FDA-approved drug must be consistent with best practices for treatment of the stage of cancer and included in the insurer's prescription drug formulary.

The Social and Financial Impacts of the Proposed Mandated Coverage of Investigational Drugs

While we construe the bill to mandate coverage of investigational new drugs for an insured diagnosed with stage 2 through stage 5 cancer,[10] we did not assess the social or financial impacts associated with that part of the mandatory coverage.

[10] HMSA interprets SB 2316 to prevent insurers from utilizing step therapy as a basis for not providing coverage for drugs prescribed by an insured's health care provider but does not construe the bill to mandate coverage of investigational drugs. HMSA's interpretation ignores the bill's plain language, which will require insurers to cover the drug prescribed by the insured's health care provider if the prescribed drug is either "[a]n investigational new drug," or "[a] prescription drug" approved by the FDA.

The bill requires insurers to cover "the drug ***prescribed*** by the insurer's health care provider." (Emphasis added.) It is our understanding, however, that investigational drugs are not – and cannot be – prescribed. The associate director of Cancer Research Education and Training at the University of Hawai'i Cancer Center told us that an investigational drug cannot be prescribed by a practicing physician. Investigational drugs are available only through clinical studies, expanded access, or right-to-try laws. See Textbox, "Investigational New Drugs" on page 7. Both pathways require the patient to apply, either to be accepted in a clinical trial or to be provided the investigational drug through expanded access, and neither is guaranteed.

Further, the uncertainty about the cost of investigational drugs is reflected in the surveyed insurers' responses, with HMSA stating that investigational drugs would be "the most expensive option" and UHA claiming that the cost to cover investigational drugs "would be exponentially higher." While the FDA allows companies to charge patients or their insurers for the "direct costs" of an investigational drug, the FDA reports that most manufacturers do not charge for their investigational drugs. But, that too is not guaranteed.

Based on the information that we obtained through our research about investigational drugs and the surveyed insurers' responses, we are unable to reasonably estimate the likelihood that an insured diagnosed with stage 2 to stage 5 cancer can access an investigational drug and, if the insured does receive an investigational drug, the cost of that drug to the insured. Without that information, neither we nor the insurers can meaningfully assess the social or financial impacts of mandating coverage of investigational drugs for insureds diagnosed with stage 2 to stage 5 cancer. Accordingly, we did not consider that portion of the proposed mandate relating to coverage of investigational drugs.

The Proposed Mandate Will Have Minimal, If Any, Social or Financial Impacts

In response to our survey about the restriction on the use of step therapy proposed in SB 2316, four of the five insurers – HMSA, Kaiser Permanente, HMAA, and 'Ohana Health Plan – represented that they do not impose step therapy protocols on insureds diagnosed with stage 2 to stage 5 cancer. For example, Kaiser Permanente said that cancer "treatments are dictated by the healthcare providers who make treatment recommendations." We interpret that response and the other insurers' similar responses to mean that they currently cover an FDA-approved drug that is prescribed by its insured's health care provider as treatment for stage 2 to stage 5 cancer without requiring the insured to first try another drug or series of drugs, if the prescribed drug is consistent with best practices for treatment of the insured's stage of

cancer and is included in the insurer's prescription drug formulary. See Textbox, "Prior Authorization" on page 4.

Only one of the five insurers – UHA – said that it uses step therapy protocols for chemotherapy, stating:

> Virtually all chemotherapy is prescribed by members of our provider network who are board certified medical oncologists, gynecologic oncologists, urologists and dermatologists, all of whom apply [American Society of Clinical Oncology] and [National Comprehensive Cancer Network] appropriate use guidelines. These guidelines use sequential and escalating medication recommendations which have been shown to afford the greatest overall survival. They are, in a form, "step therapy." Insofar as these broadly endorsed and academically accepted guidelines are "very, very infrequently" enforced when a prescriber does not follow their own professional society's therapeutic recommendations, it can be said that UHA does engage in step therapy management, conducted by our own medical directors (often in collaboration with our PBM.).

The five insurers that we surveyed, collectively, provide health insurance to over 1.2 million residents (about 84 percent of Hawai'i's population); of that total, HMSA, Kaiser Permanente, HMAA, and 'Ohana Health Plan cover more than 95 percent of those residents.

