

Pharm 543 Alternatives

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Group 1 Limit sales of methamphetamine precursors

Group Members: Etsegenet Assefa, Louisa Chu, Dennis Go, Marshall Heaster, Marcie Hume, Kristen Kai, Robert Lambert, Jill Mack

1) Existing law and objections:

We propose changes to **RCW 69.43.110** in order to limit the diversion of pseudoephedrine, ephedrine, phenylpropylamine, their salts, isomers, or salts of isomers, or a combination of any of these substances (hereafter referred to as pseudoephedrine) products to the production of methamphetamine. The current law limits pseudoephedrine sales to a total of 6 grams in 24 hours. This limit gives ample opportunity for people to buy pseudoephedrine for illicit use. We will further limit the amount of sales to 1.2g per package/per person and a maximum purchase of 2 packages in 24 hours and limit the quantity purchased in a 60 day time period to a total of 4 (1.2g) packages.

Comment [t1]: Are you proposing legislative change (i.e., RCW) or operate within the BOP's authority (i.e., WAC)?

2) Alternative 1: One alternative is to make pseudoephedrine a prescription only medication. This could be a regular legend drug, or making a controlled substance.

3) Alternative 2: Require that the tablet form of pseudoephedrine be pulled from the market, allowing only combination products, liquid, or liquid gel capsules to continue on the market.

4) Alternative 3: Leave the current legislation as it is, hoping it will control the diversion of pseudoephedrine to illicit purposes.

Group #2: Prescription Only Pseudoephedrine

Group members: Elyse Tung, Leigh Brown, Angela Hitt, Vu Hoang, Jared Judd, Young Mi Kim, Kaddin Moretsky, Shawn Hancey

1. By January 1, 2006, OTC sales of pseudoephedrine will be further limited in quantity, restricted to purchasers 18 years of age or older, require photo ID, and require that a record of each sale be recorded (some of these new requirements went into effect on October 1, 2005). We believe that making

pseudoephedrine a legend drug would be more effective in terms of reducing production of methamphetamine in WA state.

2. Alternative 1: Make pseudoephedrine a schedule V legend drug. Similar to our proposed changes, this would further restrict access by reducing the number of legal refills allowed per Rx. While this alternative has many of the benefits of our proposal, we believe that scheduling is not necessary, and by not doing so that we would allow patients with a legal prescription to obtain their medication with less hassle.

3. Alternative 2: Keep the current law in place until such a time that federal legislation is passed, and then adopt the new federal rules. This is a valid alternative, however, it is not known how long the proposed federal legislation will be pending.

Comment [t2]: Recall Don Williams comment about WA adopting federal rescheduling "by reference". So this may be automatic.

4. Alternative 3: Make pseudoephedrine part of a new "third class" of drugs available at the pharmacy without a prescription, but sold at the discretion of the pharmacist. While this alternative would probably reduce OTC sales intended for methamphetamine production, it is likely that it would be implemented with some degree of variation from pharmacy to pharmacy.

Group 3—"Show and Tell" – Alternatives

Joe Johnson, Helen Song, Connor Christy, Olga Shvartsur, Zachary Beard, Aaron Chin, Lydia Zou, Tina Ngo

We want to add an amendment to WAC 246-869-220 requiring patient counseling to include the showing of the medication (opening the actual bottles) to the patient for all new prescriptions and all refills with changes. We think this is a necessary part of counseling because we want to make sure the patient verbally and visually understands what they are receiving. The issues of dispensing the medication to the wrong patient, dispensing a different medication to the correct patient, or other misunderstandings (same drug, different manufacturer) have unfortunately not been uncommon in the pharmacies that we've worked in. In some pharmacies that have implemented mandatory showing of medication, this problem has been greatly reduced or nearly eliminated by this simple procedure. We just think that it's an easy and efficient additional check to ensure patient safety and pharmacists should incorporate this into their counseling routines.

Comment [t3]: citations?

Alternatives:

- 1) Make exception for mail-order pharmacies for alternative "showing" methods such as description of medication and/or picture of medication on the bottles.
- 2) Exempt mail-order pharmacies or any prescriptions filled from pharmacies that provide mail-order services.

3) Allow pharmacies to choose their preferred method of “showing” as they deem appropriate. This can include the description of medication and/or picture of medication on the bottles.

