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Testimony in OPPOSITION to SB505 SD1 HD1
RELATING TO HEALTH.

REPRESENTATIVE ROY TAKUMI, CHAIR
HOUSE COMMITTEE ON CONSUMER PROTECTION & COMMERCE
Hearing Date: March 28, 2017 Room Number: 329

Fiscal Implications: Estimated $250,000 in additional operating expenses.

Department Testimony: The Department of Health (DOH) respectfully opposes SB505 SD1 HD1 as 1) an unfunded mandate, 2) not aligned with current department activities, and 3) an imprudent use of resources. Requiring informed consent may contribute to diminished injuries and death for non-medically indicated opioid use, but there is little to no value requiring providers to send forms in to DOH.

As a result, the department requests deferment of this measure or amendments as attached in a PROPOSED HD2 that acknowledge the value of informed consent procedures in a more effective manner.

Unfunded Mandate

The Department of Health is unable to absorb most of the proposed work effort with existing resources. Preliminary estimates are based on:

- 300 prescribing physicians, nurses, and dentists, or 10% of Hawaii's approximately 3,000 active licenses;
- Each writing at least 1 qualifying script for each of 125 qualifying patients, or 5% of an average physician's patient panel of approximately 2,500 patients; and
- Producing 37,500 documents per year (excluding refills), or 18 forms submitted per hour:

- 1.0 FTE clerical support to intake, file, and manage basic correspondence with submitting offices, e.g. legibility, completeness of form, etc.
- 1.0 FTE nurse to perform preliminary clinical review, flag and prepare files for further review, and coorespond with submitting offices, e.g. supporting medical records, interviews and follow up, etc.
- 0.10 FTE consulting medical and/or dental director to confirm findings, conduct professional relationship management, and if necessary refer out.

- A statistically significant sample size for monitoring 37,500 documents at a 99% confidence level is 654 documents – the minimum work effort – of all forms as mandated by proposed SB505 SD1 HD1.
  - Note that all forms require handling and storage per state and federal law, e.g. Health Insurance Portability and Accountability Act and 43 Code of Federal Reguslation, Part 2.

More precise esimates are unavailable due to general lack of participation with the Department of Public Safety's electronic prescription accountability system, for which provider registration is mandatory as of July 1, 2016 (Act 28 SLH 2016), and other data definciencies.

Current Department of Health Activities

To address data deficiencies, the Department of Health in 2014 executed with the Department of Public Safety a Memorandum of Agreement to:

1. Link data sources related to drug poisonings and overdoes and how those substances were accessed by victims, including death certificates and controlled substance data;
2. Promote use of the electronic prescriotion accountability system; and
3. Enhance IT infrastructure to improve analytics.

Further information on Department of Health resources may be found at this link: http://health.hawaii.gov/injuryprevention/home/poisoning-prevention/preventing-prescription-drug-overdose-in-hawaii/

Although the department supports informed consent for medical treatment in general, the proposed template and force of law may contribute to stigmatization of substance abuse as a chronic disease. The Department of Health is willing to facilitate development of community standards for opioid therapy informed consent but currently finds the proposed wording invasive to clinical practice and patient sensibilities, and potentially too punative. That said, the department defers to organizations like the Hawaii Medical Association and Hawaii Medical Board on professional issues.

Better Allocation of Resources

Appropriation of resources to implement proposals in this measure are more wisely invested in increasing public, patient, and professional education as well as focusing on high-risk communities for targeted dependence and overdose prevention.

Provider organizations (as well as payers) operate electronic medical records systems in which informed consent agreements may be required as part of a clinical workflow and stored, and from which reports may be generated for compliance. Retrospective monitoring of forms by the Department of Health is unlikely to yield better compliance and case-finding than what can be achieved by provider organizations themselves, and at much less cost.

Offered Amendments: In lieu of mandating the use, colletion, monitoring, and referral of forms that are impractical to implement, the Department of Health proposes a standard for prescribers and relevant organizations to adopt and maintain a written opioid therapy informed consent policies that will better accomodate variations in business operations and clinical practices, but incorporate community standards and evidence-based practices derived by stakeholder consensus. See attached PROPOSED HD2.

- Amend Bill Section 2, subsection (a) to require adoption and maintenance of informed consent policies.
- Add definition to Bill Section 2 for “qualifying opioid therapy patient” based on wording from SB505 SD1 HD1.

THE SENATE
TWENTY-NINTH LEGISLATURE, 2017

STATE OF HAWAII

S.B. NO. 505 S.D. 1 H.D. 2 PROPOSED

A BILL FOR AN ACT

RELATING TO HEALTH.

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

SECTION 1. The legislature finds that a nationwide drug epidemic exists related to prescription pain relieving drugs that are causing alarming rates of addiction, overdose, and death. According to the National Institute on Drug Abuse, an estimated 2.1 million people in the United States suffer from substance use disorders related to prescription opioid pain relievers. Society is facing the devastating consequences of this epidemic, with the number of unintentional overdose deaths from prescription pain relievers more than quadrupling since 1999. According to data provided by the PEW Charitable Trusts, opioid pain relievers killed nearly 20,000 Americans in 2014.

According to the National Institute on Drug Abuse, in terms of abuse and mortality, opioids account for the greatest proportion of the prescription drug abuse problem. The rise of prescription opioids started in the beginning of the twenty-first century, but by 2002 opioids caused more deaths than heroin or cocaine. The National Institute on Drug Abuse reports that the increase in the availability of opioid pain relievers is the result of a drastic increase in the

number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by pharmaceutical companies. As a result of the staggering number of people suffering from substance use disorders related to prescription opioid pain relievers, the United States Centers for Disease Control and Prevention, national and state legislators, and many others are trying to curb this epidemic through public education and limiting liberal opioid prescribing practices.

The legislature also finds that informed consent is an effective process between a provider and patient that relates to a specific medication or a form of treatment such as safe opioid therapy. The informed consent process allows the patient to better understand the goals of treatment, potential benefits of treatment, realistic outcomes, potential risks, how to use the medication, and alternative treatment options. The informed consent process is one approach to begin addressing the nationwide opioid epidemic.

The purpose of this Act is to reduce addiction, overdose, and death related to the use of opioids by:

(1) Requiring an opioid therapy informed consent process agreement to be executed between a patient and any prescriber of opioids under certain conditions;

(2) Requiring all prescribers who are authorized to prescribe opioids to register with Hawaii's electronic prescription accountability system; and

(3) Limiting initial prescriptions for opioids and benzodiazepines to a maximum of seven consecutive days with certain exceptions.

SECTION 2. Chapter 329, Hawaii Revised Statutes, is amended by adding a new section to be appropriately designated and to read as follows:

"**§329- Opioid therapy; informed consent process; requirement for written policies.** (a) Any provider authorized to prescribe opioids shall adopt and maintain written policy or policies, including but not limited to clinical practice guidelines, that include execution of a written agreement to engage in an informed consent process between the prescribing provider and qualifying opioid therapy patient.

