MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

2312

2005 SENATE HUMAN SERVICES

SB 2312

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2312

Senate Human Services Committee

❑ Conference Committee

Hearing Date January 26, 2005

Tape Number	Side A	Side B	Meter #
1		x	4930-end
2	x		00-2366
Committee Clerk Signature			

Minutes:

Chairman Lee opened the public hearing on SB 2312. All members were present.

Chairman Lee welcomed the students in the room and gave an overview of the bill process and some of the bills that they would hear.

Testimony in favor of SB 2312

Chairman Lee was the main sponsor of this bill and introduced it. The bill has a fiscal note and it would provide for the establishment of a centralized electronic prescription monitoring system for medical assistance recipients.

Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services.

See written testimony (Attachment 1)

Dr. Joyce testified that this system would help control those patients who try to bypass the system when buying drugs. They pay cash and go to multiple pharmacies.

Sen. Warner: Can you explain how controlled substances fit into this?

Dr. Joyce explained the different classes of drugs. Also mentioned, that unamended, the bill only deals with controlled substances.

Howard C. Anderson, Jr., Executive Director of the North Dakota State Board of Pharmacy. See written testimony (Attachment 2, 2A) The committee needs to look at this information and decide what you want to do with it. There are a few more things that will help decide what to do. (Attachment 2B) It will take about $150,000 to operate it annually.

Chairman Lee: Sounds like a great idea. Is the $10,000 to set up and $150,000 to operate, just on the Medicaid side? Is there any place besides state general funds where this money can come from in order to establish something that would be a benefit?

Anderson: Blue Cross could benefit from this too, Chip said. Right now, in the controlled substance act of 19-03, North Dakota has the authority already through the board of pharmacy, to issue a controlled substances number to all the subscribers, (pharmacies, physicians, etc) to do that. It is very similar and works the same way as the DEA number. We've said in the past, they have a DEA number, why do we issue another one and charge them some more. So we're never done that in North Dakota. The authority is there in 19-03; if we did that, that money could be used to fund that program, and that's actually how I had envisioned it would happen. One of my reservations, I'm a conservative and don't like to charge people for licenses and regulations that we really need. But if we felt that we needed this, we have that option. Nevada has something in place (Attachment 2C)--they have a look-in capacity. The system can also track who's in there.

Chairman Lee mentioned the fiscal note. Mr. Anderson said other states run this system for less than $150,000 a year. There is also grant money available for the future. Dr. Joyce added that he got a quote of about $100,000 a year.

Sen. Dever: Is it safe to assume that all pharmacies have the capability to participate?.

Anderson: Yes, almost all. Everyone is computerized. We would also require mail-order pharmacies to submit data to us also.

Sen. Dever: Could the system be set up so it would "red flag" people who need review?

Anderson: Yes, that's possible

Sen. Warner: I would hope that Mike Mullen would be involved and feel uncomfortable with law enforcement and the "look-in" process.

Neutral Testimony

Arnold Thomas, President of the North Dakota Healthcare Association

Thomas: I'm here today to find out the direction of this measure is pointing to. The concept is refreshing, and making this information available to all practitioners would enhance health care. I thought it was interesting that in groups that were included, I'm just trying to look at this might go; noticeably absent in any hospital participation. With all do respect to the physician community, most medicine in North Dakota is being delivered on a systems basis. And all of the information requirements to support that system delivery are organizationally driven, funded, planned and would need to be connected to this activity is some way and we'd like to be in on the front end in pursuing this. In terms of making sure that what happens does work. In another area, federally, we are engaged in electronic medical records in developing the format that would allow that to be available. The time is now to develop this is now, and we'd like to be involved

now instead of having to come back to the committee to say we're not ready at this time. Money is not the issue. We need to know what we're trying to accomplished and with whom.

Chairman Lee: Consider yourself officially invited to the party. There wasn't enough time as we'd normally have, because we were really under the gun.

Sen. Dever: What does organizationally funded mean?

Rob St. Aubyn: I share Mr. Thomas' concern and also wonder if there are any HIPAA concerns. Another general concern, as the bill is written now, gives a lot of latitude to the department that might have a major effect. I'm wondering if this should be studied instead of going through as it is now.

There was no more testimony on SB 2312.

Chairman Lee closed the public hearing on SB 2312.

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2312

Senate Human Services Committee

☐ Conference Committee

Hearing Date February 7, 2005

Tape Number	Side A	Side B	Meter #
1	x		1020-1550
Committee Clerk Signature			

Minutes:

Chairman Lee reopened discussion on SB 2312. All members were present.

