# HB 344

<TARGET><BILL>HB 344</BILL><SUBJECT>HB 344</SUBJECT><COMM>HHSS29</COMM></TARGET>

# Alaska State Legislature

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**REPRESENTATIVE PAUL SEATON**
Rep.Paul.Seaton@akleg.gov

**Sponsor Statement**
House Bill 344

HB 344 aims to strengthen the existing Prescription Drug Database into a more effective tool that dispensers and providers can use to combat the growing epidemic of opioid abuse. HB 344 would require all practitioners that *prescribe or dispense* controlled substances to be registered with the prescription drug database, ensuring they have access to this important patient information. It would also require dispensers to update the database at near real time whenever possible and to check the database for their specific patient before dispensing. The bill will allow an authorized employee or agent to access or submit to the database on the provider's behalf, removing some of the administrative burden from the provider or pharmacist. Furthermore, an electronic alert system will notify pharmacists or a practitioner if their patient has passed the recommended threshold for prescription dosage or frequency. The board of pharmacy has established this threshold as obtaining a controlled substance from five prescribers and five pharmacies in a three month period. Without checking the database or receiving these alerts, health care providers would be unaware of this concerning usage pattern in their patient. Finally, following the recommendations of the Controlled Substance Advisory Committee, access to the database is also granted to specific individuals responsible for reviewing Medicaid drug utilization.

Our existing statute requires that licensed and registered pharmacists submit information regarding controlled substances that they have dispensed on a monthly basis, leaving a significant time gap in prescription data. There is also no current requirement that prescribers or dispensers check the database before they prescribe or dispense an opioid. If used appropriately, the database can inform practitioners if their patient is receiving unusually high dosages or multiple prescriptions. However, only approximately 13.5% of prescribers and 40% of dispensers are registered with the database today. The remaining practitioners do not have immediate access to this important information. By strengthening this tool and requiring engagement from all providers, HB 344 can help reduce overutilization of prescription drugs and lower the number of Alaskans that risk becoming addicted

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## House Bill 344

## Sectional

**Section 1** *(Pg 1, Line 4)*

This section allows pharmacists or providers delegate the submittal of information to the database to an authorized employee or agent. This section also requires that pharmacists submit data in near real time, in the procedure established by the Board of Pharmacy.

**Section 2** *(Pg 2, Line 20)*

This section requires that the information in the database remain confidential and describes who is permitted to access the database. Under this bill, a practitioner or pharmacist may delegate access to an authorized agent or employee. Access is also granted to the lead Medicaid pharmacist and the Medicaid Utilization review committee to review drug utilization in the Medicaid program. It is also granted to the State Medical Examiner for investigation into cause of death. Finally, this section allows that authorized employees of Health and Social Services may receive de-identified information from the database for public health.

**Section 3** *(Pg 4, Line 5)*

AS 17.30.200 (e) is amended to state that the failure of the pharmacists or providers to ***register*** or submit information to the database is grounds for the board to take disciplinary action.

**Section 4** *(Pg 4, Line 11)*

Deletes language stating that dispensers or practitioners are not obligated to check the database prior to dispensing, to conform to the requirement on dispensers in section 5.

**Section 5** *(Pg 4, Line 20)*

This section requires that a dispenser or their authorized agent or employee shall check the database prior to dispensing and submit the prescription information to the database in near real time.

**Section 6** *(Pg 5, Line 6)*

This section adds new subsections that include in subsection (o) an exemption made for practitioners or pharmacist who cannot update the database in near real time due to technological barriers and in subsection (p) creates an automatic electronic alert system when someone has prescriptions inconsistent with general standards. Subsection (q) requires all healthcare providers who prescribe, dispense, or administer a controlled substance to register with the prescription drug database and subsection (r) directs the board of pharmacy to notify the necessary medical board when a practitioner registers with the database.

**Section 7** *(Pg 5, Line 27)*

This section allows the board of pharmacy to adopt the regulations necessary to implement this act.

**Section 8** *(Pg 6, Line 2)*

This section directs that all dispensers *and prescribers* shall register with the database within 180 of the effective date of the bill, allowing additional time to register. The board of pharmacy shall provide information to other boards on how to register and comply with database.

**Section 9** *(Pg 6, Line 12)*

The regulatory authority under this act takes effect July 1, 2016.

**Section 10** *(Pg 6, Line 13)*

Except in section 9, the changes created by this act take effect January 1, 2017.

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**Sponsor Statement**
House Bill 344
Version N

HB 344 aims to strengthen the existing Prescription Drug Database into a more effective tool that dispensers and providers can use to combat the growing epidemic of opioid abuse. HB 344 would require all practitioners that *administer, prescribe or dispense* controlled substances to be registered with the prescription drug database, ensuring they have access to this important patient information. The bill also requires a limit of 7 days for initial opioid prescriptions. It would also require dispensers to update the database weekly, and would require all practitioners to check the database for their specific patient before *prescribing, dispensing, or administering* a schedule II, III, or IV controlled substance. The bill will allow an authorized employee or agent to access or submit to the database on the provider's behalf, removing some of the administrative burden from the provider or pharmacist. Furthermore, an electronic alert system will notify pharmacists or a practitioner if their patient has passed the recommended threshold for prescription dosage or frequency. The board of pharmacy has established this threshold as obtaining a controlled substance from five prescribers and five pharmacies in a three month period. Without checking the database or receiving these alerts, health care providers would be unaware of this concerning usage pattern in their patient. Finally, following the recommendations of the Controlled Substance Advisory Committee, access to the database is also granted to specific individuals responsible for reviewing Medicaid drug utilization.

Our existing statute requires that licensed and registered pharmacists submit information regarding controlled substances that they have dispensed on a monthly basis, leaving a significant time gap in prescription data. There is no current requirement that prescribers or dispensers check the database before they prescribe or dispense an opioid. If used appropriately, the database can inform practitioners if their patient is receiving unusually high dosages or multiple prescriptions. However, only approximately 13.5% of prescribers and 40% of dispensers are registered with the database today. The remaining practitioners do not have immediate access to this important information. By strengthening this tool and requiring engagement from all providers, HB 344 can help reduce overutilization of prescription drugs and lower the number of Alaskans that risk becoming addicted

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**Summary of Changes: Version H to Version N**
**HB 344 – Drug Prescription Database**

**Title**
On lines 2- 4 the title has been expanded to include 'relating to the prescription of opiates; relating to the practice of dentistry; relating to the practice of medicine; relating to the practice of nursing; relating to the practice of optometry; relating to the practice of veterinary medicine' to reflect the inclusion of seven day prescription restriction.

**Section 1-12**
New sections 1-12 were added to limit opiate prescriptions under the following boards; dentistry, medicine, nursing, and optometry. Under each board, an initial opiate prescription is limited to seven days unless the practitioner documents a logistical or medical need for a longer supply, and prescriptions in excess of the dosage without documented reasons can be grounds for disciplinary action. Additional language was added to section 1 (Board of Dental Examiners), section 7 (Board of Nursing), and section 10 (Board of Optometry) allowing disciplinary action if drugs are dispensed, prescribed or sold drugs in violation of law regardless of whether there has been criminal actions. This mirrors existing language in the State Medical Board (section 4).

**Section 13**
This new section adds language to the Board of Veterinary Examiners allowing disciplinary action if drugs are dispensed, prescribed or sold drugs in violation of law regardless of whether there has been criminal actions. This mirrors existing language in the State Medical Board (section 4).

**Section 14**
Language referencing the state controlled substance schedules and federal schedules I and V has been removed; this will limit the database to only drugs in the federal schedules II, III, and IV. Language regarding the Department of Commerce, Community, and Economic Development assisting the board of pharmacy with implementing the database has been moved to a later section.

**Section 15**
Language referencing the state controlled substance schedules and federal schedules I and V has been removed; this means the database will only be accessed for drugs in the federal schedule II, III, and IV. The reporting requirement in this section has changed, from *near-real-time* to *at least weekly*.

**Section 16**
AS 17.30.200(d)(3) has been amended to state that a licensed *or registered* practitioner with prescription authority is allowed access to the database. This is intended to capture practitioners in federal facilities that are not required to be licensed with the state but that may be registered.

**Section 19**
Language directing dispensers to access the database prior to dispensing and to report the prescription at near real time has been deleted and replaced with subsections k (3), k (4), and k (5) requiring all practitioners to check the database prior to dispensing, prescribing, or administering schedule II, III, or IV controlled substances but creating exemptions for emergent situations, surgery or medical procedures. This section also creates alternate procedures for practitioners with technological barriers, previously included in a later section.

**Section 20**
The language previously in subsection (o), creating a technology exemption, has been moved to section 18. The remaining subsections have been reordered.
Subsection (p) (*previously subsection q)* has been amended to reflect that the database has been limited to only schedule II, III, or IV controlled substances.
A new subsection (q) has been added to state that a practitioner may only delegate database access or information submittal to an agent or employee who is who is licensed or registered in the state.
Subsection (r) directs the Department of Commerce, Community, and Economic Development to notify each board when a practitioner registers with the database (previously required of the Board of Pharmacy). The Board of Veterinary Examiners was and to assist the Board of Pharmacy in implementing this section, language that was previously under AS 17.30.200(a). Additionally, the department shall establish regulations for registration with the database, which will cover the cost of the database minus all federal funds.

**Section 21**
The transition regulatory authority has been expanded from just the Board of Pharmacy to now include the Department of Commerce, Community, and Economic Development and each board whose licensees will be required to register.

**Section 22**
The transition language has been amended to require the Board of Pharmacy to provide information and training on this act to the other boards. Subsection (b) has been deleted.

**New Subsection 23**
New subsection 23 has been added which will enact AS 17.30.200(r) in September 1, 2016. This is the section the Department to establish registration fees.

**Section 24**
The effective date (relating to transition language) has been amended to take effect immediately.

**Section 25**
The effective date of the bill has been amended to July 1, 2017.

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**House Bill 344**

**Sectional- Version N**

*Sections 1-12 will repeat the same language for the Board of Dental Examiners, the State Medical Board, the Board of Nursing, the Board of Optometry, and the Veterinary Board.*

**Section 1**

AS 08.36.315 is amended to state that dispensing an opiate in excess of the maximum dosage is grounds for disciplinary actions under the Board of Dental Examiners. Procuring, selling, prescribing, or dispensing drugs in violation of a law is also grounds for disciplinary action regardless of criminal action.

**Section 2**

This creates a new section 08.36.355 that limits initial prescriptions for an opiate to 7 days for an adult; any prescription of an opiate to a minor is limited to 7 days. Licensee may write prescription exceeding the 7 day limit if the patient's medical condition calls for a larger prescription, or for patients who is unable to access a practitioner within the time necessary for a refill of the 7 day supply.

**Section 3**

Defines opiate in AS 11.71.900.

**Section 4**

AS 08.64.326(a) is amended to state that dispensing an opiate in excess of the maximum dosage is grounds for disciplinary actions under the State Medical Board.

**Section 5**

This creates a new section 08.64.363 that limits initial prescriptions for an opiate to 7 days for an adult; any prescription of an opiate to a minor is limited to 7 days. Licensee may write prescription exceeding the 7 day limit if the patient's medical condition calls for a larger prescription, or for patients who is unable to access a practitioner within the time necessary for a refill of the 7 day supply.

**Section 6**

Defines opiate in AS 11.71.900.

**Section 7**

AS 08.68.270 is amended to state that dispensing an opiate in excess of the maximum dosage is grounds for disciplinary actions under the Board of Nursing. Procuring, selling, prescribing, or dispensing drugs in violation of a law is also grounds for disciplinary action regardless of criminal action.

**Section 8**

This creates a new section 08.68.705 that limits initial prescriptions for an opiate to 7 days for an adult; any prescription of an opiate to a minor is limited to 7 days. Licensee may write prescription exceeding the 7 day limit if the patient's medical condition calls for a larger prescription, or for patients who is unable to access a practitioner within the time necessary for a refill of the 7 day supply.

**Section 9**

Defines opiate in AS 11.71.900.

**Section 10**

AS 08.72.240 is amended to state that dispensing an opiate in excess of the maximum dosage is grounds for disciplinary actions under the Board of Examiners in Optometry. Procuring, selling, prescribing, or dispensing drugs in violation of a law is also grounds for disciplinary action regardless of criminal action.

**Section 11**

This creates a new section 08.72.277 that limits initial prescriptions for an opiate to 7 days for an adult; any prescription of an opiate to a minor is limited to 7 days. Licensee may write prescription exceeding the 7 day limit if the patient's medical condition calls for a larger prescription, or for patients who is unable to access a practitioner within the time necessary for a refill of the 7 day supply.

**Section 12**

Defines opiate in AS 11.71.900.

**Section 13**

Procuring, selling, prescribing, or dispensing drugs in violation of a law is also grounds for disciplinary action regardless of criminal action.

**Section 14**

The purpose of the controlled substance prescription database is amended to only contain prescription information for schedule II, II, or IV controlled substances under federal law.

**Section 15**

This section allows pharmacists or providers to delegate the task of submitting schedule II, III, or IV controlled substance prescription information to the database to an authorized employee or agent; according to AS 17.30.200(r) of this bill this may only be delegated to an employee who is licensed or registered with the state. This section also requires that pharmacists submit data at least weekly. Language directing the department to assist the board of pharmacy has been moved to another section of statue.

**Section 16**

This section requires that the information in the database remain confidential and describes who is permitted to access the database. Under this bill, a licensed or registered practitioner or pharmacist may

delegate access to an authorized agent or employee; according to AS 17.30.200(r) of this bill this may only be delegated to an employee who is licensed or registered with the state.

Access is also granted to the lead Medicaid pharmacist and the Medicaid Utilization review committee to review drug utilization in the Medicaid program. It is also granted to the State Medical Examiner for investigation into cause of death. Finally, this section allows that authorized employees of Health and Social Services may receive de-identified information from the database for public health.

**Section 17**

AS 17.30.200 (e) is amended to state that the failure of the pharmacists or providers to ***register*** or submit information to the database is grounds for the board to take disciplinary action.

**Section 18**

Deletes language stating that dispensers or practitioners are not obligated to check the database prior to dispensing, to conform to the requirement on dispensers in section 19.

**Section 19**

This section requires that a pharmacist or practitioner shall *review* the information from the database prior to prescribing, dispensing, or administering a controlled substance to a patient. Subsection 4 creates exemptions to this requirement for inpatient settings, in an emergency situation, or immediately before, during, or after a surgery or a medical procedure. Subsection 5 directs the board of pharmacy to create an alternative procedure to allow practitioners with a technological or infrastructure barrier to comply with these requirements.

**Section 20**

This section adds new subsections that include in subsection (o) an automatic electronic alert system when someone has prescriptions inconsistent with general standards. Subsection (p) requires all healthcare providers who prescribe, dispense, or administer a controlled substance to register with the prescription drug database.

Subsection (q) states that a pharmacist or practitioner may only delegate access to the database to licensed or registered employee or agent.

Subsection (r) directs the Department of Commerce, Community, and Economic Development to assist the board in implementing this section and to promptly notify all appropriate boards when a licensee registers with the database. The department is further directed to establish fees for registration with the database to cover the operational costs of the database minus all available federal funds.

**Section 21**

This section allows the Department of Commerce and all boards with practitioners who will register with the database to adopt the regulations necessary to implement this act.

**Section 22**

This section creates transition language directing the board of pharmacy to provide information and training to other boards on how to register and comply with database.

**Section 23**

This section creates an effective date of September 1, 2016 for AS 17.30.200(r), establishing fees for registration.

**Section 24**

The regulatory authority under sections 21 and 22 takes effect immediately.

**Section 25**

Except in sections 23 and 24, the changes created by this act take effect July 1, 2017.

29-LS1378\N
Bruce
3/14/16

**CS FOR HOUSE BILL NO. 344(HSS)**

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-NINTH LEGISLATURE - SECOND SESSION

**BY THE HOUSE HEALTH AND SOCIAL SERVICES COMMITTEE**

**Offered:**
**Referred:**

**Sponsor(s): REPRESENTATIVE SEATON**

**A BILL**

**FOR AN ACT ENTITLED**

**"An Act relating to the controlled substance prescription database; relating to the duties of the Board of Pharmacy; relating to the prescription of opiates; relating to the practice of dentistry; relating to the practice of medicine; relating to the practice of nursing; relating to the practice of optometry; relating to the practice of veterinary medicine; and providing for an effective date."**

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

* **Section 1.** AS 08.36.315 is amended to read:

**Sec. 08.36.315. Grounds for discipline, suspension, or revocation of license.** The board may revoke or suspend the license of a dentist, or may reprimand, censure, or discipline a dentist, or both, if the board finds after a hearing that the dentist

(1) used or knowingly cooperated in deceit, fraud, or intentional misrepresentation to obtain a license;

(2) engaged in deceit, fraud, or intentional misrepresentation in the

course of providing or billing for professional dental services or engaging in professional activities;

(3) advertised professional dental services in a false or misleading manner;

(4) received compensation for referring a person to another dentist or dental practice;

(5) has been convicted of a felony or other crime that affects the dentist's ability to continue to practice dentistry competently and safely;

(6) engaged in the performance of patient care, or permitted the performance of patient care by persons under the dentist's supervision, regardless of whether actual injury to the patient occurred,

(A) that did not conform to minimum professional standards of dentistry; or

(B) when the dentist, or a person under the supervision of the dentist, did not have the permit, registration, or certificate required under AS 08.32 or this chapter;

(7) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(8) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) addiction or dependence on alcohol or other drugs that impair the dentist's ability to practice safely;

(C) physical or mental disability;

(9) engaged in lewd or immoral conduct in connection with the delivery of professional service to patients;

(10) permitted a dental hygienist or dental assistant who is employed by the dentist or working under the dentist's supervision to perform a dental procedure in violation of AS 08.32.110 or AS 08.36.346;

(11) failed to report to the board a death that occurred on the premises used for the practice of dentistry within 48 hours;

(12) falsified or destroyed patient or facility records or failed to

maintain a patient or facility record for at least seven years after the date the record was created;

**(13) prescribed or dispensed an opiate in excess of the maximum dosage authorized under AS 08.36.355; or**

**(14) procured, sold, prescribed, or dispensed drugs in violation of a law, regardless of whether there has been a criminal action**.

* **Sec. 2.** AS 08.36 is amended by adding a new section to read:

**Sec. 08.36.355. Maximum dosage for opiate prescriptions.** (a) A licensee may not issue an initial prescription for an opiate that exceeds a seven-day supply to an adult patient for outpatient use.

(b) A licensee may not issue a prescription for an opiate that exceeds a seven-day supply to a minor. At the time a licensee writes a prescription for an opiate for a minor, the licensee shall discuss with the parent or guardian of the minor why the prescription is necessary and the risks associated with opiate use.

(c) Notwithstanding (a) and (b) of this section, a licensee may issue a prescription for an opiate that exceeds a seven-day supply to an adult or minor patient if, in the professional judgment of the licensee, more than a seven-day supply of an opiate is necessary for

(1) the patient's acute medical condition, chronic pain management, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the licensee may write a prescription for an opiate for the quantity needed to treat the patient's medical condition, chronic pain, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the licensee shall document in the patient's medical record the condition triggering the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; or

(2) a patient who is unable to access a practitioner within the time necessary for a refill of the seven-day supply because of a logistical or travel barrier; the licensee may write a prescription for an opiate for the quantity needed to treat the patient for the time that the patient is unable to access a practitioner; the licensee shall document in the patient's medical record the reason for the prescription of an opiate in

a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; in this paragraph, "practitioner" has the meaning given in AS 11.71.900.

(d) In this section,

(1) "adult" means

(A) a person who has reached 18 years of age; or

(B) an emancipated minor;

(2) "emancipated minor" means a minor whose disabilities have been removed for general purposes under AS 09.55.590;

(3) "minor" means a person under 18 years of age who is not an emancipated minor.

* **Sec. 3.** AS 08.36.370 is amended by adding a new paragraph to read:

(10) "opiate" has the meaning given in AS 11.71.900.

* **Sec. 4.** AS 08.64.326(a) is amended to read:

(a) The board may impose a sanction if the board finds after a hearing that a licensee

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation while providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted, including conviction based on a guilty plea or plea of nolo contendere, of

(A) a class A or unclassified felony or a crime in another jurisdiction with elements similar to a class A or unclassified felony in this jurisdiction;

(B) a class B or class C felony or a crime in another jurisdiction with elements similar to a class B or class C felony in this jurisdiction if the felony or other crime is substantially related to the qualifications, functions, or duties of the licensee; or

(C) a crime involving the unlawful procurement, sale,

prescription, or dispensing of drugs;

(5) has procured, sold, prescribed, or dispensed drugs in violation of a law regardless of whether there has been a criminal action;

(6) intentionally or negligently permitted the performance of patient care by persons under the licensee's supervision that does not conform to minimum professional standards even if the patient was not injured;

(7) failed to comply with this chapter, a regulation adopted under this chapter, or an order of the board;

(8) has demonstrated

(A) professional incompetence, gross negligence, or repeated negligent conduct; the board may not base a finding of professional incompetence solely on the basis that a licensee's practice is unconventional or experimental in the absence of demonstrable physical harm to a patient;

(B) addiction to, severe dependency on, or habitual overuse of alcohol or other drugs that impairs the licensee's ability to practice safely;

(C) unfitness because of physical or mental disability;

(9) engaged in unprofessional conduct, in sexual misconduct, or in lewd or immoral conduct in connection with the delivery of professional services to patients; in this paragraph, "sexual misconduct" includes sexual contact, as defined by the board in regulations adopted under this chapter, or attempted sexual contact with a patient outside the scope of generally accepted methods of examination or treatment of the patient, regardless of the patient's consent or lack of consent, during the term of the physician-patient relationship, as defined by the board in regulations adopted under this chapter, unless the patient was the licensee's spouse at the time of the contact or, immediately preceding the physician-patient relationship, was in a dating, courtship, or engagement relationship with the licensee;

(10) has violated AS 18.16.010;

(11) has violated any code of ethics adopted by regulation by the board;

(12) has denied care or treatment to a patient or person seeking assistance from the physician if the only reason for the denial is the failure or refusal

of the patient to agree to arbitrate as provided in AS 09.55.535(a); [OR]

(13) has had a license or certificate to practice medicine in another state or territory of the United States, or a province or territory of Canada, denied, suspended, revoked, surrendered while under investigation for an alleged violation, restricted, limited, conditioned, or placed on probation unless the denial, suspension, revocation, or other action was caused by the failure of the licensee to pay fees to that state, territory, or province**; or**

**(14) prescribed or dispensed an opiate in excess of the maximum dosage authorized under AS 08.64.363**.

*** Sec. 5.** AS 08.64 is amended by adding a new section to article 3 to read:

**Sec. 08.64.363. Maximum dosage for opiate prescriptions.** (a) A licensee may not issue an initial prescription for an opiate that exceeds a seven-day supply to an adult patient for outpatient use.

(b) A licensee may not issue a prescription for an opiate that exceeds a seven-day supply to a minor. At the time a licensee writes a prescription for an opiate for a minor, the licensee shall discuss with the parent or guardian of the minor why the prescription is necessary and the risks associated with opiate use.

