

JAN 18 2008

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## A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUG COST CONTAINMENT AND AFFORDABLE  
ACCESS.

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

1 SECTION 1. The purpose of this Act is to reduce the cost  
2 of providing prescription drugs while maintaining the high  
3 quality of prescription drug therapies available to Hawaii's  
4 residents.

5 SECTION 2. The Hawaii Revised Statutes is amended by  
6 adding a new chapter to be appropriately designated and to read  
7 as follows:

8 "CHAPTER

9 PRESCRIPTION DRUG COST CONTAINMENT

10 § -1 **Definitions.** As used in this chapter, unless the  
11 context clearly requires otherwise:

12 "Board" or "drug utilization review board" means the drug  
13 utilization review board established pursuant to section -3  
14 in connection with the state medicaid program.

15 "Department" means the department of human services.

16 "Director" means the director of human services.



1 "Health benefits plan" means a health benefits plan with  
2 prescription drug coverage offered or administered by a health  
3 insurer and the out-of-state counterparts to such a plan. The  
4 term includes:

5 (1) Any state public assistance program with a health  
6 benefits plan that provides coverage for prescription  
7 drugs;

8 (2) Any health benefits plan offered by or on behalf of  
9 the State or any instrumentality of the State  
10 providing coverage for government employees and their  
11 dependents that agrees to participate in the program;  
12 and

13 (3) Any insured or self-insured health benefits plan that  
14 agrees to participate in the program.

15 "Health insurer" means any health insurance company,  
16 nonprofit hospital, medical service corporation, managed care  
17 organization, or, to the extent permitted under federal law, any  
18 administrator of an insured, self-insured, or publicly funded  
19 health benefits plan offered by public or private entities.

20 "Participating health benefits plan" means a health  
21 benefits plan that has agreed to participate in one or more  
22 components of the program.



1 "Program" means the pharmacy best practices and cost  
2 control program established by this chapter.

3 "State public assistance program" includes the state  
4 medicaid program, including QUEST and the state children's  
5 health insurance program, and the out-of-state counterparts to  
6 these programs.

7 **§ -2 Pharmacy best practices and cost control program;**  
8 **established.** (a) The director shall establish a pharmacy best  
9 practices and cost control program designed to reduce the cost  
10 of providing prescription drugs while maintaining high quality  
11 in prescription drug therapies. The program shall include:

12 (1) A preferred list of covered prescription drugs that  
13 identifies preferred choices within therapeutic  
14 classes for particular diseases and conditions,  
15 including generic alternatives; provided that:

16 (A) The directors of human services and health shall  
17 implement the preferred drug list as a uniform,  
18 statewide preferred drug list by encouraging all  
19 health benefits plans in this State to  
20 participate in the program;

21 (B) The board of trustees of the Hawaii employer-  
22 union health benefits trust fund shall use the



1 preferred drug list in the health benefits plan  
2 or plans established by that board under section  
3 87A-16 only if participation in the program will  
4 provide economic and health benefits to those  
5 health benefits plans and to beneficiaries of  
6 those plans, and only if agreed to through the  
7 collective bargaining process between the State  
8 and the authorized representatives of the  
9 employees of the State. This subparagraph does  
10 not authorize the actuarial pooling of the health  
11 benefits plans established by the board of  
12 trustees with any other health benefits plan,  
13 unless otherwise agreed to through the collective  
14 bargaining process between the State and the  
15 authorized representatives of the employees of  
16 the State; and

17 (C) The director shall encourage all health benefits  
18 plans to implement the preferred drug list as a  
19 uniform, statewide preferred drug list by  
20 inviting the representatives of each health  
21 benefits plan providing prescription drug  
22 coverage to residents of this State to



1            participate as observers or nonvoting members in  
2            the proceedings of the drug utilization review  
3            board pursuant to section            -3(e), and  
4            inviting those plans to use the preferred drug  
5            list in connection with the plans' prescription  
6            drug coverage;

7            (2) Utilization review procedures, including a prior  
8            authorization review process;

9            (3) Any strategy designed to negotiate with pharmaceutical  
10            manufacturers to lower the cost of prescription drugs  
11            for program participants, including a supplemental  
12            rebate program;

