NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

March 28, 2016

The Honorable Representatives Mark Neuman and Steve Thompson
Co-Chairs, House Finance Committee
Honorable Members of the House Finance Committee
Alaska State Capitol
Juneau, AK

RE: Senate Bill 74, Sections 14, 15, 18 and 19

Representatives Neuman and Thompson and members of the House Finance Committee:

On behalf of the members of the National Association of Chain Drug Stores (NACDS) operating in Alaska, I respectfully ask you to consider our suggested amendments to Senate Bill 74 – Medicaid Reform.

NACDS Members in Alaska operate 64 store fronts and employ over 10,000 Alaska residents. In addition, they pay over $12 million in state taxes.

While we sincerely appreciate all the work the Senate and House have dedicated to the passage of Senate Bill 74, as community pharmacies, we have serious concerns about some of the requirements in sections 14, 18 and 19.

We supported and worked hard on original passage of the law implementing the controlled substance prescription database. We believe the information reported to the database has been a significant deterrent in manipulating prescribers and dispensers for the purposes of acquiring legal drugs for illicit purposes. It also has allowed pharmacists and practitioners to better manage their patient's health care regimen.

In Section 14, we would like to offer the database be updated "within one business day from when the prescription is sold". We believe with the current prescription drug abuse more timely reporting could be helpful. The more timely the information is reported and available, the better prescribing decisions can be made by the practitioners.

We would also ask that the language in subsection 8 be amended to delete the nebulous reference to "other appropriate identifying information".

In Section 15, we offer our support for the expansion of who may access the prescription drug database. Allowing prescribers and pharmacists to delegate authority to addition **licensed** personnel will ensure the appropriate review of the patient's controlled substance prescription history. We believe it is important due to the sensitive nature of the information that any delegation of access to the database be to a licensed person in the unfortunate event disciplinary action is necessary.

In Section 18, we would respectfully ask that pharmacists not be included in the requirement to check the database prior to the dispensing of a prescription since the increase reporting timeframe will give the prescribers the information they need when checking the database prior to issuing a prescription. The need for pharmacists to check the database is redundant when the prescriber is required to do so prior to issuing a prescription. It is not the intent of NACDS and its members to eliminate pharmacists checking the database prior to dispensing when they believe there is reason to be concerned with a patient presenting a prescription. Pharmacists check today, and will continue to do so whenever they believe something may not be appropriate. We are asking for the elimination of the mandate to check the database when that function has already been performed per this bill in the prescriber's office.

Pharmacists today perform a large number of patient services such as immunizations, disease management and screening for cholesterol, blood pressure, and diabetes, just to name a few. To take them away from direct patient care by requiring checking the database each time a prescription comes in for a controlled substance is a burdensome use of their time and training.

We would also respectfully request that the exemption for "emergency room" checking of the database be eliminated as this is a frequent stop for those inclined to abuse controlled substances.

The database could be checked during ER triage so it is done prior to the ER physician or nurse practitioner actually seeing the patient.

In Section 19, we would again like to ask to increase the reporting frequency to "within one business day from when the prescription is sold" to be consistent with Section 14.

We appreciate your consideration of our comments and proposed changes to pertinent sections of Senate Bill 74.

Sincerely,

Lis Houchen
Regional Director, State Government Affairs
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*Sec. 14. AS 17.30.200(b) is amended to read:

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule [IA, IIA, IIIA, IVA, OR VA CONTROLLED SUBSTANCE UNDER STATE LAW OR A SCHEDULE I,] II, III, **or** IV [, OR V] controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule [IA, IIA, IIIA, IVA, OR VA CONTROLLED SUBSTANCE UNDER STATE LAW OR A SCHEDULE I,] II, III, **or** IV [, OR V] controlled substance under federal law other than those administered in a patient at a health care facility, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database ***[~~on at least a weekly basis~~] within one business day from when the prescription is sold:***

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

(2) the date of the prescription;

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

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

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

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

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

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

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

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

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

(2) authorized board personnel or contractors as required for operational and review purposes;
(3) a licensed practitioner having authority to prescribe controlled substances **or a~~n~~ *licensed* agent or *licensed* employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf**, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance;
(4) a licensed or registered pharmacist having authority to dispense controlled substances **or a~~n~~ *licensed* agent or *licensed* employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf**, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance;
(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant, subpoena, or order issued by a court establishing probable cause for the access and use of the information; [AND]
(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;
(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;
(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the inforamiton relates specifically to utilization review of prescption drugs provided to recipients of medical assistance;

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

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber.

