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Testimony of the Department of Commerce and Consumer Affairs

**Before the
House Committee on Health and Homelessness
Wednesday, January 31, 2024
8:30 a.m.**

State Capitol, Conference Room 329 and via Video Conferencing

**On the following measure:
H.B. 2194, RELATING TO HEALTH INSURANCE**

Chair Belatti and Members of the Committee:

My name is Gordon Ito, and I am the Insurance Commissioner for 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 insurer from requiring an insured diagnosed with stage two through stage five cancer to undergo step therapy prior to covering the insured for certain drugs 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, we note that it is unclear whether the amendments in sections 2 through 5 of this bill, which require health plans to provide benefits for the cost drugs, including investigational new drugs, so long as a provider prescribes them, would be construed as “in addition to the essential health benefits” within the meaning of 45 Code of Federal Regulations (CFR) § 155.170(a), or subject to defrayment provisions under 45 CFR § 155.170(b) which apply to benefits “in addition to the essential health benefits.”

For the Committee’s information, Hawaii Revised Statutes section 23-51 provides, in part, that “[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, [sic] can be considered, there shall be concurrent resolutions passed requesting the auditor to prepare and submit to the legislature a report[.]”

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.”

January 31, 2024

To: Chair Belatti, Vice Chair Takenouchi, and Members of the House Committee on Health and Homelessness

From: The Hawaii Association of Health Plans Public Policy Committee

Date/Location: Jan. 31, 2024; 8:30 a.m./Conference Room 329 & Videoconference

Re: Testimony with comments on HB 2194 - Relating to Health Insurance; Step Therapy; Prohibition

The Hawaii Association of Health Plans (HAHP) would like to offer comments on HB 2194. HAHP is a statewide partnership that unifies Hawaii's health plans to improve the health of Hawaii's communities together. A majority of Hawaii residents receive their health coverage through a plan associated with one of our organizations.

HAHP and our member organizations appreciate the efforts of this committee to ensure that individuals diagnosed with cancer are able to get the life-saving drugs they need. We do, however, believe this bill adds new mandates and request an auditor's study to determine the impacts and respectfully offer additional comments and requested amendments:

1. We would appreciate clarity on this bill's reference applicability to those diagnosed with stage two through stage five cancer. Reference to a "stage five" cancer is not medically accurate. The accurate cancer stages are stage 0, stage 1, stage 2, stage 3 and stage 4; and
2. Amend the bill to remove the mandated coverage for investigational drugs since these experimental drugs have not passed the typical U.S. Food and Drug Administration review and approval process; and
3. Adding off-label usage for cancer treatments under "Prescription Drugs".

Thank you for the opportunity to offer comments on HB 2194.

Sincerely,

HAHP Public Policy Committee

cc: HAHP Board Members

[AlohaCare](#) | [HMAA](#) | [HMSA](#) | [Humana](#) | [HWMG](#) | [Kaiser Permanente](#) | [MDX Hawaii](#) | [Ohana Health Plan](#) | [UHA Health Insurance](#) | [UnitedHealthcare](#)

hahp.org | info@hahp.org



January 31, 2024

The Honorable Della Au Belatti, Chair
The Honorable Jenna Takenouchi, Vice Chair
House Committee on Health & Homelessness

Re: HB 2194 – RELATING TO HEALTH INSURANCE

Dear Chair Belatti, Vice Chair Takenouchi, and Members of the Committee:

Hawaii Medical Service Association (HMSA) appreciates the opportunity to provide comments on HB 2194, which will prohibit a health insurer from requiring an insured diagnosed with stage two through stage five cancer to undergo step therapy prior to covering the insured for certain drugs prescribed by the insured's health care provider, under certain conditions.