13            (4) Educational programs, including a counter-detailing  
14            program that provides information and education on the  
15            therapeutic and cost-effective utilization of  
16            prescription drugs to physicians, pharmacists, and  
17            other health care professionals authorized to  
18            prescribe and dispense prescription drugs;

19            (5) Alternative pricing mechanisms, including  
20            consideration of using maximum allowable cost pricing  
21            for generic and other prescription drugs;



1 (6) Alternative coverage terms, including consideration of  
2 providing coverage of over-the-counter drugs where  
3 cost-effective in comparison to prescription drugs,  
4 and authorizing coverage of dosages capable of  
5 permitting the consumer to split each pill if cost-  
6 effective and medically appropriate for the consumer;

7 (7) A simple, uniform prescription form designed to  
8 implement the preferred drug list and to enable  
9 prescribers and consumers to request an exception to  
10 the preferred drug list with a minimum of cost and  
11 time to prescribers, pharmacists, and consumers; and

12 (8) Any other cost containment activity adopted by the  
13 director by rule pursuant to chapter 91 that is  
14 designed to reduce the cost of providing prescription  
15 drugs while maintaining high quality in prescription  
16 drug therapies.

17 (b) The director shall implement the program for medicaid  
18 and all other state public assistance program health benefits  
19 plans to the extent permitted by federal law.

20 (c) The director may implement the program for any other  
21 health benefits plan within or outside this State that agrees to  
22 participate in the program.



1           (d) The director shall take all steps necessary to enable  
2 participation in joint prescription drug purchasing agreements  
3 with any other health benefits plan or organization within or  
4 outside this State that agrees to participate in a joint  
5 purchasing agreement. The director shall:

6           (1) Execute any joint purchasing agreements or other  
7 contracts with any participating health benefits plan  
8 or organization within or outside the State that the  
9 director determines will lower the cost of  
10 prescription drugs for residents of this State while  
11 maintaining high quality in prescription drug  
12 therapies;

13           (2) With regard to participation by a health benefits plan  
14 established by the board of trustees of the Hawaii  
15 employer-union health benefits trust fund, execute any  
16 joint purchasing agreements or other contracts with  
17 any health benefits plan or organization within or  
18 outside the State that the director determines will  
19 lower the cost of prescription drugs and provide  
20 overall quality of integrated health care services to  
21 that health benefits plan and the beneficiaries of the  
22 plan, and that is negotiated through the collective



1           bargaining process between the State and the  
2           authorized representatives of the employees of the  
3           State;

4           (3) Renegotiate and amend existing contracts to which the  
5           department is a party if renegotiation and amendment  
6           will be of economic benefit to the health benefits  
7           plans subject to those contracts and to the  
8           beneficiaries of those plans. Any renegotiated or  
9           substituted contract shall be designed to improve the  
10          overall quality of integrated health care services  
11          provided to beneficiaries of those plans; and

12          (4) Report annually to the governor and the legislature on  
13          progress in securing Hawaii's participation in joint  
14          purchasing agreements.

15          (e) The directors of human services and health shall  
16          collaborate with physicians, pharmacists, health insurers,  
17          consumers, employer organizations and other health benefits plan  
18          sponsors, pharmaceutical manufacturer organizations, and other  
19          interested parties to consider and make recommendations to  
20          reduce the cost of prescription drugs for all Hawaii residents.

21          (f) A participating health benefits plan other than a  
22          state public assistance program may agree with the director to





1 limit the plan's participation to one or more program  
2 components. The director may include those insured or self-  
3 insured health benefits plans that agree to use the preferred  
4 drug list or otherwise participate in one or more program  
5 components in any hearing, deliberation, or other proceeding  
6 required by this chapter.

7 (g) The director shall develop procedures for the  
8 coordination of state public assistance program health benefits  
9 plan drug benefits with pharmaceutical manufacturer patient  
10 assistance programs offering free or low-cost prescription  
11 drugs, including the development of a single application form  
12 for participation in those programs. The director may contract  
13 with a nongovernmental organization to develop the single  
14 application form.

