

HB

216

HD1

A BILL FOR AN ACT

RELATING TO HEALTH CARE INSURANCE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 PART I

2 SECTION 1. The legislature finds that, according to the
3 department of health, cancer is the second leading cause of
4 death among Hawaii residents, claiming more than two thousand
5 two hundred Hawaii residents each year. The legislature further
6 finds that cancer patients should have full access to effective
7 treatment options at early stages of their illnesses.

8 The purpose of this Act is to prohibit health insurers that
9 cover treatment for stage two cancer from requiring an insured
10 diagnosed with stage two cancer to undergo step therapy prior to
11 covering the insured for the drug prescribed by the insured's
12 health care provider, under certain conditions.

13 SECTION 2. Chapter 431, Hawaii Revised Statutes, is
14 amended by adding a new section to part I of article 10A to be
15 appropriately designated and to read as follows:

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
3 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.

14 (b) For the purposes of this section:

15 "Investigational new drug" has the same meaning as provided
16 under 21 Code of Federal Regulations section 312.3.

17 "Step therapy" means a protocol that requires an insured to
18 use a prescription drug or sequence of prescription drugs, other
19 than the drug that the insured's health care provider recommends
20 for the insured's treatment, before the insurer provides
21 coverage for the recommended prescription drug."



1 SECTION 3. Chapter 431, Hawaii Revised Statutes, is
2 amended by adding a new section to part II of article 10A to be
3 appropriately designated and to read as follows:

4 "§431:10A- Step therapy prohibited; stage two cancer.

5 (a) No group accident and health or sickness policy issued or
6 renewed in the State after December 31, 2019, that provides
7 coverage for the treatment of stage two cancer shall require an
8 insured who is diagnosed with a stage two cancer to undergo step
9 therapy prior to covering the drug prescribed by the insured's
10 health care provider if the prescribed drug is:

11 (1) An investigational new drug; or

12 (2) A prescription drug:

13 (A) That is approved by the United States Food and
14 Drug Administration;

15 (B) Whose use is consistent with best practices for
16 the treatment of the stage two cancer; and

17 (C) That is listed on the insurer's prescription drug
18 formulary.

19 (b) For the purposes of this section:

20 "Investigational new drug" has the same meaning as provided
21 under 21 Code of Federal Regulations section 312.3.



1 "Step therapy" means a protocol that requires an insured to
2 use a prescription drug or sequence of prescription drugs, other
3 than the drug that the insured's health care provider recommends
4 for the insured's treatment, before the insurer provides
5 coverage for the recommended prescription drug."

6 SECTION 4. Chapter 432, Hawaii Revised Statutes, is
7 amended by adding a new section to part VI of article 1 to be
8 appropriately designated and to read as follows:

9 "§432:1- Step therapy prohibited; stage two cancer. (a)
10 No individual or group hospital or medical service plan contract
11 issued or renewed in the State after December 31, 2019, that
12 provides coverage for the treatment of stage two cancer shall
13 require a subscriber or member who is diagnosed with a stage two
14 cancer to undergo step therapy prior to covering the drug
15 prescribed by the subscriber's or member's health care provider
16 if the prescribed drug is:

17 (1) An investigational new drug; or

18 (2) A prescription drug:

19 (A) That is approved by the United States Food and
20 Drug Administration;



- 1 (B) Whose use is consistent with best practices for
- 2 the treatment of the stage two cancer; and
- 3 (C) That is listed on the mutual benefit society's
- 4 prescription drug formulary.

5 (b) For the purposes of this section:

6 "Investigational new drug" has the same meaning as provided
7 under 21 Code of Federal Regulations section 312.3.

8 "Step therapy" means a protocol that requires a subscriber
9 or member to use a prescription drug or sequence of prescription
10 drugs, other than the drug that the subscriber's or member's
11 health care provider recommends for the subscriber's or member's
12 treatment, before the mutual benefit society provides coverage
13 for the recommended prescription drug."

14 SECTION 5. Chapter 432D, Hawaii Revised Statutes, is
15 amended by adding a new section to be appropriately designated
16 and to read as follows:

17 "§432D- Step therapy prohibited; stage two cancer. (a)
18 No policy, contract, plan, or agreement issued or renewed in the
19 State after December 31, 2019, that provides coverage for the
20 treatment of stage two cancer shall require an enrollee who is
21 diagnosed with a stage two cancer to undergo step therapy prior



1 to covering the drug prescribed by the enrollee's health care
2 provider if the prescribed drug is:

3 (1) An investigational new drug; or

4 (2) A prescription drug:

5 (A) That is approved by the United States Food and
6 Drug Administration;

7 (B) Whose use is consistent with best practices for
8 the treatment of the stage two cancer; and

9 (C) That is listed on the health maintenance
10 organization's prescription drug formulary.