(c) Notwithstanding (a) and (b) of this section, a licensee may issue a prescription for an opiate that exceeds a seven-day supply to an adult or minor patient if, in the professional medical judgment of the licensee, more than a seven-day supply of an opiate is necessary for

(1) the patient's acute medical condition, chronic pain management, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the licensee may write a prescription for an opiate for the quantity needed to treat the patient's medical condition, chronic pain, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the licensee shall document in the patient's medical record the condition triggering the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; or

(2) a patient who is unable to access a practitioner within the time necessary for a refill of the seven-day supply because of a logistical or travel barrier;

the licensee may write a prescription for an opiate for the quantity needed to treat the patient for the time that the patient is unable to access a practitioner; the licensee shall document in the patient's medical record the reason for the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; in this paragraph, "practitioner" has the meaning given in AS 11.71.900.

(d) In this section,

(1) "adult" means

(A) a person who has reached 18 years of age; or

(B) an emancipated minor;

(2) "emancipated minor" means a minor whose disabilities have been removed for general purposes under AS 09.55.590;

(3) "minor" means a person under 18 years of age who is not an emancipated minor.

* **Sec. 6.** AS 08.64.380 is amended by adding a new paragraph to read:

(7) "opiate" has the meaning given in AS 11.71.900.

* **Sec. 7.** AS 08.68.270 is amended to read:

**Sec. 08.68.270. Grounds for denial, suspension, or revocation.** The board may deny, suspend, or revoke the license of a person who

(1) has obtained or attempted to obtain a license to practice nursing by fraud or deceit;

(2) has been convicted of a felony or other crime if the felony or other crime is substantially related to the qualifications, functions, or duties of the licensee;

(3) habitually abuses alcoholic beverages, or illegally uses controlled substances;

(4) has impersonated a registered or practical nurse;

(5) has intentionally or negligently engaged in conduct that has resulted in a significant risk to the health or safety of a client or in injury to a client;

(6) practices or attempts to practice nursing while afflicted with physical or mental illness, deterioration, or disability that interferes with the individual's performance of nursing functions;

(7) is guilty of unprofessional conduct as defined by regulations adopted by the board;

(8) has wilfully or repeatedly violated a provision of this chapter or regulations adopted under this chapter or AS 08.01;

(9) is professionally incompetent;

(10) denies care or treatment to a patient or person seeking assistance if the sole reason for the denial is the failure or refusal of the patient or person seeking assistance to agree to arbitrate as provided in AS 09.55.535(a)**;**

**(11) prescribed or dispensed an opiate in excess of the maximum dosage authorized under AS 08.68.705; or**

**(12) has procured, sold, prescribed, or dispensed drugs in violation of a law, regardless of whether there has been a criminal action**.

*** Sec. 8.** AS 08.68 is amended by adding a new section to article 6 to read:

**Sec. 08.68.705. Maximum dosage for opiate prescriptions.** (a) An advanced nurse practitioner licensed in the state may not issue an initial prescription for an opiate that exceeds a seven-day supply to an adult patient for outpatient use.

(b) An advanced nurse practitioner licensed in the state may not issue a prescription for an opiate that exceeds a seven-day supply to a minor. At the time an advanced nurse practitioner writes a prescription for an opiate for a minor, the advanced nurse practitioner shall discuss with the parent or guardian of the minor why the prescription is necessary and the risks associated with opiate use.

(c) Notwithstanding (a) and (b) of this section, an advanced nurse practitioner licensed in the state may issue a prescription for an opiate that exceeds a seven-day supply to an adult or minor patient if, in the professional judgment of the advanced nurse practitioner, more than a seven-day supply of an opiate is necessary for

(1) the patient's acute medical condition, chronic pain management, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the advanced nurse practitioner may write a prescription for an opiate for the quantity needed to treat the patient's medical condition, chronic pain, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the advanced nurse practitioner shall document in the patient's medical

record the condition triggering the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; or

(2) a patient who is unable to access a practitioner within the time necessary for a refill of the seven-day supply because of a logistical or travel barrier; the advanced nurse practitioner may write a prescription for an opiate for the quantity needed to treat the patient for the time that the patient is unable to access a practitioner; the advanced nurse practitioner shall document in the patient's medical record the reason for the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; in this paragraph, "practitioner" has the meaning given in AS 11.71.900.

(d) In this section,

(1) "adult" means

(A) a person who has reached 18 years of age; or

(B) an emancipated minor;

(2) "emancipated minor" means a minor whose disabilities have been removed for general purposes under AS 09.55.590;

(3) "minor" means a person under 18 years of age who is not an emancipated minor.

* **Sec. 9.** AS 08.68.850 is amended by adding a new paragraph to read:

(11) "opiate" has the meaning given in AS 11.71.900.

* **Sec. 10.** AS 08.72.240 is amended to read:

**Sec. 08.72.240. Grounds for imposition of disciplinary sanctions.** The board may impose disciplinary sanctions when the board finds after a hearing that a licensee

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or other crime which affects the

licensee's ability to continue to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the licensee's supervision which does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or other drugs which impairs the licensee's ability to practice safely;

(D) physical or mental disability;

(8) engaged in lewd or immoral conduct in connection with the delivery of professional service to patients;

(9) failed to refer a patient to a physician after ascertaining the presence of ocular or systemic conditions requiring management by a physician**;**

**(10) prescribed or dispensed an opiate in excess of the maximum dosage authorized under AS 08.72.277; or**

**(11) procured, sold, prescribed, or dispensed drugs in violation of a law, regardless of whether there has been a criminal action**.

*** Sec. 11.** AS 08.72 is amended by adding a new section to read:

**Sec. 08.72.277. Maximum dosage for opiate prescriptions.** (a) A licensed optometrist may not issue an initial prescription for an opiate that exceeds a seven-day supply to an adult patient for outpatient use.

(b) A licensed optometrist may not issue a prescription for an opiate that exceeds a seven-day supply to a minor. At the time a licensed optometrist writes a prescription for an opiate for a minor, the licensed optometrist shall discuss with the parent or guardian of the minor why the prescription is necessary and the risks associated with opiate use.

(c) Notwithstanding (a) and (b) of this section, a licensed optometrist may issue a prescription for an opiate that exceeds a seven-day supply to an adult or minor patient if, in the professional judgment of the licensed optometrist, more than a seven-day supply of an opiate is necessary for

(1) the patient's acute medical condition, chronic pain management, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the licensed optometrist may write a prescription for an opiate for the quantity needed to treat the patient's condition, chronic pain, pain associated with a cancer diagnosis, or pain experienced while the patient is in palliative care; the licensed optometrist shall document in the patient's medical record the condition triggering the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; or

(2) a patient who is unable to access a practitioner within the time necessary for a refill of the seven-day supply because of a logistical or travel barrier; the licensed optometrist may write a prescription for an opiate for the quantity needed to treat the patient for the time that the patient is unable to access a practitioner; the licensed optometrist shall document in the patient's medical record the reason for the prescription of an opiate in a quantity that exceeds a seven-day supply and indicate that a non-opiate alternative was not appropriate to address the medical condition; in this paragraph, "practitioner" has the meaning given in AS 11.71.900.

(d) In this section,

(1) "adult" means

(A) a person who has reached 18 years of age; or

(B) an emancipated minor;

(2) "emancipated minor" means a minor whose disabilities have been removed for general purposes under AS 09.55.590;

(3) "minor" means a person under 18 years of age who is not an emancipated minor.

* **Sec. 12.** AS 08.72.300 is amended by adding a new paragraph to read:

(6) "opiate" has the meaning given in AS 11.71.900.

* **Sec. 13.** AS 08.98.235 is amended to read:

**Sec. 08.98.235. Grounds for imposition of disciplinary sanctions.** After a hearing, the board may impose a disciplinary sanction on a person licensed under this chapter when the board finds that the person

(1) secured a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or other crime which affects the person's ability to continue to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of animal care by the person's supervisees which does not conform to minimum professional standards regardless of whether actual injury to the animal occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) continued to practice after becoming unfit due to

(A) professional incompetence;

(B) addiction or severe dependency on alcohol or other drugs which impairs the person's ability to practice safely;

(C) physical or mental disability;

(8) engaged in lewd or immoral conduct in connection with the delivery of professional service**;**

**(9) procured, sold, prescribed, or dispensed drugs in violation of law, regardless of whether there has been a criminal action**.

* **Sec. 14.** AS 17.30.200(a) is amended to read:

(a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule [IA, IIA, IIIA, IVA, OR VA CONTROLLED SUBSTANCE UNDER STATE LAW OR A SCHEDULE I,] II, III,

**or** IV [, OR V] controlled substance under federal law dispensed in the state to a person other than those administered to a patient at a health care facility. [THE DEPARTMENT OF COMMERCE, COMMUNITY, AND ECONOMIC DEVELOPMENT SHALL ASSIST THE BOARD AND PROVIDE NECESSARY STAFF AND EQUIPMENT TO IMPLEMENT THIS SECTION.]

*** Sec. 15.** AS 17.30.200(b) is amended to read:

(b) The pharmacist-in-charge of each licensed or registered pharmacy, **or an agent or employee of the pharmacist-in-charge whom the pharmacist-in-charge has authorized to submit to the database on the pharmacist-in-charge's behalf,** regarding each schedule [IA, IIA, IIIA, IVA, OR VA CONTROLLED SUBSTANCE UNDER STATE LAW OR A SCHEDULE I,] II, III, **or** IV [, OR V] controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule [IA, IIA, IIIA, IVA, OR VA CONTROLLED SUBSTANCE UNDER STATE LAW OR A SCHEDULE I,] II, III, **or** IV [, OR V] controlled substance under federal law **or an agent or employee of the practitioner whom the practitioner has authorized to submit to the database on the practitioner's behalf,** other than those administered to a patient at a health care facility, shall submit to the **database at least weekly** [BOARD], by a procedure and in a format established by the board, the following information [FOR INCLUSION IN THE DATABASE]:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

* **Sec. 16.** AS 17.30.200(d) is amended to read:

(d) The database and the information contained within the database are confidential, are not public records, and are not subject to public disclosure. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:

(1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;

(2) authorized board personnel or contractors as required for operational and review purposes;

(3) a licensed **or registered** practitioner having authority to prescribe controlled substances **or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf**, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance;

(4) a licensed or registered pharmacist having authority to dispense controlled substances **or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf**, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance;

(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant, subpoena, or order issued by a court establishing probable cause for the access and use of the information; [AND]

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;

**(7) a pharmacist who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;**

**(8) a person responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs under the program;**

**(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death; and**

**(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not identify patients, prescribers, dispensers, or dispenser locations, for the purpose of identifying and monitoring public health issues in the state**.

* **Sec. 17.** AS 17.30.200(e) is amended to read:

(e) The failure of a pharmacist-in-charge, pharmacist, or practitioner to **register with or** submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist or for another licensing board to take disciplinary action against a practitioner.

* **Sec. 18.** AS 17.30.200(h) is amended to read:

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. [NOTHING IN THIS SECTION REQUIRES OR OBLIGATES A DISPENSER OR PRACTITIONER TO ACCESS OR CHECK THE DATABASE

BEFORE DISPENSING, PRESCRIBING, OR ADMINISTERING A MEDICATION, OR PROVIDING MEDICAL CARE TO A PERSON.] Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

* **Sec. 19.** AS 17.30.200(k) is amended to read:

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

**(3) a procedure and time frame for registration with the database;**

**(4) that a pharmacist or practitioner shall review the information in the database to check a patient's prescription records before prescribing, dispensing, or administering to a patient a schedule II, III, or IV controlled substance under federal law; the regulations must provide that a pharmacist or practitioner is not required to review the information in the database before dispensing, prescribing, or administering a controlled substance to a person who is receiving treatment**

**(A) in an inpatient setting;**

**(B) at the scene of an emergency or in an ambulance; in this subparagraph, "ambulance" has the meaning given in AS 18.08.200;**

**(C) in an emergency room; or**

**(D) immediately before, during, or within the first 24 hours after surgery or a medical procedure;**

**(5) an alternate procedure and format that complies with the requirements of this section for a pharmacist or practitioner who is unable to directly access the database by electronic means because of a technological or infrastructure barrier; the board may authorize the use of the alternate procedure and format for a pharmacist or practitioner who provides evidence to**

**the board sufficient to establish that the pharmacist or practitioner has a technological or infrastructure barrier that prevents the pharmacist or practitioner from directly accessing the database by electronic means**.

* **Sec. 20.** AS 17.30.200 is amended by adding new subsections to read:

(o) The board shall develop in the database an alert system that automatically sends an electronic notification to a pharmacist and practitioner at the time the pharmacist or practitioner enters a prescription for a patient into the database if the same patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance.

(p) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.

(q) A pharmacist or practitioner may only delegate access to the database under (b) or (d) of this section to an employee or agent who is licensed or registered in the state.

(r) The Department of Commerce, Community, and Economic Development shall

(1) promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Veterinary Examiners, and the Board of Examiners in Optometry when a practitioner registers with the database under (p) of this section;

(2) assist the board and provide necessary staff and equipment to implement this section; and

(3) establish fees for registration with the database by a pharmacist or practitioner required to register under (p) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall

(A) set the fees for registration with the database so that the

fees are the same for all practitioners and pharmacists required to register; and

(B) consult with the board to establish the fees under this subsection.

* **Sec. 21.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITION: REGULATIONS. The Department of Commerce, Community, and Economic Development, the Board of Pharmacy, the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Veterinary Examiners, and the Board of Examiners in Optometry may adopt regulations necessary to implement the changes made by secs. 14 - 20 of this Act. The regulations take effect under AS 44.62 (Administrative Procedure Act), but not before the effective date of the relevant provision of secs. 14 - 20 of this Act implemented by the regulation.

* **Sec. 22.** The uncodified law of the State of Alaska is amended by adding a new section to read:

TRANSITION. The Board of Pharmacy shall provide necessary information and training to the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Veterinary Examiners, and the Board of Examiners in Optometry for implementing the requirements of secs. 14 - 20 of this Act.

* **Sec. 23.** AS 17.30.200(r), enacted by sec. 20 of this Act, takes effect September 1, 2016.

* **Sec. 24.** Sections 21 and 22 of this Act take effect immediately under AS 01.10.070(c).

* **Sec. 25.** Except as provided in secs. 23 and 24 of this Act, this Act takes effect July 1, 2017.

29-LS1378\N.1
Bruce
3/14/16

**A M E N D M E N T**

OFFERED IN THE HOUSE BY REPRESENTATIVE SEATON

TO: CSHB 344(HSS), Draft Version "N"

Page 13, lines 18 - 19:

Delete "**database at least weekly** [BOARD]"

Insert "board**, at least weekly**"

Page 13, line 20:

Delete "[FOR INCLUSION IN THE DATABASE]"

Insert "for inclusion in the database"

Page 18, following line 3:

Insert a new subsection to read:

"(s) The board shall, on a weekly basis, update the database with the information submitted to the board under (b) of this section."

29-LS1378\N.2
Bruce
3/15/16

# AMENDMENT

OFFERED IN THE HOUSE BY REPRESENTATIVE SEATON

TO: CSHB 344(HSS), Draft Version "N"

Page 16, line 16:

Delete "**II, III, or IV**"

Insert "**II or III**"

Page 16, line 17:

Delete "**; the regulations must provide that a pharmacist or practitioner is not required to review the information in the database**"

Insert "**or before first prescribing, dispensing, or administering a benzodiazepine to a patient; the regulations must provide that a pharmacist or practitioner review the database at least annually for benzodiazepines after first prescribing, dispensing, or administering a benzodiazepine to a patient;**

**(5) that a pharmacist or practitioner is not required to review the information in the database as provided in (4) of this subsection**"

Renumber the following paragraph accordingly.

29-LS1378\N.3
Bruce
3/17/16

# AMENDMENT

OFFERED IN THE HOUSE BY REPRESENTATIVE SEATON

TO: CSHB 344(HSS), Draft Version "N"

Page 16, line 16, following "**patient**":

Insert "**more than a three-day supply of**"

29-LS1378\N.5
Bruce
3/17/16

# AMENDMENT

OFFERED IN THE HOUSE BY REPRESENTATIVE SEATON

TO: CSHB 344(HSS), Draft Version "N"

Page 17, line 17, following "state":

Insert "for an occupation or activity listed under AS 08.01.010"

29-LS1378\N.6
Bruce
3/18/16

# AMENDMENT

OFFERED IN THE HOUSE BY REPRESENTATIVE SEATON

TO: CSHB 344(HSS), Draft Version "N"

Page 18, line 15, following "TRANSITION.":

Insert "(a)"

Page 18, following line 18:

Insert a new subsection to read:

"(b) On or before October 1, 2019, the Department of Commerce, Community, and Economic Development shall solicit comments on the level of burden on providers created by the review requirement in AS 17.30.200(k)(4), enacted by sec. 19 of this Act. The department shall summarize, in a report to the legislature, the comments received by the department and its findings based on the comments. The department shall deliver the report to the senate secretary and the chief clerk of the house of representatives not later than October 1, 2019, and notify the legislature that the report is available. The legislature may assess whether the review requirement under AS 17.30.200(k)(4), enacted by sec. 19 of this Act, remains necessary or if alternative language should be considered based on the report."

29-LS1378\N.6
Bruce
3/18/16

# AMENDMENT

OFFERED IN THE HOUSE BY REPRESENTATIVE SEATON

TO: CSHB 344(HSS), Draft Version "N"

Page 18, line 15, following "TRANSITION.":

Insert "(a)"

Page 18, following line 18:

Insert a new subsection to read:

"(b) On or before ~~October~~ January 1, 2019, the Department of Commerce, Community, and Economic Development shall solicit comments on the level of burden on providers created by the review requirement in AS 17.30.200(k)(4), enacted by sec. 19 of this Act. The department shall summarize, in a report to the legislature, the comments received by the department and its findings based on the comments. The department shall deliver the report to the senate secretary and the chief clerk of the house of representatives not later than ~~October~~ January 1, 2019, and notify the legislature that the report is available. The legislature may assess whether the review requirement under AS 17.30.200(k)(4), enacted by sec. 19 of this Act, remains necessary or if alternative language should be considered based on the report."

# Fiscal Note

State of Alaska
2016 Legislative Session

Bill Version: HB 344
Fiscal Note Number:
() Publish Date:

Identifier: HB344-DCCED-CBPL-02-27-16
Title: DRUG PRESCRIPTION DATABASE
Sponsor: SEATON
Requester: (H) Health and Social Services

Department: Department of Commerce, Community and Economic Development
Appropriation: Corporations, Business and Professional Licensing
Allocation: Corporations, Business and Professional Licensing
OMB Component Number: 2360

**Expenditures/Revenues**

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

| | FY2017 Appropriation Requested | Included in Governor's FY2017 Request | Out-Year Cost Estimates | | | | |
|---|---|---|---|---|---|---|---|
| **OPERATING EXPENDITURES** | **FY 2017** | **FY 2017** | **FY 2018** | **FY 2019** | **FY 2020** | **FY 2021** | **FY 2022** |
| Personal Services | 100.6 | | 100.6 | 100.6 | 100.6 | 100.6 | 100.6 |
| Travel | 3.0 | | 3.0 | 3.0 | 3.0 | 3.0 | 3.0 |
| Services | 34.5 | | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |
| Commodities | 5.0 | | | | | | |
| Capital Outlay | | | | | | | |
| Grants & Benefits | | | | | | | |
| Miscellaneous | | | | | | | |
| **Total Operating** | **143.1** | **0.0** | **113.6** | **113.6** | **113.6** | **113.6** | **113.6** |
| **Fund Source (Operating Only)** | | | | | | | |
| 1156 Rcpt Svcs | 143.1 | | 113.6 | 113.6 | 113.6 | 113.6 | 113.6 |
| **Total** | **143.1** | **0.0** | **113.6** | **113.6** | **113.6** | **113.6** | **113.6** |
| **Positions** | | | | | | | |
| Full-time | 1.0 | | 1.0 | 1.0 | 1.0 | 1.0 | 1.0 |
| Part-time | | | | | | | |
| Temporary | | | | | | | |
| **Change in Revenues** | 143.1 | | 113.6 | 113.6 | 113.6 | 113.6 | 113.6 |

**Estimated SUPPLEMENTAL (FY2016) cost:** 0.0 *(separate supplemental appropriation required)*
*(discuss reasons and fund source(s) in analysis section)*

**Estimated CAPITAL (FY2017) cost:** 0.0 *(separate capital appropriation required)*
*(discuss reasons and fund source(s) in analysis section)*

**ASSOCIATED REGULATIONS**

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? Yes
If yes, by what date are the regulations to be adopted, amended or repealed? 07/01/17

**Why this fiscal note differs from previous version:**

Not applicable, initial version.

| | | | |
|---|---|---|---|
| Prepared By: | Janey Hovenden, Division Director | Phone: | (907)465-2536 |
| Division: | Corporations, Business and Professional Licensing | Date: | 02/27/2016 12:25 PM |
| Approved By: | Catherine Reardon, Director | Date: | 02/27/16 |
| Agency: | Division of Administrative Services | | |

## FISCAL NOTE ANALYSIS

**STATE OF ALASKA** **BILL NO.** HB 344
**2016 LEGISLATIVE SESSION**

### Analysis

HB344 requires a pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses controlled substances to register with the database and allows the Board of Pharmacy or another licensing board to discipline those required to register if they fail to do so. It allows for a pharmacist or practitioner to receive an exemption from reporting through the database.
It requires the Board of Pharmacy to adopt regulations for pharmacists, practitioners, and their delegates to access the database to check a patient's prescription records before dispensing to a patient, to enter a prescription into the database at "near real time" when dispensing, and the procedures and time frame for registering with the database. This bill does not require practitioners to check the database before prescribing. It requires the Board of Pharmacy to develop an alert system in the database when prescription/dispensation exceeds limitations.

This legislation allows access to the Prescription Drug Monitoring Database (PDMP) by the pharmacist responsible for administering prescription drug coverage for the Medicaid medical assistance program; the person responsible for utilization review of prescription drugs for the Medicaid medical assistance program, the state medical examiner, and an authorized employee of DHSS who may receive undisclosed information for the purpose of identifying and monitoring public health issues in the state, and limits that access. In addition, it allows delegation of authority by pharmacists and practitioners and mandates information be submitted to the database at near real time to when the prescription is dispensed.

HB344 allows transitional language that requires the Board of Pharmacy to provide necessary information and training to the State Medical Board, Board of Nursing, the Board of Dental Examiners, and the Board of Optometry for implementing the requirements of this Act. This fiscal note provides for one Program Coordinator, range 18; expansion of the scope and functionality of the PDMP will require staff such as a Program Coordinator I in Juneau to manage all aspects of the PDMP, including registration, reporting, collaboration and engagement with the state's opioid control program, grant writing and reporting, vendor solicitation, and other facets of the PDMP.

If the bill passes the following expenses will be incurred:
Personal Services: $100.6 (one full time permanent Program Coordinator, range 18)

Travel: $3.0 (program coordinator to attend two board meetings and engagement with committees and stakeholders in the state's opioid control program)

Services: $12.5 (legal costs to amend regulations, printing, and postage in first year)
$12.0 (printing and postage to notify prescribers who would be required to register)
$10.0 (department-wide services support for one new position)

Commodities: $5.0 in first year (computer, office panels, office furniture and other one-time needs for one new position)

The PDMP as it is currently operating is funded by a federal grant through a reimbursable service agreement (RSA) with the Department of Health and Social Services (DHSS). The department is seeking additional federal grant funding in collaboration with DHSS. If awarded, costs of this program enhancement could be covered by federal grant funds instead of program receipts. In absence of the grant it would be paid for by Board of Pharmacy licensees.

