HB

239

REPRESENTATIVE
MIKE CHENAULT

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STATE OF ALASKA

HOUSE OF REPRESENTATIVES

Official Business

Session:
Capitol Building, Room 432
Juneau, Alaska 99801-1182
(907) 465-3779
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House Bill 239
By Representative Mike Chenault

Tracking of Controlled Substances

Substance abuse has been a problem on the Kenai Peninsula and throughout Alaska for many years. This bill will track all controlled substances through a secure internet tracking system.

Revised 02/10/04

Representative_Mike_Chenault@legis.state.ak.us

23-LS0897\S
Mischel
4/27/04

CS FOR HOUSE BILL NO. 239( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-THIRD LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): REPRESENTATIVE CHENAULT

A BILL

FOR AN ACT ENTITLED

"An Act requiring the Board of Pharmacy to establish a tracking system for controlled substances."

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

* **Section 1.** AS 08.80 is amended by adding a new section to read:

Sec. 08.80.075. Controlled substance data base. (a) The board shall adopt regulations establishing a controlled substance secure networked server-based data base and procedures under which each pharmacist in the state will be required to determine, by consulting the secure data base, whether a prescription for a controlled substance that is being dispensed by the pharmacist to cover a certain time period for a human patient duplicates a prescription already dispensed for the same patient that was intended to cover a substantial portion of the same time period. The board shall design the secure networked server-based data base in a manner that

(1) maintains the confidentiality of the information in the secure networked server-based data base;

(2) provides access to each practitioner of the healing arts who is authorized to prescribed controlled substances; and

(3) provides real-time information pertaining to schedule IA controlled substances as described under AS 11.71.140.

(b) The regulations adopted under (a) of this section must include a provision for secure and verifiable delivery to each person designated as the patient on the prescription for controlled substances, including in-person and certified mail delivery.

(c) In this section, "practitioner of the healing arts" has the meaning given in AS 47.17.290.

23-LS0897\H
Mischel
4/1/04

CS FOR HOUSE BILL NO. 239( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-THIRD LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): REPRESENTATIVE CHENAULT

A BILL

FOR AN ACT ENTITLED

"An Act directing the Board of Pharmacy to establish an Internet-based identification and tracking system relating to controlled substances that are prescribed for human use; and relating to the manner in which prescriptions for controlled substances may be filled by a pharmacist."

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

*** Section 1.** AS 08.80.158(b) is amended to read:

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; [AND]

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy; **and**

(5) proof satisfactory to the board that the pharmacy meets the requirements under AS 08.80.305 by consulting the secure Internet data base developed under that section and by requiring a copy of picture identification and a verified signature of the person designated on the prescription, before dispensing a controlled substance to a person who is located in the state.

* **Sec. 2.** AS 08.80 is amended by adding a new section to read:

Sec. 08.80.305. Controlled substance data base. (a) The Board of Pharmacy, in consultation with the State Medical Board, shall develop a controlled substance secure Internet data base that will allow each pharmacist in the state to determine, by consulting the secure Internet data base, whether a prescription for a controlled substance that is being dispensed by the pharmacist to cover a certain time period for a human patient duplicates a prescription already dispensed for the same patient that was intended to cover a substantial portion of the same time period. The board shall design the secure Internet data base in a manner that maintains the confidentiality of the information in the secure Internet data base so that the secure Internet data base can only be used by pharmacists for the purposes identified in this section. The secure Internet data base shall use a unique identifying number for each patient for whom a controlled substance is prescribed and for each person designated by a patient as a person entitled to obtain a prescribed controlled substance on behalf of the patient. The board, in consultation with the State Medical Board, shall determine how and by whom the identifying numbers and prescription information will be entered into the secure Internet data base.

(b) Before dispensing a controlled substance for human use, a pharmacist shall require picture identification from the person designated on the prescription or a

person entitled to obtain a prescription on behalf of the person designated on the prescription, if the entitled person is attempting to obtain the controlled substance, and shall consult the secure Internet data base developed under (a) of this section. The pharmacist may not dispense a controlled substance if

(1) the secure Internet data base indicates that a prescription for the same controlled substance has been filled for the same patient in an amount intended to cover a substantial portion of the same time period as the prescription drug order presented to the pharmacist; or

(2) the person's identification does not reasonably substantiate that the person is either the patient for whom the controlled substance is intended or the person designated in the secure Internet data base as a person entitled to obtain a controlled substance on behalf of the patient.

~~FAX~~ TRANSMITTAL

STATE OF ALASKA
DEPARTMENT OF COMMUNITY
AND ECONOMIC DEVELOPMENT

DIVISION OF OCCUPATIONAL
LICENSING
P.O. BOX 110806
JUNEAU, AK 99811-0806
TELEPHONE: (907) 465-2534
FAX: (907) 465-2974

TO: LINDA MILLER DATE: 4/16/04

COMPANY: REP. PEGGY WILSON

FAX NO. DELIVER - ROOM 106 CAPITOL

FROM: Barbara Roche
Licensing Examiner
Telephone: (907) 465-2589
E-mail: barbara_roche@dced.state.ak.us

HB 239
CORRESPONDENCE FROM BOARD OF PHARMACY

NUMBER OF PAGES INCLUDING COVER: _____

HARD COPY TO FOLLOW? [ ] YES [✓] NO

RE: FEB 15, 2004 LETTER TO REP. WOLF RE: HB 239, HB 408, HJR 33
NOV. 17, 2003 LETTER TO REP. CHENAULT - RE HB 239
DEC. 10, 2003 LETTER TO MR JOEL GILBERTSON - RE HB 239
JUNE 4, 2003 LETTER TO REP. CHENAULT W/ NATIONAL ASSOC. OF STATE CONTROLLED SUBSTANCES AUTHORITIES - FINDINGS & RECOMMENDATIO OF PRESCRIPTION MONITORING STANDARDS.
OCT 2-3, 2003 - BOARD OF PHARMACY MINUTES p. 13-14
SEPT. 29. 2003 NOTES ON HB 239
APRIL 24-25, 2003 - BOARD OF PHARMACY MINUTES P. 13

If FAX does not transmit properly, please call
(907) 465-2589 immediately.

4/1/04 "WORK DRAFT" & LETTER OPPOSING FROM MEDCO HEALTH

Frank H. Murkowski, Governor

Alaska Department of Community and Economic Development

Division of Occupational Licensing
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February 15, 2004

Representative Kelly Wolf
State Capitol, Room 418
Juneau, AK 99801-1182

Cc: Mr. Rick Urion, Director
Department of Community and Economic Development
Division of Occupational Licensing
PO Box 110806
Juneau, AK 99811-0806

Dear Representative Wolf:

Re: HB 408 and HJR 33

At the February 5 and 6, 2004 meet ng of the Alaska Board of Pharmacy, we discussed House Bill 408 and House Joint Resolution 33, which you introduced in the legislature this session. Both of these reflect your concerns with the misuse/abuse of the controlled substance oxycodone and its controlled release formulation, OxyContin. The Board of Pharmacy has had an on-going committee on prescription drug abuse issues in Alaska. At our October meeting, we discussed HB 239, introduced by Representative Chenault, and heard a report from a representative for the Anchorage office of the Federal Drug Enforcement Administration (DEA). Alaska has a real problem with the abuse of prescription drugs and the abuse/misuse costs the state millions of dollars every year. HB 239 would establish a tracking system for certain controlled substances.

The Board of Pharmacy is in support of the spirit of both HB 408 and HB 239 but we have some concerns. Most successful state prescription monitoring systems are under the auspices of a unit of state government that deals with health care rather than law enforcement. Prescribers, as well as pharmacists, are an important part of these programs. Although these programs cost a significant amount of money to set up and maintain, the costs may be offset by the decrease in funds needed to treat the harmful effects of prescription drug abuse. I am enclosing a copy of a model that includes the key points in developing a state prescription-monitoring program for controlled substances.

The points you make in HJR 33 about the misuse and abuse of oxycodone, and, more specifically OxyContin, are true, but the Alaska Board of Pharmacy feels that removing oxycodone from the market would not be in the best interests of patients with severe pain. Most hospitals routinely use oxycodone for post-operative pain relief since it can be given by mouth. When used appropriately, OxyContin, has allowed patients with chronic pain more consistent pain management. The problems arise because both of these drugs are over-prescribed, inappropriately prescribed, diverted, abused, or used in inappropriate ways. Instead of seeking a withdrawal of these drugs, the Board again feels that a controlled substances prescription monitoring system would allow for the continued use of these drugs in managing patients with pain but might also assist in detecting over-prescribing, prescription fraud, and doctor shopping.

If you would like more information about the Board of Pharmacy's on-going interest in prescription drug abuse issues, you can contact the two pharmacist members of the board who serve on our committee tasked with following this area of concern, Bill Altland of Craig, Alaska, or me.

Thank you,
Margaret Soden
Chair, Alaska Board of Pharmacy

Barbara A. Rooke,
LICENSING EXAMINER
ALASKA BOARD OF PHARMACY
FOR: MARGARET SODEN

Margaret Soden, RPh
(907) 479-6793, cardinal@ptialaska.net

Bill Altland, RPh
(907) 826-5750, bsaltland@hotmail.com

Enclosures:

Model State Prescription Monitoring System outline
Board of Pharmacy Roster

Model State Prescription Monitoring Programs

Purpose: The purpose of this document is to outline a model state PMP that contains the attributes that will maximize the benefit to the public health, provide useful information for clinical management to authorized healthcare professionals[1], assist in the detection of prescription fraud and doctor shopping, allow for case management interventions based on pharmaceutical usage and, while fulfilling these objectives, will protect patient privacy and create little or no intrusion into or additional burden on the practices of prescribers and dispensers. It is imperative that any PMP not interfere with access to appropriate pharmaceutical therapies for patients with legitimate medical need.

1. Pharmacy transactions involving every federally controlled substance in schedule II, III, and IV and any other drug of concern shall be entered into the database[2].

2. Individual authorized practitioners may query the database on specific individuals who are their patients or are contemplating initiating a practitioner – patient relationship[3].

3. Data must be entered in a timely and efficient manner[4], with appropriate checks for accurate and complete data[5] from every eligible prescription[6].

4. A unit of state government primarily dealing with healthcare issues should control access to the database[7].

5. Appropriate security measures must exist to protect the integrity[8] of and access[9] to the data.

6. Means of sharing information from the database about specific individuals in a state PMP database with out of state authorized healthcare professionals and out of state authorized law enforcement officials must be provided[10].