(b) The department of health shall develop and make available a template of an opioid therapy informed consent process agreement for use in the State. The template for the opioid therapy informed consent process agreement shall include, at a minimum, the following:

(1) A statement that advises the qualifying opioid therapy patient that initial prescriptions for opioids and benzodiazepines shall be limited to a maximum of seven consecutive days unless certain conditions are met;

(2) A statement that the prescriber has discussed with the qualifying opioid therapy patient the possibility of overdose on opioids, the availability of co-prescribing naloxone, and education about how and when to use the prescribed opioids and naloxone;

(3) A statement that the prescriber has discussed with the qualifying opioid therapy patient non-opioid treatment options for chronic pain;

(4) For women patients ages eighteen to fifty, an assessment of the qualifying opioid therapy patient's reproductive health plans and a statement that the prescriber has discussed with the qualifying opioid therapy patient the risks of opioid use during pregnancy and has offered information on how to avoid pregnancy while using opioids;

(5) An outline of initial and ongoing functional treatment goals established at the initiation of the informed consent process, and a plan for the ongoing assessment of progress toward the goals;

(6) Consent to an initial assessment using an established questionnaire or screening tool of the p qualifying opioid therapy patient's potential risk for opioid or alcohol abuse, as well as other psychosocial factors that contribute to abuse risk, at the initiation of the informed consent process, and a plan for the ongoing assessment of risk thereafter;

(7) Consent to urine drug screening at the initiation of the informed consent process and at least two times each year thereafter;

(8) Consent to be referred to a psychologist, psychiatrist, or advanced practice registered nurse for concurrent care or

consultation if the opioid therapy continues for longer than six months; and

(9) Confirmation that the electronic prescription accountability system has been checked at the initiation of the informed consent process and agreement that the system will be checked at least quarterly thereafter.

For purposes of this section, "qualifying opioid therapy patient" means:

(1) A patient requires opioid treatment for more than three months;

(2) A patient is prescribed benzodiazepines and opioids together; or

(3) A patient is prescribed a dose of opioids that exceeds ninety morphine equivalent doses."

SECTION 3. Section 329-38, Hawaii Revised Statutes, is amended to read as follows:

"**§329-38 Prescriptions.** (a) No controlled substance in schedule II may be dispensed without a written prescription of a practitioner, except:

(1) In the case of an emergency situation, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization from a prescribing practitioner; provided that:

(A) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond

the emergency period shall be pursuant to a written prescription signed by the prescribing practitioner);

(B) If the prescribing practitioner is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a registered practitioner, which may include a callback to the prescribing practitioner using the phone number in the telephone directory or other good faith efforts to identify the prescriber; and

(C) Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of this subsection, the prescription shall have written on its face "Authorization for Emergency Dispensing". The written prescription may be delivered to the pharmacist in person or by mail, and if by mail, the prescription shall be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach

this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the administrator if the prescribing practitioner fails to deliver a written prescription to the pharmacy within the allotted time. Failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner. Any practitioner who fails to deliver a written prescription within the seven-day period shall be in violation of section 329-41(a)(1);

(2) No schedule II narcotic controlled substance may be prescribed or dispensed for more than a thirty-day supply, except where such substances come in a single unit dose package that exceeds the thirty-day limit or where a terminally ill patient is certified by a physician to exceed the thirty-day limit;

(3) When dispensed directly by a practitioner, other than a pharmacist, to the ultimate user. The practitioner in dispensing a controlled substance in schedule II shall affix to the package a label showing:

(A) The date of dispensing;

(B) The name, strength, and quantity of the drug dispensed;

(C) The dispensing practitioner's name and address;

(D) The name of the patient;

(E) The "use by" date for the drug, which shall be:

(i) The expiration date on the manufacturer's or principal labeler's container; or

(ii) One year from the date the drug is dispensed, whichever is earlier; and

(F) Directions for use, and cautionary statements, if any, contained in the prescription or as required by law.

A complete and accurate record of all schedule II controlled substances ordered, administered, prescribed, and dispensed shall be maintained for five years. Prescriptions and records of dispensing shall otherwise be retained in conformance with the requirements of section 329-36. No prescription for a controlled substance in schedule II may be refilled; or

(4) In the case of an electronic prescription, a pharmacist may dispense a controlled substance listed in schedule II upon receiving an electronic prescription.

(b) A schedule II controlled substance prescription shall:

(1) Be filled within seven days following the date the prescription was issued to the patient; and

(2) Be supplied to a patient only if the prescription has been filled and held by the pharmacy for not more than seven days.

(c) Initial prescriptions for opioids and benzodiazepines shall not be for longer than seven consecutive days unless a supply of longer than seven days is determined to be medically necessary for the treatment of:

(1) Pain experienced while the patient is in post-operative care;

(2) Chronic pain and pain management;

(3) Substance abuse or opioid or opiate dependence;

(4) Pain experienced while the patient is in palliative care; or

(5) Pain experienced while the patient is in hospice care;

provided that if a prescribing practitioner issues a prescription for more than a seven-day supply of an opioid and benzodiazepine, the practitioner shall document in the patient's medical record the condition for which the practitioner issued the prescription and that an alternative to the opioid and benzodiazepine was not appropriate treatment for the condition.

(d) After an initial prescription for opioids and benzodiazepines has been made, a prescribing practitioner may authorize subsequent prescriptions through a telephone consultation with the patient when the prescribing practitioner deems such action to be medically necessary for post-operative and pain management

patients; provided that a prescribing practitioner shall consult with a patient in person at least once every thirty days for the duration during which the practitioner prescribes opioids and benzodiazepines to the patient.

[~~(c)~~] (e) The transfer of original prescription information for a controlled substance listed in schedule III, IV, or V for the purpose of dispensing is permissible between pharmacies on a one time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization. Transfers are subject to the following requirements:

(1) The transfer shall be communicated directly between two licensed pharmacists, and the transferring pharmacist shall:

(A) Write or otherwise place the word "VOID" on the face of the invalidated prescription;

(B) Record on the reverse of the invalidated prescription the name, address, and Drug Enforcement Administration registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; and

(C) Record the date of the transfer and the name of the pharmacist transferring the information;

(2) The pharmacist receiving the transferred prescription information shall reduce to writing the following:

(A) Write or otherwise place the word "transfer" on the face of the transferred prescription;

(B) Record all information required to be on a prescription, including:

(i) The date of issuance of original prescription;

(ii) The original number of refills authorized on original prescription;

(iii) The date of original dispensing;

(iv) The number of valid refills remaining and dates and locations of previous refills;

(v) The pharmacy's name, address, Drug Enforcement Administration registration number, and original prescription number from which the prescription information was transferred;

(vi) The name of the transferor pharmacist; and

(vii) The pharmacy's name, address, and Drug Enforcement Administration registration number, along with the prescription number from which the prescription was originally filled;

(3) Both the original and transferred prescription shall be maintained for a period of five years from the date of last refill; and

(4) Any pharmacy electronically accessing a prescription record shall satisfy all information requirements of a manual mode prescription transferal.