Talking points for Taneeka on HB 344- concerns and potential changes to the bill

- **Database updating frequency:** The department of Commerce has indicated that the current bill does not instruct them to update the database more frequently then it currently is. Reading both versions of the bill closely, it appears we have instructed the *dispensers* to submit information to the database at least weekly but there is no direction regarding update of the database to include the submitted information.
- *Potential solution*: Adding a new subsection to AS 17.30.200 to state "the board shall update the database on an at least weekly basis with the information submitted under (b) of this section". We believe this may address the concern and ensure the database is being updated frequently.
- **Effective date issues**: The department is concerned with having enough time to create regulation, notify licensees, issue a new data base contract for the changes being made, and create the registration requirement and fee *before* the registration and other sections become mandatory.
- *Potential solution*: Make the regulatory transition authority effective immediately and add the department of commerce to this section, so that they can make the necessary changes, contract, fee registration, etc (currently this transition authority is only given to the board of pharmacy. Make the effective date of the bill (registration manadate, reviewing the database, etc.) effective July 1 2017 to give enough time. [note, this means that undersec 21(b) practitioners would have 180 more days or until approximately January 1 2018 until they are required to be registered. *But* they will be required to review the database before then. Consider removing the 180 days or delaying the effective date of the review requirement}. Also consider making the fee section (section 19(s)) effective before the full bill is effective- practitioners already can register voluntarily, so if we want the fee to cover the potential cost we will need to have it in place before they all register, unless the department is going to collect "back- registration fees"
- **Veterinarians and notification requirement on the board of pharmacy**- under AS 17.30,200p, veterinarians would be required to register with the database, because they dispense opioids. However, they are not mentioned in subsection (q) where the board of pharmacy is directed to inform the other boards of registration of their licensees. Additionally, the department feels this requirement on the board of pharmacy is onerous and redundant because the division manages all the boards. However we want to be sure these boards (previously less connected to the PDMP) are not left to implement things on their own. This is why we added sec 21(a) directing the board of pharmacy to provide training and information to the boards.
- *Potential solution:* Change "board of pharmacy" to "department of commerce" in both section AS 17.30.200(q) [page 16] and section 21(a), so the department is coordinating the training and information sharing among all the boards. Add the vet board to section 19 (q).

Potential changes to HB 344
Distributed by Rep Seaton.

- *Further question*: Vet board is currently left out of the opiate prescription limitation in sections 1-12. Is it necessary to add this here? Would a vet every prescribe to a person?
- **Disciplinary authority:** There are no provisions to allow boards with licensees who have delegated authority to access the database to adopt regulations to provide for disciplinary action of a current licensee beyond the failure to register. We have in the cs limited delegation to only licensed or registered employees: however, it is still unclear whether additional disciplinary authority is necessary. It is only directly spelled out regarding failure to submit or register (e).
- *Potential solution:* give the board explicit authority to discipline if information is misued. I will have to check with legal to find out if this is necessary. Or, leave it as is because under 17.30.200(l) lays out criminal charges if information in the database is misused.
- **Unlicensed practitioners (federal)**- this is mainly a non-issue (legal opinion- definition of practitioner). However, we will add to section 15 (d)(3) [access to the database] "licensed or registered practitioner."
- **Alaska Medical associations**: **concerned with the burden of the mandatory look-up:** The medical association supports the PDMP as a tool but is concerned about going from many not even being registered to having a mandatory lookup for most controlled substances. They are worried that having the database apply too broadly will suck up patient time and lead to unnecessary checks on certain medications.
- *Potential solutions:* 1). Add "or procedure" to the section (4D)[page 15] exempting review immediately during or surrounding surgery. Procedure would cover things like putting an arm back in the socket- very painful but not a surgery [prescription would still go into the database when dispensed]. 2). Limit ***review*** prior to prescribing, dispensing or administering schedule II or III drugs. Schedule IV would still be entered into the database, but schedule IV drugs do not include many opiates, mostly things like ambien etc- supposedly low chance of physical addiction but perhaps some chance of psychological addiction- physicians online perhaps the best to address this. So under this change, schedule IV drugs would be entered into the database but would not prompt a mandatory review.

NATIONAL CONFERENCE *of* STATE LEGISLATURES

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To: Rep. Seaton
Attn: Taneeka Hansen
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Date: January 20, 2016

Subject: Telehealth and Prescription Drug Abuse

Hi Taneeka,

We have compiled the following information in response to your request for information regarding Telehealth and prescription drug abuse. We hope this provides a helpful overview of the topics and if there are any areas we can expand on or provide additional information, we would be happy to do so.

Telehealth

As we mentioned on the phone, NCSL recently released a new white paper on telehealth, Telehealth: Policy Trends and Considerations, which is available through this link and on our website as a free PDF. The report provides an overview of the issues and state policy trends in relation to telehealth coverage and reimbursement, licensure, and patient safety and security. Effectiveness is also discussed on page 7. We are happy to talk more about any of the issues in the report or provide more information in an areas of interest.

Licensure

States have addressed licensure for out-of-state providers through a few different mechanisms. In some cases, these efforts are directed specifically toward telehealth, and in other cases, they apply

more broadly. For example, some states have reciprocity or other allowances with contiguous states to allow for practice across state lines. Nine states also have special licenses that allow out-of-state providers to offer telehealth services in the state if they meet certain conditions. For example, Nevada issues a special purpose license for telehealth providers from outside the state.

Many states are also looking at the Federation of State Medical Boards' Interstate Licensure Compact. The Compact allows for an expedited process to license eligible out-of-state physicians, with the goal to increase access to care (including through telehealth). Twelve states passed the Compact language in 2015 and the Interstate Commission—on which two representatives from each state sit—began meeting in October. The Commission will oversee the administration and implementation.

Licensure, including licensure compacts, is also discussed in more depth in the Telehealth: Policy Trends and Considerations report beginning on page 16. More information about the compact can be found on FSMB's website at licenseportality.org.

Additional Resources

- The Center for Connected Health Policy is a nonpartisan organization that also tracks legislation and has other resources available on their website.
    - CCHP has a comprehensive report on state telehealth reimbursement laws and other policies as well; Alaska's policies as of July 2015 start on page 1 of the report (page 15 of the PDF).
- In regards to behavioral health and effectiveness, The Center for Connected Health Policy gathered research on telemental health in a Research Catalogue.
- The American Telemedicine Association is telehealth advocacy organization. They have examined state policies in various areas, and also "grades" states based on their criteria. They have two recent reports:
    - 50-state Telemedicine Gaps Analysis: Coverage and Reimbursement, which includes Medicaid reimbursement and private payer laws.
    - 50-state Telemedicine Gaps Analysis: Physician Practice Standards and Licensure, which includes policies related to licensure and patient-provider relationships, among others.

Overview: Prescription Drug Abuse Prevention

For general information on prevention of prescription drug overdose and abuse NCSL's webpage includes an overview of several policies states consider to reduce prescription drug abuse. NCSL also maintain an injury prevention legislation database. Within this database you can search for 2015 and 2016 legislation relating to prescription drug monitoring programs, rescue drugs (e.g., Naloxone) and pain clinics. NCSL houses 2014 legislation for related topics on the following web page.

The Centers for Disease Control and Prevention similarly maintains a "What States Need to Know about the Epidemic" webpage that provides an overview of prescription drug abuse and links to additional resources for state policies, "state successes," state programs and other state specific

examples of efforts to decrease opioid abuse. You can find these resources at the bottom of their webpage under "related pages."

Prescription Drug Monitoring Programs

Statewide Prescription Drug Monitoring Programs (PMDPs) electronically track prescriptions for controlled substances using data submitted by pharmacies. When suspicious prescribing behavior is detected, these programs can notify certain entities or agencies of possible abuse. These programs can curb inappropriate prescribing behavior and prevent patients from obtaining controlled substances from multiple providers. Legislatures in 49 states enacted laws to create PDMPs, and each state's program operates differently. Promising strategies legislators may want to consider to strengthen PDMPs follow.

- Encourage interstate exchange of PDMP data by developing interoperability standards with neighboring states.
- Require real-time data reporting to make prescription information, including details on the patient and the provider, available to providers immediately after a drug has been dispensed.
- Require prescribers of controlled substances to participate in the PDMP.
- Allow programs to generate and distribute routine reports to prescribers that track usage and prescribing rates.
- Encourage PDMP data sharing among clinicians, licensure boards, law enforcement, Medicaid Program Integrity offices, researchers, etc., in appropriate circumstances.
- Ensure that providers are knowledgeable about the state's PDMP and other overdose prevention tools to increase participation.

The above information is from NCSL's prescription drug overdose webpage, which provides additional information on prescription drug abuse.

NCSL Prescription Drug Monitoring Program Resources

- Using Prescription Drug Monitoring Programs to Address Drug Abuse is a 2015 LegisBrief that looks at state activity and policy aimed at addressing drug abuse through PDMPs.
- Spotlight on Prescription Drug Monitoring Program Best Practices is a webinar that examines PDMP review best practices and highlight ways states can maximize the return on investment with their program.
- NCSL's injury prevention legislation database (referenced above) is a searchable database for legislation relating to various issues. The search can be narrowed to 2015 and 2016 legislation for all 50-states, relating to prescription drug monitoring programs.

Additional PDMP Resources

- The National Alliance for Model State Drug Laws provides state profiles of PDMP programs. These profiles include state law and policy profiles.
- The Prescription Drug Monitoring Program Training and Technical Assistance Center out of Brandeis University provides various resources that aim to "to help PDMPs promote best

practices and consistency in their programs." This site houses many resources, including state profiles, policy and procedures, and other reports.

THE STATE
of ALASKA
GOVERNOR BILL WALKER

Controlled Substances Advisory Committee

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January 29, 2016

Honorable Bill Walker
Office of the Governor
PO Box 110001
Juneau, Alaska 99811-0001

Dear Governor Walker:

The Controlled Substances Advisory Committee (CSAC), created under AS 11.71.100, is an advisory board made up of various subject-matter experts in the field of controlled substances, with expertise in medicine, law enforcement, and citizenry. One of the duties of the CSAC is to recommend regulatory changes to the Board of Pharmacy regarding the prevention of "excessive prescribing of controlled substances and the diversion of prescription drugs into illicit channels." *See* AS 11.71.110(2). According to the Alaska Division of Public Health, 54 Alaskans died of prescription opioid overdose in 2015 and an additional 33 died of heroin overdose. A significant percentage of heroin users become dependent on opioids through the use of prescription drugs. As discussed in more detail below, the CSAC has concluded that Alaska's Prescription Drug Monitoring Program (PDMP), as currently enacted, faces unnecessary limitations in its effort to respond to the opioid epidemic currently being seen in Alaska.

Due to the fact that the committee's recommended modifications require a statutory change – as opposed to a regulatory change – the CSAC is advising you of its proposed modifications. The reasons and rationale for the proposed modifications are set forth in the attached white paper entitled, "*Increasing the Effectiveness of Alaska's Prescription Drug Monitoring Program (Alaska's PDMP)*".

In short, Alaska's PDMP, managed by the Board of Pharmacy, is a statutorily created electronic controlled substance database designed to enhance patient care and reduce misuse, abuse, and diversion of controlled substances. Over the past several months, the CSAC has reviewed Alaska's PDMP and discovered several areas that limit the overall effectiveness of the PDMP. In the opinion of the committee, those limitations are easily addressed, and in so doing, would increase the effectiveness of the PDMP and reduce the recurring opioid abuse occurring in Alaska. Specifically, the CSAC recommends nine modifications to Alaska's PDMP:

1. Require all prescribers and all pharmacists to register with the Alaska PDMP.
2. Require prescribers and pharmacists to review the PDMP database when prescribing or dispensing a controlled substance to a patient.
3. Authorize prescribers and pharmacists to delegate database access to supervised employees or clinical staff.

4. Authorize the Board of Pharmacy to forward unsolicited notifications to prescribers and dispensers database information about patients who may be obtaining controlled substances inconsistent with generally recognized standards of care.
5. Collect dispensing data and updating the PDMP database weekly.
6. Authorize PDMP database access to the State of Alaska Medicaid Pharmacy Program.
7. Authorize PDMP database access to the State of Alaska Medicaid Drug Utilization Review Committee.
8. Authorize PDMP database access to the State of Alaska Medical Examiner.
9. Authorize de-identified PDMP data access to the State of Alaska Department of Health and Social Services (Alaska DHSS) Division of Public Health.

These modifications are consistent with national recommendations of the American Medical Association's Task Force to Reduce Opioid Abuse, which urges states and providers to utilize prescription drugs monitoring programs to reduce prescription drug misuse, overdose, and death. The effects of heroin and opiate abuse in Alaska are well-documented. The CSAC recommends that action be taken to strengthen one of Alaska's most important tools in combating this epidemic – the PDMP.

Sincerely,

Robert E. Henderson
Chief Assistant Attorney General
Chair, Controlled Substance Advisory Committee

Enclosures as stated

cc: CSAC members (*via* email)

# State of Alaska

## Controlled Substances Advisory Committee

## White Paper

# Increasing the Effectiveness of Alaska's Prescription Drug Monitoring Program (Alaska's PDMP)

January 29, 2016

1. **Deaths from opiates and heroin are increasing in the U.S.**
   - Since 1990, the annual death rate from drug overdose has more than tripled.[1]
   - Since 2000, the age-adjusted death rate from drug overdose has more than doubled.[2]
   - From 2000 to 2014, almost 500,000 people have died from drug overdoses.[2]
   - Opiates, primarily prescription pain relievers and heroin, are the main drugs associated with overdose deaths.[2]
   - In 2006, the total cost of nonmedical use of prescription opiates was $53.4 billion.[3]
   - Between 2007 and 2013, the prevalence of heroin addiction almost doubled.[4]
   - In 2010, drug related poisoning was the leading cause of unintentional death.[3]
   - Since 2010, heroin death rates have more than tripled.[2]
   - Between 2011 and 2013, 45% of people who used heroin were addicted to prescription opiates.[4]
   - From 2013 to 2014, heroin overdose death rates increased 26%.[2]
   - In 2014, 61% of drug overdose deaths involved some type of opiate, including heroin.[2]
   - In 2014, more persons died from drug overdoses than during any previous year on record.[2]
   - In 2014, there were approximately one and a half times more deaths from drug overdoses than deaths from motor vehicle accidents.[2]
   - Forty-four (44) people die every day from prescription opiate overdoses.[5]

2. **Deaths from opiates and heroin are increasing in Alaska**
   - In 2008, Alaska ranked 5th for highest rate of drug overdose death (18.1 per 100,000).[1]
   - Between 2002 and 2013, the Substance Abuse and Mental Health Services Administration (SAMHSA) estimated that the annual average number of people using heroin increased four-fold (4x) and the annual average number of people with heroin addiction doubled (2x).[6]
   - Between 2008 and 2013, the incidence of heroin-associated deaths more than tripled.[6]
   - Between 2008 and 2013, there were more deaths by prescription opiate overdose and heroin overdose than by motor vehicle accident.[7]

3. **Other public health evidence of opiate and heroin use increasing in Alaska**
   - Between 2004 to 2013, Alaska Medicaid payment requests for heroin poisoning increased almost ten-fold (10x).[6]
   - From 2009 to 2013, substance treatment admissions for Alaskans 21-29 years of age with primary heroin use disorders increased 74% and heroin arrests increased 140%.[6,8]
   - Between 2010 and 2012, inpatient hospital discharge rates for heroin poisoning increased almost six-fold (6x).[6]

**4. Outbreak of HIV and Hepatitis C in Indiana**

Sharing syringes and injection paraphernalia increase the risk of being exposed to HIV and viral hepatitis.[9] Austin, Indiana (population 4,300) experienced an outbreak of HIV and Hepatitis C in 2015.[7] The majority of new cases (more than 170) were due to syringe sharing among individual who had injected the prescription oral opiate oxymorphone.[10] The lifelong medical care costs for treating the new cases of HIV and Hepatitis C will be more than $80 million (more than $470,000/new case).[10]

**5. What is the link between heroin and prescription opiates?[11]**

- Ninety-six percent (96%) of people who use heroin use at least one other drug in the past year with sixty-one percent (61%) using at least three other drugs.
- Misusing a prescription opiate is the strongest risk factor for a heroin use disorder.
- People who abuse or are dependent on prescription opiates are forty times (40x) more likely to use heroin than people who do not misuse prescription opiates.
- People who abuse or are dependent on:
    - alcohol are two times (2x) more likely to use heroin.
    - marijuana are three times (3x) more likely to use heroin.
    - cocaine are fifteen times (15x) more likely to use heroin.

**6. How do people who misuse prescription opiates obtain prescription opiates?[1]**

- Less than five percent (5%) obtain them from a stranger or "drug dealer."
- More than seventeen percent (17%) obtain them from one health care provider.
- More than seventy percent (70%) obtain them from a friend or relative.

**7. Who is at highest risk for prescription opiate overdose?[1]**

People at highest risk for prescription opiate overdose include:

- People who obtain multiple controlled substance prescriptions from multiple providers.
- People who take high daily doses of prescription opiates.
- People who misuse multiple abuse-prone prescription medications.
- People with substance use disorders or a history of substance use disorders.
- People with mental illness.
- People on Medicaid.

**8. What can be done to reduce hospitalizations and deaths from prescription opiate and heroin overdose?**

Several public health measures reduce the risk of opiate prescription misuse, heroin use, and overdose death:

- Increase medical professional training regarding pain management and the risks associated with opiate medications.
- Increase screening for and access to treatment for opiate and heroin addiction, including medication-assisted treatment (MAT).
- Improve recognition and management of acute opiate and heroin overdoses: the physical effects of these overdoses can be reversed with the drug naloxone (Narcan). Increasing the availability of naloxone can reduce the risk of death after overdose.

- Maximize PDMP database utilization to identify:
    - Prescription opiate misuse such as high dose opiate prescribing without medical justification.
    - Prescription opiate misuse such as long-term opiate therapy that may be inappropriate or outside commonly recognized standards of care.
    - Prescription opiate abuse.
    - Prescription opiate diversion.
    - Prescriptions for other controlled substances (medications) that may be inappropriate or outside commonly recognized standards of care.

**9. What is a prescription drug-monitoring program (PDMP)?**

- A PDMP is a state public health effort to facilitate appropriate prescribing and dispensing of controlled substances. A PDMP includes a centralized electronic database of prescribed and dispensed controlled substances (medications).
- PDMPs improve clinical decision-making, reduce "doctor shopping," reduce controlled substance (medication) misuse, and help identify controlled substance (medication) diversion.[3]
- Several states established PDMPs beginning in the 1990s. Currently, forty-nine (49) states have operational PDMPs.[3]
- In an impact survey of the Indiana PDMP, ninety percent (90%) of medical professionals who responded, prescribed fewer controlled substances (medications) and fifty percent (50%) reported the PDMP was the primary reason for the decrease.[3]
- In an impact survey of the Maine PDMP, ninety-seven percent (97%) of prescribers and dispensers who responded, rated the PDMP useful in monitoring medication prescriptions and identifying and reducing doctor shopping.[3]
- Kentucky, Florida, Oklahoma, and Washington all reported decreased opiate overdose death rates, at least partially attributable to requiring prescriber PDMP registration and utilization.[3]

**10. Does Alaska have a PDMP?**

Yes, the Alaska Prescription Drug Monitoring Program (Alaska PDMP) was established in 2008 (AS 17.30.200). The Board of Pharmacy manages the Alaska PDMP. Alaska's PDMP goals are to identify:

1. Prescribing and dispensing practices and patterns regarding controlled substances (Alaska Schedule IA-VA and Federal Schedule I-V medications).*

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* Pursuant to AS 17.30.200, Alaska's PDMP gathers prescription information for every prescription for a "schedule I, II, III, IV, or V controlled substance under federal law." The committee recognizes that federal schedule I controlled substances are defined as drugs with "no currently accepted medical use in treatment" and have "a high potential for abuse." Accordingly, such drugs are not monitored within the PDMP. However, in an effort to ensure consistency with the enabling statute, the committee has mirrored the language of AS 17.30.200 with regard to the monitored controlled substances.

2. Practitioners who prescribe controlled substances in an unprofessional or unlawful manner.
3. Individuals who receive prescriptions from licensed practitioners and who obtain controlled substances from a dispenser or pharmacy in quantities or frequencies inconsistent with generally recognized standards.
4. Individuals who present forged, false, or altered prescriptions for controlled substances.

Alaska's PDMP has a centralized electronic database containing the following information:

1. Name and federal Drug Enforcement Administration (DEA) registration number of the prescriber (MD, DO, ANP, RNA, PA, DDS, DVM, and DPM).
2. Date the prescription was ordered.
3. Date the prescription was filled and dispensed.
4. Name, address, and date of birth of the person for whom the prescription was ordered.
5. Name, strength, and quantity of the controlled substance dispensed.
6. Dispensing practitioner (most commonly RPh) and the location where dispensed.
7. The patient's method of payment.

All pharmacies and dispensing practitioners are required to report the controlled substance dispensing information to the PDMP by no later than the fifth day of each month. The Board of Pharmacy or licensing board may take disciplinary action against a dispenser failing to submit information to the PDMP database as required.

Federal funding from the Substance Abuse and Mental Health Services Administration (SAMHSA) began supporting the Alaska PDMP in 2015. Federal funding may increase if PDMP utilization increases.

**11. Who uses Alaska PDMP data?**

- Only licensed prescribers (most commonly MD, DO, ANP, PA, DDS) and licensed dispensers (most commonly Pharmacists) who have registered with the Alaska PDMP may access the Alaska PDMP database. Both registering and reviewing controlled substance prescription information within the Alaska PDMP is voluntary.
- Approximately 13.5% of prescribers are registered with the PDMP. These prescribers review the database regarding specific patients in their care.
- Approximately 40% of dispensers (pharmacists) are registered with PDMP. These dispensers (pharmacists) review the PDMP database regarding patient specific prescriptions for controlled substance (medication) before dispensing.
- Information in the database is confidential and not subject to public disclosure. Unauthorized access and disclosure of PDMP database information is unlawful.
- Federal, state, and local law enforcement authorities must obtain a search warrant, subpoena, or court order prior to obtaining Alaska PDMP data.
- The Alaska Legislature receives non-clinical Alaska PDMP performance measures annually.

Dispensers and practitioners may not be held civilly liable for damages for accessing or not accessing information in the PDMP database.

A person with authority to access the PDMP database who knowingly accesses information in the database beyond the scope of that person's authority commits a class A misdemeanor. A person with authority to access the PDMP database who knowingly accesses information in the database and recklessly discloses the information to a person not entitled to access or to receive the information commits a class C felony. A person who knowingly allows another person who is not authorized to access the PDMP database to access the database commits a class C felony. A person without authority to access the PDMP database who knowingly accesses the database or knowingly receives database information from another person commits a class C felony.