7. Law enforcement officials may query the database with regard to a specific individual when possessing appropriate legal authority to do so[11].

8. Data must be collected and entered into an electronic database that is searchable by any field or combination of fields[12].

9. Requisite data from each dispensing episode must include, at a minimum, identification of the patient, prescriber, dispenser, the drug, quantity, strength, signature, refills, and date of dispensing[13].

10. Dispensing of controlled substances directly by non-pharmacy healthcare professionals must be entered into the database[14].

11. The PMP must operate an ongoing continuous quality improvement program that ensures, at a minimum, provisions to monitor the compliance of dispensers, accuracy and completeness of the data, appropriate controls over access, and protection and integrity of the data[15].

[1] In the context of this document, the term "authorized health care professional" means an individual licensed by the state who is authorized to either prescribe or dispense controlled substances, as defined in the US Controlled Substances Act of 1970 (CSA), as amended (21 USC 803, et seq). This specifically excludes those licensed health care professionals who may administer a controlled substance upon the order of an authorized health care professional, but who lack prescriptive or dispensing authority under the conditions of licensure.

[2] To maintain complete information, each eligible transaction shall be entered into the database, regardless of payment source. This obviates a current problem in some states where the Medicaid database, which might otherwise function to some degree as a PMP, only includes data from transactions with recipients when these are billed to Medicaid. Cash transactions are not recorded in the Medicaid database and, in fact, the pharmacist may have no knowledge that a cash customer is also a Medicaid recipient.

[3] This requirement allows the prescriber or dispenser to inquire about a specific person with whom they have or are contemplating starting a practitioner – patient relationship. This specifically precludes searches of the database by an individual practitioner by drug name, by dispenser, by prescriber, or other fields, to ensure appropriate privacy safeguards.

[4] This does not require real time data entry capabilities and allows for states that require pharmacies to batch download data at specified intervals. Real time data entry, which would eventually allow real time searching of the database by authorized health care professionals, such as before prescribing or dispensing, is thought to be the preferable system design and long-term goal that will most effectively reduce doctor shopping and prescription fraud.

[5] Quality control systems should be in place to verify the identity of individuals suspected of appearing in the database as more than one unique person (e. g., A.J. Smith and Albert J. Smith, both having the same birth date and address) and to investigate and correct information that is incomplete, missing or suspected of being invalid.

[6] The term "eligible prescription" allows for specification of which types of medications would be tracked by the PMP. The ideal system will include every drug scheduled under the CSA. This provision allows for other drugs of concern to be tracked by the system, such as drugs that are scheduled by a state but are not federally scheduled or drugs that are unscheduled both by the state and the federal government but are of concern to health or law enforcement officials (e.g., carisoprodol).

[7] This is important for adequate protection of the rights of patients, prescribers and dispensers. Although the database itself may reside outside of a health function or out of state, the access to it must be controlled by an appropriate health agency, as the primary goal is to optimize public health.

[8] Sufficient systems shall exist to ensure the regular backup of data at a frequency that would protect the integrity of the information in the event the primary database or server was irreparably damaged.

[9] Access to the data shall be secure, using firewalls, encryption, passwords and the like to minimize the possibility of unauthorized access and to protect the privacy of patients, prescribers and dispensers.

[10] Current limitations of existing programs include data collection, storage and retrieval in ways that do not facilitate transfer of data across systems when legitimate need dictates, and the inability of a practitioner licensed in one state to query the database maintained by another state. This becomes especially important in areas near state boundaries, where persons engaging in diversion will attempt to defeat the system by obtaining and filling prescriptions in different states.

[11] This requirement allows law enforcement officials access to the data only when there is reasonable suspicion about a specific individual (patient, prescriber or dispenser) to justify a search of the data. This does not confer or remove any existing access to data by law enforcement, but does preclude searching the database for prescribers above a certain threshold as a means of beginning an investigation ("witch hunts").

[12] This requires that the data from prescriptions be ultimately entered into a searchable electronic database. It does not mandate that every pharmacy must have the capacity to enter data electronically. In Nevada, for example, pharmacies that do not have the requisite hardware and software to enter data electronically and who fill below a certain number of prescriptions for controlled substances per month, may submit the data by mail or facsimile to the Board of Pharmacy, who will then enter the information into the electronic database.

[13] States should require minimal datasets from each transaction so as to allow the system to function as intended and to facilitate complex database queries. Means of identification of patient, prescriber or dispenser can be alphanumeric coding, such as DEA registration number to identify a prescriber or license number to identify a dispenser, instead of name. Other data could include the date of prescribing, the address of the prescriber, etc. Federal regulation and some state regulations require these elements are required to be on the prescription itself. The decision to include these data in the PMP should be made with consideration to minimizing redundancy and burden on the pharmacist.

[14] This provision will place a burden on practitioners who dispense controlled substances or other drugs of concern from their places of practice, which has been identified as a source of diversion in some prominent cases.

[15] PMPs are only as useful as the data they collect and manage. Lack of compliance with provisions of PMPs was pointed out as a problem during a recent meeting of a task force dealing with prescription drug abuse and diversion in Kentucky. Appropriate controls over access to the data are vital to protection of privacy of individuals listed in the database and will be crucial to garnering support for institution of new or changes to existing PMPs from the health care communities and the populace at large.

State of Alaska

Office of Boards and Commissions Roster

PHARMACY BOARD (078)

Member	Date Appointed	Reappointed	Term Expires
William R. (Bill) Altland Pharmacist P.O. Box 709 Craig, AK 99921	4/25/2003		3/1/2007
Cindy Bueler, R.Ph. Pharmacist Providence Hospital 7010 Travis Circle Anchorage, AK 99507-2580	6/5/2000	1/16/2004	3/1/2008
Gary M Givens Pharmacist Alaska Native Medical Center 4315 Diplomacy Drive Anchorage, AK 99508	3/1/2004		3/1/2008
Gerry Knasiak Public 119 Austin Street, Apt. 611 Ketchikan, AK 99901-5945	4/16/1998	6/7/2001	3/1/2005
Laura Lee Nelson Pharmacist 9336 Betty Court Juneau, AK 99801-8827	6/29/1999	6/7/2001	3/1/2005
Michael Pauley Public P.O. Box 770522 Eagle River, AK 99577-0522	3/25/2003	1/16/2004	1/3/2008
Margaret Davis Soden, RPh Pharmacist P.O. Box 61328 Fairbanks, AK 99706-1328	12/11/1998	3/8/2002	3/1/2006

Return to the fact sheet

Frank H. Murkowski, Governor

Alaska Department of Community and Economic Development

Division of Occupational Licensing
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Email: License@dced.state.ak.us • Website: www.dced.state.ak.us/occ/

November 17, 2003

Representative Mike Chenault
145 Main St Loop, Ste 220
Kenai, AK 99611

Dear Representative Chenault:

RE: House Bill 239

In August I called your office and spoke with your aide, Sue Wright, about your HB 239 introduced in the first session of the Twenty-Third Legislature of the State of Alaska. I was hoping to get some background on the bill since this is being introduced as an amendment to Chapter 08.80 which is the chapter in our statutes governing pharmacists and pharmacies. The Board of Pharmacy is responsible for the control and regulation of the practice of pharmacy under this chapter. I am a pharmacist member of the Alaska Board of Pharmacy and currently serve as its chair. I also serve on our on-going committee on Prescription Drug Abuse Issues with fellow member and pharmacist from Craig, Alaska, Bill Altland.

At our October board meeting we discussed your bill and heard a report from a representative of the Anchorage office of the Drug Enforcement Administration (DEA). Alaska **DOES** have a problem with the abuse of prescription drugs. Pharmacists and prescribers have discussed various ways to address this issue. Several other states have enacted regulations establishing internet prescription monitoring programs similar to what you have proposed. We feel, however, that for any monitoring program to work, the prescribers must be included along with pharmacists and law enforcement agencies. We also feel that this monitoring program should be under a department that deals with health care rather than law enforcement and made a motion to that effect at our meeting. We are hoping that you will consider changing your bill to follow the guidelines of the Model State Prescription Monitoring Programs and under the auspices of the Department of Health and Social Services rather than the Department of Public Safety. I have enclosed a copy of the "draft" minutes from our October meeting as well as a copy of an

outline of the key points in developing a state prescription monitoring program for controlled substances.

If you would like more information, you can contact Bill or me. Our next board meeting will be in Juneau, February 5 and 6.

Thank you,

Barbara A. Roche

Barbara Roche
Licensing Examiner
Alaska Board of pharmacy
For: Margaret Soden
Chair, Alaska Board of Pharmacy

Margaret Soden, RPh
(907) 479-6793, cardinal@ptialaska.net

Bill Altland, RPh
(907) 826-3750, bsaltland@hotmail.com

Enclosures:
"Draft" minutes of Alaska State Board of Pharmacy meeting, October 2-3, 2003, pages 13-14 and 17.

Model State Prescription Monitoring Programs outline

Portions of Chapter 80. Pharmacists and Pharmacies

Board of Pharmacy Roster

prescribers and dispensers, and that the language follow the criteria included the NABP Prescription Monitoring Program Model Regulation. The Board will contact the DCED Legislative Liaison and Representative Chenault, the bill sponsor, to express these concerns.

Mr. Altland stated that the Substance Abuse Counselors will be meeting in Fairbanks at the end of the month and suggested that a board member attend. Ms. Knasiak suggested that Pam Watts, the Executive Director of the Alcoholism and Substance Abuse Board be contacted. Ms. Soden will contact Ms. Watts.

Discussion of prescription drug abuse issues and presentation by DEA Agent Terry Marquart will continue after lunch.

Agenda Item 5 **Regulations (Continued from October 2, 2003 Discussion)**

2. 12 AAC 52.480 (GENERIC LABELING) Will be tabled to Agenda Item 19, New Business.

3. 12 AAC 52.130 REVIEW OF APPLICATIONS FOR REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. The regulation, which was included in the May 9, 2003 "Supplemental Notice of Proposed Changes in the Regulations of the Board of Pharmacy", was adopted by the Board at the July 25, 2003 meeting. Original language ("A pharmacy located outside the state that ships, mails, or delivers prescription drugs more than twice annually to individual patients in the state shall register with the board.") was inadvertently deleted from the "Supplemental Notice...." The Board stated that its intention was to keep the original language that defined "regularly" and to add the checksheet regulation as stated in the "Supplemental Notice....", not to repeal the first sentence of 12 AAC 52.130. Mr. Brower of the Dept. of Law stated in an email that a new public notice would not be required.