Failure to comply with this subsection shall void the authority of the pharmacy to transfer prescriptions or receive a transferred prescription to or from another pharmacy.

[~~(d)~~] (f) A pharmacy and an authorized central fill pharmacy may share information for initial and refill prescriptions of schedule III, IV, or V controlled substances. The following requirements shall apply:

(1) A pharmacy may electronically transmit, including by facsimile, prescriptions for controlled substances listed in schedule III, IV, or V to a central fill pharmacy. The pharmacy transmitting the prescription information shall:

(A) Ensure that all information required to be on a prescription pursuant to subsection [~~(g)~~] (i) is transmitted to the central fill pharmacy either on the face of the prescription or electronically; and

(B) Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract

carrier) and the identity of the pharmacy employee accepting delivery; and

(2) The central fill pharmacy receiving the transmitted prescription shall:

(A) Keep for five years a copy of a prescription received by facsimile or an electronic record of all the information transmitted by the pharmacy, including the name, address, and Drug Enforcement Administration registration number of the pharmacy transmitting the prescription;

(B) Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacists filling the prescription, and the dates the prescription was filled or is refilled; and

(C) Keep a record of the date the filled prescription was shipped to the pharmacy.

[~~(e)~~] (g) No controlled substance in schedule III, IV, or V may be dispensed without a written, facsimile of a written, oral prescription of a practitioner, or receipt of an electronic prescription, except when a controlled substance is dispensed directly by a practitioner, other than a pharmacist, to an ultimate user. The practitioner, in dispensing a controlled substance in schedule III, IV, or V, shall affix to the package a label showing:

(1) The date of dispensing;

(2) The name, strength, and quantity issued of the drug;

(3) The dispensing practitioner's name and business address;

(4) The name of the patient;

(5) The "use by" date for the drug, which shall be:

(A) The expiration date on the manufacturer's or principal labeler's container; or

(B) One year from the date the drug is dispensed, whichever is earlier;

(6) Directions for use; and

(7) Cautionary statements, if any, contained in the prescription or as required by law.

A complete and accurate record of all schedule III, IV, and V controlled substances administered, prescribed, and dispensed shall be maintained for five years. Prescriptions and records of dispensing shall be retained in conformance with the requirements of section 329-36 unless otherwise provided by law. Prescriptions may not be filled or refilled more than three months after the date of the prescription or be refilled more than two times after the date of the prescription, unless the prescription is renewed by the practitioner.

[~~(f)~~] (h) The effectiveness of a prescription for the purposes of this section shall be determined as follows:

(1) A prescription for a controlled substance shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of the practitioner's professional practice. The responsibility for the proper prescribing and dispensing of controlled

substances shall be upon the prescribing practitioner, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or for legitimate and authorized research shall not be deemed a prescription within the meaning and intent of this section, and the person who knowingly fills such a purported prescription, as well as the person who issues the prescription, shall be subject to the penalties provided for violations of this chapter;

(2) A prescription may not be issued to allow an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients;

(3) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for the purpose of "detoxification treatment" or "maintenance treatment" except as follows:

(A) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug-dependent person for "detoxification treatment" or "maintenance treatment" shall be deemed to be "in the course of a practitioner's professional practice or research" so long as the practitioner is

registered separately with the department and the federal Drug Enforcement Agency as required by section 329-32(e) and complies with Title 21 Code of Federal Regulations section 823(g) and any other federal or state regulatory standards relating to treatment qualification, security, records, and unsupervised use of drugs; and

(B) Nothing in this section shall prohibit a physician or authorized hospital staff from administering or dispensing, but not prescribing, narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction;

(4) An individual practitioner shall not prescribe or dispense a substance included in schedule II, III, IV, or V for that individual practitioner's personal use, except in a medical emergency; and

(5) A pharmacist shall not dispense a substance included in schedule II, III, IV, or V for the pharmacist's personal use.

[~~(g)~~] (i) Prescriptions for controlled substances shall be issued only as follows:

(1) All prescriptions for controlled substances shall originate from within the State and be dated as of, and signed on,

the day when the prescriptions were issued and shall contain:

(A) The first and last name and address of the patient; and

(B) The drug name, strength, dosage form, quantity prescribed, and directions for use. Where a prescription is for gamma hydroxybutyric acid, methadone, or buprenorphine, the practitioner shall record as part of the directions for use, the medical need of the patient for the prescription.

Except for electronic prescriptions, controlled substance prescriptions shall be no larger than eight and one-half inches by eleven inches and no smaller than three inches by four inches. A practitioner may sign a prescription in the same manner as the practitioner would sign a check or legal document (e.g., J.H. Smith or John H. Smith) and shall use both words and figures (e.g., alphabetically and numerically as indications of quantity, such as five (5)), to indicate the amount of controlled substance to be dispensed. Where an oral order or electronic prescription is not permitted, prescriptions shall be written with ink or indelible pencil or typed, shall be manually signed by the practitioner, and shall include the name, address, telephone number, and registration number of the

practitioner. The prescriptions may be prepared by a secretary or agent for the signature of the practitioner, but the prescribing practitioner shall be responsible in case the prescription does not conform in all essential respects to this chapter and any rules adopted pursuant to this chapter. In receiving an oral prescription from a practitioner, a pharmacist shall promptly reduce the oral prescription to writing, which shall include the following information: the drug name, strength, dosage form, quantity prescribed in figures only, and directions for use; the date the oral prescription was received; the full name, Drug Enforcement Administration registration number, and oral code number of the practitioner; and the name and address of the person for whom the controlled substance was prescribed or the name of the owner of the animal for which the controlled substance was prescribed.

A corresponding liability shall rest upon a pharmacist who fills a prescription not prepared in the form prescribed by this section. A pharmacist may add a patient's missing address or change a patient's address on all controlled substance prescriptions after verifying the patient's identification and noting the identification number on the back of the prescription document on file. The pharmacist shall not make changes to the patient's name, the controlled

substance being prescribed, the quantity of the prescription, the practitioner's Drug Enforcement Administration number, the practitioner's name, the practitioner's electronic signature, or the practitioner's signature;

(2) An intern, resident, or foreign-trained physician, or a physician on the staff of a Department of Veterans Affairs facility or other facility serving veterans, exempted from registration under this chapter, shall include on all prescriptions issued by the physician:

(A) The registration number of the hospital or other institution; and

(B) The special internal code number assigned to the physician by the hospital or other institution in lieu of the registration number of the practitioner required by this section.