Group 4 Expiration of Schedule II Prescriptions

Group Members: Quyen Nguyen, Mai Linh, Andrea Eberly, Jeff Loor, Goeff Meer, Jennifer Law, Nick Wyatt, Sareh Ghazanfarpour

1. Description of existing law and objections - use information from the previously submitted problem definition, or revise if your thinking has changed. Two-three sentences.

We are proposing to change the expiration date of all schedule II prescriptions from one year to 90 days. Narcotics and stimulants are used to treat conditions that need careful monitoring and evaluation. Allowing patients to fill the prescription one year after the written date is unsafe.

2. Alternative 1: 2-3 sentences

Instead of having schedule II prescriptions expire within 90 days as suggested, expiration can be extended to 6 months. This corresponds with other control substances (CIII and IV). However, no refills are allowed.

3. Alternative 2: 2-3 sentences

Expiration of schedule II prescriptions can be changed to expire within 90 days. However, refills are allowed within this time frame (maximum of 3 refills). This allows prescribers to see patients more often for monitoring and decreases the hassle of patients having to obtain several prescriptions. (We are now considering this alternative)

4. Alternative 3: 2-3 sentences-

Do nothing, keep the law as is.

Group 5 Rescheduling of the Benzodiazepines

Group Members: Rachel Nowak, Osama Saleh, Hae Young Zhang, Vivian Villanueva, Benjamin Davis, Kevin Hiroo, Carolyn Sear, BJ Gleason

Existing Current Plan:

RCW 69.50.210 ranks the family of Benzodiazepines within the Schedule IV status. Under this schedule, risks of dependence and abuse associated with administration of many of the members within the Benzodiazepines are being excessively disregarded in comparison to similar Schedule III narcotics. Furthermore, the chances for access to and use as recreational “street-

drugs” are greater under the Schedule IV status as regulations upon suppliers of Benzodiazepines such as extended health care facilities, hospitals, and pharmacies are less stringent. Unwarranted and over prescribing of Benzodiazepines (especially Alprazolam, Lorazepam, Clonazepam, and Diazepam) by medical authorities has been shown to be indicative of increased illicit use, and as national data has shown a marked increase in overall Benzodiazepine prescriptions, it is apparent that the legal and clinical awareness of all involved prescribers is inadequate. It is therefore necessary and pertinent to reschedule this drug class to C-III status.

Alternative 1:

Persuade the FDA to enforce the issuance of a “Black Box Warning” on all Benzodiazepine containers. This may also be effective in increasing prescriber and pharmacist awareness although it would probably not impact the street-drug using population.

Comment [t4]: petition. See <http://www.fda.gov/opacom/bac/kgrounders/voice.html> ; scroll down to “petition”

Alternative 2:

Raise awareness through educational outreach programs. Classes could be provided to physicians, pharmacist, and the general public to educate them on the addictive properties of Benzodiazepines. Supplied information would focus on studies and epidemiological statistics would effectively employ “Shock and Awe” tactics to minimize the current misuse of these drugs.

Alternative 3:

Alert prescribers of the same information as in Alternative 2, through various methods, such as mass mailing. Provide recommendations on which patient populations should and should not be prescribed Benzodiazepines.

Alternative 4:

Do nothing and allow the over-use and abuse of Benzodiazepines and the resulting morbidity and mortality to continue.

Group #6 – putting the “indicated use” on every prescription

1) (There is no existing law about writing the “indicated use” on paper prescriptions)

The law should be:

Mandating the “indicated use” be written on every prescription by the primary health care provider. Can be very helpful for pharmacists to provide the most appropriate and relevant information to the patients when counseling, as well as verifying the correct drug and strength for each patient’s condition. As a result, we would like to offer a state law that would require physicians to make this piece of information available to pharmacists, through a designated area on each prescription.

2) Alternative 1: Create an area on paper prescriptions to encourage the “indicated use” to be written by the prescriber. This is much like a designated area on paper prescriptions for “Allergies”, and helps pharmacists give better quality health care to their patients.

3) Alternative 2: Mandate the “indicated use” be written in the sig of the prescription; i.e. - “take one tablet by mouth every morning for ADHD”. This

is for prescribers who do not want to/can't afford to reprogram their computer system, or print new prescription pads.