On a motion duly made by Ms. Bueler, seconded by Ms. Knasiak, and approved unanimously, it was

RESOLVED that in 12 AAC 52.130, the original definition of "regularly" ("A pharmacy located outside the state that ships, mails, or delivers prescription drugs more than twice annually to individual patients in the state shall register with the board.") should be included in the final regulation along with the checksheet regulation (a) and (b).

The Board noted that they considered the cost to private persons when adopting these regulations and acted in the interest of public health and safety. The Board requests that the Notice of Changes to regulations above be sent to all pharmacies and pharmacists (license types R, P, and O).

Break — Recess for Lunch at 12:05 PM.

Back on record at 1:02 PM.

Agenda Item 14 — **Discuss Prescription Drug Abuse Issues (Continued)**

Terry Marquart, DEA, spoke to the Board on pharmaceutical narcotic drug trends in Alaska and nationwide. The DEA monitors all pharmaceuticals, paying special attention to Schedule II, which tend to be the drugs abused. Mr. Marquart noted that Alaska ranks in the top five in the nation for per capita use of Oxycontin, oxycodone, hydrocodone, r peridine and fentanyl and methadone. Methodone use in Alaska is almost four times the national average. Mr. Marquart discussed DEA policy cornerstones: 1) Controlled substances have useful and legitimate medical purposes. 2) Practitioners are not limited in their ability to administer and prescribe medications for patients with intractable pain. 3) Prescriptions must be for legitimate medical purpose, by a practitioner acting in the usual course of professional practice. 4) Corresponding responsibility rests with the filling pharmacist.

Agenda Item 15 — **Legislative Update**

Senator Dyson and Jason Hooley joined the meeting at 1:15PM

SB 156 ("An Act relating to the posting and giving of certain warnings about drinking alcohol during pregnancy when selling or dispensing pregnancy testing kits, birth control devices, or birth control prescriptions") was discussed by the Board. Senator Dyson stated that he is pursing the interstate commerce issues related to product labeling and is contacting manufacturers and retailers. Ms. Soden suggested a standardized sign could be distributed to retailers. Mr. Altland distributed a letter from a grocery storeowner commenting on SB 156.

HB 51 ("An act requiring pharmacists to include generic drug information on containers in which brand-name drug orders are dispensed"). Mr. Bohrer distributed a memo and outlined the "key points" relating to HB 51.

- Public comment noted that several pharmacies would not be able to comply with the regulation.

Model State Prescription Monitoring Programs

Purpose: The purpose of this document is to outline a model state PMP that contains the attributes that will maximize the benefit to the public health, provide useful information for clinical management to authorized healthcare professionals[1], assist in the detection of prescription fraud and doctor shopping, allow for case management interventions based on pharmaceutical usage and, while fulfilling these objectives, will protect patient privacy and create little or no intrusion into or additional burden on the practices of prescribers and dispensers. It is imperative that any PMP not interfere with access to appropriate pharmaceutical therapies for patients with legitimate medical need.

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2. Individual authorized practitioners may query the database on specific individuals who are their patients or are contemplating initiating a practitioner – patient relationship[3].

3. Data must be entered in a timely and efficient manner[4], with appropriate checks for accurate and complete data[5] from every eligible prescription[6].

4. A unit of state government primarily dealing with healthcare issues should control access to the database[7].

5. Appropriate security measures must exist to protect the integrity[8] of and access[9] to the data.

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[1] In the context of this document, the term "authorized health care professional" means an individual licensed by the state who is authorized to either prescribe or dispense controlled substances, as defined in the US Controlled Substances Act of 1970 (CSA), as amended (21 USC 803, et seq). This specifically excludes those licensed health care professionals who may administer a controlled substance upon the order of an authorized health care professional, but who lack prescriptive or dispensing authority under the conditions of licensure.

[2] To maintain complete information, each eligible transaction shall be entered into the database, regardless of payment source. This obviates a current problem in some states where the Medicaid database, which might otherwise function to some degree as a PMP, only includes data from transactions with recipients when these are billed to Medicaid. Cash transactions are not recorded in the Medicaid database and, in fact, the pharmacist may have no knowledge that a cash customer is also a Medicaid recipient.

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[4] This does not require real time data entry capabilities and allows for states that require pharmacies to batch download data at specified intervals. Real time data entry, which would eventually allow real time searching of the database by authorized health care professionals, such as before prescribing or dispensing, is thought to be the preferable system design and long-term goal that will most effectively reduce doctor shopping and prescription fraud.

[5] Quality control systems should be in place to verify the identity of individuals suspected of appearing in the database as more than one unique person (e. g., A.J. Smith and Albert J. Smith, both having the same birth date and address) and to investigate and correct information that is incomplete, missing or suspected of being invalid.

[6] The term "eligible prescription" allows for specification of which types of medications would be tracked by the PMP. The ideal system will include every drug scheduled under the CSA. This provision allows for other drugs of concern to be tracked by the system, such as drugs that are scheduled by a state but are not federally scheduled or drugs that are unscheduled both by the state and the federal government but are of concern to health or law enforcement officials (e.g., carisoprodol).

[7] This is important for adequate protection of the rights of patients, prescribers and dispensers. Although the database itself may reside outside of a health function or out of state, the access to it must be controlled by an appropriate health agency, as the primary goal is to optimize public health.

[8] Sufficient systems shall exist to ensure the regular backup of data at a frequency that would protect the integrity of the information in the event the primary database or server was irreparably damaged.

[9] Access to the data shall be secure, using firewalls, encryption, passwords and the like to minimize the possibility of unauthorized access and to protect the privacy of patients, prescribers and dispensers.

[10] Current limitations of existing programs include data collection, storage and retrieval in ways that do not facilitate transfer of data across systems when legitimate need dictates, and the inability of a practitioner licensed in one state to query the database maintained by another state. This becomes especially important in areas near state boundaries, where persons engaging in diversion will attempt to defeat the system by obtaining and filling prescriptions in different states.

[11] This requirement allows law enforcement officials access to the data only when there is reasonable suspicion about a specific individual (patient, prescriber or dispenser) to justify a search of the data. This does not confer or remove any existing access to data by law enforcement, but does preclude searching the database for prescribers above a certain threshold as a means of beginning an investigation ("witch hunts").

[12] This requires that the data from prescriptions be ultimately entered into a searchable electronic database. It does not mandate that every pharmacy must have the capacity to enter data electronically. In Nevada, for example, pharmacies that do not have the requisite hardware and software to enter data electronically and who fill below a certain number of prescriptions for controlled substances per month, may submit the data by mail or facsimile to the Board of Pharmacy, who will then enter the information into the electronic database.

[13] States should require minimal datasets from each transaction so as to allow the system to function as intended and to facilitate complex database queries. Means of identification of patient, prescriber or dispenser can be alphanumeric coding, such as DEA registration number to identify a prescriber or license number to identify a dispenser, instead of name. Other data could include the date of prescribing, the address of the prescriber, etc. Federal regulation and some state regulations require these elements are required to be on the prescription itself. The decision to include these data in the PMP should be made with consideration to minimizing redundancy and burden on the pharmacist.

[14] This provision will place a burden on practitioners who dispense controlled substances or other drugs of concern from their places of practice, which has been identified as a source of diversion in some prominent cases.

[15] PMPs are only as useful as the data they collect and manage. Lack of compliance with provisions of PMPs was pointed out as a problem during a recent meeting of a task force dealing with prescription drug abuse and diversion in Kentucky. Appropriate controls over access to the data are vital to protection of privacy of individuals listed in the database and will be crucial to garnering support for institution of new or changes to existing PMPs from the health care communities and the populace at large.

State of Alaska

Office of Boards and Commissions Roster

PHARMACY BOARD (078)

Member	Date Appointed	Reappointed	Term Expires
William R. (Bill) Altland Pharmacist P.O. Box 709 Craig, AK 99921	4/25/2003		3/1/2007
Mark D. Bohrer Pharmacist P.O. Box 971309 Chugiak, AK 99567-1309	11/10/1999	5/24/2000	3/1/2004
Cindy Bueler, R.Ph. Pharmacist 7010 Travis Circle Anchorage, AK 99507-2580	6/5/2000		3/1/2004
Gerry Knasiak Public 119 Austin Street, Apt. 611 Ketchikan, AK 99901-5945	4/16/1998	6/7/2001	3/1/2005
Laura Lee Nelson Pharmacist 9336 Betty Court Juneau, AK 99801-8827	6/29/1999	6/7/2001	3/1/2005
Michael Pauley Public P.O. Box 770522 Eagle River, AK 99577-0522	3/25/2003		3/1/2004
Margaret Davis Soden, RPh Pharmacist P.O. Box 61328 Fairbanks, AK 99706-1328	12/11/1998	3/8/2002	3/1/2006

Return to the fact sheet

Subject: Fw: Letter to Legislative Liason
Date: Sun, 14 Dec 2003 08:27:59 -0900
From: Soden's <cardinal@ptialaska.net>
To: "Younkins, Rick" <richard_younkins@dced.state.ak.us>,
"Roche, Barbara" <barbara_roche@dced.state.ak.us>,
Mike Pauley <mikepauley@alaska.com>, Mark Bohrer <markboh@aol.com>,
Laura Lee Nelson <pharmhog@alaska.net>, Gerry Knasiak <g.knasiak@worldnet.att.net>,
"Bueler, Cindy" <cbueler@alaska.com>, Bill Altland <bsaltland@hotmail.com>

Dear Board members,

Here is a copy of the letter Barbara and I wrote to Mr Gilberton, Director for HSS and Rick Urion. I also got a call from Nancy Lewis of Purdue Pharma and she and Linda Barefoot have a meeting with Rep Chenault and a Senator from that area this week. She will let me know how it went later.

