



HOUSE COMMITTEE ON FINANCE
The Honorable Sylvia Luke, Chair
The Honorable Ty J.K. Cullen, Vice Chair

S.B. NO. 493, S.D. 2, H.D. 1, RELATING TO HEALTH CARE INSURANCE

Hearing: Friday, March 29, 2019, 2:30 p.m.

The Office of the Auditor has **no position** regarding S.B. No. 493, S.D. 2, H.D. 1, which prohibits health care insurers from requiring an insured diagnosed with stage two cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider. **However, with respect to Section 6 of the bill, we offer the following comments.**

Section 6 of S.B. No. 493, S.D. 2, H.D. 1, requires that we conduct a review to determine:

1. If an impact assessment report pursuant to Section 23-51, Hawai'i Revised Statutes (HRS), is warranted for coverage of the benefits mandated in this Act;
2. If the benefits mandated in this Act trigger any requirement to defray the cost of new mandated benefits in excess of the essential health benefits as required by Section 1311(d)(3) of the federal Patient Protection and Affordable Care Act (P.L. 111-148); and
3. If the prohibition of step therapy under certain conditions would circumvent the medical necessity provisions in Section 432E-1.4, HRS.

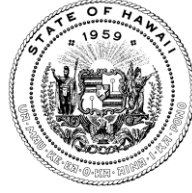
We do not typically conduct a review to determine if an impact assessment is warranted pursuant to Section 23-51, HRS. Rather, Section 23-51, HRS, specifically requires the passage of a concurrent resolution requesting an impact assessment by the Auditor “[b]efore any legislative measure that mandates health insurance coverage for specific health services, specific diseases, or certain providers of health care services as part of individual or group health insurance policies.” We respectfully defer to the Legislature as to whether the proposed legislation triggers the requirement for an impact assessment.

Whether the benefits provided by the bill are a new mandate that would trigger the requirement of an impact assessment under Section 23-51, HRS, may be best addressed by the Department of Commerce and Consumer Affairs' Insurance Division, which, in testimony submitted to prior committees, provided insight into this bill's interaction with the “medical necessity” provisions in Hawai'i Revised Statutes (Section 432E-1.4) and certain provisions of the Patient Protection and Affordable Care Act.

We also note that the bill, as proposed, will require us to prepare a report on the need for an impact assessment prior to the 2020 legislative session. As a result, any concurrent resolution requesting an impact assessment would likely be passed no earlier than the 2020 legislative

session and any legislative action on the proposed legislation would not occur at the earliest until the 2021 session, 2 years from now.

Thank you for considering our testimony related to S.B. No. 493, S.D. 2, H.D. 1.



DAVID Y. IGE
GOVERNOR

JOSH GREEN
LT. GOVERNOR

**STATE OF HAWAII
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Testimony of the Department of Commerce and Consumer Affairs

**Before the
House Committee on Finance
Friday, March 29, 2019
2:30 p.m.
State Capitol, Conference Room 308**

On the following measure:

S.B. 493, S.D. 2, H.D. 1, RELATING TO HEALTH CARE INSURANCE

Chair Luke and Members of the Committee:

My name is Colin Hayashida, and I am the Insurance Commissioner of the Department of Commerce and Consumer Affairs' (Department) Insurance Division. The Department offers comments on this bill.

The purpose of this bill is to prohibit a health care insurer from requiring an insured diagnosed with stage two cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider, under certain conditions.

By prohibiting step therapy under certain conditions, this measure may create the potential for bypassing of medical necessity provisions in Hawaii Revised Statutes (HRS) section 432E-1.4. Section 432E-1.4(a) provides in relevant part, "A health intervention may be medically indicated and not qualify as a covered benefit or meet the definition of medical necessity. A managed care plan may choose to cover health interventions that do not meet the definition of medical necessity." This bill may be

construed as prohibiting step therapy without considering whether it is medically necessary.

In addition, the Department is concerned that an investigational new drug prescribed to the insured is one condition that will trigger the prohibition of step therapy, as “investigational new drug” is broadly defined.¹

Further, the Department has concerns that language on page 1, line 16 to page 2, line 13; page 3, lines 4-18; page 4, line 9 to page 5, line 4; and page 5, line 17 to page 6, line 10 is vague and may be construed as creating a new mandate that requires coverage for drugs, including investigational new drugs, so long as a provider prescribes them. The addition of new mandated coverage may trigger section 1311(d)(3) of the federal Patient Protection and Affordable Care Act (PPACA), which requires states to defray the additional cost of any benefits in excess of the essential health benefits of the State’s qualified health plan under the PPACA.