4) Alternative 3: If the state finds this law to be inappropriate, there could be no action taken towards putting the "indicated use" on a prescription.

Comment [t5]: This doesn't seem to be an alternative.

Group 7: Label Requirements – description and picture

Madeline Lorraine Fry, Caroline Kimani, Casey D. Lirot, Suejin Park, Catherine Dela Cruz Ulep, Dimay Wang, Caroline Yuan-Chi Wu, Chris B. Yocom

1. Description of existing law and objections.

The current law that describes labeling requirements of prescription drugs (RCW 69.41.050) states that to every box, bottle, jar, or any other container that contains a legend drug, that is dispensed must include the name of the prescriber, complete directions, name and strength of the drug, name of the patient, and the date, with the exception that the physician may request for the name and dosage of the drug to be omitted.

Comment [t6]: do you want legislative change, or a modification of **WAC 246-869-210 Prescription labeling?** The latter could be done by the Board.

By adding one mandatory picture and description of drug onto this labeling requirement law, many medication errors that result in the patient going home with the wrong drug, or taking the wrong drug can be substantially reduced.

2. Alternative 1- Applying mandatory picture and description only to high risk sound-a-like and look-a-like drugs identified by JACHO. By applying this law to only high risk drugs, the cost of implementing this program will be reduced. Also pharmacies that do not have the technology to print these pictures and descriptions directly onto the label can use auxiliary labels, without having too many of these labels to worry about (meaning that non-high risk drugs won't need a picture/description). By targeting high risk drugs only errors can still be substantially reduced, since these drugs where most errors occur anyways.

Comment [t7]: do you mean ISMP?

Comment [t8]: Suggest that you find some evidence that this is so

3. Alternative 2- Allow the use auxiliary labels instead of requiring picture with description to be directly on the label. This will cut costs down for pharmacies that do not have the technology to print labels with picture and description. The downside of this idea is that pharmacies will have to find space to fit and organize hundreds of auxiliary labels, also the possibility of placing the wrong auxiliary label of the drug exists.

4. Alternative 3- Allow the implementation of law in a step-wise fashion. This will allow pharmacies who do not have the funding to implement this program transition and update their technology slowly as to cut down cost and frenzy in the pharmacy. After the law is implemented pharmacies can start off using auxiliary labels on high risk drugs initially. By year 10 we

should require that all pharmacies have the necessary equipment such as computers and printers, in order to implement the law. Then by year 15 all pharmacies should be required to have software that can support printing pictures with description onto labels. Finally by year 20, all pharmacies should have this law fully implemented.

Group 8 Spacers

Reilly Benz, Heidi Colpitts, Viet Lam, Brian Seiki, Alesya Vlasenko, Holly Warner

The primary goal of our project is to allow pharmacists to make decisions regarding the dispensing of prescription spacers, or in other words, to permit pharmacists to write prescription orders for spacers under the protocol when there is a strong belief that a patient will greatly benefit from the use of a spacer. The objective is to improve the technique for delivering medications in the form of metered dose inhalers to the target tissue (which is especially important in certain populations, such as children and elderly) by making spacers more accessible and thus improving therapeutic outcomes.

Alternatives:

Attempt to make it possible for pharmacists to prescribe spacers at their discretion without an existing protocol. This way a pharmacist can dispense a spacer to a patient if he or she thinks it will likely improve the patient's therapeutic outcome.

Petition manufactures which produce "Rx Only" spacers to change classification of their products such that they could be sold OTC. This would increase the availability of spacers in drug stores and other pharmacies.

Another option is to leave the issue where it is.

Group #9 Reschedule Tramadol

Amy Little, Holly Dirks, Gigi Wong, Mike King, Adam McCowen, Pavel Miten, Brad Seigfreid

We have not revised our project, we still intend to reschedule Tramadol to a schedule IV, using the criteria from RCW 18.64.210

Alternatives:

1. Do nothing
2. Initiate a "med-watch" program in the state of WA for future increased awareness
3. Send out a "Dear Doctor Letter" to WA Physicians describing our thoughts on abuse potential of Tramadol in hopes of increasing awareness.