Margaret
----- Original Message -----
From: "Barbara Roche" <barbara_roche@dced.state.ak.us>
To: "Margaret Soden" <cardinal@ptialaska.net>
Sent: Wednesday, December 10, 2003 1:08 PM
Subject: Letter to Legislative Liason

> *Dear Margaret,*
>
> *Here is the letter to Mr. Gilbertson and Rick Urion, with the addresses, etc. If this looks OK to you, I will send the letter and the attachments out from here. I will sign "Barbara Roche for Margaret Soden" under your name and then send you a copy of the signed letter.*
>
> *Barbara*
>

Legislative Liason letter on rx drug abuse.doc	**Name:** Legislative Liason letter on rx drug abuse.doc **Type:** Microsoft Word Document (application/msword) **Encoding:** base64 **Download Status:** Not downloaded with message

Frank H. Murkowski, Governor

Alaska Department of Community and Economic Development

Division of Occupational Licensing
P.O. Box 110806, Juneau, AK 99811-0806
Telephone: (907) 465-2534 • Fax: (907) 465-2974 • Text Telephone: (907) 465-5437
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December 10, 2003

Mr. Joel Gilbertson, Commissioner
Department of Health & Social Services
Office of the Commissioner
PO Box 110601
Juneau, AK 99811-0601

CC: Mr. Rick Urion, Director
Department of Community and Economic Development
Division of Occupational Licensing
PO Box 110806
Juneau, AK 99811-0806

Dear Mr. Gilbertson and Mr. Urion,

The Alaska State Board of Pharmacy has had an on-going committee on prescription drug abuse issues. In the first session of the Twenty-Third Legislature of the State of Alaska, Representative Mike Chenault of Kenai introduced HB 239, which would establish an Internet database for tracking controlled substances. At our board meeting October 2-3, 2003, we discussed HB 239 and Internet monitoring systems in general. We also heard a report from a representative of the Anchorage office of the Federal Drug Enforcement Administration (DEA). Alaska has a real problem with the abuse of prescription drugs and this abuse/misuse costs the State of Alaska millions of dollars every year.

The Board of Pharmacy is in support of the spirit of HB 239 but we have some concerns. Most successful state prescription monitoring systems are under the auspices of a unit of state government that deals with health care rather than law enforcement. Prescribers, as well as pharmacists, are an important part of these same programs. Although these programs cost a significant amount of money to set up and maintain, the costs may be offset by the decrease in funds needed to treat the harmful effects of prescription drug abuse. At our meeting the Board made a motion to recommend changes to HB 239 to have the Department of Health and Social Services establish the monitoring database following the guidelines of the National Association of Boards of Pharmacy model. We have contacted Representative Chenault with our request. I am enclosing a copy of the

letter we wrote to Representative Chenault, the draft minutes of our discussion and motion from our October Board meeting, and an outline of the model for state drug-monitoring programs.

If you would like more information you can contact the members of the Board's committee on prescription drug abuse issues, Bill Altland or Margaret Soden, or our Licensing Examiner, Barbara Roche.

Thank you,
Margaret Soden
Chair, Alaska Board of Pharmacy

Barbara Roche, LICENSING EXAMINER, BOARD OF PHARMACY
FOR
MARGARET SODEN, CHAIR,

Margaret Soden, RPh
(907) 479-6793, cardinal@ptialaska.net

Bill Altland, RPh
(907) 826-5750, bsaltland@hotmail.com

Encl: "Draft"minutes of Alaska State Board of Pharmacy meeting, October 2-3, 2003
Model State Prescription Monitoring Programs outline
Board of Pharmacy Roster

abuse of Schedule II drugs in general, and Oxycontin in particular, seems to be more widespread in Alaska than in other areas of the country.

- Ms. Soden distributed copies of "Model State Prescription Monitoring Programs" and a memo with "Notes on HB 239". HB 239, sponsored by Representative Chenault, is pending legislation that would establish an Internet database for tracking controlled substances. Although the Board supports a tracking system for controlled substances, they felt that there are some areas that HB 239 does not address and recommends that the bill be more in line with the NABP Model Regulations and state prescription monitoring programs adopted or being looked at by many states. Ms. Soden noted that the current HB 239 does not require prescriber participation in the tracking database and that prescriber buy-in is critical for a prescription monitoring program to be effective. Ms. Soden stated that starting up a state online tracking system is costly, noting that for a similar system in Kentucky, the start up costs was $415,000 with yearly operating costs of $500,000. On the other hand, the Board noted that there are costs to the public health and safety in not committing resources to the prescription drug abuse problem. Ms. Soden noted that the Model Regulations recommend a combined effort by all members of the health care community to achieve an effective prescription-monitoring program. In addition the Board noted that the responsibility for the online tracking system by Department of Health and Social Services instead of the Department of Public Safety could result in greater participation by the whole health care community. The Board discussed effective ways to make recommendations to Representative Chenault for changes in HB 239. Mr. Pauley suggested that representatives of the Board contact the Department of Community and Economic Development Legislative Liason and Department of Health and Human Services Commissioner Gilbertson, as well as sending proposed rewording of the bill to Representative Chenault. Mr. Pauley noted that the bill is at the stage where the sponsor may file a "Sponsor Substitute" of a reworded bill. Ms. Soden and Mr. Altland will draft a letter recommending proposed language based on the Prescription Monitoring Program Model Regulations for HB 239 to be sent to Representative Chenault and the DCED Legislative Liaison.

On a motion duly made by Mr. Pauley, seconded by Ms. Bueler, and approved unanimously, it was

RESOLVED that the Board of Pharmacy recommend proposed legislative language relating to HB 239 that would state that the Department of Health and Social Services develop the data base and that the language of the legislation be amended to provide access to the data base by both

prescribers and dispensers, and that the language follow the criteria included the NABP Prescription Monitoring Program Model Regulation. The Board will contact the DCED Legislative Liaison and Representative Chenault, the bill sponsor, to express these concerns.

Mr. Altland stated that the Substance Abuse Counselors will be meeting in Fairbanks at the end of the month and suggested that a board member attend. Ms. Knasiak suggested that Pam Watts, the Executive Director of the Alcoholism and Substance Abuse Board be contacted. Ms. Soden will contact Ms. Watts.

Discussion of prescription drug abuse issues and presentation by DEA Agent Terry Marquart will continue after lunch.

Agenda Item 5 **Regulations (Continued from October 2, 2003 Discussion)**

2. 12 AAC 52.480 (GENERIC LABELING) Will be tabled to Agenda Item 19, New Business.

3. 12 AAC 52.130 REVIEW OF APPLICATIONS FOR REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. The regulation, which was included in the May 9, 2003 "Supplemental Notice of Proposed Changes in the Regulations of the Board of Pharmacy", was adopted by the Board at the July 25, 2003 meeting. Original language ("A pharmacy located outside the state that ships, mails, or delivers prescription drugs more than twice annually to individual patients in the state shall register with the board.") was inadvertently deleted from the "Supplemental Notice...." The Board stated that its intention was to keep the original language that defined "regularly" and to add the checksheet regulation as stated in the "Supplemental Notice....", not to repeal the first sentence of 12 AAC 52.130. Mr. Brower of the Dept. of Law stated in an email that a new public notice would not be required.

On a motion duly made by Ms. Bueler, seconded by Ms. Knasiak, and approved unanimously, it was

RESOLVED that in 12 AAC 52.130, the original definition of "regularly" ("A pharmacy located outside the state that ships, mails, or delivers prescription drugs more than twice annually to individual patients in the state shall register with the board.") should be included in the final regulation along with the checksheet regulation (a) and (b).

Subject: **Fw: Draft of letter to Chenault**
Date: Sun, 14 Dec 2003 08:34:24 -0900
From: Soden's <cardinal@ptialaska.net>
To: "Younkins, Rick" <richard_younkins@dced.state.ak.us>,
"Roche, Barbara" <barbara_roche@dced.state.ak.us>,
Mike Pauley <mikepauley@alaska.com>, Mark Bohrer <markboh@aol.com>,
Laura Lee Nelson <pharmhog@alaska.net>, Gerry Knasiak <g.knasiak@worldnet.att.net>,
"Bueler, Cindy" <cbueler@alaska.com>, Bill Altland <bsaltland@hotmail.com>

Board members,

Another copy of letter-this one to Rep Chenault. Barbara sent it out on official department stationery. She has really done alot of work on this, plus getting stuff together for the lawsuit and working with Gayle on that, getting travel authorizations for Mark and me to attend the MPJE meeting in January, PLUS all the other stuff she does for us all the time.

Margaret
—— Original Message ——
From: Soden's
To: Roche, Barbara
Sent: Monday, November 24, 2003 8:55 AM
Subject: Draft of letter to Chenault

Barbara,

Here is a pretty clean draft of a letter to Rep Chenault. Would you look it over and make comments please. I am going to mark the copies of the pages of the minutes with big words "draft" since they haven't been approved yet but the wording you used for our discussions was so good that I thought it was easier to send the "draft minutes" rather than rewrite it. I would like to get it out in the next few days.

Thanks,

Margaret

Letter to Chenault.doc	**Name:** Letter to Chenault.doc **Type:** Microsoft Word Document (application/msword) **Encoding:** base64 **Download Status:** Not downloaded with message

Frank H. Murkowski, Governor

Alaska Department of Community and Economic Development

Division of Occupational Licensing
P.O. Box 110806, Juneau, AK 99811-0806
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June 4, 2003

Representative Mike Chenault,
District 34
State Capitol, Room 502
Juneau, AK 99801-1182

RE: HB 239

Dear Representative Chenault,

Please find enclosed information from the National Association of State Controlled Substances Authorities on "Prescription Monitoring" and recommendations for "real-time data collection systems.

This information was forwarded to the Alaska Board of Pharmacy and may be helpful for your recently introduced HB 239.

Please contact the Board of Pharmacy for additional information or assistance.

Sincerely,

Barbara Roche
Licensing Examiner
Alaska Board of Pharmacy

Encl: Findings and Recommendations of the
Prescription Monitoring Standards Workgroup

NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES
Katherine Keough, Executive Director
72 Brook Street, Quincy MA 02170
Tel: 617-472-0520 Fax: 617-472-0521

Findings and Recommendations of the Prescription Monitoring Standards Workgroup

February 26, 2003

Background:

At the October 2002 Annual Educational Conference of the National Association of State Controlled Substances Authorities (NASCSA) held in Myrtle Beach, SC, the Organization adopted resolution 2002-02 stating its opposition to passage of federal legislation establishing the National All Schedules Prescription Electronic Reporting Act of 2002 (NASPER). The resolution also charged the NASCSA Executive Committee with the task of convening a working group to include the Alliance of States with Prescription Monitoring Programs (Alliance), the U.S. Drug Enforcement Administration, state, federal and industry representatives and others, to make recommendations on prescription monitoring standards and methods to implement such standards. The Resolution also stated that methods should be explored by which data could be shared between states, with the federal government and with prescribing practitioners.