Thank you for the opportunity to testify on this bill.

¹ The bill references the definition of “investigational new drug” in 21 Code of Federal Regulations section 312.3, which reads: “*Investigational new drug* means a new drug or biological drug that is used in a clinical investigation. The term also includes a biological product that is used in vitro for diagnostic purposes. The terms “investigational drug” and “investigational new drug” are deemed to be synonymous for purposes of this part.”



STATE OF HAWAII
HAWAII EMPLOYER-UNION HEALTH BENEFITS TRUST FUND

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TESTIMONY BY DEREK MIZUNO
ADMINISTRATOR, HAWAII EMPLOYER-UNION HEALTH BENEFITS TRUST FUND
DEPARTMENT OF BUDGET AND FINANCE
STATE OF HAWAII
TO THE HOUSE COMMITTEE ON FINANCE
ON SENATE BILL NO. 493 S.D. 2, H.D. 1

March 29, 2019
2:30 p.m.
Room 308

RELATING TO HEALTH CARE INSURANCE

Chair Luke, Vice Chair Cullen, and Members of the Committee:

The Hawaii Employer-Union Health Benefits Trust Fund (EUTF) Board of Trustees opposes the section of the bill mandating coverage of investigational new drugs. The EUTF Board has not taken a position on prohibition of step therapy programs for stage two cancer since the EUTF medical and prescription drug plans currently do not have such step therapy programs in place for stage two cancer.

The EUTF medical and prescription drug plans are currently limited to coverage of U.S. Food and Drug Administration (FDA) approved drugs. The EUTF Board is concerned with an expansion to mandate coverage of investigational new drugs that have not completed testing for efficacy and safety by the FDA. Such a change will add additional costs to the EUTF medical and prescription drug plans that are generally borne by the pharmaceutical manufacturers.

Thank you for the opportunity to testify.



HAWAII MEDICAL ASSOCIATION

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To:

HOUSE COMMITTEE ON FINANCE

Rep. Sylvia Luke, Chair

Rep. Ty Cullen, Vice Chair

Date: March 29, 2019

Time: 2:30 p.m.

Place: Room 308

From: Hawaii Medical Association

Jerry Van Meter, MD, President

Christopher Flanders, DO, Executive Director

Re: SB 493 SD 2 HD 1 – Relating to Health Care Insurance

Position: SUPPORT, WITH COMMENTS

On behalf of Hawaii's physician and student members, the HMA supports SB 493 which would prohibit health care insurers from requiring an insured diagnosed with Stage II cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider.

Step therapy, or "fail first" therapy is a form of prior authorization that requires preferred drugs be prescribed first, and proven ineffective, before physicians can try other, potentially higher cost agents. For cancer patients, selecting the proper personalized treatment as quickly as possible can be critical to survival. Delays in getting patients the right treatments at the right time many times leads to unnecessary complications in the physician-patient decision-making and treatment process.

Step therapy likewise places a significant administrative burden on physician practices. Physicians do not currently have ready access to patient benefit and formulary information, as there is currently no capability making this information available through electronic health records or other means at the point of prescribing. This lack of transparency makes it exceedingly difficult to determine what treatments are preferred by a particular payor at the point of care and places practices at financial risk for the cost of administered drugs if claims are later denied for unmet (yet unknown) step therapy requirements.

Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them burdensome for both busy physician practices and patients awaiting treatment. It is our hope that another layer of administrative complication will not be added on to an already strained system.

While we support the bill as currently written, we prefer the version as it passed the Senate.

Thank you for allowing testimony on this issue.

HMA OFFICERS

President – Jerry Van Meter, MD President-Elect – Michael Champion, MD Secretary – Thomas Kosasa, MD
Immediate Past President – William Wong, Jr., MD Treasurer – Elizabeth A. Ignacio, MD
Executive Director – Christopher Flanders, DO



Testimony of
John M. Kirimitsu
Legal & Government Relations Consultant

Before:
House Committee on Finance
The Honorable Sylvia Luke, Chair
The Honorable Ty J.K. Cullen, Vice Chair

March 29, 2019
2:30 pm
Conference Room 308

Re: SB 493, SD2, HD1 Relating to Health Care Insurance

Chair, Vice Chair, and committee members, thank you for this opportunity to provide testimony on this measure prohibiting a health insurer from requiring step therapy prior to covering the insured for a cancer drug prescribed by the insured's provider.

Kaiser Permanente Hawaii requests that this bill be deferred.