The hospital or other institution shall forward a copy of this special internal code number list to the department as often as necessary to update the department with any additions or deletions. Failure to comply with this paragraph shall result in the suspension of that facility's privilege to fill controlled substance prescriptions at pharmacies outside of the hospital or other institution. Each written prescription shall have the name

of the physician stamped, typed, or hand-printed on it, as well as the signature of the physician;

(3) An official exempted from registration shall include on all prescriptions issued by the official:

(A) The official's branch of service or agency (e.g., "U.S. Army" or "Public Health Service"); and

(B) The official's service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee shall be the employee's social security or other government issued identification number.

Each prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer; and

(4) A physician assistant registered to prescribe controlled substances under the authorization of a supervising physician shall include on all controlled substance prescriptions issued:

(A) The Drug Enforcement Administration registration number of the supervising physician; and

(B) The Drug Enforcement Administration registration number of the physician assistant.

Each written controlled substance prescription issued shall include the printed, stamped, typed, or hand-printed name, address, and phone number of both the supervising physician and physician assistant, and shall be signed by the physician assistant. The medical record of each written controlled substance prescription issued by a physician assistant shall be reviewed and initialed by the physician assistant's supervising physician within seven working days.

[~~(h)~~] (j) A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of the pharmacist's professional practice and either registered individually or employed in a registered pharmacy, central fill pharmacy, or registered institutional practitioner. A central fill pharmacy authorized to fill prescriptions on behalf of a pharmacy shall have a contractual relationship with the pharmacy that provides for this activity or shall share a common owner with the pharmacy. A central fill pharmacy shall not prepare prescriptions for any controlled substance listed in schedule II.

[~~(i)~~] (k) Partial filling of controlled substance prescriptions shall be determined as follows:

(1) The partial filling of a prescription for a controlled substance listed in schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written, electronic prescription, or emergency oral

prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription (or written record of the electronic prescription or emergency oral prescription). The remaining portion of the prescription may be filled within seventy-two hours of the first partial filling; provided that if the remaining portion is not or cannot be filled within the seventy-two-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity shall be supplied beyond seventy-two hours without a new prescription;

(2) The partial filling of a prescription for a controlled substance listed in schedule III, IV, or V is permissible; provided that:

(A) Each partial filling is recorded in the same manner as a refilling;

(B) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed;

(C) No dispensing occurs more than three months after the date on which the prescription was issued; and

(D) The prescription is refilled no more than two times after the initial date of the prescription,

unless the prescription is renewed by the practitioner; and

(3) A prescription for a schedule II controlled substance issued for a patient in a long-term care facility or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription document on file whether the patient is "terminally ill" or a "long-term care facility patient". For the purposes of this section, "TI" means terminally ill and "LTCF" means long-term care facility. A prescription that is partially filled and does not contain the notation "TI" or "LTCF patient" shall be deemed to have been filled in violation of this section. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II

controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed, nor shall a prescription be partially filled more than three times after the initial date of the prescription. Schedule II controlled substance prescriptions for patients in a long-term care facility or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed thirty days from the issue date unless sooner terminated by the discontinuance of medication.

[~~(j)~~] (l) A prescription for a schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile equipment; provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in subsections [~~(k), (l), and~~] (m)[~~.~~], (n), and (o). The original prescription shall be maintained in accordance with section 329-36. A prescription for a schedule III, IV, or V controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy by facsimile; provided that:

(1) The information shall be communicated only between the prescribing practitioner or the prescriber's authorized agent and the pharmacy of the patient's choice. The original prescription shall be maintained by the practitioner in accordance with section 329-36;

(2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient

and shall include the physician's oral code designation and the name of the recipient pharmacy;

(3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval on a per prescription per order basis. Facsimile prescription information shall not be altered by any system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy;

(4) The prescription information processing system shall provide for confidentiality safeguards required by federal or state law; and

(5) Prescribing practitioners and pharmacists shall exercise prudent and professional judgment regarding the accuracy, validity, and authenticity of any facsimile prescription information. The facsimile shall serve as the original written prescription for purposes of this section and shall be maintained in accordance with section 329-36.

[~~(k)~~] (m) A prescription prepared in accordance with subsection [~~(g)~~] (i) written for a narcotic listed in schedule II to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion, but does not extend to the dispensing of oral dosage units of controlled substances, may be transmitted by the practitioner or the practitioner's agent to the pharmacy by facsimile. The original

prescription shall be maintained by the practitioner in accordance with section 329-36. The pharmacist shall note on the face of the facsimile prescription in red ink "Home Infusion/IV" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

[~~(l)~~] (n) A prescription prepared in accordance with subsection [~~(g)~~] (i) written for a schedule II substance for a patient enrolled in a hospice care program certified or paid for by medicare under Title XVIII or a hospice program that is licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The practitioner or practitioner's agent shall note on the prescription that the patient is a hospice patient. The pharmacist shall note on the face of the facsimile prescription in red ink "HOSPICE" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

[~~(m)~~] (o) A prescription prepared in accordance with subsection [~~(g)~~] (i) written for a schedule II controlled substance for a resident of a state-licensed long-term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The original prescription shall be maintained by the practitioner in accordance with section 329-36. The pharmacist shall note on the face of the facsimile prescription in red

ink "LTCF" and this facsimile shall serve as the original written prescription for purposes of this section and it shall be maintained in accordance with section 329-36.

[~~(n)~~] (p) An electronic prescription for a schedule II, III, IV, or V controlled substance may be electronically transmitted by the practitioner to a pharmacy; provided that:

(1) The information shall be communicated only between the prescribing practitioner and the pharmacy of the patient's choice. The electronic prescription shall be maintained by the practitioner in accordance with section 329-36;

(2) The information shall be communicated in a retrievable, recognizable format acceptable to the intended recipient;

(3) No electronic system, software, or other intervening mechanism or party shall alter the practitioner's prescription, order entry, selection, or intended selection without the practitioner's approval on a per-prescription, per-order basis. Transmitted prescription information shall not be altered by any electronic system, software, or other intervening mechanism or party prior to receipt by the intended pharmacy;

(4) The prescription information processing system shall provide for confidentiality safeguards required by any applicable federal or state law; and

(5) Prescribing practitioners and pharmacists shall exercise prudent and professional judgment regarding the accuracy,

validity, and authenticity of any electronic prescription information."