In response to this charge, the NASCSA Executive Committee convened a meeting of the Prescription Monitoring Standards Workgroup in Orlando, Florida on January 23 -25, 2003. The working group was comprised of sixteen individuals representing the constituencies set forth in the resolution. The list of participants is attached to this report (see attachment A).

Recommendations of the Workgroup:

The Workgroup discussed both general concepts and methodology relative to standards for data collection that would facilitate uniformity among states. It also reviewed the specific data elements that comprise the optimal data set identified in the Alliance/NASCSA Prescription Monitoring Program Model Act of 2002, as well as those additional elements that are collected by each of the existing state prescription monitoring programs. Noted below, are the general procedural concepts that the Workgroup recommends as necessary to facilitate optimal data sharing, standards for the data elements recommended in the Model Act and where appropriate a listing of the best sources of that data.

- **General concepts:**

1. While not discouraging the development of "real-time" data collection systems, it was the consensus of the group that the advantages of such systems are presently outweighed by the substantially higher costs associated with their development and operation. Additionally, directing resources at "real-time" data collection would almost certainly siphon funding and other available resources from regulatory and enforcement programs that must accompany a data collection system to ensure its overall

effectiveness. The Workgroup recommends that monitoring programs collect data no less than every thirty days. This collection period, considering available technologies and the ability to provide a timely regulatory response, is believed to be appropriate;

2. Legislative language concerning prescription monitoring programs should be technology neutral to allow for commonly accepted electronic methods of transmitting data as well as the implementation of new technologies. Any specific requirements should be set forth in regulations, rather than statute, to allow for greatest flexibility and adaptability to new technologies. Current technologies include, but are not limited to, secure Internet browsers, modems and hard media including diskettes and tape cartridges. The use of hardcopy reporting is discouraged because it is time consuming and prone to increased rates of errors in data entry;

3. There is much to be gained by each of the participating groups, specifically organizations that set standards, regulatory entities and industry, in agreeing on common standards for data collection. Organizations that set standards can more effectively develop accepted standards among their respective groups, while commonality in the data collected by various state regulatory entities can facilitate interstate sharing of data among these groups in an efficiently and effective manner. Additionally, industry benefits in that they have a single set of standards by which to collect data for all states;

4. It is imperative that data collection programs operating in different states collect universally understood and accepted data elements. Failure to achieve this goal represents a primary barrier to the interstate sharing of data. As an example, if a state uses their own "in-state license number" to identify the pharmacy provider, that number has no meaning in another state. It would be preferable to utilize a universally accepted identifier such as the Drug Enforcement Administration (DEA) registration number that is recognizable across state boundaries. If this isn't feasible, states should at least ensure that they have translation tables to enable states to translate state-specific data elements into standard elements.

- **Recommended Data Elements:**

In its review, the Workgroup utilized the data elements contained in Section 5(b) of the Prescription Monitoring Program Model Act of 2002 (see attachment B) that was jointly adopted by the "Alliance" and "NASCSA", as well as a recent survey that was conducted by NASCSA identifying the data that was being collected by state prescription monitoring programs. The Workgroup recommends that the data elements enumerated in the Model Act as well one additional element specifically, "days supply", be collected by prescription monitoring programs. Where appropriate, the Workgroup has listed what it believes to be the best source of such data. Next best data sources are listed as second and third.

To ensure a full understanding of the Workgroups recommendations it is important that we define the terminology used in our discussions:

- **Data element**– a specific data field that is collected as part of a monitoring program such as the "prescription number"

- **Data source** – where specific data is obtained from, such as the patient's Social Security number or their motor vehicle operator's license number
- **"NCPDP number"-** the provider number established by the National Council for Prescription Drug Programs that is used by pharmacies to file claims for services. (This has also been referred to as the NABP number)

The Workgroup recommends that the following standards be applied to the data elements that the Alliance and NASCSA recommend be collected by state prescription monitoring programs:

Data Element	Data Source
1. Dispenser identification number	1. DEA number 2. NCPDP provider number
2. Date prescription filled	
3. Prescription number	1. Pharmacy or dispenser assigned number
4. Prescription is new or is a refill	
5. NDC code for drug dispensed	
6. Quantity of drug dispensed	1. Metric quantities should be used where appropriate (i.e. liquids, injectables)
7. Number of days supply of the drug	1. Indicated on prescription or calculated by the dispenser
8. Patient identification number	1. Government issued ID such as motor vehicle operator's license number 2. Social Security number (raises confidentiality issues) 3. Universal patient insurance number if it becomes available in future
9. Patient last name	
10. Patient first name	
11. Patient street address	
12. Patient city	
13. Patient state	
14. Patient postal code	1. Allow 9 digit zip codes to be entered
15. Patient date of birth	
16. Prescriber identification number	1. DEA number
17. Date prescription issued by practitioner	
18. Person who receives the prescription from the dispenser, if other than the patient	1. Government issued ID such as motor vehicle operator's license number 2. Social Security number (raises confidentiality issues) 3. Individual's name
19. Source of payment for prescription	1. This element should allow for distinction between "Cash" / "Medicaid" / "3rd party" / "Medicare" or other federal option as it becomes available
20. State issued serial number	If state chooses to establish a serialized prescription system

- **Additional recommendations:**

1. The Workgroup recommends that NASCSA and the Alliance jointly adopt a modification to Section 5 (b) of the Prescription Monitoring Program Model Act of 2002, specifically to add the data element "number of days supply".

2. The Workgroup recommends that NASCSA and the Alliance jointly approve and adopt the findings and recommendations of this report as a means of ensuring that members of both organizations are provided with uniform information concerning prescription monitoring data standards.

3. The Workgroup recommends that all standards organizations modify their present standards, where necessary, to establish the "source of payment" as a standard data element to be collected in a manner that provides for a distinction between the following sources of payment "cash" / "Medicaid" / "3rd party" / "Medicare".

4. Since no state currently requires the reporting of "source of payment for prescription", the Workgroup recommends that states that are considering requiring the reporting of this data element, be aware that there may be a temporary delay in achieving full compliance, as dispensers and software vendors work to modify their data management systems to provide for the capture of this data.

Adoption of the report:

This report was approved by vote of the Executive Committee of the National Association of State Controlled Substances Authorities on March 3, 2003.

Attachment A

NATIONAL ASSOCIATION OF STATE CONTROLLED SUBSTANCES AUTHORITIES
Katherine Keough, Executive Director
72 Brook Street, Quincy MA 02170
Tel: 617-472-0520 Fax: 617-472-0521

Prescription Monitoring Program Standards Work Group
January 24-25, 2003 – Orlando, Florida
List of Participants

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GRANT CARROW, Ph.D. Director, Drug Control Program MA Department of Public Health 305 South Street Jamaica Plain, MA 02130 Tel: 617-983-6700 Fax: 617-524-8062 E-Mail: grant.carrow@state.ma.us	**LYNNE GILBERTSON** National Council For Prescription Drug Programs 9240 E. Raintree Drive Scottsdale, AZ Tel: 480-477-1000 X120 E-mail: lgilbertson@ncpdp.org
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DAVID DRYDEN Director, Office of Narcotics & Dangerous Drugs Jesse Cooper Building, PO Box 637 Dover, DE 79903 Tel: 302-739-4798 Fax: 302-739-3071 E-mail: ddryden@state.de.us	**WILL LOCKWOOD** American Society for Automation in Pharmacy 492 Norristown Road, Suite 160 Blue Bell, PA 19422 Tel: 610-825-7783 Fax: 610-825-7641 E-mail: will@computertalk.com

ALAN MUST Executive Director State Government & legislative Affairs Purdue Pharma L.P. One Stamford Forum 201 Tresser boulevard Stamford, CT 06901-3431 Tel: 203-588-8121 Fax: 203-588-6033 E-mail: alan.must@pharma.com	**MARY RYAN** Vice President, Regulatory Affairs Medco Health Solutions Inc. 100 Parsons Pond Drive Franklin Lakes, NJ 07417 Tel: 201-269-6900 Fax: 201-269-1258 E-mail: mary_ryan@medcohealth.com
KEVIN NICHOLSON Director, Pharmacy Regulatory Affairs National ASSN of Chain Drug Stores 413 N. Lee Street Alexandria, VA 22314 Tel: 703-837-4183 Fax: 703-549-0771 E-mail: knicholson@nacds.org	**VICKI SEEGER** U.S. Drug Enforcement Admin. 600 Army Navy Drive ODLP Arlington, VA 22202 Tel: 202-307-7283 Fax: 202-353-1079 E-mail: vseeger@dialup.usdoj.gov
CHARLES RAY NIX Director, Pharmacy Department Department of Public Health P.O. Box 1700 Jackson, MS 39205 Phone: (601) 713-3471 Fax: (601) 364-2670 Email: cnix@msdh.state.ms.us	**KAREN TANNERT** Drugs & Medical Devices Division Texas Department of Health 1100 West 49th Street Austin, Texas 78756 Tel:(512) 719-0237 E-mail: karen.tannert@tdh.state.tx.us
JOANEE QUIRK Nevada Board of Pharmacy 555 Double Eagle Court #1100 Reno, NV 89511 Tel: 775-850-1440 Fax: 775-850-1444 E-mail: jquirk@govmail.state.nv.us	**WILLIAM P. WARD** Chief of Enforcement Operations CT Department of Consumer Protection 165 Capitol Avenue Hartford, Connecticut 06106 Tel:(860) 713-6078 Fax:(860) 713-7233 E-mail: william.ward@po.state.ct.us

Attachment B

Alliance of States with Prescription Monitoring Programs and National Association of State Controlled Substances Authorities

PRESCRIPTION MONITORING PROGRAM MODEL ACT

October 2002

Section 1. Short Title.

This Act shall be known and may be cited as the "Prescription Monitoring Program Model Act."

Section 2. Legislative Findings

[insert state findings]

Section 3. Purpose

This act is intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances or other licit drugs of abuse.

Section 4. Definitions

(a) "Controlled substance" has the meaning given such term in [section of the state controlled substances act].

(b) [Designated state agency] means the state agency responsible for the functions listed in Section 5.

(c) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued and/or for whom a drug is dispensed.