Since it appears that health insurers do not require step therapy for *cancer treatment*, Kaiser respectfully requests that this bill be deferred.

If this bill should move forward, Kaiser requests the following amendments: (1) removing the mandated coverage for investigational drugs, and (2) including the widely accepted practice of allowing coverage for off label drugs for cancer treatments. Both amendments were included in the Senate's prior version of this bill, SB 493, SD1.

As for the removal of the experimental drugs, Kaiser is concerned that insurance premiums may need to be significantly increased to keep up with the high cost of experimental drugs, and this mandatory coverage of experimental drugs could drive up the cost of medicine and health insurance for everyone.

Additionally, Kaiser is concerned that these experimental drugs have not passed the typical U.S. Food and Drug Administration (FDA) review and approval process for safety. The FDA's current scientific methods and procedures are of paramount importance for determining the safety and efficacy of dangerous drugs. Clearly, circumventing the FDA's review and approval process may result in harmful unintended consequences.

With respect to adding off-label usage for cancer treatments, the National Cancer Institute (NCI) defines off-label use as "the practice of prescribing a drug for a different purpose than what the FDA approved." See <https://www.cancer.gov/about-cancer/treatment/drugs/off-label>. The NCI also recognizes that "Research has shown that off-label use of drugs is very common in cancer treatment." It is well

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recognized that once a drug is FDA approved for one indication, physicians can legally prescribe the drug for other indications as well.

Based on the foregoing, Kaiser requests the following amendments (added language is underscored and deleted language is ~~stricken~~) on Page 2, lines 1-14:

16 "§431:10A- Step therapy prohibited; stage two cancer.

17 (a) No individual accident and health or sickness policy issued

1 or renewed in the State after December 31, 2019, that provides

2 coverage for the treatment of stage two cancer shall require an

2 insured who is diagnosed with a stage two cancer to undergo step

4 therapy prior to covering the drug prescribed by the insured's

5 health care provider if the prescribed drug is:

6 (1) ~~An investigational new drug; or~~

7 (2) A prescription drug:

8 (A) That is approved by the United States Food and
9 Drug Administration;

10 (B) Whose use is consistent with best practices for
11 the treatment of the stage two cancer; ~~and~~

12 (C) That is listed on the insurer's prescription drug
13 Formulary; [and]

14 (D) That is supported by a published peer reviewed study as a recognized
off-label use for the treatment of the cancer or treatment of side effects
of the cancer.

Lastly, Kaiser supports this bill's request for an impact assessment report, as required pursuant to Sections 23-51 and 23-52 of the Hawaii Revised Statutes.

Thank you for the opportunity to comment.

The Honorable Sylvia Luke, Chair
The Honorable Ty J.K. Cullen, Vice Chair
& Members of the House Committee on Finance
Hawaii State Capitol 415 South Beretania St.
Honolulu, HI 96813

Friday, March 29, 2019
Testimony in Support of

SB 493, SD2, HD1 Relating to Health Care Insurance; Step Therapy

This measure would prohibit a health care insurer from requiring an insured patient diagnosed with stage two cancer to undergo step therapy prior to coverage for drugs prescribed by the insured's health provider. Coverage can only be authorized after two failed chemo/radiation treatments, a requirement that often spells death for many patients. It did just that for a close friend and colleague who lost her life to breast cancer at the height of the battle. The burning question for her and her family and friends through each stage of her fight was why she was denied coverage for drugs that could have prolonged her life. Instead, the cancer spread to a point where an alternative treatment was no longer a viable option.

The Hawaii Medical Association, the American Society of Clinical Oncology and the Hawaii Society of Clinical Oncology support the intent of this bill. Individualized cancer treatments that can readily adapt to a patient's progress, or lack thereof, is critical to survival. Requiring a patient to "fail" not one but two chemo/radiation treatments before gaining access to a more promising treatment is inhumane. Step therapy is an insurance company practice that requires the least expensive drug in any class to be prescribed to a patient first, even if a patient's physician believes a different therapy is a better treatment option. A patient and their doctor should get to decide together on the best medication and treatment for survival — not a health insurance company.

There are 19 States that have some version of a Step Therapy bill. State laws regarding step therapy are emerging in response to the negative impacts on patient welfare. **First do no harm** is a guiding principle of medicine. The irreversible damage of step therapy for many cancer patients is a death sentence, as it was for my friend. She was strong and determined to win when she began her fight against cancer. Failed chemo and radiation treatments drained her energy and her hope for survival. Even as she faced death, she urged a campaign against step therapy, not to save her own life but to prevent others from needlessly losing theirs. Every patient deserves a fair chance. Step therapy is not one of them.