Howard Anderson, Executive Director of the North Dakota State Board of Pharmacy:

We have been working on a rewrite of the controlled substances monitoring bill. Mike Mullen has put this together (See attachments). There was an interest group meeting and some thought this would be very beneficial for their practices and taking care of patients, and most were in agreement with the concept. The bill came rather quickly, so a lot of people feel like they haven't had enough time to hash over the details and how it would be implemented. There was another meeting in which Bruce Levi and Dave Peske expressed concern that a physician could be targeted by a search to say that they prescribed too many controlled substances and so we're going to report you to the medical board. That is not the intention. The intention is that if law enforcement is investigating somebody, they could get access, but only in those cases; which is in line with HIPAA.

Mike tried to write this without putting in a lot of detail.

Chairman Lee: Do you think this is an idea whose time has not yet come?

Anderson: I think it's a good idea and if you want to make a study resolution or put it into some kind of a study mode, or create a task force, that might be acceptable. It would also give us the opportunity to apply, next January, for U.S. Department of Justice study grant and implementation grant the following year. It would give us some money to work with without having to appropriate dollars or do something else right away. And it would us time for all those people to feel that they adequate input.

Chairman Lee: I'm also thinking about the changes in part D of Medicare and the prescription drug card and the whole new MMIS system for Medicaid, that maybe needs to be settled on. Maybe we should kill this bill. And maybe it should be done privately rather that just to concentrate on the medical assistance population.

Anderson: And the bill is written much broader. Medicaid has capabilities on their computer, so that might be where we would put the data into, but it's written so that the Board of Pharmacy would manage that rather than Medicaid and decide who could get access to the profile.

Chairman Lee: If we included a study resolution or transformed the bill into a study resolution, then you would be able to apply for the grant?

Anderson: Yes. All they're interested in is if the state has something in process.

Warner: Does a study resolution go forward as a mandated bill?

Chairmen Lee: I wasn't asking for it to be mandated, but rather strongly encourage Legislative Council to choose it as a study. But if the committee wishes to make it a mandated study, we can do that.

Warner: I would feel comfortable with a mandated study.

Chairman Lee asked Carlee McLeod (intern) to put together some wording for a mandated and nonmandated study.

Chairman Lee closed discussion on SB 2312.

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. SB 2312

Senate Human Services Committee

☐ Conference Committee

Hearing Date February 7, 2005

Tape Number	Side A	Side B	Meter #
3	X		366- 1135
Committee Clerk Signature			

Minutes:

Chairman Lee opened the meeting to discuss SB 2312. All Senators were present.

Howard Anderson, Executive Director of the North Dakota State Board of Pharmacy appeared before the committee. The bill is workable, the only thing is we need to figure out how to pay for it. Our organization would like to see a good study take place on this bill, and that some grants will be available in the future.

Chairman Lee- Would it be more practical to do just the study where we would have more access to federal grants?

Howard- That would be up to your committee to decide, but that would be fine with me.

Dave Peske, representing the North Dakota Medical Association, appeared before the committee.

We have had several meetings on this and have been aware of the concept for quite some time. Doctors and hospitals are taking a more direct interest because of this bill. We discussed the idea

of putting it as a study resolution, but think we can accomplish the goal without sending it as a legislative study.

Chairman Lee- Do you see any benefits to the potential availability of grant money? I see this as better driven by the private sector.

Dave-There may be grant dollars available from the Department of Homeland Security.

Howard- The funds that I'm making reference to is from the Department of Justice money for controlled substance monitoring programs.

Dave- Based on the meeting and the concerns of Arnold Thomas, our preference is the bill should not go forward.

Action taken:

Senator Lyson moved a Do Not Pass recommendation for the bill. Seconded by Senator Dever.

The vote was 5-0-0 in a favor of the Do Not Pass recommendation. Senator Lyson is the carrier of SB 2312.

Chairman Lee closed the meeting on SB 2312.

FISCAL NOTE

Requested by Legislative Council
01/19/2005

Bill/Resolution No.: SB 2312

1A. **State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2003-2005 Biennium		2005-2007 Biennium		2007-2009 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues	$0	$0	$0	$0	$0	$0
Expenditures	$0	$0	$310,000	$0	$309,060	$0
Appropriations	$0	$0	$310,000	$0	$0	$0

1B. **County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2003-2005 Biennium			2005-2007 Biennium			2007-2009 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts
$0	$0	$0	$0	$0	$0	$0	$0	$0

2. **Narrative:** *Identify the aspects of the measure which cause fiscal impact and include any comments relevant to your analysis.*

This bill would provide for the establishment of a centralized electronic prescription monitoring system for medical assistance recipients. The system would monitor the dispensing of prescribed controlled substances.