Table 1

Hawai'i Health Plan Provider Name	Number of members/ subscribers (2023)	Does the health insurance provider use step therapy in covering cancer drugs?
Hawai'i Medical Service Association (HMSA)	792,055	No
Kaiser Permanente Hawai'i (Kaiser Permanente)	269,199	Not currently
Hawai'i Medical Assurance Association (HMAA)	35,941	No
'Ohana Health Plan	49,267	No
University Health Alliance (UHA)	59,421	Yes

Source: Office of the Auditor

With respect to the insurers that do not use step therapy protocols in covering drugs for insureds diagnosed with stage 2 to stage 5 cancer – HMSA, Kaiser Permanente, HMAA, and ʻOhana Health Plan – we do not expect *any* material change to their current operations;[11] we do not expect *any* material social or financial impacts to the insurers or their insureds. For those insurers, the bill will serve to mandate the status quo.[12]

UHA is the only insurer of those surveyed that currently uses step therapy protocols for treatment of cancer. UHA, however, represents that it "very, very infrequently" enforces those protocols, reporting that, in 2021, 2022, and 2023, it had declined to cover the drugs prescribed by its insured's health care provider because of its step therapy policy two times each year. Because it believes that treatment for cancer is "very obtainable" with FDA-approved drugs administered consistent with National Comprehensive Cancer Network guidelines and on its prescription drug formulary, UHA did not foresee any social impacts associated with the mandate in SB 2316. Similarly, UHA does not believe that SB 2316 will result in any financial impacts.[13]

Based on the insurers' responses to our survey, we conclude that there are no material social or financial impacts that will result from the health insurance mandate proposed in SB 2316.

[11] As noted above, we did not include coverage of investigational drugs in our assessment of the impacts associated with the proposed mandate in SB 2316. Only one insurer said that, while uncommon, an investigational drug which the FDA had approved for treatment of other diseases currently would be covered, unless it was subject to prior authorization.

[12] We note that one insurer claimed that "the total cost of healthcare increases when mandates are imposed." However, without more evidence or information to support that statement, we cannot determine that the proposed mandate will increase the total cost of health care.

[13] UHA does believe that mandating coverage of investigational drugs will increase the cost of treatment, insurance premiums as well as the overall cost of health care.

Assessment of the Impact of the Federal Patient Protection and Affordable Care Act

HCR 225 also requests the Auditor to conduct an assessment of the impact of Section 1311(d)(3) of the federal Patient Protection and Affordable Care Act (ACA) on proposed mandatory health insurance coverage in SB 2316. Sections 1311(d)(3)(B)(i) and (ii) of the ACA allow a state to require a qualified health plan to offer benefits in addition to the essential health benefits.[14] A benefit required by state action on or after January 1, 2012, other than for purposes of compliance with federal requirements, is considered an addition to the essential health benefits. The State must defray the cost to the individual of those added required benefits, which the qualified health plan issuer must quantify in accordance with generally accepted actuarial principles and methodologies conducted by a member of the American Academy of Actuaries.

We, however, do not expect the mandate proposed in SB 2316 to result in additional costs to the State. HMSA's Preferred Provider Plan 2010 is the benchmark policy for plans offered under the ACA in the Hawai'i marketplace.[15] HMSA represents that it does not use step therapy in *any* of its plans offered under the ACA. Therefore, prohibiting insurers from imposing step therapy protocols for insureds diagnosed with stage 2 to stage 5 cancer will not alter the status quo.

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[14] States are required to provide coverage for 10 essential health benefits, referred to as the essential health benefits, in the health insurance plans offered under the ACA. The essential health benefits include:

1. Ambulatory patient services;
2. Emergency services;
3. Hospitalization;
4. Pregnancy, maternity, and newborn care;
5. Mental health and substance use disorder services, including behavioral health treatment;
6. Prescription drugs;
7. Rehabilitative and habilitative services and devices;
8. Laboratory services;
9. Preventative and wellness services and chronic disease management; and
10. Pediatric services, including oral and vision care.

[15] A benchmark plan establishes the specific conditions and services within the essential health benefits that are covered for each state. All ACA plans offered in Hawai'i must cover the essential health benefits in a manner that is substantially similar to the benchmark plan.