Respectfully,
Laura Figueira
59-288 Kamehameha Hwy
Haleiwa, HI 96712

The Honorable Sylvia Luke, Chair
The Honorable Ty Cullen, Vice Chair
And Members of the Committee on Finance
415 South Beretania Street
Honolulu, HI 96813

Subject: SB493 SD2 HD1 Relating to Health Care Insurance; Step Therapy
Hearing: Friday, March 29, 2019 at 2:30 pm

This testimony is to convey support for SB 493 SD2 HD1 as passed by the senate. This measure, will prohibit a health care insurer from requiring an insured diagnosed with stage two cancer to undergo step therapy prior to covering the insured for drugs prescribed by the insured's health provider, under certain conditions. Requires analysis and report by State Auditor to determine if federal ACA provisions or state sunrise analysis requirement have be triggered.


Having recently experienced the loss of a very close friend and colleague to breast cancer, I am convinced that had this step therapy requirement not been in place, she would still be alive today.

As I tried to support her through each stage of her fight, we questioned why after being initially diagnosed with stage 3 aggressive cancer, the health care insurer refused to cover prescribed drugs. Coverage would only be authorized after the requirement of two failed chemo treatments were met.

It seemed that, by the time she satisfied this requirement, it was **too** late; the cancer had spread like wildfire. This measure would have given her a fighting chance and ensured that she received alternative/additional treatment in a timely manner, and might have saved her life. This measure as passed by the senate which added important clarification would have given her a chance of survival.

It is in her memory that I respectfully request your passage of the measure.

Sincerely,

A handwritten signature in black ink, appearing to read 'Janice Salcedo', with a large, stylized flourish extending from the end of the signature.

Janice "Jan" Salcedo

The Honorable Sylvia Luke, Chair
The Honorable Ty J.K. Cullen, Vice Chair
& Members of the House Committee on Finance
Hawaii State Capitol 415 South Beretania St.
Honolulu, HI 96813

Friday, March 29, 2019
Testimony in Support of
SB 493, SD2, HD1 Relating to Health Care Insurance; Step Therapy

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Respectfully,
Laura Figueira
59-288 Kamehameha Hwy
Haleiwa, HI 96712



LATE

March 27, 2019

The Honorable Sylvia Luke, Chair
The Honorable Ty J.K. Cullen, Vice Chair
House Committee on Finance

Re: SB 493 SD2 HD1 – Relating to Health Care Insurance

Dear Chair Luke, Vice Chair Cullen, and Committee Members:

Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 493, SD2, HD1, which prohibits a health care insurer from requiring an insured diagnosed with stage two cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider, under certain conditions. It also requires an analysis and report by State Auditor to determine if federal ACA provisions or state sunrise analysis requirements have been triggered.

HMSA does not require step therapy for oncology treatment. HMSA works to ensure our members have the care and treatment they need that is safe and efficacious. We appreciate the sensitivity and skill necessary to treat cancer and defer treatment decisions to oncologists. We foster open discussion and dialogue with local oncologists whom we meet with annually for feedback on our internal policies and guidelines.

Our policies follow evidence-based clinical guidelines and are in line with national best practice guidelines issued by the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). The ASCO is a professional organization representing physicians of all oncology sub-specialties who care for people with cancer and the NCCN is a not-for-profit alliance of the 28 leading cancer centers including MD Anderson, Mayo Clinic Cancer Center, and Memorial Sloan Kettering Cancer Center. Our medical policies are not intended to dictate to providers how to practice medicine in this area.

We are concerned by the mandate for health insurers to cover investigational drugs. We are not aware of any health plan in the U.S. that provides coverage for investigational drugs. Investigational drugs are used in clinical trials and are currently covered by pharmaceutical companies as part of research and development for new prescription and biological drugs. These drugs have not passed clinical trials showing safety and efficacy. Moreover, we calculate that the liability of providing coverage for investigational drugs for HMSA members to be at least \$188 million a year. This estimate represents our best guess based on new oncology drugs as investigational drugs are not presently reimbursed.

Should this bill move forward, we respectfully request that Part I be removed and that the measure requests the State Auditor to first conduct an impact assessment report pursuant to Section 23-51 of the Hawaii Revised Statutes.

Thank you for the opportunity to provide testimony on this measure.



Sincerely,

A handwritten signature in black ink, appearing to read 'Pono Chong', with a long, sweeping flourish extending to the right.

Pono Chong
Vice President, Government Relations