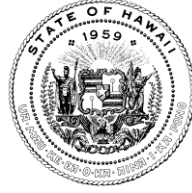


SB493

Measure Title:	RELATING TO HEALTH CARE INSURANCE.
Report Title:	Health Care Insurance; Step Therapy
Description:	Prohibits a health care insurer from requiring an insured diagnosed with stage two through stage five cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider, under certain conditions.
Companion:	
Package:	None
Current Referral:	CPH, WAM
Introducer(s):	DELA CRUZ, INOUYE, RIVIERE, RUDERMAN



DAVID Y. IGE
GOVERNOR

JOSH GREEN
LT. GOVERNOR

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

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JO ANN M. UCHIDA TAKEUCHI
DEPUTY DIRECTOR

Testimony of the Department of Commerce and Consumer Affairs

**Before the
Senate Committee on Commerce, Consumer Protection, and Health
Monday, February 11, 2019
9:30 a.m.
State Capitol, Conference Room 229**

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

Chair Baker 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 circumvention 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 p. 1, line 17 to p. 2, line 15; p. 3, line 6 to p. 4, line 2; p. 4, line 15 to p. 5, line 11; and p. 6, line 5 to p. 6, line 20 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. In a similar measure, H.B. 216, H.D. 1, the Committee on Health is requiring the State Auditor to perform an analysis to determine whether: (1) the benefits mandated by H.B. 216 warrant a report pursuant to HRS section 23-51; and (2) H.B. 216 would trigger defrayment provisions pursuant to section 1311(d)(3) of 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.”



Hawaii Association of Health Plans

February 8, 2019

The Honorable Rosalyn H. Baker, Chair
The Honorable Stanley Chang, Vice Chair
Senate Committee on Commerce, Consumer Protection, and Health

Senate Bill 493 – Relating to Health Care Insurance

Dear Chair Baker, Vice Chair Chang, and Members of the Committee:

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to testify on SB 493, which prohibits a health care insurer from requiring an insured diagnosed with stage two cancer through stage five cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider, under certain conditions.

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 are also opposed to the mandated coverage of investigational drugs. These drugs are still awaiting the approval of the U.S. Food and Drug Administration and do not have any longitudinal data on effectiveness and patient safety.

Finally, as this is a new mandated benefit, it is 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.

Sincerely,

HAHP Public Policy Committee



Hawaii Senate Committee on Commerce, Consumer Protection, and Health

Senate Bill 493: Prohibiting health care insurer from requiring an insured diagnosed with stage two through stage five cancer to undergo step therapy

February 11, 2019

The Hawaii Society of Clinical Oncology (HSCO) and the American Society of Clinical Oncology (ASCO) are pleased to support legislation pending in the Hawaii Senate Committee on Commerce, Consumer Protection, and Health. Senate bill 493 would prevent health plans in the state of Hawaii from requiring a patient to undergo step therapy while battling stage two through five cancers.

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.

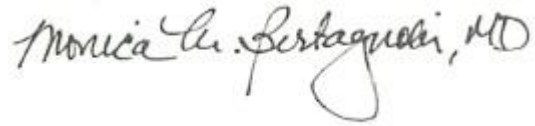
As the bill is considered, we urge the Committee to ensure that the bill does not unintentionally impede access to off-label drug use by adding in the following language under (2) "is listed in one of the approved compendia and is supported in published, peer reviewed studies."

ASCO and HSCO thank you for your leadership and encourage the Hawaii Senate Committee on Commerce, Consumer Protection, and Health to pass Senate Bill 493 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 on a light gray background. The signature is stylized and appears to read 'Keola Beale'.

Keola Beale, MD
President, Hawaii Society of Clinical Oncology

A handwritten signature in black ink. The signature is cursive and clearly reads 'Monica A. Bertagnoli, MD'.

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

SB-493

Submitted on: 2/10/2019 9:27:04 AM

Testimony for CPH on 2/11/2019 9:30:00 AM

Submitted By	Organization	Testifier Position	Present at Hearing
Melodie Aduja	Testifying for O`ahu County Committee on Legislative Priorities of the Democratic Party of Hawai`i	Support	No

Comments:



February 8, 2019

The Honorable Rosalyn H. Baker, Chair
The Honorable Stanley Chang, Vice Chair
Senate Committee on Commerce, Consumer Protection, and Health

Re: SB 493 – Relating to Health Care Insurance

Dear Chair Baker, Vice Chair Chang, and Committee Members:

Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 493, which prohibits a health care insurer from requiring an insured diagnosed with stage two through stage five cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider, under certain conditions.

HMSA plans ensure our members have the care and treatment that they need. We follow evidence-based clinical guidelines to ensure our members receive care that is safe and efficacious. Our policies are in line with national best practice guidelines issues by the ASCO (American Society of Clinical Oncology) and the NCCN (National Comprehensive Cancer Network). The ASCO is a professional organization representing physicians of all oncology subspecialties 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. We also solicit input for our policies from local oncologists and provide a 90 day comment period for these policies.

We are concerned with the mandated coverage of investigational drugs, which have not yet been approved by the U.S. Food and Drug Administration and do not have any long-term data on safety and efficacy.

Finally, as this would be a new mandated benefit, we believe that it is subject to an impact assessment report by the State Auditor pursuant to Sections 23-51 of the Hawaii Revised Statutes.

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

Sincerely,

Pono Chong
Vice President, Government Relations

The Honorable Rosalyn H. Baker, Chair
The Honorable Stanley Chang, Vice Chair
And Members of the Committee on Commerce, Consumer Protection, and Health
415 South Beretania Street
Honolulu, HI 96813

Subject: SB 493 Relating to Health Care Insurance; Step Therapy
Hearing: Monday, February 11, 2019, 9:30 am, Room 229

This testimony is to convey my strong support for SB 493. This measure will prohibit a health care insurer from requiring an insured diagnosed with stage two cancer or greater to undergo step therapy prior to covering the insured for drugs prescribed by the insured's health provider.

This measure will save lives. 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.

It is in her memory that I respectfully request your passage of SB 493.

Sincerely,

Janice Salcedo