15 **§ -3 Drug utilization review board; establishment. (a)**

16 The drug utilization review board is established within the  
17 department of human services for administrative purposes and  
18 shall consist of the following members who shall be  
19 appointed by the governor pursuant to section 26-34:

20 (1) members of executive branch agencies;

21 (2) members of the private sector;



1 (3) members to be appointed from a list of nominees  
2 submitted by the president of the senate, at least one  
3 of whom shall be a member of the private sector; and

4 (4) members to be appointed from a list of nominees  
5 submitted by the speaker of the house of  
6 representatives, at least one of whom shall be a  
7 member of the private sector.

8 (b) The board shall meet at least quarterly and shall  
9 comply with the requirements of chapter 92.

10 (c) In carrying out its duties under this chapter, the  
11 board may request staff assistance from the department of human  
12 services and other appropriate state agencies. The board may  
13 also employ, without regard to chapters 76 and 89, persons it  
14 finds necessary for the performance of its functions and fix  
15 their compensation.

16 (d) The members of the board shall serve without  
17 compensation, but shall be reimbursed for expenses, including  
18 travel expenses, necessary for the performance of their duties.

19 (e) The board shall:

20 (1) Make recommendations to the director concerning the  
21 adoption of the preferred drug list. The board's



1            recommendations shall be based upon considerations of  
2            clinical efficacy, safety, and cost-effectiveness;

3            (2) To the extent feasible, review all drug classes  
4            included in the preferred drug list at least every  
5            twelve months, and as appropriate, recommend that the  
6            director make additions to or deletions from the  
7            preferred drug list; and

8            (3) Establish procedures for the timely review of  
9            prescription drugs newly approved by the federal Food  
10           and Drug Administration, including procedures for the  
11           review of newly-approved prescription drugs in  
12           emergency circumstances.

13           **§ -4 Consumer protection rules; prior authorization.**

14           (a) When a patient's health care provider prescribes a  
15           prescription drug that is not on the preferred drug list, or  
16           that is not the list's preferred choice, the program shall  
17           authorize pharmacy benefit coverage if:

18           (1) The prescriber determines after consultation with the  
19           pharmacist or with the participating health benefits  
20           plan if required by the terms of the plan that:



1 (A) The preferred choice has not been effective, or  
2 with reasonable certainty is not expected to be  
3 effective in treating the patient's condition; or

4 (B) The preferred choice causes or is reasonably  
5 expected to cause an adverse or harmful reaction  
6 in the patient;

7 provided that a prescriber's determination under this  
8 paragraph shall be final; and

9 (2) The patient agrees to pay any additional cost in  
10 excess of the benefits provided by the patient's  
11 health benefits plan that is participating in the  
12 program. This paragraph shall not apply to the extent  
13 that it may be inconsistent with any federal medicaid  
14 laws and regulations. This paragraph shall not affect  
15 implementation by a participating health benefits plan  
16 of tiered copayments or other similar cost sharing  
17 systems.

18 (b) The program or any participating health benefits plan  
19 shall provide information on:

20 (1) How prescribers, pharmacists, beneficiaries, and other  
21 interested parties can obtain a copy of the preferred  
22 drug list;



1           (2) Whether any change has been made to the preferred drug  
2           list since it was last issued; and

3           (3) The process by which exceptions to the preferred list  
4           may be made.

5           (c) The program shall include a prior authorization  
6 process that shall:

7           (1) Be designed to minimize administrative burdens on  
8           prescribers, pharmacists, and consumers;

9           (2) Ensure real-time receipt of requests, by telephone,  
10          voice mail, facsimile, electronic transmission, or  
11          mail on a twenty-four-hour, seven days a week basis;

12          (3) Provide an in-person response to emergency requests by  
13          a prescriber with telephone answering queues that do  
14          not exceed ten minutes;

15          (4) Any request for authorization or approval of a drug  
16          that the prescriber indicates is for an emergency or  
17          urgent condition shall include the clinical reasons  
18          for the request, and be responded to in no more than  
19          four hours from the time the program or participating  
20          health benefits plan receives the request;

21          (5) In emergency circumstances, or if the response to a  
22          request for prior authorization is not provided within



1 the time period established in paragraph (4), a  
2 seventy-two hour supply of the drug prescribed shall  
3 be deemed to be authorized by the program or the  
4 participating health benefits plan; provided that:

5 (A) It is a prescription drug approved by the federal  
6 Food and Drug Administration; and

7 (B) For drugs dispensed to a medicaid beneficiary, it  
8 is subject to a rebate agreement with the Centers  
9 for Medicare and Medicaid Services; and

10 (6) The program or participating plan shall provide to  
11 participating providers a prior authorization request  
12 form for each enrolled beneficiary that:

13 (A) Permits the prescriber to make prior  
14 authorization requests in advance of the need to  
15 fill the prescription;

16 (B) May be completed without unnecessary delay; and

17 (C) May be stamped with information relating to the  
18 participating provider.

19 If feasible, at least one form capable of being copied  
20 shall contain known patient information.

21 (d) The program's prior authorization process shall allow  
22 the prescriber to request a prior authorization exception to the



1 requirements of this section. The program may exempt a  
2 prescriber from the need to secure prior authorization for a  
3 specific drug category if the program determines that the  
4 prescriber has written a minimum number of prescriptions in that  
5 category and the prescriber prescribes prescription drugs on the  
6 preferred drug list at or above the minimum threshold for that  
7 category.

8 (e) The program's prior authorization process shall not  
9 apply to prescription drugs used in the treatment of serious  
10 mental illness, including schizophrenia, major depression, and  
11 bipolar disorder.

12 **§ -5 Pharmacy benefit management.** (a) The director may  
13 implement all or a portion of the program through a contract  
14 with a third party with expertise in the management of pharmacy  
15 benefits.

16 (b) The director shall not enter into a contract with a  
17 pharmacy benefit manager unless the pharmacy benefit manager has  
18 agreed to disclose to the director the terms and the financial  
19 impact on the State and on beneficiaries in the State of:

20 (1) Any agreement with a pharmaceutical manufacturer to  
21 favor the manufacturer's products over a competitor's  
22 products, to place the manufacturer's drug on the



- 1 pharmacy benefit manager's preferred list or  
2 formulary, or to switch the drug prescribed by the  
3 patient's health care provider with a drug agreed to  
4 by the pharmacy benefit manager and the manufacturer;
- 5 (2) Any agreement with a pharmaceutical manufacturer to  
6 share manufacturer rebates and discounts with the  
7 pharmacy benefit manager or to pay "soft money" or  
8 other economic benefits to the pharmacy benefit  
9 manager;
- 10 (3) Any agreement or practice to bill state health  
11 benefits plans for prescription drugs at a cost higher  
12 than the pharmacy benefit manager pays the pharmacy;
- 13 (4) Any agreement to share revenue with a mail order or  
14 internet pharmacy company;
- 15 (5) Any agreement to sell prescription drug data or other  
16 information concerning the consumers or participants  
17 in the program, or data concerning the prescribing  
18 practices of the health care providers participating  
19 in the program; and
- 20 (6) Any other agreement of the pharmacy benefit manager  
21 with a pharmaceutical manufacturer, or with wholesale





1           and retail pharmacies, affecting the cost of pharmacy  
2           benefits provided through the program.

3           (c) The director shall not enter into a contract with a  
4 pharmacy benefit manager who has entered into an agreement or  
5 engaged in a practice described in subsection (b) unless the  
6 director determines and certifies in the fiscal report required  
7 by section       -6(d)(4) that the agreement or practice furthers  
8 the financial interests of the State and does not adversely  
9 affect the medical interests of program consumers or  
10 participants.

11           **§ -6 Reporting and oversight.** (a) The director shall  
12 report prior to initial implementation of the program, as well  
13 as prior to any subsequent modifications of the program, the  
14 following information for review by the auditor:

15           (1) The preferred drug list and list of drugs subject to  
16           prior authorization;

17           (2) Any utilization review procedures, including any prior  
18           authorization procedures; and

19           (3) The procedures by which drugs will be selected for  
20           placement on the preferred drug list, prior  
21           authorization, or for any other utilization review  
22           procedure.



1           (b) The director shall report quarterly to the auditor  
2 concerning the following aspects of the pharmacy best practices  
3 and cost control program:

4           (1) The efforts undertaken to educate health care  
5 providers about the preferred drug list and the  
6 program's utilization review procedures;

7           (2) The number of prior authorization requests made; and

8           (3) The number of utilization review events, other than  
9 prior authorization requests.