SECTION 4. Section 457-12, Hawaii Revised Statutes, is amended by amending subsection (a) to read as follows:

"(a) In addition to any other actions authorized by law, the board shall have the power to deny, revoke, limit, or suspend any license to practice nursing as a registered nurse or as a licensed practical nurse applied for or issued by the board in accordance with this chapter, and to fine or to otherwise discipline a licensee for any cause authorized by law, including but not limited to the following:

(1) Fraud or deceit in procuring or attempting to procure a license to practice nursing as a registered nurse or as a licensed practical nurse;

(2) Gross immorality;

(3) Unfitness or incompetence by reason of negligence, habits, or other causes;

(4) Habitual intemperance, addiction to, or dependency on alcohol or other habit-forming substances;

(5) Mental incompetence;

(6) Unprofessional conduct as defined by the board in accordance with its own rules;

(7) Wilful or repeated violation of any of the provisions of this chapter or any rule adopted by the board;

(8) Revocation, suspension, limitation, or other disciplinary action by another state of a nursing license;

(9) Conviction, whether by nolo contendere or otherwise, of a penal offense substantially related to the qualifications, functions, or duties of a nurse, notwithstanding any statutory provision to the contrary;

(10) Failure to report to the board any disciplinary action taken against the licensee in another jurisdiction within thirty days after the disciplinary action becomes final;

(11) Submitting to or filing with the board any notice, statement, or other document required under this chapter, which is false or untrue or contains any material misstatement of fact, including a false attestation of compliance with continuing competency requirements; [~~or~~]

(12) Violation of the conditions or limitations upon which any license is issued[~~.~~]; or

(13) Violation of chapter 329, the uniform controlled substances act, or any rule adopted thereunder except as provided in section 329-122."

SECTION 5. Statutory material to be repealed is bracketed and stricken. New statutory material is underscored.

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

DAVID Y. IGE
GOVERNOR

NOLAN P. ESPINDA
DIRECTOR

Cathy Ross
Deputy Director
Administration

Jodie F. Maesaka-Hirata
Deputy Director
Corrections

Renee R. Sonobe Hong
Deputy Director
Law Enforcement

STATE OF HAWAII
DEPARTMENT OF PUBLIC SAFETY
919 Ala Moana Boulevard, 4th Floor
Honolulu, Hawaii 96814

No. _____

TESTIMONY ON SENATE BILL 505, SENATE DRAFT 1, HOUSE DRAFT 1
RELATING TO HEALTH
by
Nolan P. Espinda, Director
Department of Public Safety

House Committee on Consumer Protection and Commerce
Representative Roy M. Takumi, Chair
Representative Linda Ichiyama, Vice Chair

Tuesday, March 28, 2017; 2:00 p.m.
State Capitol, Conference Room 329

Chair Takumi, Vice Chair Ichiyama, and Members of the Committee:

The Department of Public Safety (PSD) **supports the intent** of Senate Bill (SB) 505, Senate Draft (SD) 1, House Draft (HD) 1, which proposes to: 1) require an opioid therapy informed consent process agreement to be executed between a patient and any prescriber; and 2) limit initial prescriptions for opioids and benzodiazepines to a maximum of seven consecutive days. PSD supports the intent to reduce dependency, overdose, and death related to the use of opioids. PSD, however, offers the following comments.

First, PSD requests clarifying wording to page 10, line 19 through page 11, line 2, which currently proposes: "Initial prescriptions for opioids and benzodiazepines shall not be for longer than seven consecutive days unless a supply of longer than seven days is determined to be medically necessary…" As proposed, it is unclear whether the seven day limitation is triggered by the issuance of one single prescription order that lists both an opioid and benzodiazepine, or whether the seven day limitation is triggered by a single initial opioid prescription, or a single initial benzodiazepine prescription, or both. PSD requests clarification for

this important triggering event. The same clarification is requested for page 4, lines 6 - 9, which also provides for this same triggering event of "an initial prescription for opioids and benzodiazepines."

Second, PSD further requests clarifying wording to page 5, line 20 through page 6, line 3, which currently proposes that the opioid therapy agreement executed between patient and prescriber include "confirmation that the electronic prescription accountability system has been checked at the initiation . . . and at least quarterly thereafter." PSD requests clarifying wording that the agreement template include a statement that the prescriber will do this confirmation initially and at least quarterly.

Finally, page 11, line 16 through page 12, line 4 proposes to authorize telephonic prescriptions for opioids and benzodiazepines by the prescriber after the initial seven-day prescription was issued. PSD notes that federal law in Title 21, part 1306, and section 329-38(a), generally, restrict the prescribing of Schedule II drugs, including an Schedule II opioids and benzodiazepines to the use of a written prescription. Telephonic prescriptions would only be legal for those opioids and benzodiazepines specified in Schedules III – V under both federal and state law. If SB 505, SD 1, HD 1 proposes to allow telephonic prescriptions for opioids and benzodiapenizes specified in Schedule II, then this specific proposed section would be contrary to current federal and state law.

Thank you for the opportunity to present this testimony.

PRESENTATION OF THE
HAWAII MEDICAL BOARD

TO THE HOUSE COMMITTEE ON
CONSUMER PROTECTION & COMMERCE

TWENTY-NINTH LEGISLATURE
Regular Session of 2017

Tuesday, March 28, 2017
2:00 p.m.

WRITTEN COMMENTS

TESTIMONY ON SENATE BILL NO. 505, S.D.1, H.D. 1, RELATING TO HEALTH.

TO THE HONORABLE ROY M. TAKUMI, CHAIR,
AND MEMBERS OF THE COMMITTEE:

The Hawaii Medical Board ("**Board**") thanks you for the opportunity to submit written comments on Senate Bill No. 505, S.D. 1, H.D.1, Relating to Health. This measure proposes, among other things, to:

- Require an execution of an informed consent process, subject to administration and monitoring by the Department of Health, between a patient and prescribing practitioner in circumstances that carry an elevated risk creating dependency;
- Establish quantitative limits on opioid and benzodiazepine prescriptions, subject to certain exceptions; and
- Clarify the Board and Board of Nursing's authority to enforce compliance with the Uniform Controlled Substance Act.

The Board has not had an opportunity to review this most current version of the bill; however, it reviewed the S.D.1 at its meeting on March 9, 2017. At that meeting, a majority of the members supported the intent of the measure as it puts safety mechanisms in place which protects consumers of this State. A small minority of

members expressed their concern that criminalizing elements of medical practice may compromise the delivery of care to patients.

Thank you for the opportunity to submit written comments on Senate Bill No. 505, S.D. 1, H.D. 1, Relating to Health.

March 26, 2017

To: Rep. Roy M. Takumi, Chair
Rep. Linda Ichiyama, Vice Chair
House Committee on Consumer Protection & Commerce

From: Karen Worthington, Project Coordinator
Early Childhood Action Strategy

Re: SB505-SD1-HD1 – Relating to Health
Hawaii State Capitol, Room 329, March 28, 2017, 2:00 PM

Position: Action Strategy supports SB505-SD1-HD1 Relating to Health

Dear Representative Takumi, Representative Ichiyama, and Committee Members:

Thank you for the opportunity to provide testimony on behalf of Hawaii's Early Childhood Action Strategy, a public private collaborative that recognizes the strength of communities and works across sectors to increase the number of young children in Hawaii who are born healthy, developing on track, ready for school when they enter kindergarten, and proficient learners by third grade.