11 (b) For the purposes of this section:

12 "Investigational new drug" has the same meaning as provided
13 under 21 Code of Federal Regulations section 312.3.

14 "Step therapy" means a protocol that requires an enrollee
15 to use a prescription drug or sequence of prescription drugs,
16 other than the drug that the enrollee's health care provider
17 recommends for the enrollee's treatment, before the health
18 maintenance organization provides coverage for the recommended
19 prescription drug."



1 PART II

2 SECTION 6. The state auditor shall conduct a review to
3 determine:

- 4 (1) If an impact assessment report pursuant to section 23-
5 51, Hawaii Revised Statutes, is warranted for coverage
6 of the benefits mandated in this Act;
- 7 (2) If the benefits mandated in this Act trigger any
8 requirement to defray the cost of new mandated
9 benefits in excess of the essential health benefits as
10 required by section 1311(d)(3) of the federal Patient
11 Protection and Affordable Care Act (P.L. 111-148); and
- 12 (3) If the prohibition of step therapy under certain
13 conditions would circumvent the medical necessity
14 provisions in section 432E-1.4, Hawaii Revised
15 Statutes.

16 The state auditor shall submit a report of its findings and
17 recommendations, including any recommended legislation, no later
18 than twenty days before the convening of the 2020 session of the
19 legislature.



1

PART III

2 SECTION 7. This Act does not affect rights and duties that
3 matured, penalties that were incurred, and proceedings that were
4 begun before its effective date.

5 SECTION 8. New statutory material is underscored.

6 SECTION 9. This Act shall take effect on July 1, 2050.



Report Title:

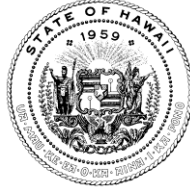
Health Care Insurance; Step Therapy; State Auditor

Description:

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. Requires analysis and report by State Auditor to determine if federal ACA provisions or state sunrise analysis requirements have been triggered. (HB216 HD1)

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.





DAVID Y. IGE
GOVERNOR

JOSH GREEN
LT. GOVERNOR

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

335 MERCHANT STREET, ROOM 310
P.O. BOX 541
HONOLULU, HAWAII 96809
Phone Number: 586-2850
Fax Number: 586-2856
cca.hawaii.gov

CATHERINE P. AWAKUNI COLÓN
DIRECTOR

JO ANN M. UCHIDA TAKEUCHI
DEPUTY DIRECTOR

Testimony of the Department of Commerce and Consumer Affairs

**Before the
House Committee on Consumer Protection and Commerce
Thursday, February 7, 2019
2:00 p.m.
State Capitol, Conference Room 329**

**On the following measure:
H.B. 216, H.D. 1, RELATING TO 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. H.D. 1 adds a new part II to this bill, directing the State Auditor to: (1) conduct a review to determine whether a report pursuant to Hawaii Revised Statutes (HRS) section 23-51 is warranted; (2) whether the bill will trigger section 1311(d)(3) of the federal Patient Protection and Affordable Care Act (PPACA), requiring defrayment of costs; and (3) whether the bill would circumvent provisions of HRS section 432E-1.4.

With respect to (3), the Department believes that prohibiting step therapy under certain conditions may circumvent medical necessity provisions in 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.

Additionally, 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

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

H.B. NO. 216, H.D. 1, RELATING TO HEALTH CARE INSURANCE

Hearing: Thursday, February 7, 2019, 2:00 p.m.

The Office of the Auditor has **no position** regarding H.B. No. 216, 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 H.B. No. 216, 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 defer to the Legislature as to whether the proposed legislation triggers the requirement and suggest that the committee consult with the its attorneys or the Department of the Attorney General for advice as to whether the proposal triggers the requirement of an impact assessment under Section 23-51, HRS.

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 H.B. No. 216, H.D. 1.



Hawaii House Consumer Protection & Commerce Committee
Relating to House Bill 216: Prohibiting a health care insurer from requiring an insured diagnosed with stage two cancer to undergo step therapy

February 6th, 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 House Protection and Commerce Committee. House Bill 216 would prevent health plans in the state of Hawaii from requiring a patient to undergo step therapy while battling stage two 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.

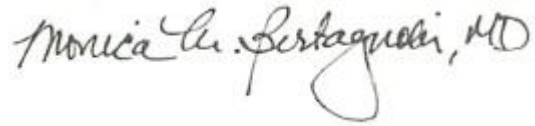
As the bill is considered, we urge you to make two important clarifications to the text. First, the language should make clear that step therapy is prohibited not only for stage II cancers, but also for stage III and IV cancers. Second, ensure that the bill does not unintentionally impede access to off-label 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 House Consumer Protection and Commerce Committee to pass House Bill 216 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 reads 'Monica A. Bertagnoli, MD'.