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 would request amendments to the current language:

1. Clarification on this bill's reference applicability to those diagnosed with stage two through stage five cancer.
2. Removing 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
3. Adding off-label usage for cancer treatments under "Prescription Drugs"



While HMSA appreciates the intent of this measure, we believe that as currently written this bill creates a new mandated benefits which would increase costs for our members. Therefore, we would like to respectfully request that, should this bill move forward, the State Auditor conduct an impact assessment report first pursuant to Section 23-51 and 23-52 of the Hawaii Revised Statutes.

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

Sincerely,

A handwritten signature in black ink, appearing to read 'Dawn Kurisu', is positioned above the typed name.

Dawn Kurisu
Assistant Vice President
Community and Government Relations



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: HB 2194 Relating to Health 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 would like to offer comments.

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 moves forward, Kaiser requests clarity on this bill's reference to those diagnosed with stage two through stage five cancer, since reference to a "stage five" cancer is not medically accurate. It is well recognized that the appropriate stages of cancer are stages 0 through 4:

- Stage 0 means there's no cancer, only abnormal cells with the potential to become cancer.
- Stage I means the cancer is small and only in one area. This is also called early-stage cancer.
- Stage II and III mean the cancer is larger and has grown into nearby tissues or lymph nodes.
- Stage IV means the cancer has spread to other parts of your body. It's also called advanced or metastatic cancer.

Additionally, Kaiser requests the following amendments: (1) 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 for safety, and (2) include the widely accepted practice of allowing coverage for off label drugs for cancer treatments, since the National Cancer Institute (NCI) recognizes that "*Research has shown that off-label use of drugs is very common in cancer treatment.*" See <https://www.cancer.gov/about-cancer/treatment/drugs/off-label>.

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E-mail: John.M.Kirimitsu@kp.org

Therefore, Kaiser requests the following amendments (added language is underscored and deleted language is ~~stricken~~) on Page 6, lines 4-20:

"§432D- Step therapy prohibited; stage two through stage five cancer. (a) No policy, contract, plan, or agreement issued or renewed in the State after December 31, 2024, that provides coverage for the treatment of stage two through stage five cancer shall require an enrollee who is diagnosed with a stage two through stage five cancer to undergo step therapy prior to covering the drug prescribed by the enrollee's health care provider if the prescribed drug is:

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

(2) A prescription drug:

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

(B) Whose use is consistent with best practices for the treatment of the cancer in its respective stage; ~~and~~

(C) That is listed on the health maintenance organization's prescription drug formulary; and

(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.

Thank you for the opportunity to comment.

HB-2194

Submitted on: 1/29/2024 12:30:29 PM

Testimony for HLT on 1/31/2024 8:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Cards Pintor	Individual	Support	Written Testimony Only

Comments:

Aloha,

I support this bill.

Mahalo nui,

Cards Pintor

HB-2194

Submitted on: 1/30/2024 6:54:17 PM

Testimony for HLT on 1/31/2024 8:30:00 AM

Submitted By	Organization	Testifier Position	Testify
Stefanie Y Sakamoto	Individual	Support	Written Testimony Only

Comments:

I am in support of this bill. My father died from stage 3 non-hodgkins lymphoma, and I witnessed first-hand how expensive advanced cancer treatment can be. While someone is fighting cancer, they should not have to worry about whether or not their health insurance plan is adequate. Thank you.

1045 Kaumoku Street
Honolulu, HI 96825

January 31, 2024

COMMITTEE ON HOUSING AND HOMELESSNESS

Dear Rep. Della Au Belatti, Chair, Rep. Jenna Takenouchi, Vice Chair and Committee members,

I am writing in complete support of HB2 2194.

This bill will expedite possible life-saving treatments for seriously ill residents with advanced cancers, as recommended by their physicians (rather than as controlled by the insurance industry).

The current insurance-mandated step therapy can severely delay receipt of prescribed drugs that are approved by the Food and Drug Administration and consistent with best practices treatments for the respective stage of the ongoing cancers. The delay can be potentially deadly for the patient.

Please adopt HB 2194. Let's not allow delays of potentially life-saving medications.

Sincerely,



Mary M. Schmidtke