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

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

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

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

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

(4) that a [*~~pharmacist or~~*] practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a controlled substance to the patient; the regulations must provide that a [*~~pharmacist or~~*] practitioner is not required to review the information in the database before dispensing, prescribing, or administering a controlled substance to a person who is receiving treatment

(A) in an outpatient setting;

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

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

[(D)] **(C) immediately before, during, or within the first 24 hours after surgery.**

***Sec. 19.** AS 17.30.200 is amended by adding new subsections to read:

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

(p) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, and the Board of Examiners in Optometry when a practitioner registers with the database under (o) of this section.

(q) The board is authorized to provide unsolicited notification to a pharmacist or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice.

(r) The board shall update the data base [~~***on at least a weekly basis***~~] ***within one business day of the prescription being sold*** with the information submitted to the board under (o) of this section.

March 28, 2016

Alaska State Legislature
Juneau, Alaska

RE: SB 74, Sections regarding the prescription drug database

I am a retired community pharmacist from Fairbanks, Alaska. I served on the Alaska Board of Pharmacy for two terms in the 1980's and again from 1998-2004. During my tenure as President of the Board, we began work on the statutes setting up the controlled substance prescription database. As an active member of the Alaska Pharmacists Association, I also testified on the importance of having such a database to help deter some of the controlled substance prescription drug misuse and abuse in our state. Now that it has been implemented, I believe it is has been very helpful for both prescribers and pharmacists to check on those patients who try to manipulate the system to acquire legal drugs for illegal purposes.

I do have some concerns with some of the proposed changes, though:

- I think it important to allow prescribers and pharmacists to delegate authority to access the database, but, I feel that that delegated authority should only be to **licensed** personnel. This is sensitive information and it should be handled appropriately.
- I don't think pharmacists should be included in the **requirement** to check the database prior to dispensing if the prescriber is required to do so. Pharmacists will check the database as a matter of course if they have concerns with the patient presenting the prescription, i.e. someone they are not familiar with, someone who wishes to pay cash rather than bill their insurance, or someone who seems to be getting inappropriate quantities of controlled substances.
- I do not feel that Emergency Rooms should be exempt from checking the database since this is often where "doctor shoppers" go to get additional prescriptions for controlled substances.

Thank you for considering my comments,

Margaret D. Soden
PO Box 61328
Fairbanks AK 99706-1328
margaretdsoden@gmail.com

From:
Sent: Tuesday, March 29, 2016 10:13 AM
To:
Subject: FW: HB 344 SB 74

One more email and I'll shut up.

My wife corrected me. The current drug database does contain information of other scheduled drugs. I forgot that as I have found the database really only helpful for patients abusing schedule II medications.

John Nolte, MD

-----Original Message-----
From: John Nolte [mailto:johnnolte@gmail.com]
Sent: Monday, March 28, 2016 10:26 PM

Subject: Re: HB 344 SB 74

Hello Legislators,

I have received some feedback from my letter I'd like to pass on to all.

>> I apologize, I read an incorrect version of the bill regarding class V drugs which are not included in the current version, however - classes 2,3,4 includes 28 meds we prescribe regularly. I figure this will cost about an hour of time per full clinic day - if the database is always up and the connection isn't slowed.

I am aware the database was started in 2008 but it was voluntary, very helpful, and did not include threats against providers and pharmacist or include schedule III - IV drugs. The federal regulations changed several schedule III drugs to schedule II - inconveniencing many patients.
>>
>> The new telehealth bill does set two sets of standards by not requiring physical examinations - it says clearly in the bill that these standards will be national standards. The only requirement is that they send records to us (to pick up the pieces) and "the requirement that a licensed healthcare provider be available". That is unbelievably vague and an unenforceable loophole. What defines an available licensed provider? Is it an orthopedist at Anchorage Fracture when the patient has a mental health problem? Does "available" mean the provider has an opening in 6 weeks. Or perhaps it is a family physician, the patient waits 6 weeks and the doctor then says he doesn't do OB. Does that absolve the "Teledoc" from responsibility dictated by a "doctor patient relationship"? That requirement is a joke. I have notes from Teledocs who have "treated" my patients and sent me "records". I will be happy to produce them if desired. The notes