**12. What is the Controlled Substances Advisory Committee (CSAC)?**

The CSAC was established in 1982 (AS 11.71.100-11.71.120). CSAC goals are to:

1. Advise the governor about adding, deleting, and rescheduling controlled substances.
2. Recommend regulations to the Board of Pharmacy regarding the prevention of excessive prescribing and the diversion of controlled substances.
3. Evaluate the effectiveness of treatment resources for persons with controlled substance use disorders.
4. Evaluate the enforcement policies and practices regarding crimes involving controlled substances.
5. Review budget requests and recommend appropriations regarding:
    a. Enforcing criminal laws pertaining to controlled substances.
    b. Providing treatment and counseling of persons who abuse controlled substances.
    c. Regulating the legitimate handling of controlled substances.

**13. How could Alaska's PDMP be more effective?**

Alaska's PDMP was created to improve patient care and reduce misuse, abuse, and diversion of controlled substances. Alaska PDMP effectiveness is limited by:

1. Registering with the Alaska PDMP is voluntary. Only 13.5% of prescribers and 40% of dispensers have registered with the PDMP.
2. Prescribers and dispensers are not permitted to delegate PDMP access to an employee.
3. The Alaska PDMP is not permitted to notify prescribers or dispensers regarding specific patients who may be at high risk of controlled substance prescription misuse, addiction, or diversion (i.e., unsolicited notification).
4. The Alaska PDMP database is not updated in real time. Database updates may be delayed for up to one month.
5. The director of the State of Alaska Medicaid Pharmacy Program is not permitted access the PDMP database.
6. The State of Alaska Medicaid Drug Utilization Review Committee is not permitted access to the PDMP database.
7. The State of Alaska Medical Examiner is not permitted access to the PDMP database.

8. No State of Alaska public health agency is permitted access to the PDMP database.

The CSAC believes increasing PDMP utilization will increase PDMP effectiveness.

Greater PDMP utilization has reduced prescription opiate misuse, addiction, overdose, and death in states with higher PDMP utilization.

Research shows that there is a direct correlation between heroin use and prescription opiate addiction. The CSAC believes increasing PDMP utilization will reduce prescription opiate addiction and will reduce the number of people switching from prescription opiate use to heroin use.

**14. The CSAC recommends the following modifications to Alaska's PDMP:**

1. Require all prescribers and all pharmacists to register with the Alaska PDMP.
2. Require prescribers and pharmacists to review the PDMP database when prescribing or dispensing a controlled substance to a patient.
3. Authorize prescribers and pharmacists to delegate database access to supervised employees or clinical staff.
4. Authorize the Board of Pharmacy to forward unsolicited notifications to prescribers and dispensers database information about patients who may be obtaining controlled substances inconsistent with generally recognized standards of care.
5. Collect dispensing data and updating the PDMP database weekly.
6. Authorize PDMP database access to the State of Alaska Medicaid Pharmacy Program.
7. Authorize PDMP database access to the State of Alaska Medicaid Drug Utilization Review Committee.
8. Authorize PDMP database access to the State of Alaska Medical Examiner.
9. Authorize de-identified PDMP data access to the State of Alaska Department of Health and Social Services (Alaska DHSS) Division of Public Health.

The American Medical Association Task Force to Reduce Opioid Abuse urges states and providers to utilize prescription drug monitoring programs to reduce prescription drug misuse, overdose, and death.[12]

A partial list of Task Force members includes:

- American Academy of Family Physicians
- American Academy of Hospice and Palliative Medicine
- American Academy of Orthopaedic Surgeons
- American Academy of Pain Medicine
- American Academy of Pediatrics
- American College of Emergency Physicians
- American Dental Association
- American Medical Association
- American Osteopathic Association
- American Psychiatric Association
- American Society of Addiction Medicine

- American Society of Anesthesiologists

Each modification requires a statutory change to AS 17.30.200.

**15. Require all prescribers and all dispensers register with the Alaska PDMP**
The Alaska PDMP cannot meet its mandate or reach its full potential if underutilized.

Forty-nine (49) states have operational PDMPs.[3] When prescriber and dispenser registration is voluntary, less than fifty percent (50%) of possible prescribers and dispensers register.[13]

As of June 2014, all prescribers are required to register for their state PDMP in twenty (20) states.[13]

Registering for Alaska's PDMP is voluntary. 13.5% of Alaska prescribers and 40% of Alaska dispensers have registered with the PDMP. Requiring PDMP registration will increase registration to one hundred percent (100%).

Registering for Alaska's PDMP may be done on line. Linking PDMP registration with state professional licensing application or renewal would facilitate PDMP registration.

Some prescribers may oppose mandatory PDMP registration believing it an intrusion into clinical practice, workflow, and threaten patient privacy and confidentiality. Evidence supports the benefits of a state PDMP with high utilization. Reaching out to the medical community and other stakeholders will increase awareness and support for PDMP utilization.

**16. Require prescribers and dispensers review the PDMP database[13]**
Twenty-two (22) states require PDMP database review by prescribers and sometimes dispensers.[13]

Nevada requires prescribers review the PDMP database when "the practitioner has a reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition."

Oklahoma requires prescribers and dispensers review the PDMP database when prescribing, administering, or dispensing methadone.

Kentucky requires prescribers review the PDMP database before prescribing any Federal Schedule II drug and any Federal Schedule III drug containing hydrocodone and then every three months before prescribing refills. Between 2012 and 2013 prescriptions for controlled substances (medications) decreased more than eight percent (8.5%).

Tennessee requires prescribers review the PDMP database when first prescribing opiates and benzodiazepines for more than seven days and at least annually thereafter if prescribing

continues. Between 2012 and 2013 there was a thirty-six percent (36%) decrease in patients going to multiple prescribers and seeking the same prescription medications.

Some prescribers may oppose requiring PDMP database review believing that it as an intrusion into clinical practice and workflow. Permitting prescribers to delegate PDMP access to supervised employees may reduce concerns about the impact on clinical practice and workflow.

The CSAC believes communicating and coordinating with the medical community and other stakeholders before implementing any change is recommended. PDMP education, negotiation, and consensus building will improve Alaska PDMP awareness, utilization, and effectiveness.

The CSAC believes this will reduce controlled substance misuse, addiction, and diversion. The CSAC believes this will reduce opiate overdose deaths and the incidence of patients switching from prescription opiate use to heroin use.

**17. Authorize PDMP database access to supervised employees (delegates)**
Prescribers and dispensers may be concerned that reviewing the PDMP database will negatively impact clinical practice and workflow. Accessing and reviewing PDMP data may be perceived as time consuming.

Thirty-six (36) states authorize prescribers and dispensers to delegate PDMP database access to employees.[14] Employees (delegated users) input patient names to download PDMP data for prescribers and dispensers. Prescribers and dispensers are responsible for their employees' (the delegated users) use of PDMP information.

"Delegate accounts, properly supervised and maintained..., are a secure and effective means to increase PDMP utilization."[14]

At some point in the future, the PDMP database will likely be automatically incorporated into electronic health records.

**18. Authorize the PDMP to forward unsolicited reports to prescribers and dispensers**
A solicited report is a report initiated by a query from a prescriber or dispenser registered with the PDMP. The registered prescriber or dispenser is seeking PDMP database information about a specific patient. Solicited reports are most commonly on-line queries. The specific patient's PDMP information is most commonly provided instantaneously on-line.

An unsolicited report is a report initiated by the PDMP in response to specific patient prescription and dispensing patterns, specific prescriber patterns, and specific dispenser patterns. Possible end users of unsolicited reports include prescribers, dispensers, licensing boards, law enforcement, and public health agencies.

Thirty-eight (38) states authorize PDMPs to forward unsolicited notifications to one or more end users.[15]

Beginning in 2005, the Maine PDMP began sending prescribers written quarterly reports via the U.S. Postal Service.[15] The Maine PDMP reports are sent to prescribers who are prescribing for specific patients when the patient:

- Receives multiple prescriptions from multiple prescribers and uses multiple dispensing pharmacies.
- Is prescribed an unusually high average daily dose of an opiate.
- Is prescribed buprenorphine concurrent with another opiate.

The Maine PDMP report lists all providers, all pharmacies, and the details of all prescriptions during the prior three-month period.

In a 2009 survey[15] of Maine prescribers, a "substantial proportion" of those who had received a PDMP report took action because of the notification. The action taken was one or more of the following:

- Checking the PDMP database regarding that patient's prescription history.
- Calling other prescribers who had prescribed for the patient.
- Talking to the patient.
- Conducting a substance abuse screen and providing a brief intervention.

Between 2011 and 2012, the number of suspected "doctor shoppers" in Maine declined thirty-two percent (32%).[15]

**19. Real Time Data Collection**

The Alaska PDMP currently requires all dispensers (primarily pharmacies) to monthly report controlled substances dispensed. This means that the Alaska PDMP database may be up to four weeks out of date.

Most state PDMPs receive dispenser (primarily pharmacy) updates every 1-2 weeks.[16] Real time data collection and database updating may need to wait until health information technology facilitates this process. The CSAC recommends updating the PDMP database weekly.

**20. Permit database access by the State of Alaska Medicaid Program**

The State of Alaska Medicaid program currently has a Pharmacist Director and one supporting staff Pharmacist. The Medicaid Pharmacist Director:

1. Coordinates the Pharmacy & Therapeutics Committee.
2. Assists in coordinating the Drug Utilization Review Committee.
3. Supervises the prior authorization process.

Granting access to the PDMP for the State of Alaska Medicaid Pharmacy program would:

- Improve awareness of prescribing patterns and dispensing by prescribers and dispensers for patients in Alaska Medicaid.

- Increase awareness of those paying cash (not using their Medicaid benefits) for acquiring controlled substances.

National data indicate that people on Medicaid are prescribed opiates at twice the rate of non-Medicaid patients and are at six times the risk of prescription opiate overdose.[1]

**21. Permit database access by the State of Alaska Medicaid Drug Utilization Review Committee**

The Alaska Medicaid Drug Utilization Review Committee (Medicaid DUR) was created in 1990. The Medicaid DUR Committee conducts prospective and retrospective analyses to address safety, fraud, waste, abuse, misuse, and medically unnecessary care. The Medicaid DUR Committee is limited to prescribing and dispensing activities paid by Alaska Medicaid.

PDMP database access by the Medicaid DUR Committee would improve the ability to identify:

- Medicaid beneficiaries paying cash for controlled substances (medications).
- Medicaid beneficiaries obtaining possibly unnecessary medical care paid by Medicaid to obtain possibly unnecessary prescriptions for controlled substances paid by cash.

**22. Permit database access by the State of Alaska Medical Examiner**

The Alaska Medical Examiner investigates unexplained and/or unexpected deaths, and currently, the Medical Examiner (and/or staff) must obtain a search warrant, subpoena, or court order prior to receiving Alaska PDMP data.

Alaska's death rate from opiates and heroin is increasing. Between 2008 and 2013, there were more deaths in Alaska by prescription opioid and heroin overdoses than by motor vehicle accident.[7] Permitting access to the PDMP database is consistent with the Alaska Medical Examiner's role in investigating unexplained and/or unexpected deaths.

**23. Permit database access by the State of Alaska Department of Health and Social Services Division of Public Health**

The Alaska Department of Health and Social Services (DHSS) Division of Public Health does not have access to the Alaska PDMP database.

State PDMPs differ on their use of PDMP data to meet public health objectives. Common public heath objectives regarding controlled substances (prescription medications) include:

- Epidemiological surveillance to measure and track the incidence and prevalence of nonmedical use of prescription medications.
- Education about prescribing trends and raising awareness regarding the misuse of prescription medications.
- Early recognition and intervention of the possible misuse of prescription medications.
- Prevention of circumstances that increase the risk of prescription medication misuse, addiction, and overdose.
- Coordinate with federal and multistate efforts to prevent and reduce prescription medication misuse, addiction, and overdose.

The Division of Public Health could use de-identified data to meet public health objectives regarding controlled substances including prescription opiates. De-identified data could be similar to Medicaid DUR Committee data in that it is not identifiable data (de-identified regarding patient identity, prescriber identity, dispenser identity, and dispenser location).

**24. Summary and Suggestions**

PDMPs are increasingly utilized by states to improve clinical care and outcomes and to reduce controlled substances misuse, addiction, and overdose fatalities. Alaska has had a PDMP since 2008. But, only 13.5% of prescribers and only 40% of dispensers have registered with the Alaska PDMP. The Alaska PDMP permits access and review of the PDMP database only to providers who are registered with the Alaska PDMP. Providers who have registered with the Alaska PDMP must then query the system about specific patients.

The Alaska PDMP will be more useful and effective if database utilization is higher by:

- ✓ Requiring prescribers and dispensers to register for the PDMP.
- ✓ Requiring prescribers and dispensers to access and review the PDMP database.
- ✓ Permitting prescribers and dispensers to delegate PDMP database access by employees.
- ✓ Permitting the PDMP to alert providers of patients who may be at risk of misusing controlled substances (prescription medications).
- ✓ Updating the PDMP database weekly.
- ✓ Permitting PDMP database access by the Alaska Medicaid Pharmacists.
- ✓ Permitting PDMP database access by the Alaska Medicaid Drug Utilization Review Committee.
- ✓ Permitting PDMP database access by the Alaska Medical Examiner.
- ✓ Permitting access to de-identified PDMP data by the Alaska Department of Health and Social Services Division of Public Health.

The CSAC does not have recommendations regarding negative consequences for prescribers, dispensers, or pharmacies not adhering to the recommended PDMP changes should they be enacted.

Finally, Alaska's PDMP does not replace the necessity of evaluating and treating substance use disorders and does not replace controlled substances law enforcement.

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THE STATE of ALASKA
GOVERNOR BILL WALKER

**Department of Commerce, Community, and Economic Development**

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

**ALASKA PRESCRIPTION DRUG MONITORING PROGRAM**
Alaska Board of Pharmacy
550 West Seventh Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Main: 907.269.8404
Fax: 907.269.6003
akpdmp@alaska.gov

TO: 29th Alaska State Legislature

FROM: Alaska Board of Pharmacy

CC: Kevin Meyer, Senate President
Mike Chenault, House Speaker

DATE: February 11, 2016

RE: 2016 Alaska Prescription Drug Monitoring Program Report

The controlled substance prescription database was created by Senate Bill 196 and established within the Board of Pharmacy (Board). Statute states:

**Alaska Statute 17.30.200. Controlled substance prescription database.** (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule IA, IIA, IIIA, IVA, or VA controlled substance under state law or a schedule I, II, III, IV, or V controlled substance under federal law dispensed in the state to a person other than those administered to a patient at a health care facility. The Department of Commerce, Community, and Economic Development shall assist the board and provide necessary staff and equipment to implement this section.

The database operates under the name of "Alaska Prescription Drug Monitoring Program" (AKPDMP) and is a statewide electronic database that gathers information from in-state and out-of-state pharmacies (or dispensers) on dispensed prescriptions for controlled substances. AKPDMP's purpose is to improve patient care by providing prescribers and pharmacists with a controlled substance dispensing history for their patients. An additional goal is to reduce drug diversion and inappropriate use of controlled substances by assisting in the investigation of specific cases.

AS 17.30.200 (6)(g) requires that the Board notify the Legislature if federal funding fails to pay for all or part of the costs of the database. The federal funding for the AKPDMP ended on August 31, 2013, and the board submitted notification in accordance with statute.

During FY2015, the Division of Corporations, Business and Professional Licensing (Division), Board of Pharmacy (Board), and the Department of Health and Social Services (DHSS) collaborated to compete for a federal grant. They were successful, and the grant is currently funding the AKPDMP. This is accomplished via a Reimbursable Services Agreement (RSA) from the Department of Health and Social Services who was the recipient of the grant. The grant funds the program from FY2016 to FY2021; however, after that time, new funding will need to be obtained.

In a separate collaboration, the Board and Division have partnered with DHSS to pursue an additional federal grant to continue funding for the program, augmenting the deliverables to include staffing and a more robust role in the state's opioid control initiatives.

The Board requests that the Legislature be aware of the ongoing need for sustainable funding that is in line with the legislative intent of Senator Lyda Green.

*It is the intent of the Legislature that the Alaska Prescription Drug Monitoring Program be funded with federal grants and state appropriations. It is not the intent of the Legislature that the professional users of the database absorb the costs of managing this public program through their license fees or other fee structure.*[1]

The AKPDMP began using a new vendor to provide prescription monitoring services for Alaska. The new vendor was able to provide the same services for $8,500 less annually than the State previously paid for the service, recognizing a $42.5K cost savings over the five year life of the contract. The Division chose to use the PMP AWARxE prescription monitoring program software, maintained by Appriss. More information about Appriss and PMP AWARxE can be accessed by visiting http://www.appriss.com/pmpaware.html.

APPRISS began collecting data from dispensers on January 21, 2016, and began allowing practitioners and pharmacists to obtain AKPDMP reports on patients under their care on January 25, 2016.

To maximize the AKPDMP for future availability and the effective use of data among the widest range of appropriate end users, several recommended changes have been identified by the board:

- Enact legislation to maintain sufficient funding over time
- Delegate access[2]
- Transmit unsolicited reports and alerts to *appropriate* users
- Improve data timeliness and access; increase reporting to weekly
- Provide enhanced education, enrollment, and use of AKPDMP to all users or data requestors.
- Streamline certification and enrollment processing
- Optimize reporting to fit user needs
- Publicize use and impact of AKPDMP via websites, presentations, and reports
- Incorporating AKPDMP data within health information exchanges, electronic health records and pharmacy dispensing systems.

Thank you for your consideration of these ideas as you evaluate how to increase the effectiveness of the program and improve public safety. The following pages provide data on the number of registered users of the AKPDMP, reports, reasons for requested reports, and patients receiving prescriptions.

If you have any questions regarding this data or the suggested areas for improvement, please contact the Program Manager Brian Howes at 907-269-8404 / akpdmp@alaska.gov.

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[1] http://www.legis.state.ak.us/basis/get_fm_page.asp?session=25&bill=SB196&grn=1785&hsc=S

[2] Allowing prescribers to delegate access to AKPDMP records by office staff (sometimes called "sub-accounts"), may help increase utilization of AKPDMP data to detect patients at risk and improve prescribing.

***Registered Users***

| Registered Users | 2014 | 2015 | Change |
|---|---|---|---|
| Prescribers | 923 | 1,122 | 22% ↑ |
| Dispensers | 343 | 442 | 29% ↑ |
| **Total** | **1,266** | **1,564** | **24% ↑** |

***Licensed Pharmacies***

| Pharmacies | 2014 | 2015 | Change |
|---|---|---|---|
| Drug Room | 33 | 36 | 9% ↑ |
| Out of State Pharmacies | 500 | 583 | 17% ↑ |
| Pharmacy | 132 | 138 | 5% ↑ |
| Remote Pharmacy | 1 | 1 | 0% ↔ |
| Pharmacy Certification(s)[3] | 120 | 143 | 19% ↑ |

***Solicited Reports***

Providing AKPDMP data, over a given date range, to an authorized user based upon their request for the information is called a solicited report. The reports can be produced through an automated online system; bodies that directly receive these reports are registered prescribers and dispensers. Upon certification of an open investigation and the submittal of a *search warrant, subpoena, or court order,* this information may be released to law enforcement and/or regulatory boards. Finally, a patient may also request a report of his or her own prescription information, upon payment of a $10 fee.

| Number of Solicited Reports | 2014 | 2015 | Change |
|---|---|---|---|
| Pharmacists | 38,615 | 43,831 | 14% ↑ |
| Prescribers | 45,145 | 69,282 | 53% ↑ |
| Law Enforcement/Regulatory | 10 | 8 | -20% ↓ |
| **Total** | **82,760** | **112,671** | **36% ↑** |

| Reason for Request *(Law Enforcement/Regulatory)* | 2014 | 2015 | Change |
|---|---|---|---|
| Forged Prescription | 4 | 1 | -75% ↓ |
| Stolen Prescription | 2 | 0 | -100% ↓ |
| Doctor Shopper | 1 | 3 | 200% ↑ |
| Drug Diversion | 2 | 0 | -100% ↓ |
| Addiction | 0 | 0 | 0% ↔ |
| Other | 1 | 4 | 300% ↑ |
| **Total** | **10** | **8** | **-20% ↓** |

***Unsolicited Reports***

The purpose of an unsolicited report is to provide prescribers and pharmacists with additional information that they may choose to use in their clinical decision-making. Unsolicited reports typically uses a threshold as a reference for sending such a report, e.g. number of prescribers from whom a patient has obtained a controlled substance prescription, and the number of pharmacies that have dispensed the prescriptions, in a specified period of time, to a patient.

[3] Pharmacies certifying (yearly) that they do not dispense controlled substances and so they do not report to the AKPDMP; it contains an agreement that they will begin reporting if their business practice changes.

The Board has established its threshold (or reference) as *a patient who obtained a controlled substance from five (5) prescribers and five (5) pharmacies in a three (3) month period.* [4]

The Board is aware that the Department of Law has expressed some concerns regarding the Board's ability to send out this unsolicited report and does support a change in the statutory authority to allow it. Proactive reporting of AKPDMP data to prescribers and pharmacists can serve to inform them of possible questionable activity and patients at risk, increase their awareness and utilization of the AKPDMP, and contribute to lower rates of questionable activity as measured by the subsequent number of individuals meeting a threshold and prescriptions obtained by suspected "doctor shoppers".[5]

| **Number of patients receiving prescription(s)** | **2014** | **2015** | **Change** |
|---|---|---|---|
| CII | 134,524 | 202,141 | 50% ↑ |
| CII, III | 154,831 | 238,581 | 54% ↑ |
| CII, III and IV | 243,546 | 429,185 | 76% ↑ |
| **Total** | **534,915** | **869,907** | **63% ↑** |
| **Number of patients exceeding 5/5 threshold** | | | |
| CII | 313 | 61 | -81% ↓ |
| CII, III | 365 | 71 | -81% ↓ |
| CII, III and IV | 525 | 103 | -80% ↓ |
| **Total** | **1203** | **235** | **-80% ↓** |
| **Number of patients exceeding 10/10 threshold** | | | |
| CII | 4 | 1 | -75% ↓ |
| CII, III | 4 | 1 | -75% ↓ |
| CII, III and IV | 5 | 1 | -80% ↓ |
| **Total** | **13** | **3** | **-77% ↓** |

**Morphine Equivalent Dosage (MED) or Minimum Morphine Equivalent (MME)**

Individuals using opioid analgesics for extended periods of time are at increased risk of dependency, overdose, and death. Patients using opioids in excess of 100mg of a total daily Morphine Equivalent Dosage (MED) are at significant risk of overdose; however, even utilization at lower doses presents risk to the patient.(*Page 1, Alaska Medicaid Prior Authorization Criteria*)[6] "An MED is a numerical standard against which most opioids can be compared, yielding an apples-to-apples comparison of each medication's potency. Although it's easy to presume that 10 mg of medication A are equal to 10 mg of medication B, differences in how opioid medications work in the body prohibits this sort of comparison, thus the need for calculating the MED of each. It is not about a medications efficacy or how well it works, but about its relative potency." (*Page 1, Shining a Light on MEDs / www.helioscomp.com*)[7]

| **Distribution of painkillers greater than 100-mg (MED), per day** | **2014** | **2015** | **Change** |
|---|---|---|---|
| Adult | 117 | 89 | -24% ↓ |
| Youth[8] | 2 | 1 | -50% ↓ |

[4] 5/5 or 10/10
[5] Doctor shopping is defined as seeing multiple treatment providers, either during a single illness episode or to procure prescription medications illicitly.
[6] http://dhss.alaska.gov/dhcs/Documents/pharmacy/pdfs/Extended-Release-Opioids-PA_201504_APPROVED.pdf
[7] http://helioscomp.com/docs/default-source/White-Paper/cln14-15209_med-white-paper_final.pdf?sfvrsn=8
[8] Youth - patients that are under 18 years of age as of the date the prescription was filled.