The cost would be included in the department's regular appropriation.

3. **State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*
   A. **Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

Because this system is not a medicaid system, it is likely that federal title XIX funds will not be available; therefore the project would require 100% general funds.

   B. **Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

This bill, if passed, would result in new expenditures totalling $310,000 in 2005-2007 and $309,060 in 2007-2009. The expenditures would be 100% general funds.

   C. **Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, of the effect on the biennial appropriation for each agency and fund affected and any amounts included in the executive budget. Indicate the relationship between the amounts shown for expenditures and appropriations.*

This bill, if passed, would require an additional operating line appropriation totalling $310,000 in 2005-2007 and $309,060 in 2007-2009. The expenditures would be 100% general funds.

Name:	Brenda M. Weisz	**Agency:**	Human Services
Phone Number:	328-2397	**Date Prepared:**	01/25/2005

Date: 2-7-05
Roll Call Vote #: 1

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. 2312

Senate **Human Services** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do not Pass

Motion Made By Sen Lyson Seconded By Sen. Dever

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee - Chairman	✓		Sen. John Warner	✓	
Sen. Dick Dever - Vice Chairman	✓				
Sen. Richard Brown	✓				
Sen. Stanley Lyson	✓				

Total (Yes) 5 No Ø

Absent Ø

Floor Assignment Sen Lyson

If the vote is on an amendment, briefly indicate intent:

REPORT OF STANDING COMMITTEE

SB 2312: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (5 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2312 was placed on the Eleventh order on the calendar.

2005 TESTIMONY

SB 2312

Attachment 2

Dewey Schlittenhard, MBA, R.Ph.
Bismarck, President
Harvey J Hanel, PharmD, R.Ph.
Bismarck, Senior Member
Gary W. Dewhirst, R.Ph.
Hettinger
Rick L. Detwiller, R.Ph.
Bismarck
Bonnie J. Thom, R.Ph.
Granville
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

OFFICE OF THE EXECUTIVE DIRECTOR
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E-mail= ndboph@btinet.net
Howard C. Anderson, Jr, R.Ph.
Executive Director

SENATE BILL # 2312
10:00 AM – WEDNESDAY – JANUARY 26TH, 2005
HUMAN SERVICES COMMITTEE – RED RIVER ROOM

For the Record, I am Howard C. Anderson, Jr, R.Ph., Executive Director of the North Dakota State Board of Pharmacy. Thank you for the opportunity to appear before you today.

The North Dakota State Board of Pharmacy has considered the concept of a prescription monitoring program for some time now. Through your help, I just recently learned that the North Dakota Department of Human Services had capabilities, within the Department, to capture this data.

In the past, I have been reluctant to initiate a new program, with it's incumbent costs.

We have, and continue to work closely with physicians, pharmacists and law enforcement agencies, who are both trying to provide patients with adequate and appropriate care, as well as eliminate the inappropriate or illegal use of controlled substances through the prescribing and dispensing process. We currently ask pharmacies to submit profiles for patients under treatment plans with physicians, when those requests have the potential to enhance the patient care. We also gather profiles for law enforcement agencies, when specific investigations are under way. This is a time consuming, and somewhat cumbersome process, which also takes some considerable time for the pharmacies to provide a response.

An electronic monitoring system where prescription data is claims captured as the claim is transmitted through an electronic billing system would certainly make the gathering of this date easier. I believe enough time has passed so that these electronic systems can allow us to give a password and identification to physicians and pharmacists accessing the system for patient care reasons, which will both allow them real time access to the patient's controlled substances profile, as well as tracking those professionals access to the program. We can also establish a system for approval through, perhaps the Board of Pharmacy, for law enforcement agencies to receive patient profile information, based on specific active investigations. Law enforcement is not usually in a hurry for this data, so there would be time to retrieve the profile information and forward it to law enforcement, if the information was already present on the computer system. Access could also be given, in specific cases, to the online data if that happened to be necessary.

We have a few things to work out with this legislation, and of course practitioners generating the prescriptions would need to be consulted, so we can obtain their input.

I have worked with many physicians who indicated they would be happy to come and testify in favor of such a proposal. This has been a little too short of notice, though we have the Association here today, we did not have time to gather the specific physicians.

I am attaching samples of the requests I regularly receive in the Board of Pharmacy office.

