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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 Health
Thursday, March 14, 2019
9:00 a.m.
State Capitol, Conference Room 329**

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

Chair Mizuno 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.

Further, the Department has concerns that language on page 2, line 4 to page 2, line 2; page 3, line 13 to page 4, line 11; page 5, lines 2-21; and page 6, line 12 to page 7, line 9 is vague and may be construed as creating a new mandate that requires coverage for 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 amended the bill to require 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.

Finally, S.D. 2 retains amendments made to the list of items that qualifies when a prescribed drug is subject to the step therapy prohibition by deleting investigational new drugs, inserting new items, and replacing "and" with "or" after the semicolons on: page 2, line 21; page 4, line 9; page 5, line 18; and page 7, line 7. These amendments might broaden the scope of the prohibition on step therapy.

Thank you for the opportunity to testify on this bill.



March 12, 2019

The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
House Committee on Health

Re: SB 493 SD2 – Relating to Health Care Insurance

Dear Chair Mizuno, Vice Chair Kobayashi, and Committee Members:

Hawaii Medical Service Association (HMSA) appreciates the opportunity to testify on SB 493, SD2, which prohibits a health care insurer, mutual benefit society, or health maintenance organization from requiring an insured, subscriber, member, or enrollee diagnosed with stage two through stage four 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 off-label drugs. Off-labeling is the usage of a U.S. Food and Drug Administration (FDA) approved drug for an unapproved use. In many cases off-label usage does 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



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To:

HOUSE COMMITTEE ON HEALTH

Rep. John Mizuno, Chair

Rep. Bertrand Kobayashi, Vice Chair

Date: March 14, 2019

Time: 9:00 a.m.

Place: Room 329

From: Hawaii Medical Association

Jerry Van Meter, MD, President

Christopher Flanders, DO, Executive Director

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

Position: SUPPORT

On behalf of Hawaii's physician and student members, the HMA supports SB 493 SD 2 which would prohibit health care insurers from requiring an insured diagnosed with Stage II and above cancer to undergo step therapy prior to covering the insured for the drugs 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 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.

Thank you for allowing testimony on this important 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



Hawaii House Committee on Health

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

March 14, 2019

The Hawaii Society of Clinical Oncology (HSCO) and the American Society of Clinical Oncology (ASCO) are pleased to strongly support legislation pending in the Hawaii House Committee on 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 four cancers. Step therapy requires patients to try and fail on a lower cost medication before they can access medication or treatment recommended by their physician. Step therapy can: delay patient 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 holding a hearing on Senate bill 493 and encourage them to pass this important bill and 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".

Keola Beale, MD
President, Hawaii Society of Clinical Oncology

A handwritten signature in black ink, appearing to read "Monica A. Bertagnoli, MD".

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

The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
And Members of the Committee on Health
415 South Beretania Street
Honolulu, HI 96813

Subject: SB 493 SD2 Relating to Health Care Insurance
Hearing: Thursday, March 14, 2019, 9:00 am, Room 329

This testimony is to convey my strong support for SB 493 SD2. This measure will prohibit a health care insurer, mutual benefit society, or health maintenance organization from requiring an insured, subscriber, member, or enrollee diagnosed with stage two through stage four cancer to undergo step therapy prior to covering the insured for the drug prescribed by the insured's health care provider, under certain conditions.

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 SD2.

Sincerely,

Janice "Jan" Salcedo

LATE

SB-493-SD-2

Submitted on: 3/13/2019 2:16:32 PM
Testimony for HLT on 3/14/2019 9:00:00 AM

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

Comments:



Hawaii Association of Health Plans

March 12, 2019

The Honorable John M. Mizuno, Chair
The Honorable Bertrand Kobayashi, Vice Chair
House Committee on Health

Senate Bill 493 SD2 – Relating to Health Care Insurance

Dear Chair Mizuno, Vice Chair Kobayashi, and Members of the Committee:

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

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.

Sincerely,

HAHP Public Policy Committee

cc: HAHP Board Members