are substandard. Perhaps if the doctors knew the patients, the note might be acceptable, but from the note, I can't tell if the person talking to and treating my patient is a doctor, PA or NP. There is no mention of the qualifications of the provider.
>>
>> Yes there are more boards and demo projects set up in this bills but MDs are not on all these committees.
>
>> There has always been a differential pay for Medicaid patients. Medicaid pays 100% federal rate to ANMC for Alaska natives. It does save the state money but increases costs to us as taxpayers. Providers pay will be cut as we are 50% state and 50% federal the state. The State will cut our current $64 rate while the $601 federal rate ANMC gets goes up every year and is not subject to state cuts.
>>
>> Many Legislators are wrong about what this bill will do as it will not help patients but be a very expensive invasion of privacy and government data collection on us and our patients.

>> ER and surgeons ARE excluded in this bill from consulting the Database prior to prescribing.

>> http://www.legis.state.ak.us/PDF/29/Bills/SB0074E.PDF.
>>
>> Sincerely

>> John Nolte, MD

To All State Legislators: 27 March 2016

I am writing to you today to express my deep concern with the requirements of the Alaska Drug Database legislation. The registry was initially "sold" as a way to help stem the rising tide of prescription pain medication – primarily opioids. Suddenly now, the Database is to include schedules: I, II, III, IV, V. Sched III, IV and V have a low likelihood of being abused. These are medications like testosterone, cough syrup, weight loss, ADD/ADHD, seizure, sleeping, anti - anxiety, and pain medications (which are all schedule 2,3,4 medications). Before I can prescribe them to children and adults I have to stop, log into a database (which may or may not be up) to do what? To view the fact that a patient gets his testosterone shot every month? That a woman with migraines gets her 30 tablets per month? The fallacy here is that non-medical people believe the lie that there are "generally recognized standards of safe practice" that show how many tablets of all these medicines an individual can fill in a specified period of time. I would like to see a book based on scientific outcomes that tells me how many tablets of a given medication I should give Ms Jones.

(q) The board is authorized to provide unsolicited notification to a pharmacist
or practitioner if a patient has received one or more prescriptions for controlled
substances in quantities or with a frequency inconsistent with generally recognized
standards of safe practice.

Standards can be applied to populations or study groups but cannot be applied to individual people. People work out of town, people travel and need medications "in case", people live in the bush, people forget their meds or lose them and someone who isn't a physician, hasn't seen touched or talked to the patient is going to determine that they know better how much medicine any given patient requires.

This bill, increases government involvement in personal health care, and is an invasion of health privacy for children and adults to be listed on a controlled substance registry for non-narcotic or limited time medications. The FBI, CIA, DoD, and Premera all cannot keep their databases secure. Now every pharmacy, tech, clinic, medical assistant will pose a potential weak link in healthcare privacy. I know many of you will end up on that database – is that what you really want? The latest craze is hackers taking databases hostage and demanding payment to un-hijack or not disclose information. It's only a matter of time.....

What are the unintended consequences? When one of you calls on a Saturday and needs a refill of cough medication because you are heading out that evening to Juneau, even though I take after hours call for my patients – I'm not going to prescribe controlled drugs because I can't log in from the Russian river to check the database on Representative so and so to make sure he isn't abusing cough medication. The regulation change last year – changed hydrocodone from a sched III to a sched II. That means that those Rxs can't be called in or faxed. Patients with the flu, cough, broken bones, post op surgeries etc., now have to drive to a doctor's office, pick up the Rx and wait at a pharmacy to get it filled. Unintended consequences..

Anyone who has owned a business or is a competent leader, knows that programs are more likely to work if you get buy-in from the stockholders – Practitioners, pharmacists and patients, using rewards rather than sticks. Below is a stick:

Sec. 16. AS 17.30.200(e) is amended to read:
(e) The failure of a pharmacist-in-charge, pharmacist, or practitioner to
register or submit information to the database as required under this section is
grounds for the board to take disciplinary action against the license or registration of
the pharmacy or pharmacist or for another licensing board to take disciplinary action
against a practitioner.