Thank you for your time and consideration.

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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Dewey Schlittenhard, MBA, R.Ph.
Bismarck
Rick L. Detwiller, R.Ph.
Bismarck
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

February 10, 2004

To: Pharmacist-in-Charge

From: Howard C. Anderson, Jr, R.Ph.
Executive Director

The Board is assisting in a confidential investigation of . Please send me any profile you may have on from January 1, 2003 to the present.

Please provide any prescriptions she may have written as a Nurse Practitioner or Physician's Assistant during this time as well.

was licensed as both a Nurse Practitioner and Physician's Assistant for part of this time.

Thank you.

If you do not have any profile for this patient during this time period, kindly indicate by checking the appropriate box below and faxing this back to me, so I will know you / your pharmacy has responded.

SEABURG DRUG
990 Main Street
Carrington, ND 58421
Health Mart
Ph. 652-2651
1-866-833-2651
CAUTION: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

NAME OF PHARMACY: _____
Please complete so we know who has responded

PLEASE MAIL OR FAX YOUR RESPONSE AS SOON AS POSSIBLE

No Profile(s) [X]

Profile(s) Enclosed [ ]

BOARD OF PHARMACY
State of North Dakota

John Hoeven, Governor

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Hettinger
Rick L. Detwiller, R.Ph
Bismarck
Bonnie J. Thom, R.Ph.
Granville
William J. Grosz, Sc.D., R.Ph.
Wahpeton, Treasurer

December 29, 2004

To: Pharmacist-In-Charge

(Please note our Fax # has changed – yes, too close to our phone – please try not to confuse them)

From: Howard C. Anderson, Jr., R.Ph. Howard C. Anderson Jr RPh

The Board is assisting Dr Michael Martire in caring for the following patients.

Please send me a profile for the following individuals from January 1, 2004 to the present:

PERSON	DATE OF BIRTH	LAST KNOWN ADDRESS(s)

Please send the profiles to me, I will consolidate them and get them to appropriate person.

If you do not have any profile for these patients during this time period, kindly indicate by checking the appropriate box below and faxing this back to me, so I will know you / your pharmacy has responded.

HIPAA and the laws of North Dakota allow the release of this information to the State Board of Pharmacy. If you want added information call Eileen, or I and we can fax you a copy of the Attorney General's letter of explanation. Please keep this request as your record of to whom you released this information.

As always, I thank you very much for your help and cooperation.

NAME OF PHARMACY: _____
Please complete so we know who has responded

PLEASE MAIL OR FAX YOUR RESPONSE

No Profile(s) ☐

Profile(s) Enclosed ☐

North Dakota State
Board of Medical Examiners

ROLF P. SLETTEN
Executive Secretary and Treasurer

LYNETTE McDONALD
Administrative Assistant

May 29, 2003

Howard Anderson, R.Ph.
North Dakota Board of Pharmacy
PO Box 1354
Bismarck, N.D. 58502-1354

RE: , MD - Pharmacy Audit

Dear Howard:

This is a request for a pharmacy audit on . Specifically we would like to see the prescriptions he has written for controlled substances during the period from July 1, 2002 through December 31, 2002. I think it will be sufficient to audit the pharmacies in the Grand Forks area. We have a little bit of a time crunch on this one so anything you can do to speed up the process will be great.

Thanks.

Sincerely,

ROLF P. SLETTEN
Executive Secretary
and Treasurer

RPS/md

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
PROBATION OFFICE

KEVIN D. LOWRY
Chief Probation Officer
300 S 4th St., Ste. 406
Minneapolis MN 55415-1320
612-664-5400
FAX 612-664-5350

316 N Robert St., Ste. 600
St. Paul MN 55101-1465
651-848-1250
FAX 651-848-1255

P.O. Box 1159
Bemidji, MN 56619
888-766-2110
FAX 218-333-0102

515 W 1st St., Ste. 206
Duluth MN 55802-1302
218-529-3550
FAX 218-529-3546

118 S Mill St., Ste. 304
Fergus Falls MN 56537-2576
218-739-0041 or
612-664-5410
FAX 218-739-0043

Reply to: **Fergus Falls**

January 24, 2005

Mr. Howard C. Anderson
Executive Director
North Dakota Board of Pharmacy
PO Box 1354
Bismarck, ND 58502-1354

RE: Request for Prescription Profile

Dear Mr. Anderson:

The U.S. Probation Office, District of Minnesota, is presently supervising an offender who is known to obtain prescriptions for narcotics within the Fargo, North Dakota area, through various pharmacies. The individual has admitted abusing these prescriptions, as well as selling them to other parties. As such, I am requesting assistance in obtaining a prescription profile for this individual from all pharmacies in Fargo and West Fargo, North Dakota. Please provide a prescription profile to include any prescriptions obtained between March 1, 2004 through the present date. The following is a information pertaining to the offender.