10          (c) The auditor shall closely monitor implementation of  
11 the preferred drug list and utilization review procedures to  
12 ensure that the consumer protection standards established in  
13 this chapter are not diminished as a result of implementing the  
14 preferred drug list and the utilization review procedures,  
15 including any unnecessary delay in access to appropriate  
16 medications. The auditor shall ensure that all affected  
17 parties, including consumers, health care providers,  
18 pharmacists, and others with pharmaceutical expertise have an  
19 opportunity to comment on the preferred drug list and procedures  
20 reviewed under this subsection.

21          (d) Before January 1, 2009, and before December 31 of each  
22 subsequent year for the duration of any pharmacy benefit



1 management contract under section -5, the director shall  
2 submit a report to the legislature and the auditor concerning  
3 implementation of any pharmacy benefit management contract  
4 entered into by the program. The report shall include:

- 5 (1) A description of the activities of the pharmacy  
6 benefit manager;
- 7 (2) An analysis of the success of the pharmacy benefit  
8 manager in achieving each of the department's public  
9 policy goals, together with the pharmacy benefit  
10 manager's report of its activities and achievements;
- 11 (3) An assessment of medicaid program administrative costs  
12 relating to prescription drug benefits, including any  
13 recommendations for increasing the administrative  
14 efficiency of the program;
- 15 (4) A fiscal report on the costs and savings to the State  
16 of the pharmacy benefit management contract, including  
17 an accounting of any payments, fees, offsets, savings,  
18 and other financial transactions or accountings. The  
19 report shall disclose:
- 20 (A) Any agreements entered into by the pharmacy  
21 benefit manager; and



1 (B) The financial impact of these agreements on the  
2 State, and on beneficiaries in this State;

3 (5) Any recommendations for enhancing the benefits of the  
4 pharmacy benefit management contract, and the  
5 identification of, and any recommendations for,  
6 minimizing any problems with the contract; and

7 (6) If the department has not entered into a contract with  
8 a pharmacy benefit manager, or if any such contract  
9 has been rescinded, any recommendations for pursuing  
10 the State's public policy goals relating to  
11 pharmaceutical costs, quality, and access through  
12 other means.

13 **§ -7 Supplemental rebates.** (a) The director,  
14 separately or in concert with the authorized representatives of  
15 any participating health benefits plan, shall use the preferred  
16 drug list authorized by the pharmacy best practices and cost  
17 control program to negotiate with pharmaceutical companies for  
18 the payment to the director of supplemental rebates or price  
19 discounts for medicaid and for any other state public assistance  
20 health benefits plans designated by the director that are in  
21 addition to those required by Title XIX of the Social Security  
22 Act. The director may also use the preferred drug list to



1 negotiate for the payment of rebates or price discounts in  
2 connection with drugs covered under any other participating  
3 health benefits plan within or outside this State; provided that  
4 these negotiations and any subsequent agreement shall comply  
5 with 42 U.S.C. section 1396r-8. The program, or such portions  
6 of the program as the director shall designate, shall constitute  
7 a state pharmaceutical assistance program under 42 U.S.C.  
8 section 1396r-8(c)(1)(C).

9 (b) The director shall negotiate supplemental rebates,  
10 price discounts, and other mechanisms to reduce net prescription  
11 drug costs by means of any negotiation strategy that the  
12 director determines will result in the maximum economic benefit  
13 to the program and to consumers in this State, while maintaining  
14 access to high quality prescription drugs. This section does  
15 not authorize agreements with pharmaceutical manufacturers  
16 whereby financial support for medical services covered by the  
17 medicaid program is accepted as consideration for placement of  
18 one or more prescription drugs on the preferred drug list. The  
19 January 1, 2009, report of the director pursuant to section  
20 -6(d) shall include a cost-benefit analysis of alternative  
21 negotiation strategies, including:



1 (1) The strategy used by the State of Florida to secure  
2 supplemental rebates;

3 (2) The strategy used by the State of Michigan to secure  
4 supplemental rebates; and

5 (3) Any other alternative negotiation strategy that might  
6 secure lower net prescription drug costs.