EXPRESS SCRIPTS®

Cynthia Laubacher
Cynthia_Laubacher@Express-Scripts.com

February 29, 2016

To: Representative Paul Seaton, Chair
Representative Liz Vazquez, Vice Chair
House Health & Social Services Committee

From: Cynthia Laubacher, Senior Director – State Affairs
Express Scripts Holding Company

Re: House Bill 344: Controlled Substances Prescription Database
Hearing: March 1, 2016 3:15pm

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I write today on behalf of Express Scripts, one of the nation's leading pharmacy benefits managers and mail service pharmacies. Express Scripts administers prescription drug benefits on behalf of our plan sponsors – employers, health plans, unions and government health programs — for tens of millions of Americans. While we support the intent behind HB 344, we have a major concern with the reporting provision.

Express Scripts dispenses controlled substances through our mail service pharmacies to patients around the world. We have very powerful data analysis and reporting tools that allow us to flag situations that could indicate abuse, whether in the actions of physicians, pharmacies, or patients. Our Fraud, Waste and Abuse solutions help us identify doctors who are prescribing many more opioids than their practice would warrant, "pill mill" pharmacies that are filling them, and patients who may be drug seeking by visiting multiple doctors and pharmacies across a larger than expected geography.

HB 344 would require our mail service pharmacies to report in "near real time" when dispensing a controlled substance. While it is unclear as to what is meant by "near real time", in the case of mail service pharmacies, that means we're reporting before the patient receives the medication. Therefore, we respectfully request the bill be amended to allow mail service pharmacies 72 hours to report to the database. We are not opposed to checking the database before dispensing, nor to reporting, but simply ask that we be allowed additional time to report to the database given the volume we deal with as opposed to a retail pharmacy that may fill one or two prescriptions a day.

With this change, we would be pleased to support this important legislation. Please feel free to contact me with any questions. Thank you for your consideration of our concerns.

**Eric P. Douglas**
Senior Director, Government Affairs

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The Honorable Representative Paul Seaton
Chair, House Health & Social Services Committee

Tuesday, March 1, 2016

**RE: HB 344 – Prescription Monitoring Program ("PMP")**

Chair Seaton, Vice Chair Rep. Liz Vazquez and members of the Committee:

CVS Health appreciates the opportunity to testify on HB 344. We are in support of the delegation of an agent or employee of the pharmacist to be permitted to access the PMP database. However, as currently written, this bill is burdensome and can cause delay in therapy for a patient with a legitimate controlled substance prescription. Here are our suggested changed to the bill:

- **Submission to the "database at near real time to when the prescription is dispensed" as drafted in AS 17.30.200(b) is not ideal. Submission of batch file reporting data by the next business day from the date sold, not dispensed, is a common, achievable and preferred reporting timeline.**
  - Language amendment suggested "database batch file reporting by the next business day when the prescription is sold" as an alternative for AS 17.30.200(b)

- **AS 17.30.200 (k) currently requires the pharmacist and practitioner or delegate to access the database before dispensing a controlled substance and enter the prescription into the database at near real time to when a controlled substance is dispensed under (b) of this section.**
  - Pharmacist or delegate should only have to access the PMP database when in their professional judgement, red flags are identified and further review is needed prior to dispensing
  - Limit to opioid as seen in other states (this currently includes all controlled substances)
  - CVS Health offers the same comment as above for the real time submission at time of dispensing.

- **There is no provision for mandatory review of the database by the prescriber prior to prescribing a controlled substance.**

- We would suggest adding or alternate language that the prescriber shall access the database for review of the patient initially upon prescribing and annually thereafter.
- Prevents the prescription from being written by the practitioner

- **Add language to provide and exception to when the PMP, internet or pharmacy system has lost connectivity and the PMP cannot be accessed**

- **Add exception language for patients who are institutionalized, which includes those in a nursing home or assisted living facility.**

- **Also request an amendment to AS 17.30.200(b)(8). This requires the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information to be reported to the database. CVS Health seeks removal of the words "*and other appropriate identifying information*" as this has been determined to be the license number of the pharmacist and the NPI (National Provider Identification), if the Pharmacist has one, which is not a requirement in other states. Or, alternatively we would minimally seek an exemption be added for nonresident pharmacies, as the pharmacists are not required to be licensed in Alaska and are simply reporting their resident state license number.**

We thank you for your consideration of our comments.

Respectfully,

Eric P. Douglas

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 1, 2016

The Honorable Paul Seaton
Honorable Members of the House Health and Social Services Committee
Alaska State House of Representatives
Juneau, AK

RE: House Bill 344 – Relating to the Controlled Substance Prescription Database

Chair Seaton and Members of the Committee:

On behalf of the members of the National Association of Chain Drug Stores (NACDS) operating in the State of Alaska, I would like to offer our comments on House Bill 344, which deals with substantive changes to the Controlled Substance Prescription Database.

NACDS Members in Alaska operate 78 pharmacies, employ over 9,000 full and part-time employees, and pay over $12 million in state taxes.

Our members, based on their comments are very supportive of delegating access to the CS Prescription Database. In many respects this will free pharmacists and prescribers up to focus on other discretionary tasks more pertinent to their scope of practice.

Members concerns stem from the proposed changes in Sections 1 and 5 regarding "near real time" and "access the data base to check a patient's prescription records before **dispensing** a controlled substance to the patient".

Reporting on a daily basis, not "near real time" is something that realistically can be done by both chain and independent pharmacies. At least 30 states require reporting on a daily basis. Going from monthly reporting to daily reporting would be a more realistic change. In addition, rather than make this change in legislation, the change can be made in rule by the Board of Pharmacy.

12 AAC 52.865. Requirement for dispensers.

(c) ~~No later than the fifth day of each month~~, A dispenser shall report on a daily basis to the board the controlled substance dispensing information required under AS 17.30.20 (b). ~~concerning controlled substances dispensed during the previous month.~~ The requirement in 12 AAC 02.920(b) for time computation applies to a report made under this section.

This change to the rules would address the language in both section 1 and 5 with regard to "near real time" and allow timely reporting to the database.

In section 5, we would respectfully request that pharmacists not be required to check the database prior to the dispensing of a controlled substance. This function is better performed at the time of prescribing, prior to a prescription being written.

At least 22 states have mandated the prescriber (not the pharmacist) check the database when issuing a controlled substance prescription, and understand that is a more effective approach to preventing prescription drug abuse.

Many of these states require prescribers or their designees to query the database prior to initially prescribing a controlled substance to a new patient. This approach would have a dramatic effect on curtailing "doctor shopping". In cases such as these, the pharmacist becomes the second line of defense by utilizing their professional judgement to look for additional red flags that would also warrant a check.

Language from the state of Nevada could provide a solution to section 5:

*A practitioner shall, before writing a prescription for a controlled substance listed in schedule II, III, or IV for a patient, obtain a patient utilization report regarding the patient for the preceding 12 months from the computerized program established by the Board if the practitioner has reasonable belief that the patient may be seeking the controlled substance, in whole or in part, for any reason other than the treatment of an existing medical condition and:*

1. *The patient is a new patient of the practitioner; or*
2. *The patient has not received any prescription for a controlled substance from the practitioner in the preceding 12 months.*

*The practitioner shall review the patient utilization report to assess whether the prescription for the controlled substance is medically necessary.*

In conclusion, the members of NACDS would respectfully request that the references to "near real time" and mandating the pharmacists check the database prior to dispensing be removed from House Bill 344.

Sincerely,

Lis Houchen
lhouchen@nacds.org
360.480.6990

ALASKA STATE HOSPITAL &
NURSING HOME ASSOCIATION

March 3, 2016

Representative Paul Seaton
State Capitol, Room 102
Juneau, AK 99801

Dear Representative Seaton,

The Alaska State Hospital and Nursing Home Association (ASHNHA) appreciates the work of the House Health and Social Services Committee on HB 344, addressing the controlled substances prescription drug database. We would like to provide some written comments on this legislation.

We fully support the enhanced use of the prescription drug database and the integration of the recommendations from the Controlled Substances Advisory Committee. We support efforts to increase participation in the program and believe that most aspects of the legislation will help further efforts to reduce abuse of controlled substances. However, we want to make sure the legislation does not inadvertently impact the ability of hospitals to meet the needs of patients.

We support Dr. Jay Butler's comments on the need to strike a balance between maintaining access to care and preventing abuse of controlled substances. We are concerned that in some hospital-based contexts, it is not always possible for physicians, pharmacists or their agents to check the patient's prescription record before dispensing, prescribing or administering a controlled substance. Dr. Butler has recommended that some limits be put on the requirement to check the database before dispensing medications. The four areas he recommended to exclude include:

1. Hospital inpatient care,
2. Surgery,
3. Emergency care (EMS, air ambulance and hospital ER) and
4. Hospice care.

We believe these exclusions are important to allow high quality patient care. For example, it may not be feasible for an ER doctor to check the database before providing medication to a trauma patient nor would it be feasible to check the database when providing medication to control pain following surgery. Senate Finance adopted an amendment to SB74 to add exemptions to the reporting requirements based on Dr. Butler's recommendations.

We recognize the need to have more timely data available in the database then the monthly reporting currently in place, but are concerned about whether a "near real-time" requirement

will be feasible immediately. Washington State has a similarly structured Prescription Drug Monitoring program in operation since 2011 that requires reporting weekly. We would support a requirement to report data "at least weekly" as a way to move the program forward with a future goal of real-time entry.

We appreciate the language that allows "an agent or employee" of the pharmacist or practitioner to submit to the database. This language will make compliance more practical. Although concerns have been expressed about allowing non-licensed people (such as pharmacy techs) access to the database, the HIPAA patient privacy protection laws would be in effect and help ensure patient data is not misused. HIPAA applies to all health care workers whether or not they are licensed.

We also appreciate allowing 180 days from the effective date for pharmacists and practitioners to get registered with the database. This seems to be a realistic timeframe.

Finally, the fiscal note recognizes the work involved in getting pharmacists and practitioners registered and in modifying the technology to allow more timely entry and reporting. We hope having a staff devoted to the database will ease the pressure on the Boards with the implementation. Expecting these changes to occur without adequate staffing would not be realistic. We hope the fiscal note adequately accounts for the costs of changing to a system with more frequent reporting.

Please let us know if there is anything we can do to support integrating Dr. Butler's recommendations into the bill and to keep this legislation moving forward.

Sincerely,

Becky Hultberg
President/CEO

**Taneeka Hansen**

---

**From:** Andrew Elsberg
**Sent:** Friday, March 04, 2016 12:06 PM
**To:** Rep. Paul Seaton; Taneeka Hansen
**Cc:** Jay C Butler; Anne Zink; Carl Heine
**Subject:** HB 344

Dear Representative Seaton,

I would like to comment on HB 344 on behalf of the Alaska Chapter of the American College of Emergency Physicians. Dr. Anne Zink, Dr. Carl Heine and I have been involved with the Senate version of the bill which has been incorporated into the overall medicaid expansion bill, SB 74.

Thank you for your work to improve the AK PDMP. We are very happy that the importance of this tool has been recognized by so many legislators. The ability to delegate access will help us access the system more often. There are a few changes to the language that we feel would be appropriate to our practice in the ER.

First I would like to let you know how we use narcotic pain medication in the ED. In general we are using IV medication for acute pain control in an injured or ill patient, and we are prescribing short courses (rare to see a prescription for more than 7 days, and most are for 2-5 days) of oral narcotics for pain control during a painful illness or until an injured patient can follow up with orthopedics or the appropriate specialty. All of the ER's in Anchorage have a policy against managing chronic pain from the ER, and those policies include not refilling chronic medication when a patient runs out early or when medications are "lost" or "stolen". I believe this is the case in other parts of the state as well. ER physicians rarely if ever prescribe long acting pain medication. In 2009 approximately 5% of narcotic pain medication was prescribed nationally from emergency departments. While I do not believe there is a magic time at which a patient develops dependence or addiction, a one time short prescription is likely low risk. The times when patients are at risk for developing dependence from ER prescriptions, or that our prescriptions are at risk for diversion tend to be in patients that are visiting the ER multiple times, especially in patients with subjective complaints.

The current system unfortunately takes about 3-4 minutes for me to look up a patient. When our ER (I work at Providence in Anchorage) is busy, which is most of the time, I am looking to be as efficient as possible, to keep patients from waiting too long, to make sure we see the critical patients quickly, and to keep a patient visit from getting longer than it needs to be. Every member of the staff is maxed out when we are busy, and while delegating PDMP access is helpful, there are times I simply can not add a task to others on the staff. I order only the tests I truly feel I need to order, and in the same vein I only want to access the PDMP when I really need to. 3-4 minutes per patient times 10 patients is 30-40 minutes, thats equivalent to getting 2 patients seen and work up started. So a seemingly small amount of time in our environment adds up quickly.

When I see a patient with a broken leg verified by exam and X-ray I don't feel I need to access the database prior to writing them for 3-5 days of a narcotic pain medication. When I see a patient with a subjective complaint, for whom "ibuprofen doesn't work", things like back pain, dental pain, abdominal pain etc, I absolutely feel I should look that patient up. When a patient has been in the ED more than once for an injury, or a chronic complaint I look the patient up. But I (and my colleagues) are opposed to a mandatory look up because in a busy ER that time is not available. Emergency Physicians who work in more rural places have also pointed out that they have had trouble accessing the system due to internet outages or slow internet. There are times that the PDMP is unfortunately not available to these clinicians.

When I see examples of legislation from other states they have addressed this in a number of ways. Some have an exception for drug administration or prescription »in an emergent situation«. Others have a cutoff, Ohio allows prescriptions less than 7 days to be written without mandatory look up. Some states have chosen to have no mandatory look up. In our environment we truly need the flexibility to use the database only when clinically necessary (subjective complaints, repeat visits, frequent visitors, patients with substance abuse issues and pain).

The way the bill is currently written it is unclear to me if the administration of medication in the ER is included.

From Section 5 "(A) access the database to check a patient's prescription records before dispensing a controlled substance to the patient;"

We are often actively managing an unstable patient or agitated patient before accessing the medical record. Review of the database prior to administration of medication in the ED, ICU, or by EMS, flight services or any other emergent administration should not be covered by the bill.

Alaska ACEP is working with ASHNHA to improve communication between ER's using an ED information exchange (EDIE). This allows a physician to see a patients visits to other emergency facilities in the state, in real time. In Washington state this system also automatically pushes PDMP information. We would like to see such a system in Alaska, although we do understand that adding an administrative cost to the state would likely be prohibitive (despite the later savings from such a system). EDIE that pushes PDMP information when a patient registers at an emergency department would streamline this process. Language to implement an EDIE is included currently in SB74. EDIE has been an important part of Washington states' 7 best practices initiative to save money from repeat evaluations, improve coordination of care and decrease abuse and misuse of narcotics.

Thank you very much for your work to improve the PDMP. As an emergency physician who has faced multiple families following a fatal or life altering overdose I am very glad you are addressing this issue. I hope you do not perceive our input on mandatory review as a lack of perspective on the problem. I treat the complications of IV drug abuse almost every shift. I use the database every shift. I have decreased my narcotic prescribing, and put up with patient complaints to the hospital administration for not prescribing for chronic pain. My goal is only to let you know what being required to review every patient looks like in a real world busy ED.

Respectfully,

Andrew Elsberg, MD

AK Chapter of American College of Emergency Physicians Board
EM Physician Providence Alaska Medical Center
206-661-8942 (c)

THE STATE of ALASKA
GOVERNOR BILL WALKER

Department of Commerce, Community, and Economic Development
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
P.O. Box 110806
Juneau, Alaska 99811-0806
Main: 907.465.2550
Fax: 907.465.2974

March 8, 2016

The Honorable Representative Paul Seaton
Chair, House Health & Social Services Committee
State Capitol Room 106
Juneau, AK 99801

Dear Representative Seaton,

During the House Health & Social Services Committee hearings on March 1, I was asked to follow up on questions concerning HB344 - Drug Prescription Database:

***What is the cost to upgrade to weekly/daily database updating?***

The upgrade was quoted at $2.2 per month or approximately $26.4 per year. We recently received a correction from the vendor that the software modification will only be $2.2 annually.

***Does the fiscal note for HB 344 need to change if the reporting requirement was changed to weekly or daily?***

As the bill is written, it appears that it only requires that dispensers enter the data in near real time, not that the database software be updated near real time. Therefore, the cost to upgrade the software was not included in the fiscal note.

***Is there an issue with the effective date?***

***ISSUE:*** The effective date of January 1, 2017, does not allow enough time for the Board of Pharmacy to adopt regulations, structure the program, notify licensees, and issue a new contract for the database expansion. July 1, 2017, is the earliest this could possibly be accomplished without harming the public or licensees.

***SOLUTION:*** Change the effective date to July 1, 2017, or later. Add the Department of Commerce, Community, and Economic Development, Board of Dental Examiners, Board of Nursing, Board of Examiners in Optometry, Board of Veterinary Examiners, and the State Medical Board to Sec. 7.

We hope this helps to answer some of the questions posed in committee and effectively express the Division's concerns about the bill. If you or any members of the committee have further questions or require additional information about anything provided here, please contact DCCED Special Assistant Micaela Fowler at 465-2503.

Sincerely,

Janey Hovenden
Director

Hi Taneeka,

Attached is our committee follow up for HB 344. Additionally, you had sent a list of questions you had regarding the bill which are answered in the email below

***Is there a list available or easily located which lists all health care positions that are licensed or registered with the board? (from Docs to dental techs/ pharm techs).***

| Heath Care Programs |
|---|
| Athletic Trainers |
| Acupuncturists |
| Audiologists<br>Hearing Aid Dealers*<br>Speech Language Pathologists<br>Speech Language Assistants |
| Behavioral Analysts<br>Assistant Behavior Analysts |
| Chiropractors |
| Social Workers |
| Dental Hygienists<br>Dentists<br>Dental Assistants |
| Dispensing Opticians |
| Dieticians<br>Nutritionists |
| Massage Therapists |
| Medical Physicians<br>Physician Assistants<br>Mobile IC Paramedics |
| Marital and Family Therapists<br>Marital & Family Therapy Associates |
| Certified Direct Entry Midwives<br>Certified Direct Entry Midwives Apprentices |
| Naturopaths |
| Nursing Home Administrators* |
| RN Nurses<br>LPN Nurses<br>Advanced Practitioners<br>CRNA Anesthetists<br>Certified Nurse Aides |
| Optometrists |
| Professional Counselors |
| Pharmacists<br>Pharmacy Intern<br>Pharmacy Technicians<br>Wholesale Drug Dist.* |
| Physical Therapists<br>Occupational Therapists<br>Physical Therapy Assistants<br>Occupational Therapy Assistants |
| Psychologists<br>Psychological Associates |
| *Items Listed in Red are not Licensed Individuals |

***Are Methadone clinics currently required to report to the database, and are they registered?***

No. The federal regulations at 42 CFR Part 2 concern the confidentiality of alcohol and drug abuse treatment records. Section 2.1 states:

> "Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this

section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section."

In short, the information from methadone clinics is considered psychiatric treatment and is therefore protected under federal law CFR 42.

SAMHSA (Substance Abuse and Mental Health Services Administration) is the federal agency that regulates OTP's (Opioid Treatment Programs).

In addition, nothing in 42 CFR Part 2 prevents a physician or pharmacist working for an OTP from registering for access to the PMP, and nothing would prevent a physician or pharmacist working for an OTP from requesting patient profiles from the PMP.

SAMHSA does encourage the use of PDMP's by OTP's to identify patients admitted to treatment, and periodically through treatment who are engaged in doctor-shopping and to spot irregularities, but does write that these programs should not disclose this information to the PDMP.

Additional information can be found at
http://www.samhsa.gov/sites/default/files/programs_campaigns/medication_assisted/dear_colleague_letters/2011-colleague-letter-state-prescription-drug-monitoring-programs.pdf

***How do providers currently submit information to the database? Is it all electronic, or is there a secure mail option, perhaps using a thumb-drive.***

There are several options for users to submit controlled substance reporting data files to the Prescription Drug Monitoring Clearinghouse. The options include using a secure sFTP (Secure File Transfer Protocol) account, a web portal upload page, using a manual entry Universal Claims Form (UCF) page, or submitting a zero report. All of these options are electronic methods to the Clearinghouse.

***As a long term question, please investigate if there would be ways to simplify or skip the notary requirement for registering with the database, as well as considering completely online registration.***

A notarized signature page is the best means of verifying user identity and providing only those prescribers and practitioners with genuine credentials access to this sensitive data. It is done once, at the time the account is established. The personal identification verification will become even more critical if the system is opened up to delegate accounts for trusted assistants of dispensers and practitioners. Because this is HIPAA-protected information, it is critical that identity verification is acquired for access to the database.

The Division continues to explore options to make it easier for PDMP users to register. One possible option includes linking data from the existing Division licensing database (CBP) with the PDMP software to verify credentials. However, it is premature to confirm this as a possible solution. MyAlaska is also being considered, but a thorough analysis has not been conducted. These options may be available in the future, but to only those who are a licensees in the State (CBP) or Alaska residents (MyAlaska). Out of state or non-licensees will still require a notarized signature page to verify identity.

Best,

Micaela Fowler
Legislative Liaison
Office of the Commissioner
Department of Commerce, Community, and Economic Development

# Alaska State Medical Association

4107 Laurel Street • Anchorage, Alaska 99508 • (907) 562-0304 • (907) 561-2063 (fax)


March 10, 2016

Representative Paul Seaton
House of Representatives
Room State Capital
Juneau AK 99801

RE: HB 344 (HSS) – Controlled Substance Prescription Database

Dear Representative Seaton:

The Alaska State Medical Association (ASMA) represents physicians statewide and is primarily concerned with the health of Alaskans.

ASMA is and has been very supportive of the Prescription Drug Database and has worked with the Legislature and Administration to identify funding options and incentives to keep it active and in use in Alaska. The Database provides a valuable service to patients, the medical community, physicians, and pharmacists in tracking the prescription of controlled substances in Alaska especially as it relates to opioids. We believe the database is an effective tool to combat the growing epidemic of opioid abuse in Alaska.

Alaska suffers from high rates of drug and alcohol abuse and addiction. Opioid abuse and overdose deaths is a growing national crisis nearly tripling since 1999 and Alaska currently ranks 29th among states for the highest drug overdose mortality rate. Alaska's mortality rate due to drug overdoses was about 11.6 per 100,000 people in 2010, an increase of 55 percent from 1999.