Name:
DOB:
SS#:
FBI#:

If you need additional information, please contact Aaron Rotering at 218-739-0042. My address is: U.S. Probation Office, 118 South Mill Street, Suite 304, Fergus Falls, Minnesota, 56537. My fax number is 218-739-0043. Your assistance is greatly appreciated.

Sincerely,

Aaron R. Rotering
U.S. Probation Officer

ARR:arr

Jan 24 2000 3:47PM HP LASERJET 3330 P.2

Attachment 2A

North Dakota
Prescription Monitoring Program
PRESCRIPTION MONITORING PROGRAM MODEL ACT

October 2002

Section 1. Short Title.

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

Section 2. Legislative Findings

[insert state findings]

Section 3. Purpose

This act is intended to physcicians and pharmacists ability to treat patients appropriatly, by providing them with access to information about the controlled substances and other drugs, which have addictive potential. It will 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 NDCC section 19-03.1.

(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.

(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 NDCC section 19-03.1

Section 5. Requirements for Prescription Monitoring Program.

(a) The Department of Human Services shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III , IV and V controlled substances, carisoprodal and tramadol, 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 Department of Human Services 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.
(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.
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

Attachment 2B

PRESCRIPTION CONTROLLED SUBSTANCE ELECTRONIC DATA MONITORING PROGRAMS

HISTORY

Misuse, abuse and diversion of controlled substance prescription drugs has continued to be an acknowledged long standing problem for medical practitioners, pharmacists and various state and federal agencies tasked with drug control.

Many states have attempted prescription-monitoring programs. Most notable and intrusive to healthcare providers were triplicate and duplicate prescription order schemes, where copies were collected by an agency with data derived from the collected documents. These systems, while effective within the limitations of paper transfer, collection, and reduction to statistical data, created limitations within medical care practices. However they provided solid documentary evidence of prescription use. More recently, electronic monitoring programs are being developed. Some are conducted parallel to prescription triplicate/duplicate programs, or as stand alone systems.

The goals of prescription monitoring depend upon the mission of the various state agencies that operate the program. Legislatures have authorized law enforcement, regulatory boards, and health departments to conduct such programs; consequently different goals became the focus of a variety of agencies.

Philosophical opposition to statewide collection of prescription information has been challenged in court. A New York District Court decision, which found prescription data collection unconstitutional, was reversed by the United States Supreme Court holding states have broad police power to conduct such activities. Programs that do not deprive the public of access to drugs, do not impair physicians' rights to practice medicine free from unwarranted interference, and maintain security of information can find legal precedent in Whalen vs. Roe. (#869 429 U.S.589, 51 L.Ed.2d 64)

CONCEPT

The goal of monitoring prescription drugs as public policy decision is well founded if all parties to this issue are involved. The structure of a broad based task force including medical practitioners, licensing boards, related associations, treatment people and criminal justice system representatives can benefit from the establishment of agreed upon objectives and prevent the perceived concerns of bureaucratic enforcement, medical and pharmacy practice interference, and destruction of patient confidentiality.

The ultimate goal is a public policy to assure consumers have access to appropriate pain management and medications to devise a system which is non intrusive to medical practitioners, pharmacies, and patients but provides complete, current and accurate data of drug abuse. Equally important is that operational costs should be minimal.

Public law must exist or be amended to authorize the collection of data to present improper or illegal use. Statutes should also assure the process does not infringe on the legal use of a controlled substance for the management of severe or intractable pain, but also mandates multiple doctor visits to obtain controlled substances, prescription fraud, alteration and forgery are violative acts prohibited by law.

DATA COLLECTION

Mechanisms of electronic data are well established. They have been derived from third party administration of drug benefits. States have established their own systems or have used firms expert in the business of mass data collection. Data collection firms provide a resource of data cleansing and reporting compliance prior to use by the prescription monitoring program.

As with a data collection process, various states have developed their own review mechanisms. Many are willing to share their computer system programs as well as experience to assist others. Off the shelf data base programs can be used.