7 (c) The director and the department shall prohibit the  
8 public disclosure of information revealing company-identifiable  
9 trade secrets (including rebate and supplemental rebate amounts  
10 and manufacturer's pricing) obtained by the department and by  
11 any officer, employee, or contractor of the department in the  
12 course of negotiations conducted pursuant to this section. The  
13 confidential information shall be exempt from public disclosure  
14 under chapter 92F.

15 **§ -8 Pharmacy discount plan.** (a) By July 1, 2009, the  
16 director shall implement a pharmacy discount plan for state  
17 residents without adequate coverage for prescription drugs. The  
18 director may establish an enrollment fee to support the  
19 administrative costs of the plan.

20 (b) The pharmacy discount plan authorized by this section  
21 shall include a program implemented as a Section 1115 medicaid  
22 waiver, wherein the State makes a payment of at least two per



1 cent of the cost of each prescription or refill, consistent with  
2 any appropriation for the program established by this  
3 subsection.

4 (c) The director shall implement the pharmacy discount  
5 plan authorized by this section without any financial  
6 contribution by the State other than that required by subsection  
7 (b), and without federal waiver approval during such time as  
8 federal waiver approval has not been secured.

9 (d) As used in this section:

10 "Eligible beneficiary" means

11 (1) A resident who is:

12 (A) At least sixty-five years of age; or

13 (B) Disabled; and

14 (C) Eligible for medicare or social security

15 disability benefits, with a household income

16 equal to or less than four hundred per cent of

17 the federal poverty level; or

18 (2) A resident with a household income equal to or less

19 than three hundred per cent of the federal poverty

20 level.

21 "Residents without adequate coverage" includes eligible

22 beneficiaries with no coverage for prescription drugs and



1 eligible beneficiaries whose annual maximum coverage limit under  
2 their health benefits plan has been reached.

3       **§ -9 Pharmaceutical marketers.** (a) Before December 31  
4 of each year, every pharmaceutical manufacturing company shall  
5 disclose to the board of pharmacy the value, nature, and purpose  
6 of any gift, fee, payment, subsidy, or other economic benefit  
7 provided in connection with detailing, promotional, or other  
8 marketing activities by the company, directly or through its  
9 pharmaceutical marketers, to any physician, hospital, nursing  
10 home, pharmacist, health benefits plan administrator, or any  
11 other person in the State authorized to prescribe, dispense, or  
12 sell prescription drugs in this State. Disclosure shall be made  
13 in a form and manner prescribed by the board of pharmacy.  
14 Initial disclosure shall be made before December 31, 2009, for  
15 the twelve-month period ending June 30, 2009. The board of  
16 pharmacy shall provide to the attorney general complete access  
17 to the information required to be disclosed under this  
18 subsection. The attorney general shall report on the  
19 disclosures made under this section to the legislature and the  
20 governor before March 1 of each year.

21       (b) Each pharmaceutical manufacturing company subject to  
22 this section shall also disclose to the board of pharmacy,





1 before October 1, 2009, and annually thereafter, the name and  
2 address of the individual responsible for the company's  
3 compliance with this section.

4 (c) The board of pharmacy and the attorney general shall  
5 keep confidential all trade secret information. The disclosure  
6 form prescribed by the board of pharmacy shall permit the  
7 company to identify any information that is a trade secret.

8 (d) The following shall be exempt from disclosure:

9 (1) Free samples of prescription drugs intended to be  
10 distributed to patients;

11 (2) The payment of reasonable compensation and  
12 reimbursement of expenses in connection with bona fide  
13 clinical trials. As used in this paragraph, "clinical  
14 trial" means an approved clinical trial conducted in  
15 connection with a research study designed to answer  
16 specific questions about vaccines, new therapies, or  
17 new ways of using known treatments;

18 (3) Any gift, fee, payment, subsidy, or other economic  
19 benefit the value of which is less than \$25; and

20 (4) Scholarship or other support for medical students,  
21 residents, and fellows to attend a significant  
22 educational, scientific, or policy-making conference



1 of a national, regional, or specialty medical or other  
2 professional association if the recipient of the  
3 scholarship or other support is selected by the  
4 association.