(d) "Dispenser" means a person who delivers a Schedule II–V controlled substance as defined in subsection (e) to the ultimate user, but does not include:

(I) a licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care [or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility];

(II) a practitioner, or other authorized person who administers such a substance; or

(III) a wholesale distributor of a Schedule II–V controlled substance.

(e) "Schedule II, III, IV and/or V controlled substances" mean controlled substances that are listed in Schedules II, III, IV, and V of the Schedules provided under [insert section of the state controlled substances act] or the Federal Controlled Substances Act (21 U.S.C. 812).

Section 5. Requirements for Prescription Monitoring Program.

(a) The [designated state agency] shall establish and maintain a program for the monitoring of prescribing and dispensing of ail Schedule II, III and IV controlled substances [and, if selected by the state, Schedule V controlled substances and/or additional drugs identified by the designated state agency as demonstrating a potential for abuse] by all professionals licensed to prescribe or dispense such substances in this state.

(b) Each dispenser shall submit to the [designated state agency] by electronic means information regarding each prescription dispensed for a drug included under paragraph (a) of this section. The information submitted for each prescription shall include, but not be limited to:

(I) Dispenser identification number.
(II) Date prescription filled.
(III) Prescription number.
(IV) Prescription is new or is a refill.
(V) NDC code for drug dispensed.
(VI) Quantity dispensed.
(VII) Patient identification number.
(VIII) Patient name.
(IX) Patient address.
(X) Patient date of birth.
(XI) Prescriber identification number.
(XII) Date prescription issued by prescriber.
(XIII) Person who receives the prescription from the dispenser, if other than the patient.
(XIV) Source of payment for prescription.
(XV) State issued serial number [if state chooses to establish a serialized prescription system].

(c) Each dispenser shall submit the information in accordance with transmission methods and frequency established by the [designated state agency]; but shall report at least every thirty days, between the 1st and the 15th of the month following the month the prescription was dispensed.

(d) The [designated state agency] may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or

other means, provided all information required in paragraph (b) of this section is submitted in this alternative format.

Note: the following paragraphs, (e) - (h), are intended for those states that choose to establish a serialized prescription system as part of the prescription monitoring program.

(e) A serialized [single copy or multiple copy] prescription form, shall be issued by the [designated state agency] to individual [insert "and institutional" if practitioners in health care institutions issue prescriptions that can be filled in pharmacies outside the institutions] prescribers and shall be used for all prescriptions for drugs in [Schedule II, III, IV and/or V] controlled substances. Each series of prescriptions shall be issued to a specific prescriber [in consecutively numbered blocks of ____] and shall only be used by that prescriber.

(f) Each prescriber shall only prescribe drugs in [Schedule II, III, IV and/or V] controlled substances on official serialized prescription forms issued by the [designated state agency].

(g) Each dispenser shall only dispense drugs in [Schedule II, III, IV and/or V] controlled substances on such official serialized prescription forms.

(h) The [designated state agency] shall charge each prescriber an amount sufficient to cover the costs of processing requests for forms, printing the prescription forms, and operating the prescription monitoring program.

Note: States may chose to use alternative method than paragraph (h) to pay the cost of their serialized prescription forms and monitoring system, for example, through controlled substances registration fees. In such instances, paragraph (h) can be deleted.

Section 6. Access to Prescription Information.

(a) Prescription information submitted to the [designated state agency] shall be confidential and not subject to public or open records laws, except as provided in paragraphs (c), (d), and (e) of this section.

Note: States may choose to also amend their open record statutes to specifically exclude from disclosure prescription information collected by their prescription monitoring program.

(b) The [designated state agency] shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to persons except as in paragraphs (c), (d), and (e) of this section.

(c) The [designated state agency or entity] shall review the prescription information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the [designated state agency] shall notify the appropriate law enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.

(d) The [designated state agency] shall be authorized to provide data in the prescription monitoring program to the following persons.

(I) Persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients.

(II) An individual who requests the individual's own prescription monitoring information in accordance with procedures established under [insert state statute granting individuals access to state held data concerning themselves].

(III) [insert name or type of state boards and regulatory agencies that supervise or regulate a profession that is authorized for controlled substances activity].

(IV) Local, state and federal law enforcement or prosecutorial officials engaged in the administration, investigation or enforcement of the laws governing licit drugs.

(V) [insert state Medicaid agency] regarding Medicaid program recipients.

(VI) [insert judicial authorities] under grand jury subpoena or court order [or equivalent judicial process in each state].

(VII) Personnel of the [designated state agency] for purposes of administration and enforcement of this Act, or [insert state controlled substances act], [if any other state statute is applicable, insert "or" and reference the other statutes].

(e) The [designated state agency] may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identity individual patients and/or persons who received prescriptions from dispensers.

Section 7. Authority to Contract

The [designated state agency] is authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information

in Section 6 of this Act and shall be subject to the penalties specified in Section 8 of this Act for unlawful acts.

Section 8. Rules and Regulations.

The [designated state agency] shall promulgate rules and regulations setting forth the procedures and methods for implementing this Act.

Section 9. Unlawful Acts and Penalties.

(a) A dispenser who knowingly fails to submit prescription monitoring information to the [designated state agency or entity] as required by this Act or knowingly submits incorrect prescription information shall be subject to [insert appropriate administrative, civil or criminal penalty].

(b) A person authorized to have prescription monitoring information pursuant to this Act who knowingly discloses such information in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

(c) A person authorized to have prescription monitoring information pursuant to this Act who uses such information in a manner or for a purpose in violation of this Act shall be subject to [insert appropriate administrative, civil or criminal penalty.]

Section 10. Severability.

If any provision of this Act or application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act which can be given effect without the invalid provisions or applications, and to this end the provisions of this Act are severable.

Section 11. Effective Date.

This Act shall be effective on [insert specific date or reference to normal state method of determination of the effective date].

Adopted by *Alliance of States with Prescription Monitoring Programs*, October 22, 2002.

Adopted by National Association of State Controlled Substances Authorities, October 25, 2002

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11 of 11

Subject: **Report from the Drug Abuse Ad Hoc committee**
Date: Sun, 28 Sep 2003 08:42:26 -0800
From: "Soden's" <cardinal@ptialaska.net>
To: "Younkins, Rick" <richard_younkins@dced.state.ak.us>,
"Roche, Barbara" <barbara_roche@dced.state.ak.us>,
"Mike Pauley" <mikepauley@alaska.com>, "Mark Bohrer" <markboh@aol.com>,
"Laura Lee Nelson" <pharmhog@alaska.net>,
"Gerry Knasiak" <g.knasiak@worldnet.att.net>, "Bueler, Cindy" <cbueler@alaska.com>,
"Bill Altland" <bsaltland@hotmail.com>

Dear board members,

We have a time slotted for discussing drug abuse issues and I have asked our own board member, Bill Altland, to tell us about his very bad experience with an armed robber while he was working in Wasilla. Since I would prefer that we allow plenty of time to hear from Bill, I am sending you my notes on various discussions I have had regarding HB 239. I asked Barbara to include a copy of HB 239 in your packets. I think it is interesting that we didn't know about this bill during the last session and I just stumbled across it when I was tracking HB 270 and noticed at the bottom of the "track your bill" page that you can link to other bills that contain the words or phrases "drugs", "pharmacist" etc. I am not sure if there were pharmacists in the Kenai area involved in writing this bill, but I do know that at least this board member didn't know about it but it directly effects our board since it is being placed in Chapter 80.

I know our packets looked sort of skinny, but I have a feeling that we will have a very busy meeting. Don't we always?!!

See you soon,
Margaret

Notes on House Bill 239.doc	**Name:** Notes on House Bill 239.doc **Type:** Microsoft Word Document (application/msword) **Encoding:** base64 **Download Status:** Not downloaded with message

Memo to: Board of Pharmacy members
From: Margaret Soden, ad hoc committee of one on issues dealing with drug abuse

September 28, 2003

NOTES ON HB 239:

August: Called Rep Chenault's office in late July-early August and found out that Sue Wright was the person on the staff "who knows all about the bill". Asked that she return my call, didn't hear from her, so I called the office again left several messages on the answering machine. I finally did talk with Sue personally and asked her the following questions: (answer in italics)

- Why is this bill in Chapter 80, Pharmacy statutes, when the Department in charge is Public Safety? Shouldn't it be in Chapter 30, Controlled Substances, which is enforced by the Department of Public Safety? *We are working on that, this was written in a hurry at the end of the session so it could get introduced and it is not the final bill.*
- Where do the doctors fit in this, why aren't they also supposed to tap into this internet system to see if the patient has been given these drugs recently? *Oh, we can't ask them to do that.*
- How will the pharmacist access the system? *Oh, there will be a dual transmission with an insurance claim and the patient has an ID number assigned to them. The claim is automatically transmitted to Health and Human Services.*
- What is the pharmacist supposed to do if the person has had the drug recently? *Just don't fill the Rx.*
- How is it determined that the pharmacist can't fill a prescription? *There is a "threshold" on the drugs.*
- What drugs will be covered? *Schedule II drugs and Oxy-contin for sure, you know that is really abused.*
- Why not some other drugs that are not Schedule II's, but also a problem like Vicodin? *No answer other than that she herself took Vicodin.*

Then Ms Wright got an urgent phone call that needed her attention, she said she would call me back the next day and as of September 28, I have not heard from her nor have I called her.

Follow-up questions:

- Who will pay for this?
- What about other prescribers like ANP and dentists?
- Who "assigns" these ID numbers to patients?
- How is the "person designated in the secure Internet data base as a person entitled to obtain a controlled substance on behalf of the patient" information obtained?
- Who establishes the "threshold" for the drugs? Will there be some consideration with regard to the prescriber's type of practice, i.e. oncologist, pain management?
- How does this mesh with HIPAA with regard to confidentially?