DISCUSSION

Generally, state laws establish the acts conducted in the illegal obtaining of controlled substances as criminal violations. Therefore, law enforcement appears to be an appropriate mechanism to stop drug abuse. Unfortunately, a benefit correlation between enforcement efforts and rising drug addition can not be made. Law enforcement mechanisms, throughout the criminal justice system, are often enormously expensive and not particularly effective for goals of reducing prescription drug abuse and addiction.

Issues of health care information confidentiality impact upon concepts of prescription monitoring. Patient confidentiality is currently receiving congressional attention. Any monitoring system must assure confidentiality of patient and practitioner information regarding legitimate medication use.

Pain management, often inadequately or inappropriately conducted, has state and national organizations pushing for legislation and/or regulations to assure patient comfort in cases of chronic, intractable and malignant pain. Opponents to a state's data collection argue such programs may become an impetus to reduce needed drugs. A monitoring system must not infringe upon pain management.

Practitioners who prescribe and pharmacists who dispense controlled substances are burdened with myriad requirements of documentation. While triplicate/duplicate prescription programs create an alternative to illicit prescriptions, health care providers also claim it a barrier to patient access and convenience of medications. The printed forms are sometimes unavailable, inaccessible, or lost by patients, and require handling of health providers and agencies involved in their collection. It must be noted the forms do provide significant evidence and factual data.

Electronic Monitoring Systems have proved to be "transparent" to the practitioner, patient and most pharmacists. Data collection from pharmacies can be established that require less than a few minutes per month of a pharmacists time. Many pharmacies have automated data collection mechanisms that require no involvement by personnel. Unless prescribing practitioners are advised, many never know of programs' existence, until they are advised of patient utilization.

Monitoring systems provide accurate data to prescribers of drugs. Drug abuse intervention occurs when practitioners are informed with patient information regarding illicit activities involving prescriptions. The data provided in a patient's drug utilization profile results in several potential observations by the practitioner. They include:

1. Quantities and frequency of drug use.
2. Patient prescriptions from multiple practitioners. (Law violation in some states)
3. Patients receive additional refill or altered quantities than original order. (Possible forgery)
4. Pharmacy dispensing refills early or allowing unauthorized refilled orders.
5. Illegal orders made in the practitioner's name by office personnel or others.

Practitioners find access to information regarding a patients drug use extremely beneficial.

Accurate information about drug diversion through illicit prescriptions is generally unknown. Frequent anecdotal experiences of doctors and pharmacists suggest an enormous amount of illicit activity. Monitoring programs can provide the correct data. Information and analysis of prescribing trends by geographical areas, medical specialties and drug categories can be generated. An important feature of monitoring programs is that education, intervention or even criminal justice actions can be targeted to specific violations, pharmacists and prescribers. The annoyance and fear of investigative agencies rummaging through patient records and pharmacy files to find

illicit activities is removed. Confidential patient records are actually protected by electronic review.

The overall objective of diminished controlled substance illicit use often becomes victim of competing agencies or political factions. A method of dissolving this barrier to good public policy is cooperation. The establishment and management of a quality monitoring program should include practitioners of a variety of medical discipline, drug treatment representatives, professional associations, regulatory boards, and criminal justice systems participants.

CONCLUSION

The purpose of prescription monitoring programs is manifold; spanning prevention, education and law enforcement. The principal goals of such programs are to reduce illicit prescription drug use and to assure access to appropriate pharmaceutical care by the state's citizens. The goal should not include any restriction on legitimate prescribing or dispensing of pharmaceuticals and function to be supportive of statutory mandates and least disruptive to medical and pharmacy practices.

OBJECTIVE

Each state must strategically plan the goal of a prescription monitoring process. The goal should dictate the structure and conduct of the program.

The following goals are listed without intended priority, but as potential primary and secondary objectives of a prescription-monitoring program:

Primary

- Drug Abuse Intervention
- Practitioner/pharmacist education
- Accurate Drug Utilization Statistics
- Deterrence
- Law Enforcement

Secondary

- Transparency
- Reduction of Social Impact/cost
- Reduction to criminal justice system/cost

OBJECTIVE DISCUSSION

Generally, state laws establish the violative acts conducted in the illegal obtaining of controlled substances. Therefore, law enforcement appears to be an appropriate mechanism to stop drug abuse. Unfortunately, a benefit correlation between enforcement efforts and rising drug addiction can not be made. Enforcement mechanisms, through the criminal justice system, are often enormously expensive for goals of reducing prescription drug abuse and addiction.