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



HAWAII MEDICAL ASSOCIATION

1360 S. Beretania Street, Suite 200, Honolulu, Hawaii 96814
Phone (808) 536-7702 Fax (808) 528-2376
www.hawaiimedicalassociation.org

To:

HOUSE COMMITTEE ON CONSUMER PROTECTION

Rep. Roy Takumi, Chair

Rep. Linda Ichiyama, Vice Chair

Date: February 7, 2019

Time: 2:00 p.m.

Place: Room 329

From: Hawaii Medical Association

Jerry Van Meter, MD, President

Christopher Flanders, DO, Executive Director

Re: HB 216 HD 1 – Relating to Health Care Insurance

Position: SUPPORT

On behalf of Hawaii's physician and student members, the HMA supports HB 216 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.

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



HAWAII MEDICAL ASSOCIATION

1360 S. Beretania Street, Suite 200, Honolulu, Hawaii 96814

Phone (808) 536-7702 Fax (808) 528-2376

www.hawaiimedicalassociation.org

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Executive Director – Christopher Flanders, DO

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: HB 216 HD1 Relating to Health Care Insurance; Step Therapy
Hearing: Thursday, February 7, 2019 at 2:00 pm

This testimony is to convey support for HB 216 HD1. This measure, in its original form, 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. The House Draft requests a study by the state auditor to submit a report of its findings and recommendations, including any recommended legislation, not later than twenty days before the convening of the 2020 session of the legislature.

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. 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", with a long horizontal flourish extending to the right.

Janice "Jan" Salcedo



February 5, 2019

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

Re: HB 216 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 HB 216 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 analysis and report by the State Auditor to determine if federal ACA provisions or state sunrise analysis requirements have been triggered.

We respectfully oppose this measure. We are concerned with the mandated coverage of investigational or experimental 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.

HMSA policies ensure our members have the care and treatment that they need. We follow clinical, evidence-based 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.

Should the Committee wish to move this measure forward, we respectfully ask that the State Auditor's impact assessment per HRS 23-51 be done first per Part II of the bill.

Thank you for allowing us to testify on HB 216 HD1.

Sincerely,

Jennifer Diesman
Senior Vice-President, Government Relations

HB-216-HD-1

Submitted on: 2/6/2019 3:20:49 PM

Testimony for CPC on 2/7/2019 2:00:00 PM

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

Comments:



Testimony of
John M. Kirimitsu
Legal & Government Relations Consultant

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

February 6, 2019
2:00 pm
Conference Room 329

Re: HB 216, 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 the drug prescribed by the insured's provider.

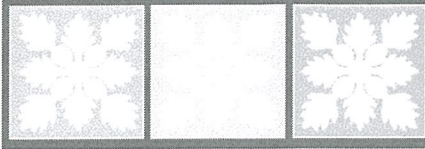
Kaiser Permanente Hawaii requests an amendment.

Kaiser requests an amendment to remove the mandated coverage for investigational drugs since these experimental drugs have not passed the typical U.S. Food and Drug Administration (FDA) review and approval process. See Page 6, line 3. The FDA's current scientific methods and procedures are of paramount importance for determining the safety and efficacy of dangerous drugs. Similarly, physicians, as scientists, rely upon the latest facts and clinical data to make recommendations about treatment that could be effective for a patient's condition. This historical data comes from clinical trials designed to pre-screen drugs that are potentially dangerous and drugs that may be safe, but don't work. Clearly, circumventing the FDA's review and approval process, as well as recognizing the lack of clinical data available to physicians, may result in harmful unintended consequences.

Additionally, 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.

711 Kapiolani Blvd
Honolulu, Hawaii 96813
Telephone: 808-432-5224
Facsimile: 808-432-5906
Mobile: 808-282-6642
E-mail: John.M.Kirimitsu@kp.org



February 5, 2019

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

LATE TESTIMONY

House Bill 216 HD1 – Relating to Health Care Insurance

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

The Hawaii Association of Health Plans (HAHP) appreciates the opportunity to testify on HB 216 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 analysis and report by the State Auditor to determine if federal ACA provisions or state sunrise analysis requirements have been triggered.

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 and experimental drugs as these drugs are still awaiting federal Food and Drug Administration (FDA) approval and do not have any longitudinal data on effectiveness and patient safety.

As this is a new mandated benefit, we appreciate the amendments made to this measure to insert Part II requesting the state auditor to conduct an impact assessment pursuant to Sections 23-51 and 23-53 of the Hawaii Revised Statutes. Should this bill move forward, we respectfully request the impact assessment be conducted first.

Thank you for allowing us to comment on HB 216 HD1.

Sincerely,

HAHP Public Policy Committee