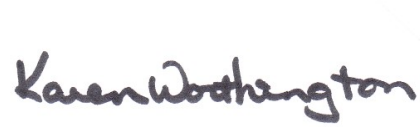
Action Strategy supports the passage of SB505-SD1-HD1 because the use of opioids or benzodiazepines by parents and by pregnant women can lead to negative outcomes for families and children, even when the medications are used legally under a physician's care. Protections such as informed consent agreements and limitations on the number of days an initial prescription can cover will help to minimize the possibility of negative outcomes such as addiction to these medications.

One of the six Action Strategy focus area teams is Team 1, Healthy and Welcome Births. The work of Team 1 is carried out by the Hawaii Maternal Infant Health Collaborative (HMIHC). The HMIHC has a "pregnancy and delivery" work group and top priorities of that group include decreasing preterm birth rates and decreasing the number of infants born substance-exposed. SB505-SD1-HD1 may impact these priorities by raising awareness about the dangers of using these medications through the informed consent process and by limiting the number of pills that can be initially prescribed.

Another of the six Action Strategy focus area teams is Team 2, Safe and Nurturing Families. A priority of Team 2 is prevention of all forms of family violence including child abuse and neglect. The use of drugs and alcohol, including overuse of prescription drugs, is a strong risk factor for family violence, unhealthy and unsafe living situations, and child abuse and neglect. In 2015, “drug abuse” was listed as a “condition that was identified as contributing to the abuse or neglect of the child” in 42% of confirmed cases of abuse of individual children in Hawaii (DHS 2015 Statistical Report on Child Abuse and Neglect in Hawaii). Increasing awareness about the potential dangers of opioid and benzodiazepine use through an informed consent process in certain circumstances and by limiting a patient’s access to the medications may help reduce the number of children who are victims of abuse or neglect because of their parents’ addiction to prescription painkillers.

Action Strategy is committed to ensuring Hawaii’s young children are healthy, safe and ready to learn and SB505-SD1-HD1 supports that vision. Please feel free to contact me for additional information. I can be reached at 808-214-9336 or karen@clnhawaii.org.

Sincerely,



Karen Worthington, JD
Project Coordinator
Early Childhood Action Strategy
700 Bishop Street, Ste. 701
Honolulu, Hawaii 96813

American Cancer Society
Cancer Action Network
2370 Nu`uanu Avenue
Honolulu, Hawai`i 96817
808.432.9149
www.acscan.org

House Committee on Consumer Protection and Commerce
Representative Roy Takumi, Chair
Representative Linda Ichiyama, Vice Chair
Members of the Committee

SB 505, HD1 – RELATING TO HEALTH

Cory Chun, Government Relations Director – Hawaii Pacific
American Cancer Society Cancer Action Network

Thank you for the opportunity to provide comments on SB 505, HD1, which would require an opioid informed consent process agreement and limits prescriptions for opioids and benzodiazepines to seven consecutive days with certain exemptions. While we recognize the concern for opioid addiction that this measure addresses, we would request the committee to consider addressing specific issues for cancer patients.

States that passed legislation to limit opioid prescriptions to seven days have included provisions to exempt individuals requiring medications for pain associated with cancer or for an individual with an active cancer diagnosis.[1] While there are exemptions in the measure for pain associated with post-surgery operative care, chronic pain management, and palliative and hospice care, these may not cover all instances of pain associated with cancer during chemotherapy and other active treatments.

According to an Institute of Medicine of report, more than 60% of individuals with advanced cancer report pain.[2] The report also detailed pain associated with breast cancer at 58%, colorectal cancer at 41%, lung cancer at 56%, multiple myeloma at 100%, and prostate cancer at 28%.[3]

In March of 2016, the CDC released Guidelines for prescribing opioids for chronic pain for the purpose of balancing pain management with over prescription of opioids. The report notes that the opioid guidelines and recommendations are "not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care because of the unique therapeutic goals, ethical considerations, opportunities for medical

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[1] *See* Maine Revised Statutes, Title 32, §2210 (2)(A)(1); and *see also* General Statutes of Connecticut, §20-14o(d)
[2] Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. Washington, DC: *National Academies Press*; 2011.
[3] *Id.*

supervision, and balance of risks and benefits with opioid therapy in such care."[4] The report takes into consideration the unique nature of pain associated with cancer separately from non-cancer opioid prescriptions.

To address this concern, we respectfully request the committee to consider inserting "pain associated with a cancer" in the exceptions section of the measure to address cancer patients.

Thank you for the opportunity to provide comments on this important issue.

[4] Dowell, M.D., Hagerich, M.D., Chou, M.D., Centers for Disease Control, *Morbidity and Mortality Weekly Report*, Early Release/Vol. 65, March 15, 2016 at page 3.

American Congress of Obstetricians and Gynecologists
District VIII, Hawaii (Guam & American Samoa) Section

TO: Rep. Roy Takumi, Chair
Rep. Linda Ichiyama, Vice-Chair

DATE: Tuesday, March 28, 2017
TIME: 2:00 PM
PLACE: Conference Room 329

FROM: Hawaii Section, ACOG
Dr. Greigh Hirata, MD, FACOG, Chair
Dr. Jennifer Salcedo, MD, MPH, MPP, FACOG, Vice-Chair
Lauren Zirbel, Community and Government Relations

Re: SB 505 Relating to Health – Opioid Informed Consent

Position: Oppose

Dear Members,

While the Hawaii Section of the American Congress of Obstetricians and Gynecologists (HI ACOG) acknowledges the severe public health consequences of the current opioid epidemic and substance use disorders, we are unable to support SB 505 due to concerns of interference in the physician-patient relationship, patient confidentiality, and the potential for criminal liability for physicians who make errors in complying with the bill's requirements.

As currently written, we are concerned that placing this measure in Section 329 could expose physicians who make errors in adhering to the bill's requirements to criminal prosecution. Additionally, while we strongly support limiting the prescription of opioids and benzodiazepines to medically appropriate indications and durations of therapy, the overly prescriptive requirements in the bill present an interference with the physician-patient relationship that sets a dangerous precedent. Further, the requirement to provide individual patient consents for opioid therapy to the Department of Health presents the concern for significant violation of patient confidentiality.

We appreciate the efforts to address this important health concern, and hope that the legislature will consider directing its efforts at clinician and patient education, increasing patient access to and insurance coverage of non-narcotic pain management treatments, and increasing access to treatment for substance use disorders.

Thank you for the opportunity to testify.

the Drug Policy Forum of hawai'i

Dedicated to safe, responsible, humane and effective drug policies since 1993

TO: House Committee on Commerce and Consumer Protection
FROM: Carl Bergquist, Executive Director
HEARING DATE: 28 March 2017, 2PM
RE: SB505 SD1 HD1, Relating to Health, **IN OPPOSITION**

Dear Chair Takumi, Vice Chair Ichiyama, Members of the Committee:

The Drug Policy Forum of Hawai'i (DPFHI) agrees with the intent behind this bill to address the growing opioid epidemic. However, we specifically disagree with the limiting prescription provision and generally worry about the focus on the supply side (prescription opioids) rather than the demand side (suffering patients). Limiting the number of pills in an initial prescription, or as this bill proposes: setting a seven-day maximum validity, risks running counter to patient needs as well as expert medical opinions.