We are continuing to review the Committee Substitute for HB 344 Version \E, Controlled Substance Prescription Database. ASMA supports the enhancement provisions in the bill to increase utilization such as those that allow for employees or agents to be authorized to access or check the database on the provider's behalf, the electronic alert that notifies a pharmacist that a patient has passed the recommended threshold for prescription dosage or frequency, and access by the Department of Health and Social Services Medicaid personnel.

However, ASMA has concerns with the proposed requirement that a physician review the database prior to prescribing a drug listed on Schedule IV. This proposed change is found on page 15, lines 10-13 in part:

> **(4) that a pharmacist or practioner shall review the information in the database to check a patient's prescription records before prescribing, dispensing, or administering a controlled substance to a patient;**

ASMA strongly believes this mandatory requirement of pre "look-up" be limited only to Schedule II and Schedule III controlled substances, and in particular to opioid and opioid-based drugs, and not be not expanded to include Schedule IV drugs. This expansion would include hundreds of drugs to be monitored and would consume an incredible amount of time and resources to comply with having little effect on reducing the real problem. ASMA also believes that adding "or procedure" at the end of line 22, page 15 is vital to avoid unnecessary and onerous requirements. Alaska is looking to reduce costs of healthcare not add to them.

The mandatory "look-up" provision also detracts from, and does very little to address, the real problem of opioid drug abuse in Alaska. Physicians are healthcare providers trained to recognize patient needs and behavior. In most cases where opioid drugs are prescribed in Alaska, outside of emergency situations, physicians have an established doctor-patient relationship. Instead of mandating a physician query of the database prior to every prescription of a Schedule IV drug it is better left to the trained physician's judgment and discretion, especially when a doctor-patient relationship exists.

Many other states limit the mandatory prior "look-up" provision specifically to opioid-based drugs, in part:

**Georgia**

***Requires each physician owning or practicing in a management clinic to register and regularly check the PMP on all new and existing patients.***

**Kentucky**

***Check database prior to initial prescribing or dispensing of any Schedule II controlled Substance or Schedule III controlled substance containing hydrocodone.***

***If the treatment extends beyond 3 months the practitioner should check the database every 3 months for the 12 months immediately preceding the query and review the data before refilling.***

**Louisiana**

***A prescriber shall access the Prescription Monitoring Program prior to initially prescribing any Schedule II controlled dangerous substance to a patient for the treatment of non-cancer-related chronic or intractable pain.***

**Delaware:**

***(e) When a dispenser has a reasonable belief that a patient may be seeking a controlled substance listed in Schedule II, III, IV or V for any reason other than the treatment of an existing medical condition, the dispenser shall obtain a patient utilization report regarding the patient for the preceding 12 months from the Prescription Monitoring Program before dispensing the prescription.***

To reiterate, the changes being requested are on page 15, line 22 after "surgery", insert the words " or procedure." And second, eliminate the lookup requirement for Schedule IV drugs.

ASMA is committed to providing the best health care to Alaskans. We believe the PDMP to be a very valuable tool in combating the epidemic of opioid abuse and supportive of strengthening it and other tools to further that end. However, as proposed HB 344 includes a "pre look-up" mandate that fails to provide a true focus on the real problem and adds more cost and delay in treating patients by expansion to all Schedule IV drugs.

Sincerely,

Melinda M. Rathkopf

Melinda Rathkopf, MD
President
Alaska State Medical Association

# Alaska Pharmacists Association



March 14, 2016

Representative Paul Seaton
Alaska State Capitol Building
Capitol Room 102
Rep.Paul.Seaton@akleg.gov
Juneau, AK 99801

Dear Representative Seaton:

I am writing to thank you for making several changes to House Bill 344 recently suggested by members of AKPhA and the Alaska pharmacist community. The changes allowing for weekly PDMP downloads and query delegation by licensed agents of pharmacist and prescribers are both much appreciated changes to this bill. AKPhA feels that several additional changes to House Bill 344 are absolutely necessary to ensure the Prescription Drug Monitoring Program (PDMP) is as effective and as efficient as possible. Essentially, we feel that Alaska's PDMP is currently functioning fairly well and only needs small tweaks to make it more effective, rather than some of the wholesale changes contained in HB 344.

While this bill addresses a very important issue, namely attempts at reducing prescription drug abuse in Alaska through changes to the PDMP, we feel that there are several necessary changes to the bill that need to be made in order to minimize unnecessary and unhelpful administrative burdens on pharmacists and physicians. In particular, we feel that the requirement in HB344 for both pharmacists and prescribers (or their licensed "agents") to check the Prescription Drug Monitoring Program database prior to prescribing and dispensing all controlled substances is overly prescriptive and burdensome for pharmacists and prescribers, and it would NOT help stem the tide of prescription drug abuse as it is intended. **For this reason, we would respectfully ask that the language in Section 18 (AS17.30.200(k) subsection 4) be removed from the bill.** We feel that professional judgment should be allowed for prescribers/pharmacists for when to utilize the database. The PDMP database is only one tool pharmacists use when trying to rule out possible narcotic abuse. For example, we also use real time insurance data to help identify possible prescription drug abuse. Mandatory checking by prescribers and pharmacists on all controlled substance prescriptions is not logistically feasible, AT ALL! Furthermore, it would not pass the "common sense" test to require pharmacists to check the PDMP database on all controlled substance prescriptions dispensed if those same prescriptions (for the same patients) were already checked by the prescriber of said controlled substance prescription(s). These regulations are overly heavy-handed in that they basically require license revocation of pharmacists and physicians for not checking the database when prescribing or dispensing a controlled substance. This is completely overboard and does not leave any room for flexibility. It also does not address our concern with the enforcement mechanisms that are

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available to implement the mandatory PDMP queries in HB 344. Without significant investments in technology and manpower, enforcement of the regulations in HB 344 will not be feasible.

As you know, opioid abuse is a national epidemic that Alaska is not immune from. Legislation, such as HB 344, is an important step in the right direction to reducing opioid abuse and addiction issues. However, Alaska has one of the lowest rates of opioid prescriptions on a per capita basis. Further, numerous studies have shown that the vast majority of abused prescription opioids are not from doctor or pharmacy shopping (that would be addressed by HB 344), but from prescriptions taken, borrowed or stolen from friends or family members. It will be the continued deliberate collaboration between pharmacists, prescribers, patients and politicians to truly put a dent in the prescription drug abuse in Alaska.

AKPhA represents over 200 pharmacists and pharmacy technicians in the State of Alaska. Our mission is to **Preserve, Promote, and Lead the Profession of pharmacy in Alaska**. Alaska HB 344 is a step in the right direction, but there are several strongly needed revisions to make it feasible and effective. Pharmacists in all parts of our state are dedicated to helping reduce prescription drug abuse. We feel that our professional judgement should supersede micromanagement of mandatory PDMP database prior to dispensing all controlled substance prescriptions.

Again, we appreciate your efforts and leadership on this critical issue. Should there be anything that I or the Alaska Pharmacists Association can do to help improve upon this legislation, please let me know.

Sincerely,

Tara Ruffner, PharmD.
President
Alaska Pharmacists Association

**E-mail: akphrmcy@alaska.net**
**203 W. 15th Ave., Suite 100 • Anchorage, Alaska 99501 • (907) 563-8880 • (907) 563-7880**

**From:** Ryan Ruggles
**Sent:** Monday, March 14, 2016 3:18 PM
**To:** Rep. Paul Seaton
**Subject:** HB 344

Representative Seaton-

In regards to HB 344:

I am a pharmacist in the Anchorage area and my thoughts and opinions are my own.

I have been working in Anchorage since 2010, and I have previously overseen 24 different pharmacies as a Regional Manager.

I believe that this bill is addressing a problem in this state, and I respect the idea that this bill is trying to accomplish.

I am in favor of the increased access to the right people in order to help prevent opioid abuse.

I think it will increase utilization if we can delegate the access to other staff members.

I also believe that this needs to be a team effort between prescribers and pharmacists in order to really reduce the problem.

The DEA would state the pharmacists and prescribers have "Dual responsibility" for controlled substances.

I do think that the wording of checking the PDMP for every Controlled Substance Rx dispensed is excessive.

If a patient has 4 refills on a medication, and I have checked on the initial fill, I am unsure that the additional checks would be helpful.

Additionally, if we are looking at the information that frequently, it becomes easy to miss the important information.

This, in the pharmacy world, has been known as "alert fatigue". The idea that being alerted constantly about information can lead to missing something simply because there are too many unnecessary alerts.

I would suggest and be more supportive of language resembling this:

"In best practice, each dispensing and prescribing of a Controlled substance should be paired with reviewing the information on the PDMP. Each time a New controlled drug, or a strength change occurs the prescribing practitioner or their delegate will review the patients record on the PDMP. In addition, each pharmacist will review the PDMP prior to dispensing a new controlled substance or dose change to a patient. Additionally, the pharmacist will review the PDMP if the prescriber is different than an original prescriber."

Please remember, that without a prescription a pharmacist cannot dispense controlled substances by laws that already exist. So encouraging prescribers to check, could remove the possibility of an Rx being filled.

Utilizing this methodology, if this procedure is met, every New patient will have their information checked. This ensures that there are checks and balances. If the prescriber misses their part, then the pharmacist should catch it. Additionally, if the prescriber is checking, and if the pharmacist misses their check, then at least a practitioner looked at the information. This method should cast a good net for limiting the problem we are facing.

This also allows us to utilize our professional judgement to either more frequently or less frequently check the database.

Please note, that there are many red flags that pharmacists should be aware of that could tip them off to identify potential behavior that could lead to diversion.

There are Continuing Education courses that can reflect this.

I support the more frequent uploading to the database as it becomes much more useful as a tool for pharmacists and prescribers to use.

Thank you for your time and consideration,

**Ryan Ruggles, PharmD**

**Pharmacy Manager**
**Anchorage Neighborhood Health Center**
**Phone:** 907-743-7203 **Fax** 907-743-7257
rruggles@anhc.org

# Alaska
DENTAL SOCIETY

March 15, 2016

Representative Paul Seaton
State Capitol Room 102
Juneau, AK

Re: HB344

Representative Seaton

The Alaska Dental Society (ADS), representing the licensed dentists of Alaska, would like to provide input on HB344, version E.

The ADS shares the Legislature's concern about the effect of opioid drug abuse on Alaskan citizens and agrees changes should be made to the current system.

HB344 provides an enhancement to the prescription database system the ADS supports. We believe allowing staff to access the database and provide the history to prescribers will greatly improve utilization of the system. The current restriction allowing only prescribers to access the system makes widespread usage impractical and deters routine lookups.

We are neutral regarding the mandatory lookup. The exceptions, as outlined, would largely exempt dentists from the requirement for most circumstances where they would prescribe narcotics. Increasing the exemption to 48 hours post-surgery, however, would encourage less "prophylactic" prescription of pain medication and more need based prescriptions. Post-surgery prescriptions, by their nature, will frequently find prescribers in locations where they will be unable to access the database. It is unclear whether 17.30.200(k) 4 provides an exception for those circumstances. Allowing staff to access the system will greatly enhance usage and would likely, by itself, accomplish the goal of this change.

In order for prescribers to reduce the number of immediate post-surgery prescriptions it will require re-education of the public. Patient's expectation is for pain medication following even minor surgery and it is unrealistic to believe counseling from prescribers will overcome this barrier. The Legislature, if the goal is reduce opioid prescriptions, will need to commit to a public awareness campaign to educate patients on reasonable expectations after minor surgery and acceptable alternatives to opioids. Patient belief in a pain medication plays an important role and without patient buy in reducing opioid prescriptions will be challenging.

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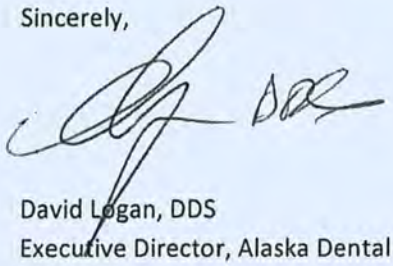
The ADS does not support the "maximum dosage for opioid prescriptions" outlined in proposed 08.36.355. The wording of the proposed addition is confusing and accomplishes little beyond reiterating a record entry for prescriptions that is already considered the standard of care. The ADS suggests encouraging prescribers to utilize current best practices for prescribing and keeping that information current on the respective licensees' professional board websites. The ADS would commit to an education effort to our members and placement on our website for this information as well.

We appreciate the committee considering these comments and look forward to working with the Legislature to help curb opioid drug abuse in Alaska.

Sincerely,



David Logan, DDS
Executive Director, Alaska Dental Society

**From:** Gerald KW Brown [mailto:GKWBROWN@ALASKAN.COM]
**Sent:** Thursday, March 17, 2016 11:30 PM
**To:** Rep. Paul Seaton <Rep.Paul.Seaton@akleg.gov>; Rep. Liz Vazquez <Rep.Liz.Vazquez@akleg.gov>; Rep. Neal Foster <Rep.Neal.Foster@akleg.gov>; Rep. Louise Stutes <Rep.Louise.Stutes@akleg.gov>; Rep. David Talerico <Rep.David.Talerico@akleg.gov>; Rep. Geran Tarr <Rep.Geran.Tarr@akleg.gov>; Rep. Adam Wool <Rep.Adam.Wool@akleg.gov>
**Subject:** HB344

Ak House
Health and Social Services
Juneau, Ak 99801
Dear Rep Seaton and Committee, 3/15/16

Thank you for your time and allowing me to testify before your committee. You asked for a written summary and an explanation of my testimony. The following are my comments.

First, Some house keeping, your amendment "N" section 14 has a Typo. you have "schedule II, II, or IV controlled substances" and it should say "schedule II, III, IV controlled substances".

Second, section 15, We appreciate that we can delegate these duties to licensed staff only.
Third, section 16, I and Alaskan pharmacists appreciate that we can delegate accessing the database with our licensed staff. Note -everyone behind the counter is licensed by the state of Alaska.

Fourth, Section 18, The purpose of the database is to provide a reference source to change prescribing behavior, not always dispensing behavior, but the pharmacist are checking and giving feedback to the prescribers when prescriptions are too early, filled by to many recent providers, or provided prescriptions by too many providers. This section cuts that process, and guts the resource of the database. By exempting the very people who need to be referencing the database. In patient, because they need to see what behavior brought them to the in-patient setting, also what they are sending them back out to. Emergency rooms, and ambulances many times the immediate past behaviors are what brought them to the emergency room in the first place. The last 6 months tells you their behavior to wander (abuse) or not to wander. Post-Op surgery, They could have filled a prescription for 120 Percocet 5 days before surgery and still have them so they do not need another 7 day or 30 day prescription of Percocet. So if you exempt those providers that you have from checking the database, you are gutting the purpose of the database.

Fifth, section 19 requires providers writing and pharmacists to check the database before filling and writing a prescription. This should occur before the writing of the prescription, Not after the prescription has been written. Have the prescriber put do not fill until a future date. But is is the prescribers duty, not the pharmacist duty to deny filling. Therefore there is duplicity of effort. The pharmacist will catch the early refill when the insurance denies the claim and then they will check the database. make it mandatory for the prescriber, not the pharmacist, stop it at the point of authorization.

Sixth, There was talk about 7 day supplies on the first prescription. This is crazy, and not logistically reasonable. First of all most ER's do limit to 3-7 days, They are only suppose to issue enough to get them to their regular provider, Monday, or next Non-Holiday Business day. Next this does not make sense in relationship to the Bush community. Before the patient can fill the second prescription, they must wait til 75% of the first prescription is used, that means they have to wait in town and additional 2-4 days before they can get the second prescription filled. Or the second pharmacy may have to order the medication, which can take 2-4 days to get providing the weather allows the delivery to the second pharmacy creating a delay in health care. This also put the 2nd pharmacy at a disadvantage also. Generally as 60-70% of the Bush prescription or 30% of the Urban prescription are Medicaid, they will lose money on the prescription. Medicaid will not pay another dispensing fee if it has been dispensed past 28 days, and requires a prior authorization for a dispensing within 19 days of the first dispensing. So, if it costs $550.00 to the pharmacy to buy it from the wholesaler, Medicaid or another insurance company reimburses $475.00 and Medicaid does not allow a dispensing fee of $11.00 that pharmacy loses $75.00 instead of only losing $64.00. This is true pharmacies are losing money monthly and this adds to the continued trend of subsidizing the public, government, and the insurance companies. My pharmacy is small, tiny we lost $2,500.00 last month in under-reimbursed claims, I know of a Big Box that lost over $10,000.00 in the first 10 days of one month in 2015, that is $30,000.00 per month. You will lose pharmacies economically, due to this policy. Dan Nelson, testified that it will take 2-3 minutes to check the database for each prescription. I believe that time is more like 3-5 minutes. Because you have to bring up the website, enter the patient's name, date of birth, address, city of record it take 3-5 minutes for each prescription to analyze the merits of prescription and the filling dates, assuming you have 25-75 prescriptions a day that represents @ 3 and 1/2 minutes = 87.5 minutes - 262.5 minutes (1 and 1/2 hours to 4 hours 20 minutes) just checking the database, that is an extra 0.125-0.5 FTE or $75-280.00 per day or more extra cost of doing business. This on top of what is not being adequate being paid to the providers in the first place. These are real dollars, the impact is as if we would ask you to get an additional $200-1500.00 less in your paycheck each month.
This policy encourages multiple prescriptions, over-lapping of prescriptions because the database will not be checked. Dentist, emergency rooms, and other providers will write for smaller days, so they do not have to check the database. This defeats the reason the database is there and adds more elements (prescriptions) to filter through in order to evaluate the patients records.

Seventh, section 20 Thank you for allowing pharmacists and providers, the ability delegate to licensed personnel the ability to access the database. Pharmacy helped establish the database, administer, and submit the data to the database. There has been a long standing understanding that pharmacies and pharmacists would not bear the cost of administering this program. Please honor this understanding.

Submitted
Respectfully yours,
Gerald KW Brown, pharmacist Co-owner of Medical Center Pharmacy
PO Box 70196 1867 Airport Way, Suite #105
Fairbanks, Ak 99707 Fairbanks, Ak 99701
gkwbrown@alaskan.com 907-452-2328
907-460-6921 medicalcenterpharmacyone@yahoo.com

Representative Seaton,

As a licensed pharmacist in the State of Alaska for the past 20 years, I would like to express some serious reservations regarding the proposed changes to the PDMP. While I wholeheartedly embrace the use of the PDMP, I fear that many of the proposed changes are both impractical and potentially very costly. I realize that your office is already aware of these concerns, such as "real time" input of data and unlicensed personnel accessing the data base, but I wanted to lend support to my colleagues who have spoken out against some of these changes.

I would like to thank you for taking the time to discuss these concerns with the people who would be impacted the most, namely pharmacists. Please let me, or my colleagues, know if there is anything further that we can do to assist in this effort.

Sincerely,

Tara Ruffner, PharmD
Soldotna,AK
907-252-2700

Tanana Chiefs Conference

March 23, 2016

To: House Health & Social Services Committee Members
Re: Tanana Chiefs Conference Concerns with House Bill 344 (HB344)

Dear House Health & Social Services Committee Members,

On behalf of Tanana Chiefs Conference, I would like to express our concerns with Alaska Senate Bill 74. While this bill addresses the critically important issue of reducing prescription drug abuse in Alaska through changes to the Prescriptions Drug Monitoring Program (PDMP) we feel that there are several aspects of this bill that are onerous and will not further the achievement of this goal. We feel that the bill, as currently written, will unnecessarily increase administrative burdens on physicians and pharmacists with overly prescriptive bureaucratic requirements without decreasing the scourge of prescription opioid drug abuse.

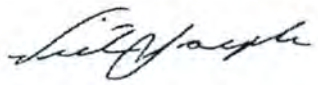
In particular, we feel that the requirement in HB344 for both pharmacists and prescribers (or their licensed/ registered "agents") to check the PDMP database prior to prescribing and dispensing all controlled substances is overly burdensome for pharmacists and prescribers, and it would NOT help stem the tide of prescription drug abuse as it is intended. **For this reason, we would respectfully ask that the language in HB 344 Version N Section 19 (AS17.30.200(k)(4) be removed from the bill.** Our pharmacy has estimated that this regulation (if passed) would require them to spend an additional 3-5 hours per day of checking the PDMP database. This would be in addition to our medical providers also spending an equivalent or greater amount of time checking the PDMP database. This will undoubtedly increase waiting times at our already busy pharmacy and also decrease appointment availability for our over-booked medical providers. We feel that professional judgment should be allowed for when prescribers/pharmacists utilize the database. The PDMP database is only one tool pharmacists and physicians use when trying to rule out possible narcotic abuse. It should not and cannot be viewed as the ONLY tool that can be used to root out prescription drug abuse. Other tools used by medical professionals to combat prescription drug abuse include pain contracts, urine drug screens, prescription insurance claim results and pill audits.

Tanana Chiefs Conference is an Alaska Native non-profit organization charged with advancing Tribal self-determination and enhancing regional Native unity. We provide services while balancing traditional Athabascan and Alaska Native values with modern demands. We work toward meeting the health and social service needs of Tribal members and beneficiaries throughout our region. As you know, opioid abuse is a national epidemic from which Alaska and the Alaska Native Community are not immune. Tanana Chiefs Conference is committed to collaborating with legislators, community members and other partners to help stem the tide of prescription opioid abuse. We feel that smart legislation, such as HB 344, is an important step in the right direction. However, the above revisions are necessary to

make this legislation as effective as possible without micromanaging the practices of Medicine or Pharmacy with heavy-handed bureaucratic regulations. Our physician's and pharmacist's professional judgement should supersede the mandatory PDMP check requirement prior to prescribing and dispensing all controlled substance prescriptions.

Again, we appreciate your efforts and leadership on this critical issue. Should there be anything that I or Tanana Chiefs Conference can do to help improve upon this legislation, please let me know.

Sincerely,
Tanana Chiefs Conference



Victor Joseph,
TCC President and CEO

**Taneeka Hansen**

**From:** Rice, Kristi D (HSC) <Kristi-Rice@ouhsc.edu>
**Sent:** Wednesday, March 23, 2016 3:00 PM
**To:** Rep. Paul Seaton
**Subject:** HB 344, an Oklahoma Pharmacy Student's perspective
**Attachments:** letter to congress on letterhead.docx

Honorable Representative Seaton,

My name is Kristi Rice and I am a Pharmacy Intern from The University of Oklahoma Health Science Center College of Pharmacy, interning at Whale Tail Pharmacy, in Craig, Alaska. I appreciate the opportunity to address the House Bill 344.

In May of 2011, I began working at an independent pharmacy, in Oklahoma, where I quickly began to realize how hectic and performance related the environment of a pharmacy can be. As I observed and now perform as an intern, one of the duties of a pharmacist is to check the usage of each medication, for each patient, and determine if the usage is excessive, within normal limits, or that it is not duplicate therapy. Pharmacists have many tools (i.e. patient's computer profile, long-term patient fill history, patient's insurance information, etc.) that help them perform this task. One other tool commonly used to perform this task is the Prescription Drug Monitoring Program (PDMP) database (in Oklahoma it is the PMP), which contains control and narcotic prescription records for patients.