5 (e) The attorney general may bring an action for  
6 injunctive relief, costs, and attorneys fees and to impose on a  
7 pharmaceutical manufacturing company that fails to disclose as  
8 required by this section (a), a civil penalty of no more than  
9 \$10,000 per violation. Each unlawful failure to disclose shall  
10 constitute a separate violation.

11 (f) As used in this section:

12 "Pharmaceutical manufacturing company" or "company" means  
13 any entity that is engaged in the production, preparation,  
14 propagation, compounding, conversion, or processing of  
15 prescription drugs, either directly or indirectly by extraction  
16 from substances of natural origin, or independently by means of  
17 chemical synthesis, or by a combination of extraction and  
18 chemical synthesis, or any entity engaged in the packaging,  
19 repackaging, labeling, relabeling, or distribution of  
20 prescription drugs. The term does not include a pharmacist  
21 licensed under chapter 461.



1 "Pharmaceutical marketer" means a person who, while  
2 employed by or under contract to represent a pharmaceutical  
3 manufacturing company, engages in pharmaceutical detailing,  
4 promotional activities, or other marketing of prescription drugs  
5 in this State to any physician, hospital, nursing home,  
6 pharmacist, health benefits plan administrator, or any other  
7 person authorized to prescribe, dispense, or sell prescription  
8 drugs. The term does not include a wholesale drug distributor  
9 or the distributor's representative who promotes or otherwise  
10 markets the services of the wholesale drug distributor in  
11 connection with a prescription drug."

12 SECTION 3. Section 461-4.5, Hawaii Revised Statutes, is  
13 amended by amending subsection (a) to read as follows:

14 "(a) In addition to any other powers and duties authorized  
15 by law, the board:

16 (1) Shall adopt, amend, and repeal rules pursuant to  
17 chapter 91, as it deems proper for the purposes of  
18 this chapter, Public Law 100-293, and 21 Code of  
19 Federal Regulations part 205;

20 (2) Shall examine, license, reinstate, and renew the  
21 licenses of qualified applicants for registered  
22 pharmacists and wholesale prescription drug



1 distributors, and issue and renew permits to operate  
2 pharmacies;

3 (3) May require the inspection of any wholesale  
4 prescription drug distributor premises in the State to  
5 ensure compliance with this chapter and rules adopted  
6 under this chapter, or may require an applicant for a  
7 pharmacy license to submit a statement that the  
8 premises, including but not limited to security and  
9 sanitation, are in conformance with the board's  
10 requirements and that the applicant possesses the  
11 reference materials and technical clinical equipment  
12 and supplies as may be specified in rules adopted  
13 under this chapter; [~~and~~]

14 (4) May fine, suspend, or revoke any license or permit for  
15 any cause prescribed by this chapter, or for any  
16 violation of the rules adopted under this chapter, and  
17 refuse to grant or renew any license or permit for any  
18 cause which would be ground for revocation or  
19 suspension of a license or permit[~~-~~]; and

20 (5) Shall develop criteria for a standardized tamper-  
21 resistant prescription pad that can be used by all  
22 health care providers who prescribe drugs. The



1           criteria shall be developed in consultation with  
2           pharmacists, hospitals, nursing homes, physicians, and  
3           other prescribers, and other affected parties."

4           SECTION 4.   **Section 1115 waiver for pharmaceutical**

5 **programs.** (a) The director of human services shall submit a  
6 request for a Section 1115 waiver or waiver amendment to  
7 maximize federal financial participation for state  
8 pharmaceutical assistance programs and to preserve continued  
9 access to the programs, unless the director determines that a  
10 waiver or waiver amendment will not provide a financial benefit  
11 to the State over the long term. The director shall report to  
12 the legislature if the director determines not to apply for a  
13 waiver or if the director determines to apply for a waiver that  
14 is not consistent with the principles established in subsection  
15 (b) in whole or in part.