As an organization, we have supported the legislature's past efforts in this arena and champione passage of Good Samaritan and Naloxone access legislation. Our Executive Director is also a member of the Governor's Hawai'i Advisory Commission on Drug Abuse and Controlled Substances (HACDACS). We advocate for harm reduction policies, and we firmly believe that an enforcement-centric approach to this very real epidemic risks mirroring the misguided War on Drugs.

This bill does not make allowances for unspecified situations where health care professionals determine that a prescription for periods of longer than seven days is required for patient pain relief. This one-size-fits-all approach was criticized over a year ago by former President Obama as unfair to rural Americans, a concern that is especially relevant in parts of Hawai'i. The SD1 HD1 version of this bill does allow for more exceptions to the seven day limits, but our concern remains that this arbitrary limit could push patients in need of pain relief towards more dangerous drugs. There is no evidence that we are aware of that shows this type of limit to be an effective policy. To the contrary, a 2016 study of 81 laws published in the New England Journal of Medicine found that:

> *"Adoption of controlled-substance laws was not associated with reductions in potentially hazardous use of opioids or overdose among disabled Medicare beneficiaries, a population particularly at risk."*

Moreover, the origin of the specific 7 day limit can be traced to 2016 Center for Disease Control guidelines that were meant to be **recommendations not mandates**. This is a case where Hawai'i does not need to follow other states. We respectfully request that the bill be deferred.

Mahalo for the opportunity to testify.

P.O. Box 83, Honolulu, HI 96810-0083 Phone: 808-518-3213 Email: info@dpfhi.org
Website: www.dpfhi.org

P.O. Box 83, Honolulu, HI 96810-0083 Phone: 808-518-3213 Email: info@dpfhi.org
Website: www.dpfhi.org

HAWAII / ACEP
AMERICAN COLLEGE OF EMERGENCY PHYSICIANS

March 27, 2017

Representative Roy Takumi
Chair
House Committee on Consumer Protection & Commerce

SB505 HD1: Relating to Health

COMMENTS

Dear Representative Takumi and Committee Members:

I am writing on behalf of the Hawaii College of Emergency Physicians, representing 150 emergency physicians in Hawaii. Hawaii's emergency physicians recognize the potential hazards of opioid and benzodiazepine medications, and support informed consent discussions between patients and physicians as an appropriate means to mitigate risk for patients on chronic opioid therapy. Given the current opioid crisis, we can accept the need for documented informed consent for those on chronic opioid therapy. However, legislating informed consent documentation for a specific drug-drug interaction will create a confusing system for physicians and patients. **We ask that you remove the provision creating a legal requirement for documented informed consent for patients receiving opioid and benzodiazepine medications together (pg 3, lines 18-19)**

While the increase in overdoses in patients taking both benzodiazepine and opioid medications is well documented, also well documented are the risks of thousands of other drug combinations that physicians may prescribe – many of which may be more dangerous our patients than the combination of benzodiazepines and opioids. On a recent shift I cared for 31 patients. I counted 57 different medications my patients were taking at home. I administered 18 types of medication during that shift and prescribed another 13 different medications for patients to take at home. In each case, I reviewed their home medications and considered possible interactions. That day, I did write an opioid prescription for a patient taking a benzodiazepine. If this bill passes, I would break the law if I failed to remember that I needed to document and send to the state informed consent paperwork for that one patient. It is unreasonable to expect several thousand physicians in the state to remember that requirement for a single potential drug-drug interaction. Further, the fact that this legislation resides in Section 329 means that physicians could face felony charges for such a mistake.

The opioid crisis is very real and very dangerous, and we agree that legislative measures must be taken. We ask your committee to consider the potential unintended consequences of adding to the administrative burden of physicians. In particular, requiring physicians to complete and file informed consent documents with the Department of Health for a certain cohort of their patients may drive physicians to avoid treating that subset of patients. In a state with a shortage of pain management physicians, we rely on our primary care physicians to manage chronic pain. We should strive to create a system in which pain is managed safely, but also in which physicians are still encouraged to care for those patients. At minimum, remove the requirement for informed consent documentation and filing for patients taking both benzodiazepine and opioid medications.

Sincerely,

WIlliam Scruggs, MD, RDMS, FACEP
Chair, Department of Emergency Medicine, Castle Medical Center
Immediate Past President, Hawaii College of Emergency Physicians

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

FROM:
HAWAII MEDICAL ASSOCIATION
Dr. Chris Flanders, Executive Director
Lauren Zirbel, Community and Government Relations

TO:
HOUSE COMMITTEE ON CONSUMER PROTECTION
Representative Roy Takumi, Chair
Representative Linda Ichiyama, Vice Chair

DATE: Tuesday, March 28, 2017
TIME: 2:00 p.m.
PLACE: Conference Room 329
State Capitol

SB 505 SD1HD1
Position: Comments

The Hawaii Medical Association is in support of efforts to encourage appropriate prescribing practices by health care providers, including the providing of patient informed consent. **However we have concerns as to the penalty for failure to comply with the program outlined in this bill.**

During the 2015 legislative session, the HMA was involved with a package of bills dealing with various aspects of opioid and benzodiazepine use. During legislative discussion, the Narcotics Enforcement Division raised the concern that, because several bills were to be placed in HRS Section 329, they would carry a **criminal Class C felony charge for non-compliance**. As a result, these bills were all deferred by the legislature.

SB 505, if passed, is destined for HRS Section 329. In that a prescribing physician may not have total personal control of this process, and that a Class C felony conviction is a career ending event for a physician, the HMA cannot support this bill as submitted. **We ask for comment on this issue from the state Attorneys General.** It is our hope that this issue can be clarified and worked out during the course of this legislative session.

Thank you for your consideration in this matter.

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To: Committee on Public Safety,

Subject: SB 505, HD1, SD1 Relating to the Controlled Substances Act

Aloha Senator Baker, Senator Nishihara and other members of the CPH Committee:

The Hawaii Society of Pain Physicians respectfully opposes the bill in its current draft.

We appreciate to provide testimony for this very critical topic.

As board certified Pain physicians, informed consent is typically a part of the pain monitoring guidelines which our specialty follows. Pain management and monitoring of a patient while on opioid therapy includes many aspects of medical clinical decision making.

We currently use informed consents in our practices for each patient whether for medication, procedures or other treatments. It is the standard of care in our specialty. But, Informed consent is only a small part of pain management and monitoring. An informed consent will not solve the problem of opioids, pain medications, addiction or prescribing outside the standard of care.

The current Opioid crisis that has increased Federal and State regulation and guidelines regarding this problem has been drafted and supported by many Pain Medicine specialists across the country.