- What about pharmacies who do not send claims to insurance companies electronically? We have several in Fairbanks who only do electronic claims for Medicaid. I'm sure there are others in the state.
- What about the person who pays cash?
- Since the prescribers have the "power of the prescription pad" why aren't they a BIG part of this whole thing?
- Is there any feedback to anyone?
- Why is this a system that targets the patients, not the overprescibing practitioners?
- Who will continuously monitor and enforce this?
- Since this is in Chapter 80, Pharmacy, and the Board of Pharmacy is responsible for implementing and enforcing statutes and regulations in this Chapter, are we supposed to now write regulations to carry this out?
- In Chapter 30, Controlled Substances, AS 17.30.100, powers of the Department of Public Safety (b) states that the "commissioner of public safety may not furnish the name or identity of a patient or research subject whose identity could not be obtained under AS 17.30.155." AS 17.30.155, Confidentiality of certain information states "A practitioner engaged in medical practice or research may not disclose the name or identity of a patient or research subject that the practitioner is required to keep confidential unless ordered by a court to disclose it within the context of a criminal investigation or proceeding". Question: is this in the "context of a criminal investigation" when it is being done **BEFORE** filling a prescription?
- Why is the information transmitted to the Department of Health and Human Services when the statute is in Board of Pharmacy Chapter 80 and under the charge of the Department of Public Safety?

NOTES FROM MEETING WITH PURDUE PHARMA REPRESENTATIVES

On September 18, I had a meeting with two representatives from Purdue Pharma. Linda Barefoot, Regional Director for State Government Affairs and Nancy Lewis, PharmD, Director, Medical Liaisons contacted me and arranged to meet while they were in Alaska. The primary reason for their visit with me was to discuss HB 239 and prescription monitoring programs in other states. They had LOTS of information about both monitoring programs and the RxPatrol Initiative that has been established to "improve pharmacy security and identify pharmacy robbers".

HB 239: Linda has been trying to talk with Rep Chenault and, particularly his aide, Sue Wright, about this bill but she is not having much more luck than I am in getting Sue to return calls. Both Linda and Nancy arranged to go to Kenai for a meeting on the evening of Sept 18 and hoped to show them some of the other state programs for internet tracking of controlled substances as well as give them a sample of model regulations. Of course, Purdue Pharma has a vested interest in seeing that their product, Oxy-contin, does not become so restricted that they are impacted financially, but they do have some very good information about what a state program should include and how it could work. I will give Board members copies their model program outline at the meeting but these are the high points:

- The internet tracking would be for drugs in all DEA schedules and any "other drug of concern", not just Schedule II or Oxy-contin. (As an aside, Hydrocodone is more of a problem in Fairbanks than Oxy-contin).
- Prescribers MUST be a part of any program-they should be able to query the database on specific individuals BEFORE they write prescriptions.
- Data must be entered in a timely and efficient manner.
- A unit of state government primarily dealing with healthcare issues should control access to the database (as opposed to it being a unit of law enforcement) but law enforcement may also query the database about specific individuals with legal authority to do so.
- Information must be secure.

I showed them my list of questions and many of them are addressed in their model. They emphasized several times that ***if prescribers don't buy in to this or are not a part of the program, it will fail.***

RxPatrol is an initiative that was just launched as a collaboration effort between law enforcement and industry "designed to collect, collate, analyze and disseminate pharmacy theft information in an attempt to:

- Help protect pharmacists
- Guard against potential robberies and burglaries, and
- Assist law enforcement to apprehend and successfully prosecute criminals"

It will also attempt to analyze theft information for trends and patterns. There is major funding from Purdue Pharma for this nationwide data clearinghouse. There is a web-site, www.rxpatrol.com set up.

I will give all of you copies of this information as well.

GAO Report: One of the other documents they had in their BIG notebook of stuff was the US General Accounting Office's May 2002 report on "Prescription Drugs: State Monitoring Programs Provide Useful Tool to Reduce Diversion". Highlights include:

- Monitoring programs must include education as well as law enforcement.
- Programs vary from state to state but most experts agree that drugs in all DEA classes should be covered and that each state should determine what their particular program will track.
- Most are electronic-not paper triplicates-to make the information more timely. Several states, which formerly had paper triplicates, have replaced that method with an electronic system.
- Most state programs operate reactively because they analyze data AFTER the fact but they are useful in suggesting trends or unusual prescribing practices or dispensing patterns that may suggest potential drug diversion, abuse or doctor shopping.
- All are costly and often the costs go up as the programs are utilized more. The more quickly the turnaround time for information, the more costly the program can become.
- These programs have helped shorten investigation time in law enforcement investigations in possible drug diversion cases.
- Programs have also helped reduce availability of abused drugs because they tend to reduce unwarranted prescribing and possible diversion. They may also impact the drugs most likely to be diverted just because the monitoring system exists.
- Confidentiality, initial cost and the challenge of maintaining funding are concerns with all states.
- **INTERESTING DEA FACT-ALASKA RANKS IN THE TOP 10 OF STATES BY THE NUMBER OF OXY-CONTIN PRESCRIPTIONS PER 100,000 PEOPLE.**

Linda and Nancy said they would let me know what they found out from Rep Chenault or Sue Wright but as of September 28, I have not heard back from them. I have e-mailed Nancy about our October meeting since she indicated that she might attend. If she isn't there in person, I hope she will send me an update.

Alaska Bureau of Alcohol and Drug Enforcement: I still hope to talk with someone involved in the Department of Public Safety's Alaska Bureau of Alcohol and Drug Enforcement. The person I have been told I need to talk to has an office in Anchorage and just returned from vacation in mid-September. Since my daughter-in-law works in the local Fairbanks office, I will keep trying (nagging??!!). My main questions for them will be are they interested in this and would they find it useful. My personal experience with forged/altered prescriptions has been rather discouraging. The local police and pharmacists work really hard to catch the forgers/scammers only to have the charges either dropped or reduced to nothing by the local District Attorney's office. Perhaps that is an issue that needs addressing.

- The board discussed streamlining licensure requirements for new pharmacy graduates who seek "Licensure by Examination." 12 AAC 52.090(2)(d) Examination Requirements and Registration requires applicants for "Licensure by Examination" to wait 60 days after submitting an application, before taking the exam. This regulation was required in the past when the board wrote and administered the pharmacist license exam, and needed the 60-day period to set up the exam. Now that the exams are administered by NABP, there is no reason for the 60 day waiting period. NABP requires that exam candidates are Pharmacy program graduates, but the board could see no reason to delay the licensing of new graduates.

On a motion duly made by Mr. Miller, seconded by Mr. Bohrer, and approved unanimously, it was

RESOLVED to revise 12 AAC 52.090(2)(d) to read "An applicant shall file with the department an [COMPLETED] application for a pharmacist license by examination and the application and examination fees established in 12 AAC 02.310. [AT LEAST 60 DAYS BEFORE THE DATE OF THE EXAMINATION]

The board noted that adopting these regulations would not result in any cost to private persons.

Agenda Item 15 **Legislative Update**

- HB No. 51 ("An act requiring pharmacists to include generic drug information on containers in which brand-name drug orders are dispensed") was discussed by the Board. Ms. Soden pointed out that there would be costs to pharmacies associated with adding the new information to prescription labels.
- HB No. 239 ("An Act directing the Department of Public Safety to establish an Internet-based identification and tracking system relating to controlled substances that are prescribed for human use; and relating to the manner in which prescriptions for controlled substances may be filled by a pharmacists.") The board discussed concerns that this bill requires the Department of Public Safety to set up a Controlled Substances Data Base, but that the bill's statute number 08.80.305 would fall under the Pharmacy Act (AS 08.80). In addition, the board noted that there would be considerable costs in establishing such a data base project, and that funding could be a problem.

- HB No. 270 ("An Act relating to licensure of pharmacists") was discussed under Agenda Item 8.
- SB No. 41 ("An Act relating to medical care and crimes relating to medical care..."). An amended copy of the bill was handed out at the meeting.
- SB No. 138 ("An Act annulling a regulation relating to the use of collaborative practice authority...") was discussed under Agenda Item 8.

Break — Recess for Lunch at 12:15 PM.
Back on record at 1:25 PM.

Agenda Item 16 **Division Updates**

Budget Report - The Board reviewed the Budget Report provided by the Division of Occupational Licensing. The licensing examiner responded to a question asked by the board at the Feb. 14, 2003 meeting about why the 2002 Direct Costs are almost double the 2001 Direct Costs. Direct costs reflect actual billed hours by staff, including the licensing examiner, supervisors, paralegal, investigators, and regulation specialist. The rise in costs is due to increased investigations, regulation projects and training. Board members requested that the division review the board's recommendations for licensing fee adjustments to cover these increased costs.

Discuss Intern Jurisprudence Exam - The licensing examiner reported that revisions to the exam have been made and that pharmacy intern applicants are taking the new exam.

2003 Annual Report Assignments - Ms. Soden noted that 2003 Annual Report submissions are due in June of each year. The board discussed which sections of the Annual Report need direct input and decided on the following:

- Letter from the board chair will be done by Margaret Soden.
- Narrative Statement will be drafted by Cindy Bueler. The 2003 Narrative Statement can be modeled after the 2002 report, but the statement should also include a note on the board's request for an Attorney General opinion on whether Alaska Native Medical Centers are considered Federally operated institutions and are exempt from regulation under AS 08.80.475.
- Statistical Overview will be submitted by the licensing examiner.
- Investigative Report information will be submitted by the investigator.
- Budget Recommendations will be submitted by the licensing examiner based on four meeting per year, travel expenses

23-LS0897\H
Mischel
4/1/04

Margaret D. Soden

CS FOR HOUSE BILL NO. 239( )

IN THE LEGISLATURE OF THE STATE OF ALASKA

TWENTY-THIRD LEGISLATURE - SECOND SESSION

BY

Offered:
Referred:

Sponsor(s): REPRESENTATIVE CHENAULT

A BILL

FOR AN ACT ENTITLED

"An Act directing the Board of Pharmacy to establish an Internet-based identification and tracking system relating to controlled substances that are prescribed for human use; and relating to the manner in which prescriptions for controlled substances may be filled by a pharmacist."

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

*** Section 1.** AS 08.80.158(b) is amended to read:

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; [AND]

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy; **and**

(5) proof satisfactory to the board that the pharmacy meets the requirements under AS 08.80.305 by consulting the secure Internet data base developed under that section and by requiring a copy of picture identification and a verified signature of the person designated on the prescription, before dispensing a controlled substance to a person who is located in the state.