16           (b) The waiver request shall conform to the following  
17 principles except when deviation is necessary to conduct  
18 successful negotiations with the Centers for Medicare and  
19 Medicaid Services:

20           (1) The waiver request shall propose a financially  
21           sustainable program designed to provide access to



1 medically necessary prescription drugs for low-income,  
2 elderly, and disabled residents;

3 (2) The waiver request shall consolidate and streamline  
4 program administration of and eligibility for  
5 pharmaceutical assistance programs; and

6 (3) The benefit plan and cost sharing provisions shall be  
7 designed to provide financial assistance and benefits  
8 based on the beneficiary's household income.

9 SECTION 5. **Application of preferred drug list to nursing**  
10 **home patients.** During fiscal year 2008-2009, the preferred drug  
11 list of the department of human services shall not apply to  
12 medicaid coverage of prescriptions for beneficiaries residing in  
13 a nursing home until the department proposes and the auditor  
14 approves a plan to notify and educate nursing home patients,  
15 their prescribers, and their pharmacy concerning the preferred  
16 drug list and the prior authorization process, and ensure that  
17 medicaid is securing the best price for covered drugs prescribed  
18 for nursing home residents. The department shall propose a plan  
19 by July 1, 2009.

20 SECTION 6. **Outcomes-based assessment and treatment.** (a)  
21 The State's health care policies shall promote outcomes-based  
22 assessment and treatment through the development of a statewide



1 quality assurance system and an effective quality improvement  
2 process that integrates best practices research, functional  
3 status assessment, patient satisfaction measurements, and cost  
4 containment goals, and that is established and implemented by  
5 nongovernmental organizations of health care providers and  
6 patients. The State shall recognize and support efforts of  
7 nongovernmental organizations to collaboratively establish and  
8 implement outcomes-based assessment and treatment.

9 (b) Statewide quality assurance inventory. Subject to the  
10 availability of grants from federal government agencies and  
11 nongovernmental organizations to support the costs of the  
12 contract authorized by this subsection, the director of health  
13 shall contract with a qualified nongovernmental organization to  
14 conduct an inventory of existing quality assurance measurements  
15 used in this State by:

- 16 (1) Public and private health plans;
- 17 (2) Hospitals serving residents; and
- 18 (3) Other state government entities.

19 The director's contractor shall report to the director with the  
20 results of the inventory and with an analysis and identification  
21 of any other information necessary to establish a statewide  
22 quality assurance system.



1           (c) Evaluation of inventory. The directors of human  
2 services and health shall convene a working group to develop a  
3 quality assurance measurement of statewide applicability. The  
4 working group shall include representatives from private and  
5 public health plans and any other members deemed appropriate by  
6 the directors. The working group shall:

7           (1) Evaluate the results of the statewide quality  
8           assurance inventory;

9           (2) Identify measurements common to all;

10          (3) Identify areas lacking measurements; and

11          (4) Make recommendations for change.

12 The working group may also propose the continuation or addition  
13 of outcomes-based assessments to identify areas of health care  
14 that need improvement, compare the quality of health care  
15 provided under public and private health benefits plans,  
16 identify ways to focus resources and programs to improve the  
17 health of beneficiary populations or discrete portions thereof,  
18 and develop additional means of expanding access to, improving  
19 the quality of, and lowering the cost of the State's health care  
20 system.

21          (d) Report to the legislature. The directors of human  
22 services and health shall submit a joint report of the findings





1 and recommendations of the working group, including any proposed  
2 implementing legislation, to the legislature no later than  
3 twenty days before the convening of the regular session of 2009.

4 The report shall include:

5 (1) A summary of the activities of the directors under  
6 this section; and

7 (2) A description of any proposals to implement outcomes-  
8 based assessment projects.

9 SECTION 7. Statutory material to be repealed is bracketed  
10 and stricken. New statutory material is underscored.

11 SECTION 8. This Act shall take effect upon its approval.

12

INTRODUCED BY: Arvid G. Ege



**Report Title:**

Prescription Drug Cost Containment; Disclosure of Gifts

**Description:**

Requires the director of human services to establish a pharmacy best practices and cost control program including medicaid and other state public assistance health benefits plans, in which any public and private health plan may participate. Includes a prescription drug preferred list and prior authorization review process. Requires drug manufacturers to disclose economic benefits of \$25 or more provided to persons who prescribe, dispense, or purchase prescription drugs.