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

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

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

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

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

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

(A) in an inpatient setting;

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

(C) in an emergency room; or

(D) immediately before, during, or within the first 24 hours after surgery.

What is the pharmacist or practitioner suppose to review that database for? What if the practitioner reviews the database and feels a patient needs more narcotics (even people who take regular narcotics for chronic conditions: fall, break or dislocate bones, get burned etc.). Why not in emergency room? Is the pharmacist – who doesn't know the patient, hasn't obtained a medical history or examined the patient, going to be able to make an intelligent decision? They already give inappropriate medical advice to patients; refuse to fill Rxs because they don't know the real conditions for which the doctor prescribed the medications.

This bill dramatically increases medical care costs to patients, as providers will have to spend time doing this data entry as staff will not know about medications that are listed, and if they miss enter data it could be a liability for the provider. This bill causes an unnecessary waste of time (close to an hour a day) for primary care providers who already know what medications their patients are on, as 26 medications are on this list, which are prescribed regularly by primary care. This database will become enormous in short order – who is going to manage this? This legislation interferes with a providers' ability to prescribe medications in a timely manner to patients, and takes providers away from patients by forcing them to do more unnecessary burdensome paperwork.
If you are bound and determined proceed with the database, start small. Start with certain specifically abused medications. That can be expanded if needed but rarely are regulations rolled back.

Lastly, regarding telemedicine. I have already received "Teledoc notes" on several patients. All of them have been substandard. While the providers may not be disciplined by the state, it won't be long until the malpractice lawyers have a new source of income.

I hope my input helpful. Best wishes – appreciate the work you folks do.

John Nolte, MD
Miriam Nolte, MD
Hillside Family Medicine, LLC

From: Lynette Bergh
Sent: Thursday, March 24, 2016 1:21 PM
To: Helen Phillips
Subject: FW: SB 74

Testimony on SB 74.

From: Ryan Ruggles [mailto:rruggles@anhc.org]
Sent: Thursday, March 24, 2016 12:46 PM
To: Rep. Steve Thompson <Rep.Steve.Thompson@akleg.gov>; Rep. Mark Neuman <Rep.Mark.Neuman@akleg.gov>; Rep. Dan Saddler <Rep.Dan.Saddler@akleg.gov>; Rep. Bryce Edgmon <Rep.Bryce.Edgmon@akleg.gov>; Rep. Les Gara <Rep.Les.Gara@akleg.gov>; Rep. Lynn Gattis <Rep.Lynn.Gattis@akleg.gov>; rep.daveguttenberg@akleg.gov; Rep. Cathy Munoz <Rep.Cathy.Munoz@akleg.gov>; Rep. Lance Pruitt <Rep.Lance.Pruitt@akleg.gov>; Rep. Tammie Wilson <Rep.Tammie.Wilson@akleg.gov>
Subject: SB 74

House Finance Chairs, Vice Chair, and Members-

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

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

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

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

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

I also have been aware that many providers (prescribers as well as pharmacists) are not aware of the PDMP or do not know how to get access. Making them aware could increase use.

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

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

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

If a patient has 4 refills on a medication, and I have checked on the initial fill, I am unsure that the additional checks would be helpful, especially in the instance of a seizure medication for a young child.

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

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

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

"When a new prescription for a controlled substance, or a change in a current one occurs, the best practice is for the prescriber or delegate to check the PDMP before issuing to the patient but not required given professional judgement on the part of the prescriber."

"When a new or changed prescription for a controlled substance is filled, the best practice is for the pharmacist or delegate to check the PDMP before issuing to the patient but not required given professional judgement on the part of the pharmacist."

Change could be defined as dose, quantity, directions, or prescriber.

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

Utilizing this methodology, if this procedure is met, every New patient will have their information checked. This ensures that there are checks and balances. If the prescriber misses their part, then the pharmacist should catch it. Additionally, if the prescriber is checking, and if the pharmacist misses their check, then at least a practitioner looked at the information. This method should cast a good net for limiting the problem we are facing without being overly aggressive, and affecting practices that the bill is not intending to affect.

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

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

There are Continuing Education courses that can reflect this.

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

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

Thank you for your time and consideration,

Ryan Ruggles, PharmD

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