The PDMP serves as a great tool for monitoring false prescriptions and patients who may have illegal intensions. Therefore, having this tool and its ability to check unknown or unfamiliar patients' prescription use is most helpful; however, **if pharmacist and prescribers are tasked with checking every patient, regardless of their professional judgment, this could become a time consuming task, taking away from important and necessary medical services, such as counseling patients.**

It would be beneficial for the providers to have the wording of this bill read, "using reasonable professional judgment" instead of the current wording of "before dispensing". The current statement in the Oklahoma Pharmacy law book has similar wording for dispensing, "pharmacist's professional judgment", page 49. Another reference is the Oklahoma Board of Medicine who requires their doctors to check the PMP for prescribing controls or narcotics to new patients, then again every 180 days, page 6 of HB 1948.

I appreciate your time.

Sincerely,

Kristi Rice

OUHSC College of Pharmacy - OKC
Pharm D Candidate, Class of 2016
CoP Student Ambassador
CoP Leadership Track candidate
kristi-rice@ouhsc.edu

## Taneeka Hansen

**From:** jsonkiss@gmail.com on behalf of Joshua Sonkiss <jsonkissmd@gmail.com>
**Sent:** Wednesday, March 23, 2016 7:53 AM
**To:** Taneeka Hansen
**Cc:** Jeannie Monk; asma@asmadocs.org; vanessa.venezia@bannerhealth.com; Alexander von Hafften Jr.; randall.burns@alaska.gov; Andrew Mayo; Donna Rollins; Elizabeth Ripley; Jeff Jessee; Matthew Dammeyer; Stephen Sundby; cbill; cindy.gough@providence.org; melissa.ring@alaska.gov; nathan_fearrington@ykhc.org; p.burrell@msrmc.com; raymond_daw@ykhc.org; whhogan@uaa.alaska.edu; Lee, John R.; Robert Letson; Gunnar Ebbesson; Burkhart, Kate (HSS)
**Subject:** Concerns and recommendations for revision of HB 344

**Follow Up Flag:** Follow up
**Flag Status:** Flagged

Dear Rep. Seaton and members of the Health and Social Services Committee:

Thank you for your efforts to improve the safety of Alaskans who receive prescriptions for controlled substances. HB 344 contains important provisions to help protect Alaskans against the epidemic of prescription opioid overdose deaths by encouraging utilization of Alaska's PDMD. PDMDs are an essential component of controlled substance regulation. However, I am concerned HB 344 may have unintended consequences if it is passed as currently written. I am writing to suggest revisions that will avoid unintended consequences. I am a board-certified medical psychiatrist, editorial board member for a publication that educates physicians about addiction, and I treat patients with addiction every day. Therefore, I am qualified to advise the legislature with respect to Alaska's controlled substance problems and how legislation may successfully address them.

Please consider the following areas of concern and recommended revisions to HB 344:

1. Sections 1, 4, 10 and 13: These Sections create grounds for the imposition of disciplinary sanctions, and they include language similar to the following:

"The board may revoke or suspend the license [of a practitioner] or may reprimand, censure or discipline [a practitioner] or both [sic], if the board finds after a hearing that [the practitioner]...(7) continued to practice after becoming unfit due to...(B) addiction or severe dependency on alcohol or other drugs which impairs [sic] the person's ability to practice safely."

This language appears to render drug addiction, which is a diagnosable medical illness, a basis for licensure sanctions. This could violate of Title IX of the Civil Rights Act, the Americans with Disabilities Act and other federal and state anti-discrimination laws. Additionally, Robinson v. California, U.S. Supreme Court 1962, and Driver v Hinnant, Fourth Circuit Court of Appeals 1966 found statutes that criminalized the status of narcotic addiction unconstitutional under the 8th and 14th Amendments. Designating addiction as the basis of professional licensure sanctions may be similarly unconstitutional.

In order to avoid constitutional and other legal challenges, HB 344 should be amended to read "..intoxication with alcohol or other drugs which impair the person's ability to practice safely."

2. Section 15: This Section mandates that all controlled substance prescriptions be reported to the PDMD. However, methadone prescriptions, when written for treatment of opioid dependence, are covered by

the privacy provisions of 42 CFR Part 2. Reporting these prescriptions to a state PDMD would be a violation of federal privacy law. For this reason, other states with PDMDs do not include methadone clinic prescriptions in their PDMD reporting requirements.

In order to avoid legal challenges and potential for the federal government to enforce privacy actions actions against Alaskan pharmacists and practitioners, HB 344 should be amended to exclude methadone clinics from PDMD reporting requirements.

3. Section 19: This Section, in combination with other Sections, requires prescribers to "review" the PDMD before each and every controlled substance prescription--under threat of licensure sanction for failure to do so. Although it would be desirable for prescribers to check the PDMD before every prescription, requiring them to do so is unreasonable for the following reasons:

a. Among other reasons, Alaskan prescribers underutilize Alaska's PDMD because its user interface makes access so difficult and time-consuming that there is no realistic way to fit database review into the average prescriber's schedule without compromising other aspects of patient care. Thus, the most appropriate way to increase prescribers' use of the PDMD is to ensure the PDMD is usable in everyday medical practice, not to punish practitioners who fail to use it.

b. Few if any prescribers will be able to comply with a 100% PDMD review requirement, even if they do not qualify for a technical or infrastructure barrier under this Section. This is because 100% compliance with any regulation is a virtual impossibility in any service industry, including medicine. Subjecting prescribers who fail to comply 100% of the time with licensure sanction--one of the most feared, stigmatizing and career-destroying events a doctor or other health professional can face--is unrealistic and unfair. Such a threat may discourage practitioners from moving to or remaining in Alaska, and thereby exacerbate our state's existing provider shortage.

c. Many medications commonly prescribed for insomnia, anxiety and attention-deficit hyperactivity disorder are scheduled, yet--even among addicts--they have very little potential for lethal overdose compared with opioids. Although it is desirable for prescribers to review PDMD data periodically for patients receiving prescriptions for these substances, it does not make sense to require PDMD review before each and every prescription for benzodiazepines or stimulants. Today's health care economy requires efficiency, and efficiency requires eliminating costly activities that contribute little to safety or quality of care. Requiring prescribers to review the PDMD before each and every benzodiazepine and stimulant prescription will impose disproportionate costs on Alaska's health care system, but will not provide commensurate gains in safety or quality.

d. A multitude of conditions may affect the average prescriber's ability to access the PDMD at any given moment. These include whether or not the internet is working; whether the PDMD is down for maintenance; whether the prescriber's password suddenly expired; whether the licensed designee responsible for checking the PDMD called in sick; whether the prescriber is behind schedule due to an emergency; whether the patient has to get back to work or pick up a child from day care; and a multitude of other contingencies. Patients should not have to forego needed prescriptions because of fluctuating practical conditions beyond their control, and prescribers should not face licensure sanctions because of those same uncontrollable variables.

Alaska's PDMD laws should be designed to increase patient safety without imposing costly burdens that add little benefit, forcing patients to go without needed prescriptions, or threatening the state's already shorthanded medical workforce with arbitrary licensure sanctions that could induce them to leave and practice elsewhere. To accomplish those goals, HB 344 should be revised to:

-Require prescribers to check the PDMD within 30 days for each patient to whom they prescribe any scheduled medication, including medications classified as opioids; and

-Require prescribers to check the PDMD no more frequently than once annually for patients to whom they prescribe scheduled medications that are not classified as opioids; and

-Hold prescribers harmless from any licensure action for failure to review the PDMD when such failure is due to the non-functionality of the PDMD itself.

Thank you for considering these recommended revisions. PDMDs are an essential part of any state's effort to prevent overdose deaths and to reduce diversion and abuse of controlled substance prescriptions. With these revisions, HB 344 is more likely to accomplish those goals.

Sincerely,

Joshua Sonkiss, MD

March 23, 2016

Representative Paul Seaton
Alaska State Capital Building
Capitol Room 102
Juneau, AK 99801
Rep.Paul.Seaton@akleg.gov

Dear Representative Seaton:

I am writing to thank you for engaging in the crucial discussion concerning the Alaska Prescription Drug Monitoring Program in HB344 . Although there are interesting topics discussed in HB344, as a licensed pharmacist in Alaska, I have significant areas of concern, including:

1. **Absolute disciplinary action** for failure to verify the PDMP prior to prescribing or dispensing a control substance. No program and no person is ever 100% accurate or effective. In a busy pharmacy and practitioner's office there is no question that there will be a prescription that is written or dispensed without verifying the PDMP; it's going to happen, even if unintentional. Should a prescriber or pharmacist face disciplinary action for not checking the PDMP for a prescription for 1 tablet of an anti-anxiety medication for the patient to take before an MRI or going to a dentist? I don't feel absolute disciplinary action is the route to take in this legislation. The PDMP is **a tool** in reviewing control substance usage; it's not the only tool and should be used with professional judgment amongst the other tools being used to make a decision.

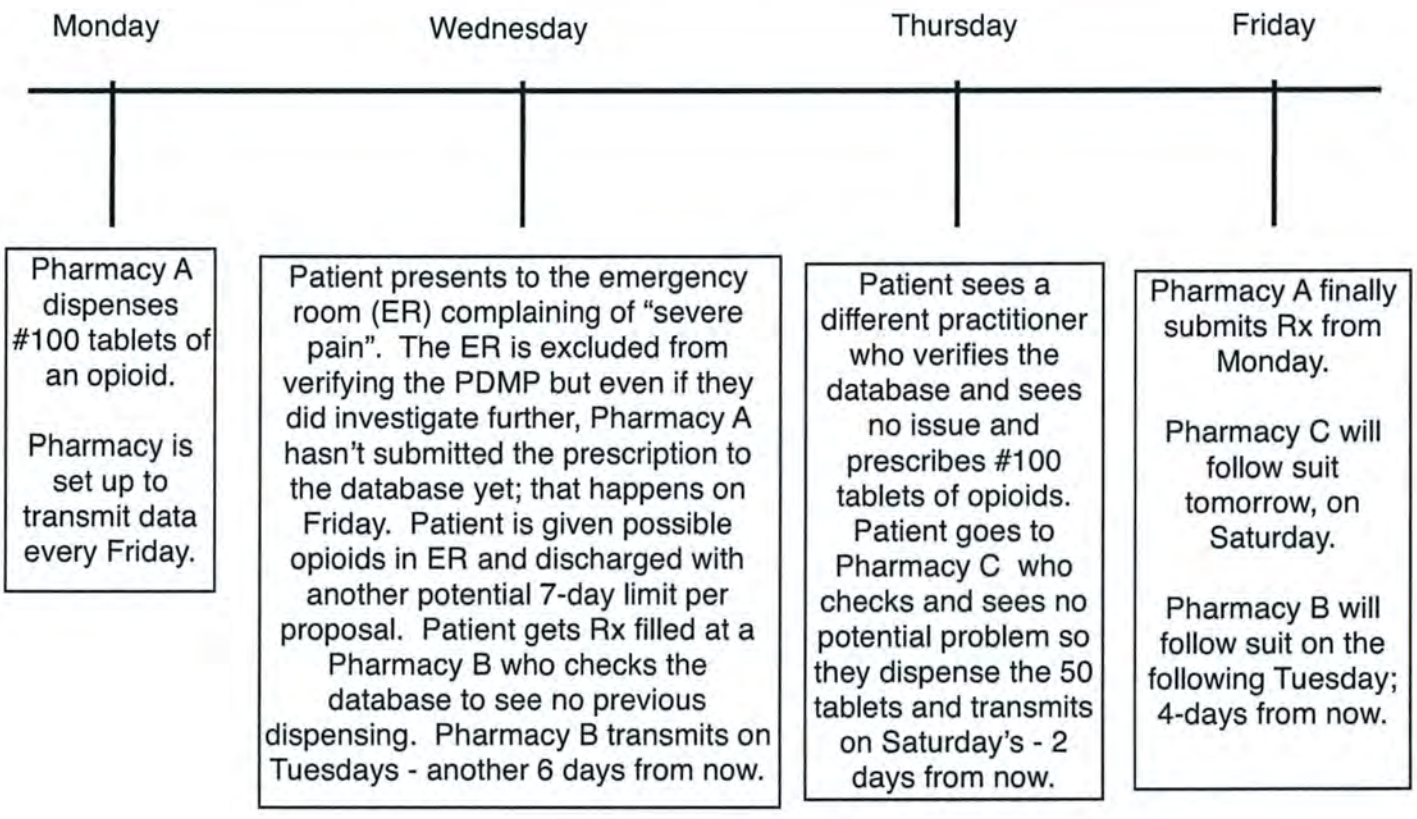
2. **Mandatory, dual, PDMP verification** by the prescriber and pharmacist. This is repetitive in nature and therefore serves no justifiable purpose. The ideal initiation point would be using professional judgment at the time of evaluating the patient and prescribing the medication, not after the fact.

3. **Mandatory review of the PDMP** prior to dispensing or prescribing. Again, if we go back to visit the 1 tablet of anti-anxiety medication to take 1-hr prior to an MRI or dentist visit to calm a patient, should that really mandate a review of the PDMP? What about a patient with a fear of flying who needs a couple of anti-anxiety tablets to help with the flight? These quantities and types of medical situations do not and should not require a professional to validate a PDMP for potential abuse.

4. **Allowing an "agent" to access the PDMP.** I am in full support of this, however, I do not read any requirement for that "agent" to register. Why isn't this "agent" required to register in Section 17 of the working draft along with other persons accessing the database? How will they then gain access if they are not personally registering and how will the board monitor their activity within the PDMP for security purposes?

5. At least weekly submission of data into the PDMP. This is certainly an improvement over the current monthly requirement but still leaves significant opportunities for abuse; see timeline example below.

The proposal states "once weekly" submission to database...it doesn't say which day. Therefore, pharmacies may be submitting on various days throughout the week and you may encounter the following




If we follow the proposal, every practitioner (except the Emergency Room) and every pharmacist would have verified the prescription monitoring database. However, because of once weekly transmissions to the database, with no definition of when during the week that happens, you will have different pharmacies transmitting on different days. This clearly still allows for a significant gap being missed and potential unnecessary opioids being dispensed. This didn't solve the potential problem.

6. The development of "an alert system that automatically sends an electronic notification to a pharmacist and practitioner at the time the pharmacist or practitioner

**enters a prescription into the database....**" From just the simple example above you can see how this "auto alert" does not function in reality. If data is submitted once weekly what good does the alert serve for that prescription when they have already received the medication and left. Submission into the database is **not** real time. Similarly, where is this "electronic notification" sent? Is it sent to the email address the applicant enrolled with? Is that a HIPAA protected email address or is it a personal email address? In pharmacies, it's not unusual to have significant firewalls that prevent external emails from entering your work environment and so these messages don't get delivered. Therefore, I would say it's not unusual that a pharmacist has used a personal email address when applying for PDMP access never thinking they could in the future receive private patient details auto-sent back to that email address.

I thank you for your engagement on the PDMP discussion and the importance this **tool** serves our healthcare community. However, I believe there are several flaws within proposition HB344 that need to be addressed before finalization with the realization that the PDMP is just a tool in making a professional decision; it is not our only tool. Thank you for taking the time to read and understand my concerns. Should there be anything that I can do to help improve upon this legislation, please let me know.

Sincerely,

Richard Holt, BS Pharm, PharmD, MBA
Alaska licensed pharmacist

http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/03/03/states-cdc-seek-limits-on-painkiller-prescribing

THE PEW CHARITABLE TRUSTS

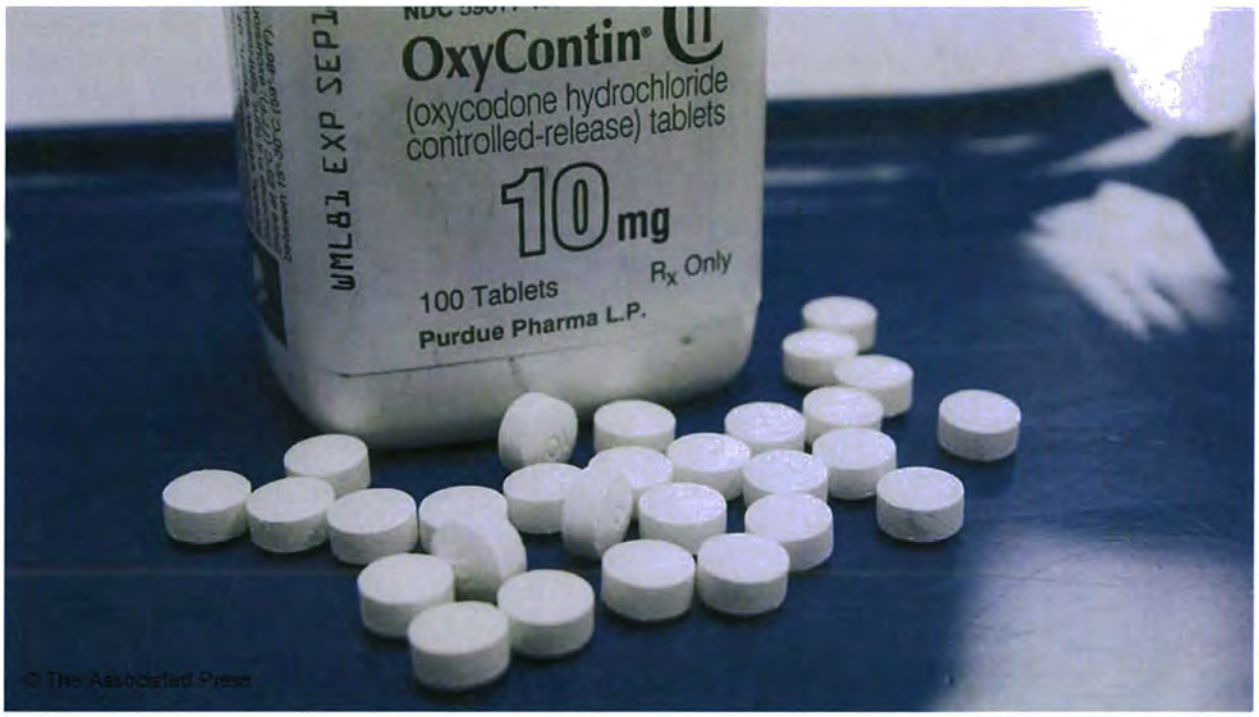


STATELINE

# States, CDC Seek Limits on Painkiller Prescribing

March 03, 2016

By Christine Vestal




HB 344 Background
Distributed by Rep Seaton

Overdoses from OxyContin and other opioid pain relievers killed nearly 20,000 Americans in 2014. States and the federal government want to stop liberal prescribing practices seen as causing the epidemic.

As medical director for the Washington state workers' compensation program in 2001, Dr. Gary Franklin made a chilling discovery: Otherwise healthy workers who took painkillers for minor injuries were ending up dead a few years later.

"It was shocking," Franklin said. "Workers are on the job, they report a back sprain, and then they are dead." In dozens of cases, patients had been prescribed opioid painkillers for chronic pain. Most had taken drugs like OxyContin consistently for months or years.

Doctors were prescribing high doses of opioid painkillers in most other states too. Doctors and their patients had been assured the pills were safe, and yet thousands of people were dying. "They would take one more pill before going to bed and never wake up," Franklin said.

Now, in the throes of the deadliest drug epidemic in U.S. history, governors, presidential candidates and major health care organizations — from insurance companies to physician associations — are calling for limits on the number and strength of opioid pills prescribed. The U.S. Centers for Disease Control and Prevention is close to taking the unprecedented step of issuing national guidelines to curb liberal opioid prescribing practices widely blamed as the cause of the epidemic.

"It isn't drug dealers that are on our South American border that are our biggest challenge," Democratic Vermont Gov. Peter Shumlin said last month at a meeting of the National Governors Association. "It is our drug dealers who are FDA-approved selling the stuff in every pharmacy in America."

Both Democratic and Republican governors unanimously support the CDC initiative and have pledged to promote the voluntary physician guidelines in their states. But the American Medical Association and pain organizations backed by drugmakers are complaining the initiative could make it difficult for chronic pain sufferers to get the pills they need.

The U.S. Food and Drug Administration approved OxyContin and other opioid pain medications in the mid-1990s for short-term pain only. But physicians quickly started prescribing the effective new pills for long-term or chronic pain. When patients built up a tolerance and the pills stopped working, pain experts and drug company representatives instructed doctors to give higher doses. They assured doctors the pills were safe and nonaddictive.

In fact, Washington and more than 20 other states made clear that doctors couldn't be disciplined for prescribing high doses of opioids by enacting so-called intractable pain acts.

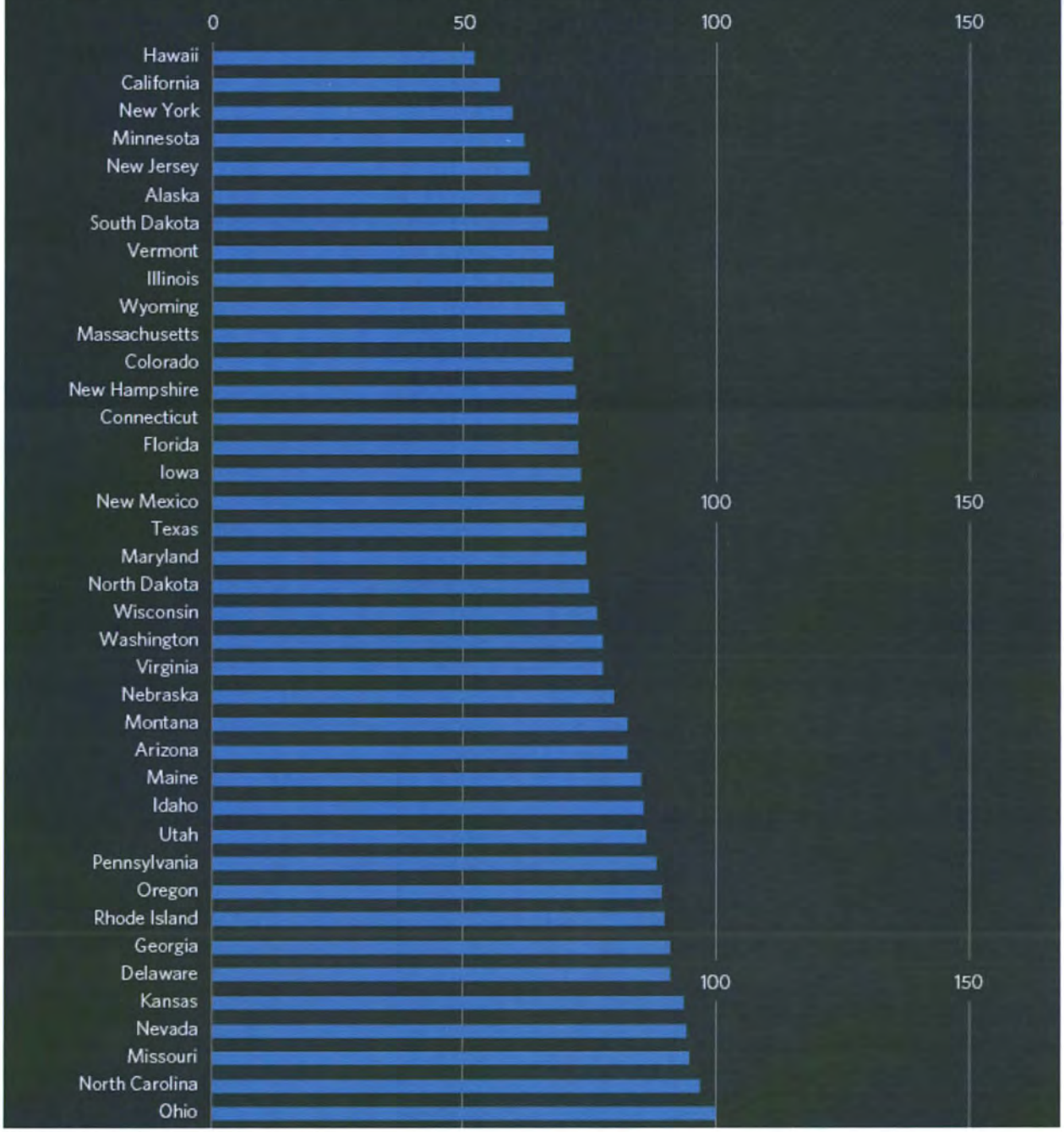
Franklin and five other researchers were the first in the U.S. to publish a study showing that the relatively new opioid pain medications were killing people. Since then, the CDC has reported more than 200,000 overdose deaths from the pills.