Group 10 –Generic Substitution

Frances McGaugh, Michael Fallon, Whitney Stoffel, Jasmine Chase, Thu Dang, Ching Chow

According to Revised Code of Washington (RCW) 69.41.120, prescribers can dispense either brand or generic drugs to their patients by signing on one of two lines at the bottom of the prescription to indicate their choice. In Washington, the right side is designated as “dispense as written” and the left side is designated as “substitution permitted”. Currently, when patient’s insurance does not cover the brand medication and the practitioner signed under “dispense as written”, pharmacists must call their physicians for approval to substitute for the generic product. Pharmacists often spend many hours with insurance claims and communicating changes with doctors. RCW 69.41.150 absolves pharmacist from any responsibility or risk as long as the prescription is filled exactly as it was written. With the extensive clinical knowledge provided in Pharm D. programs, pharmacists can assume a more active role in therapeutically helping patients choose appropriate medications. Alternative #1- Make generic substitution mandatory except whenever mandated on a prescription to “dispense brand only”. This will save time and money when brand name drugs become generic.

Comment [t9]: Evidence?

Alternative #2- Same as #1, but allow Pharmacists to accept responsibility for generic to brand interchange.

Comment [t10]: did this get backwards? I’m confused.

Alternative #3- Make the dispensing of brand or generic solely at the discretion of the Pharmacist. Push the view of the Pharmacist as the “drug expert”, and allow Pharmacists to accept liability for the substitution.

Alternative #4- Make dispensing of generic medications mandatory with the exception of a select list of low therapeutic index medications. Those medications listed would only be dispensed as generic with the consultation of the patient’s physician. This option could also be with or without Pharmacist responsibility for generic substitution.

Comment [t11]: I’m afraid that this is one of those things that make really good sense, but may impossible to implement. Who gets to make up the list? Imagine the political pressure on them?

Group 11 Revision of rules for internships

Chris Rogge, Amy Thomas, Kelly Philopant, Tuyen Huynh, Julie Sun, Stacie Chen, Rebecca Goodwin

The existing law as stated in RCW 18.64.080 is vague and does not present a sufficient framework for the establishment of a successful pharmacist:intern relationship. The description of an internship should be detailed enough to avoid the use of interns as employees. The experience should mirror that of a mentorship relationship with the preceptor. It should include monthly evaluations and progress reports for both the preceptor and intern.

Alternative 1:

To provide incentive for preceptors to adhere to the new guidelines the BOP could grant preceptors continuing education credits to be applied towards their yearly requirement. This would be acceptable only if the preceptor was meeting the standards set forth by the BOP.

Alternative 2:

Comment [t12]: The point of this exercise is to come up with alternatives in case your first choice flops.

The addition of a definition of the pharmacist:intern relationship does not necessarily require an alternative. The goals put forth are agreeable and do not need alternatives in order to aid compliance.

Alternative 3:

In order to increase the response rate of interns and preceptors we could provide all forms of feedback online. This would include quarterly email reminders to improve compliance and electronic submission.

Group 12 Extension for C-II Partial Fills

Group Members: Ashley Bean, Amy Chang, Morgan Hutchings, Rachel Schreffler, Kathleen Thornton, Kelli Watari, Jeff White

1. Description of existing law and objections:

The 21 Code of Federal Regulations 1306.13a states “the partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription). The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist shall so notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.”

We feel that this is not a sufficient amount of time to complete a partial fill for a patient and is therefore inconvenient for all of the parties involved.

Alternative 1:

One alternative to this problem would be to extend the length of time allowed for a partial fill to 5 days. This would allow enough time to order any needed controlled medications and complete a fill under any normal circumstances including weekends and holidays.

Alternative 2:

Another alternative would be to get rid of time restraint at all, so that there is no time limit after the original fill when the completed partial fill can be filled. In order to keep this from possibly slipping into making it possible to “refill” schedule II medications by dividing a large order several times, we would add that a schedule II medication can only be partially filled once. Partial fills can only occur if the pharmacy has insufficient supply to fill the order.

Alternative 3:

A third alternative would be to not allow partial fills of a schedule II prescription. If a pharmacy is unable to supply the whole amount written for they are not allowed to supply any. Patient would then be directed to another pharmacy.

Comment [t13]: Is this a realistic option?