The Hawaii Society of Pain Physicians offers these comments:

1. We are concerned that informed consent by a state agency and then monitored by the State eliminates patient privacy.
2. What does monitoring exactly mean?
3. We are concerned that a patient must reveal private medical information to an outside agency for monitoring, and this further increases the stigma that a medical condition such as chronic pain can have on a patient.
4. Monitoring such as registering or giving private information subject to a state data base, may deter a patient from seeking the appropriate medical care for their condition if they know it is not kept within the physician- patient relationship.
5. If other medical conditions are not registered and monitored in the same manner as opioid therapy, it appears to be discriminatory for one group of medical patients.
6. We support increased awareness and education regarding the appropriateness of opioids for pain conditions, due to the risk of addiction, diversion and the social impact.
7. We strongly support that any physician, regardless of specialty, any nurse practioner, physician assistant, or healthcare provider that writes a CII prescription know the risk, benefit and alternative to the medication. That they prescribe within the scope of their practice, and if they do not know how to prescribe in the current standard of care they do not start or continue a

controlled substance. The current bill, which requires an Informed consent we do not think, would address this larger issue. It may be more beneficial to work with the medical societies to update the current State medical board guidelines. Additionally, templates and information regarding pain monitoring can be updated.

8. The statistics show that many of the problems in opioid prescribing are due to primary care providers and extenders such as nurse practioners and physician assistants. For this reason, we feel it is important that patients be referred to a board certified pain specialist if pain medications are prescribed greater than 90 days, or are increased above 60meq Morphine equivalents. A specialist referral is appropriate in the standard of care as in other medical issues such as referrals to Cardiologists, Endocrinologists and Gastroenterologists.
9. We support the legislation limiting the initial prescribing of Opioids and Benzodiazepines to seven days. However, the following exceptions should be included: unless prescribed by a specialist or in certain cases when follow up within seven days would cause hardship to the patient.

We commend the committee for addressing this issue. Again, we appreciate the opportunity to provide testimony for this very important issue. The Hawaii Society of Pain Physicians and its members are committed to assisting the State to provide education, and solutions for physicians, the healthcare community, and patients.

Much Aloha,

Kerrey L B Taylor DO MBA

President and co- founder Hawaii Society of Pain Physicians
Board certified Physical Medicine & Rehabilitation
ACGME Board certified Pain Medicine
Member Hawaii Opioids & Overdose Leadership Action Working Group
Private practice physician Oahu

THE QUEEN'S HEALTH SYSTEMS

To: The Honorable Roy M. Takumi, Chair
The Honorable Linda Ichiyama, Vice Chair
Members, Committee on Consumer Protection and Commerce

From: Paula Yoshioka, Senior Vice President, The Queen's Health Systems

Date: March 27, 2017

Hrg: House Committee on Consumer Protection and Commerce; Tuesday, March 28, 2017 at 2:00PM in Room 329

Re: **Comments on SB 505, SD1 HD1 Relating to Health**

My name is Paula Yoshioka, and I am a Senior Vice President at The Queen's Health Systems (QHS). We would like to provide comments for SB 505, SD1 HD1 Relating to Health. This measure aims to reduce addictions, overdose, and death by establishing an opioid therapy informed consent process agreement and limits initial prescriptions for opioids and benzodiazepines. To the extent possible, we recommend that best practices be included in the template. As currently written, it is not clear that providers will continue to have the ability to develop the appropriate scope and standards of care for the target patient population addressed. QHS would also like to recognize concerns raised by DOH with regards to this issue.

For references relating to opioids and benzodiazepines, it is unclear if the intent is that such provisions of the bill apply to any prescription of opioids or benzodiazepines or a situation when a prescriber is concurrently prescribing both opioids and benzodiazepines. QHS believes that more clarification is needed for prescribers of opioids and benzodiazepines.

Similarly, under section 3 (c), we would request clarification for the exceptions outlined and if they are meant to cover concurrent prescriptions of opioids and benzodiazepines, all opioid prescriptions, all benzodiazepines prescriptions, or those that are prescribed just for pain. Benzodiazepines are used for other situations that do not apply to opioid abuse or pain management. For instance, benzodiazepines could be prescribed to cancer patients for nausea or could also be utilized to treat a patient with seizures. The exceptions outlined in the bill are extremely narrow and we have concerns that if the intent is to apply to all benzodiazepine prescriptions, such a provision would harm patients.

Thank you for your time and attention to this important issue.

COMMITTEE ON COMMERCE, CONSUMER PROTECTION, AND HEALTH

Senator Rosalyn H. Baker, Chair Senator Clarence K. Nishihara, Vice Chai

TESTIMONY ON SENATE BILL NO. 505, RELATING TO HEALTH.

TO THE HONORABLE ROSALYN H. BAKER, CHAIR, AND MEMBERS OF THE COMMITTEE:

My name is Christopher Taylor and as the current Vice-President of the Hawaii Society of Pain Physicians, the former Vice-President of the Hawaii Society of Physical Medicine and Rehabilitation, and a private practicing pain physician here on Oahu, I must submit testimony against the proposed SB505 relating to opioid prescribing and the recommendations surrounding the informed consent. I **oppose** the bill in its current form.

Firstly, the informed consent is a tool to be used by the prescribing physician to educate the patient about the risks, benefits and alternatives to any treatment option regarding the use of opioid medication to treat pain. As such it is specifically relating to a proposed medical treatment of the patient and belongs solely between the physician and patient. The Harm Reduction Services (HRS) branch of the DOH has no business being involved in such personal and private medical decision making process between doctor and patient. Such involvement might be considered a HIPPA violation by the patient on the State office's part.

Secondly, if the HRS is monitoring these documents, how are they securing these forms and who will have access to them as they are being "filed" as they oversee the process? Again this is a part of a medical record that is now out of the hands of the prescribing physician. It would seem that the potential for violation of the HIPPA law again is imminent under these conditions. All documents regarding the patient and their medical record need to be under the control and security of the physician so as to have direct access to them as needed during the course of treatment. Additionally, some patients may be using the opioid mediations in a transient manner. So if their ability to obtain the medication is held up while informed consents are "processed" by a state office,that would delay medical care to patients.

Thirdly, there should not be any verbiage that makes failure to comply with this action a class C felony on the part of the physician. Any failure to comply with the standard of care of proper prescribing of opioids as recommended by the CDC and NIH should be a matter for the state medical board to determine the appropriate disciplinary actions. This would apply to **all** providers including registered nurse practitioners and physician assistants and dentists who prescribe schedule II medications.

Finally, for all prescribing physicians, the best practice model is currently listed under the CDC and NIH opioid guidelines. That is the standard of care that **all** pain specialists follow. One way to decreased over prescribing of opioid medications is the early recognition of complex pain cases and proper referral of patients to pain medicine specialists. It is in the best interest of patients to have an expert who practices the specialty of pain medicine as opposed to a primary physicians and physician extenders who only manages pain.

Sincerely,

Christopher Taylor, MD FAAPMR

Board Certified PMR