But in the decade since Franklin and others began reporting those grim statistics, only Washington and a few other states have attempted to educate doctors about the overdose and addiction risks of powerful pain relievers such as OxyContin, Percocet and Vicodin.

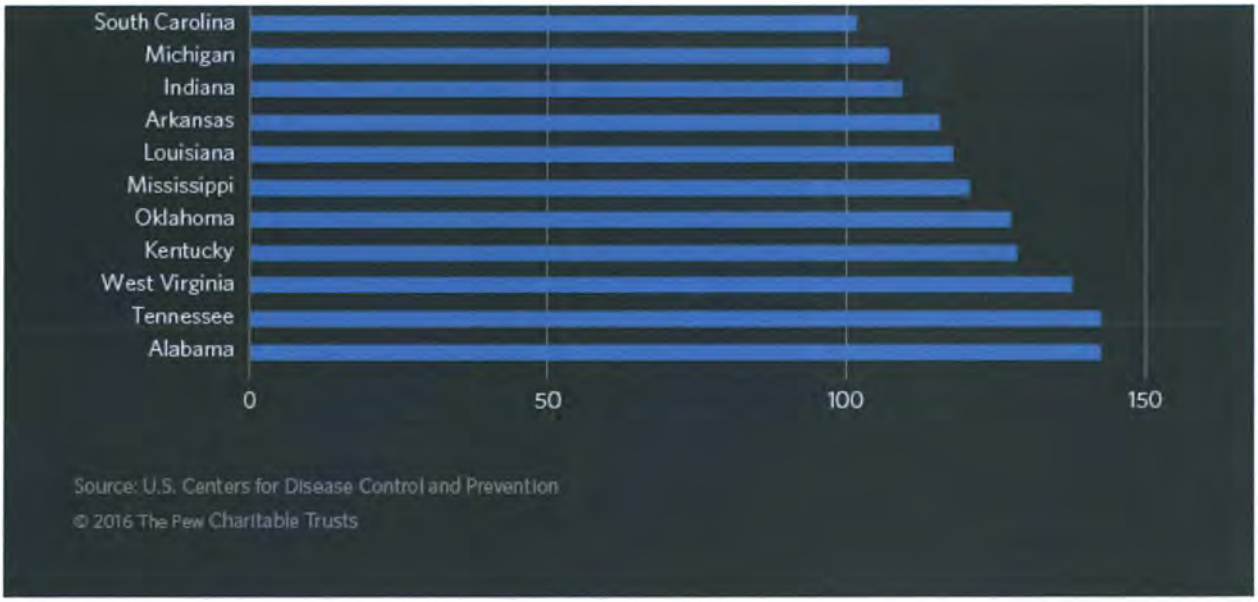
The CDC's initiative could change that.

## Painkiller Prescriptions

The number of painkiller prescriptions varies widely by state, from 52 per 100 people in Hawaii to 142.9 per 100 people in Alabama. New federal guidelines aim to reduce excessive painkiller prescribing, which has contributed to an epidemic of opioid addiction and overdose deaths.




HB 344 Background
Distributed by Rep
Seaton




## Pain Relief and Safety

The CDC's draft proposal urges primary care doctors to try drug-free methods to relieve chronic pain, such as exercise, weight loss and physical therapy, as well as non-opioid pain relievers such as acetaminophen and ibuprofen, before resorting to powerful opioid pills. If opioids are needed, the guidelines recommend starting with the smallest effective dose of immediate-release opioids, avoiding more dangerous time-release formulations except when needed.

The AMA has generally supported the concept of more cautious opioid prescribing. But the group has criticized the CDC proposal for lacking "a patient-centered view and any real acknowledgement of the problems chronic pain patients may face." More than a thousand individual patients have urged the CDC in online comments not to pressure doctors into withholding the opioid painkillers they rely on.

Purdue declined to comment on the proposed guidelines and, like other drug companies, it did not file public comments with the CDC. But the Washington Legal Foundation, a pro-business nonprofit that often represents pharmaceutical companies,

wrote a letter to the CDC expressing "extreme concern" over what it said were flawed procedures used in developing the guidelines.

Representatives from the U.S. Pain Foundation and the American Academy of Pain Management, which receive financial support from pharmaceutical companies, have also argued that the federal agency relied too heavily on the advice of addiction experts and not enough on advocates for pain patients.

Since those complaints, the agency has added 130 studies, undergone three independent peer reviews and consulted additional experts, including representatives from the groups that have been critical, according to Dr. Debra Houry, an emergency room physician on the CDC's opioid guidelines team. As a result, the CDC guidelines, originally slated for release in January, were delayed.

For acute pain resulting from non-traumatic injuries or minor surgery, the CDC's draft proposal suggests sending patients home with only three days' worth of pain pills instead of a 30-day supply, which is common practice in most U.S. hospitals and physicians' offices.

Doctors who prescribe the extra pills tell patients they are "just in case" the pain lasts longer than the expected day or two. But advocates for safer prescribing say the extras are often given to friends or taken from medicine cabinets for recreational use, further fueling the drug epidemic.

Massachusetts Gov. Charlie Baker, a Republican, proposed the same three-day limit last October and Shumlin adopted a similar measure in Vermont last month. At the governors meeting, Shumlin urged all governors to use their authority under medical licensing laws and as major health care purchasers. He called on them to limit the number of opioid pills doctors may prescribe to patients taking them for the first time following a non-traumatic injury, minor surgery or dental procedure.

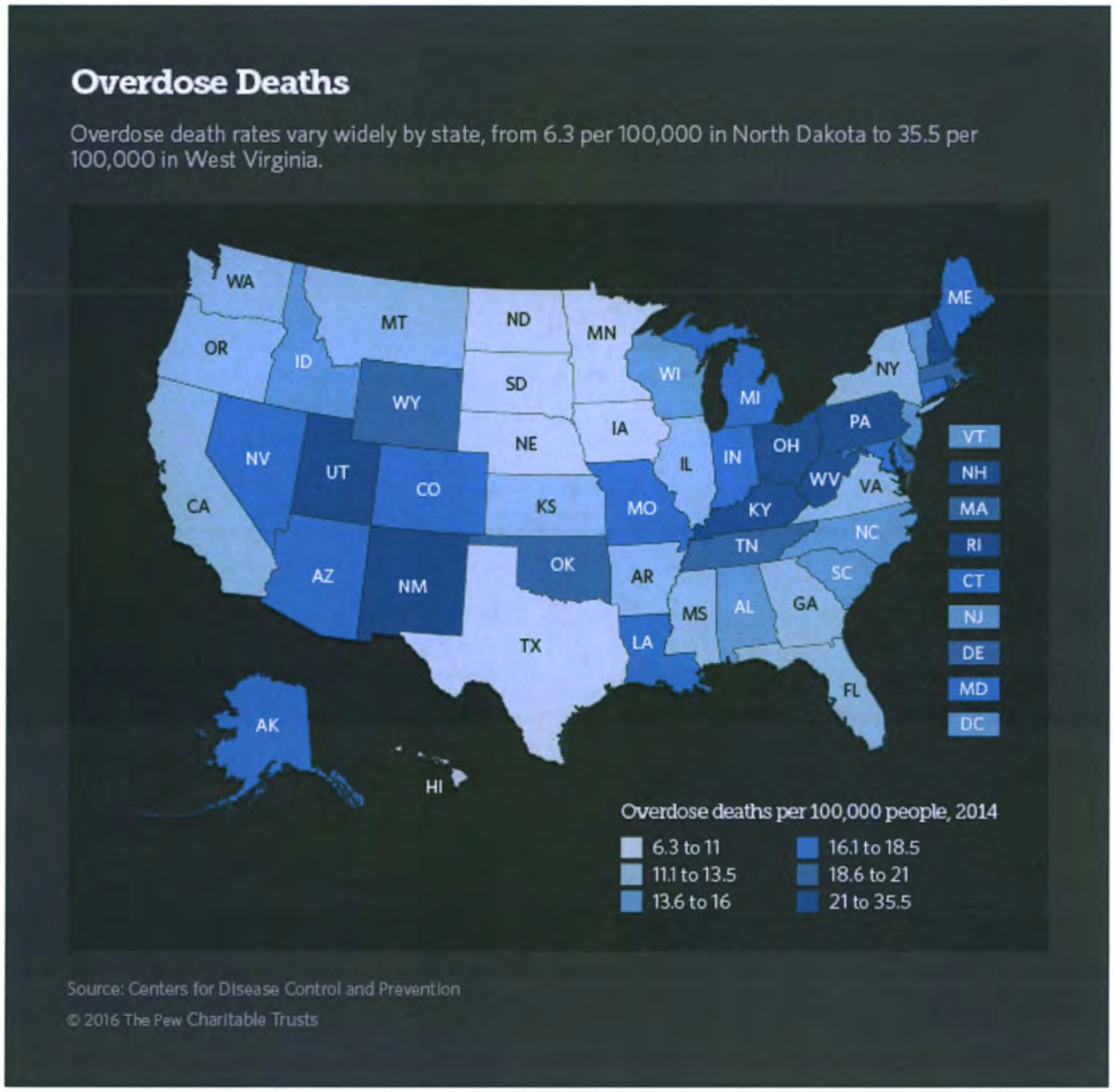
One of the most controversial recommendations in the CDC's draft proposal calls on family doctors not to prescribe opioid doses higher than the equivalent of 50 milligrams of morphine per day without consulting a pain specialist.

In 2007, Washington state set the threshold much higher: no more than the equivalent of 120 milligrams of morphine per day.

Even at that level, drugmakers were aggrieved. "We got sued immediately," Franklin said. He also received a letter from Purdue Pharma, the maker of OxyContin, calling the dose limit "too stringent" and arguing it could "interfere with access to appropriate and effective pain care for persons suffering from chronic pain."

Coincidentally, within days of sending the letter, Purdue executives pled guilty to misleading doctors and patients about OxyContin's risk of addiction.

The federal lawsuit against Washington's opioid dose limit was dropped in 2010 and doctors across the state generally adhered to the recommendations, Franklin said. Opioid overdose deaths in the state dropped from a high of more than 500 in 2009 to about 300 in 2014. The number of prescriptions also declined by nearly a third, as did the number of workdays lost to injury.




## Opioids and Heroin

Starting in the late '90s, pharmaceutical companies began telling physicians that opioid pain relievers were safe, effective and nonaddictive. As momentum for greater use of the powerful drugs grew, an organization that accredits medical professionals, the Joint

Commission, declared pain the "fifth vital sign," requiring doctors and other medical professionals to measure and treat pain as they would any other vital sign — temperature, blood pressure, pulse, breathing rate.

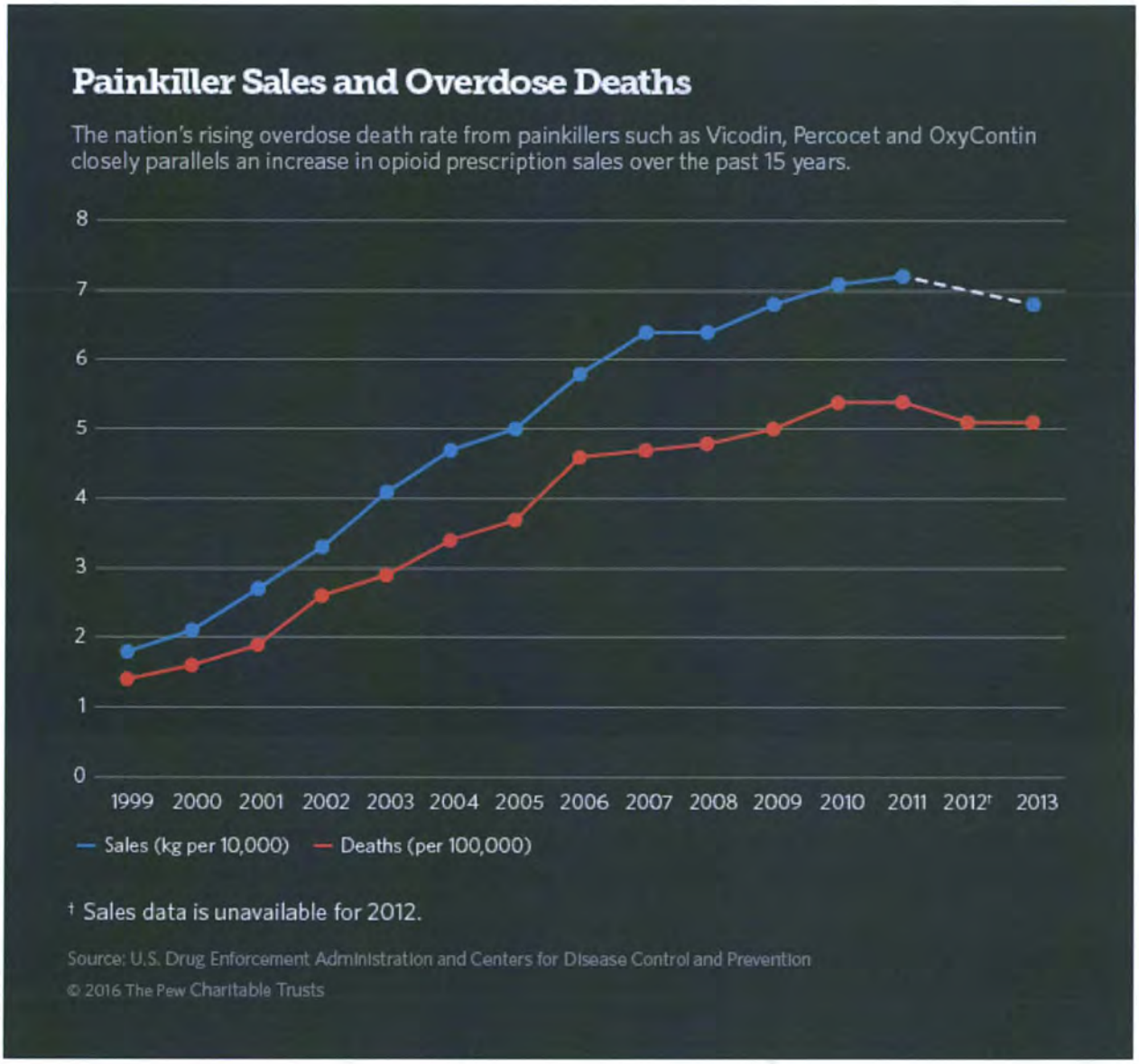
Although the FDA had recently approved OxyContin and other opioids for severe acute pain only, doctors and hospitals — which are rated on their effectiveness at eliminating pain — began using opioids as a first line of treatment for nearly every kind of acute and chronic pain, from toothaches and migraines to sports injuries, back pain and cancer.

Sales of prescription painkillers spiked immediately. By 2012, health professionals were writing more than 250 million prescriptions for painkillers per year, according to the CDC — almost enough for every American to have a bottle of pills. Vicodin or its generic, hydrocodone with acetaminophen, became the most prescribed medication in the country.

In 2014, nearly 2 million people had a prescription painkiller addiction and more than half a million were addicted to heroin, according to the National Survey on Drug Use and Health.

Following a wave of opioid painkiller overdose deaths starting in 2001, heroin overdose deaths began piling up. The CDC has reported that people who take opioid painkillers are 40 times more likely to use heroin. Another study found that three in four heroin users were introduced to opioids through prescription drugs.

Many experts have speculated that the recent rise in heroin use results, in part, from a federal and state crackdown on doctor's offices where bogus prescriptions are written in exchange for cash payments. The decline in "pill mills" cut back the supply of illicit painkillers and made them more expensive, prompting many to switch to cheaper heroin, the theory goes. A new study in the *New England Journal of Medicine* concludes there is insufficient evidence to support that theory.




## The Next Generation

Pain experts, including the head of the national organization Physicians for Responsible Opioid Prescribing, Dr. Jane Ballantyne, emphasize that prescription pain relievers are killing thousands of people who are taking them as prescribed, not just those who abuse them.

Ballantyne, who advised the CDC on its soon-to-be-released guidelines, said many people who are taking opioids for chronic pain should have their doses reduced or be weaned off them. But that is not what the CDC guidelines address.

"The CDC guidelines are not there to stop patients who are already addicted. They are there to stop new patients from becoming addicted, patients who should not be taking an opioid in a lot of cases and certainly not in big doses."

The CDC's guidelines are intended for primary care doctors, not pain specialists. They provide guidance on pain relief for minor acute pain and long-term chronic pain. They are not aimed at pain management physicians or doctors who treat cancer patients, people at the end of their lives, or patients with severe long-term pain of any kind.

Ballantyne concedes that alternative methods of relieving pain can be much more complicated than prescribing a pill. It often involves a discussion with patients that doesn't fit easily into a 15-minute office visit.

Patients need to be encouraged to work through the "everyday" pains of aging and minor injuries by staying active, she said. Doctors should suggest doing yoga, listening to music or seeking counseling. "Patients need to be reassured that their pain is not dangerous, and that there is no easy fix."

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**PLACES**

# Facing epidemic, Baker seeks to limit opioid prescriptions

PAT GREENHOUSE/GLOBE STAFF

**Governor Charlie Baker.**

By Joshua Miller | GLOBE STAFF OCTOBER 15, 2015

Governor Charlie Baker, facing a deadly scourge of prescription drug and heroin abuse, proposed Thursday to place new limits on how many opioid painkillers doctors and dentists can prescribe to a patient.



HB 344 Background
Distributed by Rep Seaton

Looking to help stanch addiction where it often begins, the wide-ranging bill would limit practitioners to prescribing no more than a 72-hour supply of opioids to patients the first time they prescribe an opioid to them, with exceptions only for certain limited emergencies.

At a State House news conference, Baker said he has heard far too many stories in recent years of people who come from a doctor's office, a dental visit, or the hospital with 30 or 60 or 80 tablets of an opioid drug, when a handful would do. "This has got to stop," he said.

Administration officials said they did not know of any other state that has enacted a similar measure.

Legislative leaders reacted positively to the proposal, but the Baker plan immediately drew concern from the medical community in Massachusetts, underscoring the tension between the government's latest effort to stem the epidemic and doctors' belief that they know their patients' needs best.

"It doesn't necessarily allow for the clinical judgment of physicians — to adjust their prescriptions for different patients with different situations," said Dr. Dennis Dimitri, president of the Massachusetts Medical Society, which represents more than 25,000 physicians and medical students.

Dr. David P. Lustbader, an oral and maxillofacial surgeon who is vice president of the Massachusetts Dental Society, said the effort is a simplistic approach to a complex problem.

"For me to tell a patient, 'I'm sorry, you can only have 72 hours of pain medication,' it's not fair and it's not realistic," he said. "You're having attorneys trying to fix health care, and you're throwing the baby out with the bathwater."

The powerful American Medical Association also expressed worry. The group's chairwoman-elect, Dr. Patrice A. Harris, said in a statement the AMA shares local doctors' "concerns over sections of the bill, including universal mandates that may be well-intentioned, but may have unintentional consequences to the patient-physician relationship."

But Dr. Sarah Wakeman, a Massachusetts General Hospital physician who served on Baker's Opioid Working Group, which delivered a lengthy set of recommendations in June that helped form the basis of the bill, described a rationale for the prescribing limit push. She said drug addiction is a disease and, as in dealing with other diseases, prevention works.

"We prevent diabetes by limiting exposure to foods and beverages. We prevent lung cancer by limiting exposure to tobacco smoke," she said at the news conference. So the proposed opioid prescription limit "will help to minimize excessive exposure to opioids."

Baker, a former health insurance company executive, explained he has lots of friends and colleagues in the health care world. "I am astonished," the Republican governor said, "by the casual nature and the casual attitude that I find when I talk to them about these medications and these issues. And that has got to change. Period."

The governor's legislation would also strengthen a prescription monitoring program, requiring every practitioner to check a database before writing an opioid prescription; increase education about the drugs for athletic coaches, parents, and physicians; and give hospitals new power to force treatment on substance abusers who pose a danger to themselves or others.

Early reviews of the bill from several powerful figures in the state were positive. Senate President Stanley C. Rosenberg and House Speaker Robert A. DeLeo, both Democrats, released warm statements about the legislation.

And in a clear nod to the bipartisan effort to tackle the crisis, Steven A. Tolman — the president of the Massachusetts AFL-CIO, a former Democratic state senator, and a sometimes Baker antagonist — stood directly to Baker's right during the news conference. In remarks, Tolman, a longtime advocate on issues of substance abuse, underscored his support for the governor's effort to address the scourge.

In another boost for the bill, Lora M. Pellegrini, president and chief executive of the Massachusetts Association of Health Plans, which represents 17 health insurers in the state, praised Baker for leading on the issue of opioid addiction.

Pellegrini said the data show a lot of heroin users start with opioid prescription drugs, and the prescription-limiting effort might help reduce the amount of those drugs on the street.

The governor also proposed ending the practice of sending women struggling with addiction — who are found by a court to pose an immediate risk of harm to themselves or others — to a Framingham prison when treatment beds are full.

Jessie Rossman, a staff lawyer with the American Civil Liberties Union of Massachusetts, which has brought a lawsuit on behalf of women civilly committed to the prison, said she is reviewing the legislation and hopes any bill that becomes law will actually accomplish the goal of ending the practice.

She also said the ACLU is carefully reviewing Baker's push to give hospitals new power to force treatment on substance abusers who pose a danger to themselves or others for up to 72 hours — and offered a note of concern about any effort that can deprive people of their liberties.

Baker's proposal mirrors existing law that permits a 72-hour period of involuntary treatment when a physician determines a person suffers from mental illness and poses a serious risk of harm.

Massachusetts has suffered from a grim rise in unintentional opioid overdose deaths. The state Department of Public Health said this year that an estimated 1,256 Massachusetts residents died from opioid overdoses in 2014, a sharp increase from 2013 and 2012.

The Senate has already passed its own bill this fall, focused on steering people away from addiction through education and prevention. Baker's bill, along with efforts by the House, may be melded into a single legislative package in the months ahead.

The governor has made a wide-ranging state government response to the crisis a centerpiece of his agenda. Aides said he is deeply committed to getting a comprehensive bill to address opioid abuse into law and is willing to use his political capital to get it done.

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