PRESCRIPTION MONITORING PROGRAM
"Nuts & Bolts" Construction

1. Form cohesive interest group
   a. Necessity must be articulated
   b. Set objectives of intervention process
   c. Avoid "turf" issues, be inclusive of participants

2. Assure legislation authorizes and supports function
   a. Approves data collection
   b. Assures confidentiality
   c. Prevents infringing on medical practices/pain management
   d. Sets basic public policy goals
   e. Defines persons to administer program

3. Structure financing
   a. Start-up costs
      1) Computer Hardware
      2) Software systems
      3) Personnel
   b. Anticipate annual expenditure
   c. Seek grants and/or other support

4. Form Task Force
   a. Establish policies & procedures
   b. Set utilization thresholds
   c. Formalize program parameters

5. Communicate policies of data collection with pharmacies
   a. Establish essential data elements
   b. Establish reporting times
   c. "Bombard" pharmacies with information to assure compliance

6. Collect data
   a. Agency structured process
   b. Contract with data companies

7. Analyze data
   a. Develop information by Task Force standards
   b. Provide data to practitioners, pharmacies
   c. Provide professional problems to respective licensing boards
   d. Provide criminal acts to law enforcement

8. Confirm activities and review with Task Force
   a. Report to legislators, Task Force members and professions
   b. Amend laws, regulations if required

Attachment 2C

Mission Statement

To prevent the inappropriate distribution
and use of prescription controlled substances

Participants

Agencies

Bureau of Alcohol & Drug Abuse
Division of Investigation
Medicaid

Boards

Dental Examiners
Medical Examiners
Osteopathic Medicine
Pharmacy
Podiatry
Veterinary Medical Examiners

Practitioners Associations

NV Osteopathic Medical Association
NV Pharmacist Association
NV Podiatric Medical Association
NV Society of Hospital Pharmacists
NV State Dental Association
NV District Attorney Association
NV State Medical Association

District Attorneys

Clark County

Practitioners

Pain Institute of Nevada
Sierra Anesthesia Associates

Proposed Amendments to Senate Bill 2312

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to provide for a legislative council interim study of a centralized electronic monitoring system.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. Centralized electronic prescription monitoring system– Legislative council study. The legislative council may consider studying, during the 2005-2006 interim, a centralized electronic prescription monitoring system, including the fiscal impact of any such program. The legislative council shall report its findings and recommendations, together with any legislation required to implement the recommendations, to the sixtieth legislative assembly."

PREPARED FOR THE BOARD OF PHARMACY
By Michael J. Mullen
Draft #5 – *1/31/2005 3:19 PM*

PROPOSED AMENDMENTS TO SENATE BILL NO. 2312

Page 1, line 1, after "A BILL" replace the remainder of the bill with "for an Act to create and enact a new chapter to title 19 of the North Dakota Century Code, relating to the establishment of a centralized electronic prescription drug monitoring system.

BE IT ENACTED BY THE LEGISLATIVE ASSEMBLY OF NORTH DAKOTA:

SECTION 1. A new chapter to title of 19 of the North Dakota Century Code is created and enacted as follows:

Definitions.

1. "Controlled substance" has the meaning given to this ~~tem~~ term in section 19-03.1.

2. "Patient" means the person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

3. "Dispenser" means a person who delivers a Schedule II–V controlled substance as defined in subsection (4) of this section to the ultimate user, but does not include:

a. a licensed hospital pharmacy that distributes such a substance for the purpose of inpatient hospital care.

b. a practitioner, or other authorized person who administers such a substance; or

c. a wholesale distributor of a Schedule II–V controlled substance.

4. "Schedule II, III, IV and/or V controlled substance" mean a controlled substance that is listed in Schedules II, III, IV, and V of the Schedules provided under chapter 19-03.1.

5. "HIPAA privacy rule" means the regulation of the use and disclosure of health information set forth in parts 160 and 164 of title 45 of the Code of Federal Regulations.

Requirements for Prescription Monitoring Program.

1. The Board of Pharmacy shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III, IV and V controlled substances, and carisoprodal and tramadol.

2. Each dispenser shall submit to the Board of Pharmacy by electronic means information regarding each prescription dispensed for a drug included under subsection (1) of this section. The information submitted for each prescription must include:

a. Dispenser identification number.

b. Date prescription filled.

c. Prescription number.

d. Prescription is new or is a refill.

e. NDC code for drug dispensed.

f. Quantity dispensed.

g. Number of day's supply of drug dispensed.

h. Patient name.

i. Patient address.

j. Patient date of birth.

k. Prescriber identification.

l. Date prescription issued by prescriber.

m. Person who receives the prescription from the dispenser, if other than the patient.

n. Source of payment for prescription.