Additional Considerations

While four of the surveyed insurers do not use step therapy for insureds diagnosed with stage 2 to stage 5 cancer, those insurers may employ other utilization management strategies to restrict or delay an insured's access to prescribed drugs. 'Ohana Health Plan reported that, while it does not have a policy that requires step therapy for people diagnosed with cancer, "[w]e may have prior authorization requirements on certain drugs, some of which may be used to treat cancer. It would depend on the drug and not the diagnosis." Prior authorization, as the term suggests, typically requires a health care provider to get advance approval from the patient's insurer before prescribing a specific drug. The insurer may not cover the drug without prior authorization, if that process is required by the insurer's policies to review how necessary a medical treatment or medication may be in treating a condition. Prior authorization requirements, including preauthorization, preapproval, and precertification, allow the insurer to review how necessary the medication may be to the insured's cancer treatment. Like other types of utilization management strategies, prior authorization is considered a process by which insurers control costs; those strategies, like step therapy, likely delay coverage of the drug or drugs recommended by the insured's health care provider.

Assessing other types of utilization management strategies that may be used by Hawai'i insurers is beyond the scope of our review under Sections 23-51 and 25-52, HRS. As we report above, we assessed the social and financial impacts of the specific coverage that will be mandated by SB 2316, which in this case is to prohibit the use of step therapy for insureds diagnosed with stage 2 to stage 5 cancer.

Should the Legislature, in the future, consider a mandate that restricts insurers' policies that may deny or delay coverage of medication recommended by an insured's health care professional, we suggest that the Legislature consider insurers' use of utilization management policies, generally. We report above about other states' laws that limit insurers' use of step therapy. While none of those states prohibit the use of step therapy, they do include more specific criteria that define when an insurer cannot require an insured to "fail first." In many instances, that criteria likely also limit insurers' use of other utilization management policies.

Conclusion

We determined that prohibiting insurers from using step therapy protocols for insureds diagnosed with stage 2 to stage 5 cancer will not result in any material social or financial impacts.

The majority of Hawai‘i health insurers who responded state they do not generally utilize step therapy in providing coverage for cancer treatment. Only one insurer stated that it follows guidelines that use sequential and escalating medication recommendations, which are similar to step therapy. However, that insurer, which covered about 4.1 percent Hawai‘i’s residents in 2023, represented that it “very, very infrequently” enforces the sequential and escalating medication recommendations when an insured’s health care provider does not follow those guidelines. Should the Hawai‘i Legislature consider enacting legislation regarding step therapy, the following non-profit organization provides a state-by-state summary of step therapy legislation that may offer useful information: Triage Cancer®: https://triagecancer.org/state-laws/health-insurance-step-therapy.

Appendix

Sections 23-51 and 23-52, Hawai‘i Revised Statutes

Section 23-51, HRS, requires passage of a concurrent resolution requesting a social and financial impact assessment by the Auditor before any legislative measure mandating health insurance coverage for a specific health service, disease, or provider can be considered. The statute also requires that the concurrent resolution designate a specific bill that has been introduced in the Legislature and includes, at a minimum, information identifying:

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

SB 2316 was introduced in the 2024 Hawai‘i legislative session and includes the information required by Section 23-51, HRS.

Section 23-52, HRS, requires the Auditor’s report to the Legislature assessing the impact of proposed mandated coverage to include, at the minimum and to the extent that information is available, the following:

Social Impact

- The extent to which the treatment or service is generally utilized by a significant portion of the population;
- The extent to which such insurance coverage is already generally available;
- If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatment;
- If coverage is not generally available, the extent to which lack of coverage results in unreasonable financial hardship on those persons needing treatment;
- The level of public demand for the treatment or service;
- The level of public demand for individual or group insurance coverage of the treatment or service;
- The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts;

- The impact of providing coverage for the treatment or service (such as morbidity, mortality, quality of care, change in practice patterns, provider competition, or related items); and
- The impact of any other indirect costs upon the costs and benefits of the coverage as may be directed by the Legislature or deemed necessary by the Auditor in order to carry out the intent of Section 23-52, HRS.

Financial Impact

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