* **Sec. 2.** AS 08.80 is amended by adding a new section to read:

Sec. 08.80.305. Controlled substance data base. (a) The Board of Pharmacy, in consultation with the State Medical Board, shall develop a controlled substance secure Internet data base that will allow each pharmacist in the state to determine, by consulting the secure Internet data base, whether a prescription for a controlled substance that is being dispensed by the pharmacist to cover a certain time period for a human patient duplicates a prescription already dispensed for the same patient that was intended to cover a substantial portion of the same time period. The board shall design the secure Internet data base in a manner that maintains the confidentiality of the information in the secure Internet data base so that the secure Internet data base can only be used by pharmacists for the purposes identified in this section. The secure Internet data base shall use a unique identifying number for each patient for whom a controlled substance is prescribed and for each person designated by a patient as a person entitled to obtain a prescribed controlled substance on behalf of the patient. The board, in consultation with the State Medical Board, shall determine how and by whom the identifying numbers and prescription information will be entered into the secure Internet data base.

(b) Before dispensing a controlled substance for human use, a pharmacist shall require picture identification from the person designated on the prescription or a

person entitled to obtain a prescription on behalf of the person designated on the prescription, if the entitled person is attempting to obtain the controlled substance, and shall consult the secure Internet data base developed under (a) of this section. The pharmacist may not dispense a controlled substance if

(1) the secure Internet data base indicates that a prescription for the same controlled substance has been filled for the same patient in an amount intended to cover a substantial portion of the same time period as the prescription drug order presented to the pharmacist; or

(2) the person's identification does not reasonably substantiate that the person is either the patient for whom the controlled substance is intended or the person designated in the secure Internet data base as a person entitled to obtain a controlled substance on behalf of the patient.

Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417
Tel: 201 269 3400
www.medcohealth.com

medcohealth
live life well

April 6, 2004

Representative Mike Chenault
State of Alaska
State Capitol, Room 502
Juneau, AK 99801-1182

Re: HB 239 (Chenault): Oppose

Dear Representative Chenault:

On behalf of Medco Health Solutions, Inc., I regret to inform you that we must respectfully oppose House Bill 239, relating to Controlled Substances. Medco is one of the largest pharmacy benefit managers in the nation with over 60 million members. In the state of Alaska, we manage the prescription drug benefit for approximately 148,000 residents through both retail and mail-order. We hold a non-resident pharmacy license with the state Board of Pharmacy.

As written, HB 239 requires that a pharmacist be presented with photo identification prior to dispensing a controlled substance. If applied to non-resident pharmacies licensed by the state, it will eliminate our ability to dispense controlled substances into the state. At Medco, every new Schedule II prescription is verified by our pharmacists who call the prescriber to validate. We re-validate every six months. Schedule II drugs are sent via the UPS "Jewel Box" delivery program whereby a signature is required. In reviewing our records for the past several years, we have only one report of a lost controlled substance in Alaska – for 30 Klonopin (Schedule IV) in January 2003.

Medco only deals with prescriptions that are part of a covered benefit and billed to a plan. For these, we have a database of dispensing and our pharmacists consult this database before dispensing <u>any</u> controlled substance to determine if it is a duplicate, or an attempt is being made to refill too soon. Any time a patient uses their Medco benefit to fill a prescription, <u>all</u> prescriptions, including those filled at retail, are contained in our database.

We have been informed by your staff of your intent to amend HB 239 to require that <u>all</u> controlled substances mailed into the state be sent via the U.S. Postal Service registered mail. This will result in significant new costs to our clients and their members. The cost to deliver via UPS to home addresses in Alaska is $16.76. The USPS has a similar service which we use when PO boxes are involved, at a cost of $17.85. A requirement to send <u>all</u> controlled substances via USPS registered mail will result in additional costs of approximately $45,000 for Medco members alone.

We share your concern with abuses surrounding controlled substances. Medco is actively involved with the National Association of State Controlled Substances Authorities which is focused on the development of monitoring standards and methods to implement those standards. We are also awaiting implementation of a Drug Enforcement Administration electronic prescribing pilot system for

qualified physicians whereby controlled substance prescriptions can only be filled if they are sent via the physician's system. We believe electronic prescribing will significantly reduce abuse.

We hope to continue to work with your staff to draft a bill that addresses your concerns without unnecessarily increasing prescription drug costs for the residents of Alaska.

Sincerely,

Cynthia Laubacher

CYNTHIA M. LAUBACHER
Director, State Government Affairs

Cc: Members, House Health, Education and Social Services Committee

RE: HB 239 ID System for Prescriptions

Copy of testimony that will be presented by Steve Cole, Pharmacist, Wrangell, Alaska during the HESS Committee Thursday, April 22nd.

Duty To Dispense:

Overcoming Uncertainty, Doubt & Fear

Sunday, October 19, 2003

Pain Management Update 2003

Overcoming Uncertainty in Therapeutics

National Community Pharmacists Association

105th Annual Convention

Satellite Symposium

October 19th, 2003

Seattle, WA

Prevalence of Chronic Pain

- Silent epidemic that is affecting 70 million Americans
- Estimated that 35% of Americans have some degree of chronic pain
- 50 million have some type of disability
- >1/2 have suffered with persistent pain for greater than 5 years
- Pharmacist are paramount in the education and treatment of chronic pain

America and Pain

- America is aging
  - 2050 – 40% of population >65
  - 2020 – 200,000 patients over 100
  - People over 85 fastest growing segment of population

Growing number of older adults at risk for chronic pain (DJD, arthritis, neuropathic pain, cancer, osteoporosis etc)

Adverse Effects of Undertreated Pain

- Adverse Physiological Responses to Pain
  - Increased catabolic demands
  - Hypertension, tachycardia, and tachypnea (acute)
  - Decreased exercise tolerance and movement
  - Water Retention
  - Decreased respiratory response (pleuritic/chronic pain)
  - Inhibited GI transit time

Adverse Effects Undertreated Pain

- Adverse Psychological Response to Pain
  - Mood disorders (depression and anxiety)
  - Insomnia
  - Chronic Pain Syndromes
- Adverse Immunological Response to Pain
  - Impaired immune system (natural killer cells decreased)

"Three Step Ladder" to Analgesia

- Opioids
  - No ceiling effect to analgesic effects
  - Side effects predictable and manageable
  - "one of the few drugs that causes no end organ damage"
  - Effective in short and long acting formulations

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Prescribing Opioids

- Short Acting
  - Drug of choice for acute pain NOT chronic pain
  - Breakthrough medication and used in circumstances of anticipated increased pain activity
  - Long term use perpetuates the pain-drug cycle
  - Greater risk of addiction (peak-trough effect)

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Prescribing Opioids

- Long Acting Opioids
  - Drug of Choice for chronic pain
  - Less risk of addiction due to fewer peaks and troughs (e.g. Treat smokers with nicotine patch/addicts with methadone)
  - Improved compliance (taken less often)
  - Does not perpetuate the pain-drug cycle (not chasing pain)
  - Better patient satisfaction and quality of life
  - Takes minimum 2-3 days to reach steady state

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Prescribing Opioids

Ideal regimen for chronic pain

- **Basal medication (baseline med)**
  - Long acting opioid
- **Breakthrough medication**
  - Short acting opioids
  - Readjust basal amount based on use of breakthrough requirements
  - Keep a pain diary of breakthrough requirement
  - Adjust after minimum 2 weeks of therapy
    - ***Similar concepts used on asthma therapy and diabetes***

60

Conclusion

- Pain is an ubiquitous symptom of mankind to permit a person to suffer in chronic pain is as wrong as to provide opioid analgesics without social discretion
- Effective communication between patient, pharmacist and physician is imperative for effective pain control of our patients
- We must provide care to our patients and above all else "first do no harm"
- The Power of Many Voices Unified for The Power of ONE ... ONE Patient, ONE Pharmacy, ONE Physician, ONE community

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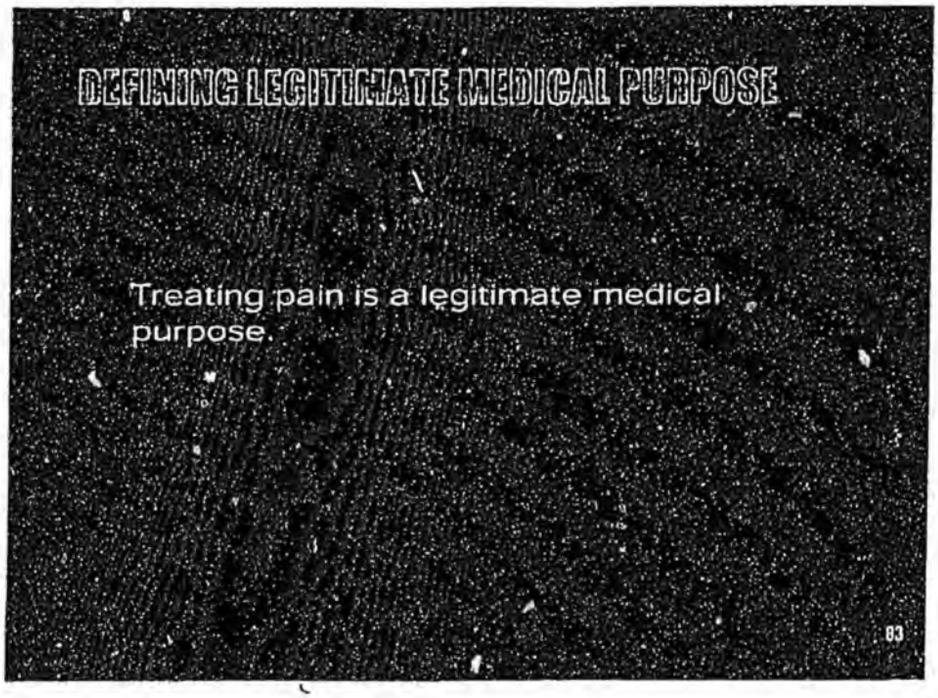
DUTY TO DISPENSE: OVERCOMING UNCERTAINTY, DOUBT, & FEAR

Richard R. Abood, R.Ph., J.D.
Professor Pharmacy Practice
University of the Pacific

70


DEFINING LEGITIMATE MEDICAL PURPOSE
Treating pain is a legitimate medical purpose.
83


CURRENT POSITION OF REGULATORY AGENCIES
The DEA and nearly all state boards of medicine and pharmacy have affirmed the use of opioids in legitimate pain management, including in chronic nonmalignant pain.
84

RATIONALE OF COURT

DUTY EXISTS BECAUSE:

- The existence of a relationship
- Foreseeability
- Burden to defendant
- Consequences to society

05

DUTY TO TREAT PAIN CORRECTLY

Borgman v. Eden Med. Ctr. (Cal. Super. Ct. 2001)

Patient won $250K judgment against a physician for under-treating his pain.

96