3. Each dispenser shall submit the information in accordance with transmission methods and frequency established by the Board of Pharmacy.

4. The Board of Pharmacy may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Any such waiver may permit the dispenser to submit prescription information by paper form or other means, if all of the information required in subsection (2) of this section is submitted in this alternative format.

Access to Prescription Information.

1. Prescription information submitted to the Board of Pharmacy is confidential.

2. The Board of Pharmacy shall safeguard the confidentiality of any confidential information received, maintained, or transmitted, and may not disclose confidential information except as permitted under subsections (3), (4), and (5) of this section.

3. The Board of Pharmacy may review the prescription information submitted to the monitoring program. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the Board of Pharmacy may, subject to the HIPAA Privacy rule, and any other federal or state law, notify the appropriate law enforcement, or professional licensing and certification or regulatory agency, and disclose any prescription drug information required for an investigation.

4. The Board of Pharmacy is authorized, subject to the HIPAA Privacy rule, and any other federal or state law, to disclose data in the prescription monitoring program to the following persons.

a. Any health care provider that: (i) is treating, or within the last year has treated, the individual by prescribing or dispensing a controlled or other substance covered by this chapter for any illness, disease, or condition; (ii) is the individual's primary care provider; or (iii) has been requested to treat the individual by prescribing or dispensing any controlled or other substance covered by this chapter for any illness, disease, or condition.

b. An individual who requests his or her own prescription monitoring information in accordance with procedures established under state and federal law.

c. The Board of Medical Examiners, Board of Nursing, the Board of Pharmacy, and any other board regulating practioners.

d. A local, state, and federal law enforcement official, including as probationer officer, or a prosecutor engaged in the administration, investigation or enforcement of the laws governing controlled substances.

e. The medical services division of the department human services and the workforce safety and insurance organization.

f. A district court or a tribal court under grand jury subpoena or court order.

g. Personnel of the Board of Pharmacy for purposes of administration and enforcement of this chapter, or chapters 19-03.1, 19-03.2 and 19-03.3.

5. The Board of Pharmacy may disclose data to public or private entities for statistical, research, or educational purposes if the information is de-identified in accordance with requirements for de-identification under subsection (a) or (b) of section 514, part 164, title 45 of the Code of Federal Regulations.

Authority to Contract

The Board of Pharmacy is authorized to contract with another agency of this state or with a private vendor to facilitate the effective operation of the prescription monitoring program. Any contractor is bound to comply with the provisions regarding confidentiality of prescription drug information in Section 3 of this Act and is subject to the penalties for unlawful acts specified in Section 6 of this Act.

Immunity

Nothing in this chapter requires a practitioner or dispenser to obtain information about a patient from the prescription monitoring program database. A health care provider may not be held liable in damages to any person in any civil action for injury, death, or loss to any individual or property on the basis that the provider did or did not seek to obtain information from the prescription monitoring program database.

Extraterritorial Application

Nothing in this chapter shall be construed to prohibit the disclosure of information about a patient from the prescription monitoring program database to a practitioner or controlled substances monitoring system in another state, if the disclosure to a practitioner or the prescription monitoring program located in this state is authorized by this chapter.

Rules and Regulations.

The Board of Pharmacy may promulgate rules and regulations that set forth the procedures and methods for implementing this Act.

Unlawful Acts and Penalties.

1. A dispenser who knowingly fails to submit prescription monitoring information to the Board of Pharmacy as required by this Act or knowingly submits incorrect prescription information is guilty of a class B misdemeanor.

2. Any person, including a vendor, who uses or discloses prescription monitoring information in violation of this Act, is subject to the penalty provided in section 12.1-13-01."

Renumber accordingly

Attachment 1

TESTIMONY BEFORE THE SENATE HUMAN SERVICES COMMITTEE

REGARDING SB 2312

JANUARY 26, 2005

Chairman Lee, members of the committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services. I appear before you to provide testimony in favor of SB 2312.

The Department feels that there is a need for such a repository, and we would willingly assist in making sure it comes to fruition. However, some changes to the bill should be considered.

First, it should include patients beyond ND Medicaid recipients. Second, the management of this data repository may be better situated in a place such as the Pharmacy Board or Medical Board. This would increase the flexibility for securing funding. It is likely that no federal Medicaid matching funds would be available to establish a repository.

The Department would certainly wish to utilize this system to aid in the care of our patients, and would welcome any guidance the legislature would wish to give on the appropriate use of such a system.

I would be happy to answer any questions you may have.