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**STATE OF HAWAII
OFFICE OF THE DIRECTOR
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS**

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Testimony of the Department of Commerce and Consumer Affairs

**Before the
House Committee on Consumer Protection and Commerce
Wednesday, March 20, 2019
2:15 p.m.
State Capitol, Conference Room 329**

**On the following measure:
S.B. 493, S.D. 2, H.D. 1, RELATING TO HEALTH CARE INSURANCE**

Chair Takumi 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

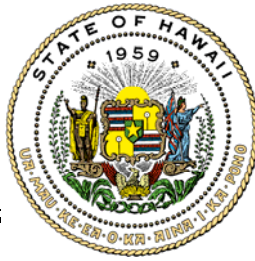
construed as prohibiting step therapy without considering whether it is medically necessary.

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.”



HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE
The Honorable Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair

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

Hearing: Wednesday, March 20, 2019, 2:15 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 the Attorney General which we believe may be able to advise on the question of the application of law.

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.



Hawaii House Consumer Protection Committee
Senate Bill 493: Prohibiting health care insurer from requiring an insured diagnosed with stage two cancer to undergo step therapy

March 19, 2019

The Hawaii Society of Clinical Oncology (HSCO) and the American Society of Clinical Oncology (ASCO) urge the Hawaii House Consumer Protection Committee to pass Senate bill 493, as it was passed by the Senate. We believe SB 493 as passed by the Senate provides stronger protections to patients with cancer than the amended version recently passed by the House Health Committee.

Step therapy requires patients to try and fail on a lower cost medication before they can access medication or treatment recommended by their physician. For patients with cancer, step therapy can: delay access to appropriate care, lead to irreversible disease progression, alter the ability of preferred treatments to achieve their desired effect, and may introduce a range of other significant patient health risks.

The Hawaii Society of Clinical Oncology (HSCO) is a powerful community of oncologists, nurse practitioners, physician assistants, and other allied health professionals who provide a voice for multidisciplinary cancer care teams and the patients they serve. ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

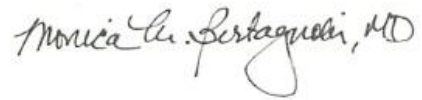
In April of 2017, ASCO released a policy statement entitled, [*The Impact of Utilization Management Policies for Cancer Drug Therapies*](#), which noted that step therapy policies are generally inappropriate in oncology because of the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options. Medically appropriate, evidence-based cancer care demands patient access to the most appropriate drug at the most appropriate time. HSCO and ASCO oppose any payer-imposed utilization management policies that interfere with this critical principle. More appropriate strategies for assuring evidence-based care include use of high-quality clinical pathways or coverage policies based on robust analyses of best clinical practices and existing scientific data.

ASCO and HSCO thank the Committee for hearing SB 493 and encourage them to re-add the important clarifications made by the Senate. We ask the Hawaii House Consumer Protection Committee Members to ensure all patients with cancer have access to the treatment best suited to their disease and clinical circumstances. If you have questions or would like assistance on any issue involving the care of individuals with cancer, please contact Kate Flannigan at ASCO at katherine.flannigan@asco.org.

Sincerely,

A handwritten signature in black ink, appearing to read "KEOLA BEALE", is placed on a light gray rectangular background.

Keola Beale, MD
President, Hawaii Society of Clinical Oncology

A handwritten signature in black ink, appearing to read "Monica Bertagnolli, MD", is written in a cursive style.

Monica Bertagnolli, MD, FACS, FASCO
President, American Society of Clinical Oncology



HAWAII MEDICAL ASSOCIATION

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To:

HOUSE COMMITTEE ON CONSUMER PROTECTION

Rep. Roy Takumi, Chair

Rep. Linda Ichiyama, Vice Chair

Date: March 20, 2019

Time: 2:15 p.m.

Place: Room 329

From: Hawaii Medical Association

Jerry Van Meter, MD, President

Christopher Flanders, DO, Executive Director

Re: SB 493 SD 1 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 until 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 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

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March 18, 2019

The Honorable Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair
House Committee on Consumer Protection & Commerce

Senate Bill 493 SD2 HD1 – Relating to Health Care Insurance

Dear Chair Takumi, Vice Chair Ichiyama, and Members of the Committee:

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to testify on SB 493, SD2, HD1.

We would like to express concerns on this legislation as it goes against policies as determined by the health plan's medical director and generally accepted evidence based medical practice.

We also believe that this is a new mandated benefit and is therefore subject to an impact assessment report by the Legislative Auditor pursuant to Sections 23-51 of the Hawaii Revised Statutes.

Thank you for allowing us to testify expressing concerns on SB 493, SD2, HD1.

Sincerely,

HAHP Public Policy Committee

cc: HAHP Board Members



March 18, 2019

The Honorable Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair
House Committee on Consumer Protection & Commerce

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

Dear Chair Takumi, Vice Chair Ichiyama, 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 which 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.

Since HMSA does not require step therapy for oncology treatment, we respectfully ask that this bill be deferred. Should this bill move forward, we respectfully request that Part I be removed and that the measure requests that State Auditor 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,

Jennifer Diesman
Senior Vice-President, Government Relations

SB-493-HD-1

Submitted on: 3/19/2019 8:38:23 AM

Testimony for CPC on 3/20/2019 2:15:00 PM

Submitted By	Organization	Testifier Position	Present at Hearing
Laura Figueira	Individual	Support	No

Comments:

The Honorable Representative Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair
And Members of the Committee on Consumer Protection & Commerce
415 South Beretania Street
Honolulu, HI 96813

Subject: SB 493 SD2 HD1 Relating to Health Care Insurance; Step Therapy
Hearing: Tuesday, March 20, 2019 at 2:15 pm in Conference Room 329

This testimony is to convey support for SB 493 SD2 HD1. 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 requirements have been triggered.

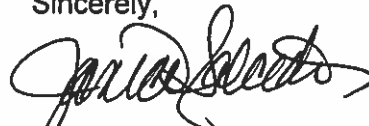
Having recently experienced the loss of a very close friend and colleague to breast cancer, I am convinced that had this step therapy requirement not been in place, she would still be alive today.

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, in its original form, 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. If a study is recommended to evaluate coverage of benefits mandated in this Act, then I welcome the study.

It is in her memory that I respectfully request your passage of the measure and to keep the discussion and studies ongoing.

Sincerely,

A handwritten signature in black ink, appearing to read "Janice Salcedo", written in a cursive style.

Janice "Jan" Salcedo

DAVID Y. IGE
GOVERNOR



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WRITTEN ONLY

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 CONSUMER PROTECTION & COMMERCE
ON SENATE BILL NO. 493 S.D. 2, H.D. 1

March 20, 2019
2:15 p.m.
Room 329

RELATING TO HEALTH CARE INSURANCE

Chair Takumi, Vice Chair Ichiyama, 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.

Thank you for the opportunity to testify.

EUTF's Mission: We care for the health and well being of our beneficiaries by striving to provide quality benefit plans that are affordable, reliable, and meet their changing needs. We provide informed service that is excellent, courteous, and compassionate.