5543 Detailed Outline

Overall Comments:

1. check grammar
2. check formatting – all footnotes, no endnotes, please
3. verify RCWs and WACs so you don’t get asked embarrassing questions
4. be sure that citations are thorough
5. check word usage, especially with >25¢ words
6. use the strikethrough and underline formatting for new and deleted language
7. remember that this is a group project and there is individual responsibility for the final product

Note: if anyone is interested in doing a independent study project as a project implementation follow-on, please contact me. We will notify individual groups regarding invitations to present their projects at the WSPA and SOP Board meetings.

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Group #2: Prescription Only Pseudoephedrine
Elyse Tung, Leigh Brown, Angela Hitt, Vu Hoang, Jared Judd, Young Mi Kim, Karyn Moretsky, Shawn Hancey

I. Introduction and Summary <summarize the problem with existing law and your proposed alternative>
Currently there are no laws or restrictions on the dispensing or sales of the methamphetamine precursor drug pseudoephedrine over the counter. However, in January 2006 new sales restrictions limiting the amount on hand, amount purchased at one time and record keeping of sales will be insufficient, unrealistic, and too much of a burden to stop the illegal synthesis of methamphetamine. (RCW 69.43.105, 69.43.110, and 69.43.120) Our alternative is to make pseudoephedrine a prescription only drug, thereby increasing drug control and decreasing its accessibility

II. Problem definition:
Pseudoephedrine is a decongestant found in many over the counter drugs and the manufacturing of methamphetamine form pseudoephedrine is a major contributing factor to

Comment [1]: what about RCW 69.43.105 Ephedrine, pseudoephedrine, phenylpropanolamine -- Sales restrictions--Exceptions -- Penalty. (Effective October 1, 2005.)
Washington State’s significant methamphetamine problem. Methamphetamine is a potent CNS stimulant with a high abuse potential. It is well documented that abuse of this drug leads to a very destructive addiction and is a significant risk to public health.\(^1\)

Methamphetamine not only pose many health risks on the drug user, but there is also a high correlation with increased social crimes and arrests, increased child abuse cases and increased environmental contamination.\(^2\)

### III. Language of Proposed Law:

A new statute RCW 69.43.XXX will be created for pseudoephedrine as a legend drug. Number 4 of RCW 69.43.030 will be removed. This changes the exemption that pseudoephedrine can be sold OTC, even though it is listed as a precursor drug RCW 69.43.105, 69.43.110, and 69.43.160 will no longer be necessary and will be removed.

Section 1c of RCW 69.43.120 will be changed to exclude shopkeepers or registered vendors since pseudoephedrine will only be sold by prescription.

### IV. Evaluation of alternatives:

#### A. Evaluation criteria:

The production of methamphetamine per year in the state of Washington would decrease. The effect of this policy can be seen by the amount of pseudoephedrine sold per year and how much of that pseudoephedrine goes toward legitimate use and toward methamphetamine production before and after the enactment of this policy. Therefore, the effectiveness of the rescheduling of pseudoephedrine as prescription only drug will manifest through a decrease in the number of methamphetamine lab seizures in the state of Washington by an additional 25% in two years after the law takes into effect. Restricting easy access of pseudoephedrine to the public will promote the appropriate usage of this medication while suppressing any opportunity for illegitimate use of this drug. In addition, the adoption of this policy in the state of Washington would further support and enforce the efforts of Oregon and decrease interstate drug trafficking where this law is already taking effect, and would discourage any remaining methamphetamine producers in Oregon from resorting to Washington for methamphetamine precursor sources.

#### B. Alternatives to existing law:

Alternative 1: Make pseudoephedrine a schedule V legend drug.

Alternative 2: Keep the current law in place until such a time that federal legislation is passed. 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.

#### C. Stake holders:

- Washington State Department of Ecology
- Pseudoephedrine manufacturer: Pfizer
- Non-pharmacy retail groups (gas stations, smaller grocery stores)
- Pharmacists
- Professional organization - Washington State Pharmacy Association
- Drug addicts
- Doctors:
- Law enforcement agency - police
- DSHS - Washington State Child Protective Services –
- Pseudoephedrine consumers

### V. Conclusion:

\(^{1}\) Block J, Beale J. Wilson and Gisvold’s Textbook of Organic Medicinal and Pharmaceutical Chemistry. 11\(^{\text{th}}\) edition. Baltimore, MD; © 2004: 512

Illegal methamphetamine manufacturing and use is a growing epidemic and new regulations on its current over the counter sales needs to be addressed. The new laws taking into effect in January of 2006 are too inconvenient and will not realistically decrease illegal methamphetamine manufacturing or use. Making pseudoephedrine a prescription only drug will be the best alternative. (Summarizing reasons state above.)

Group 3—“Show and Tell” – Detailed Outline
Joe Johnson, Helen Song, Connor Christy, Olga Shvartsur, Zachary Beard, Aaron Chin, Lydia Zou, Tina Ngo

I. Introduction and Summary
Our goal is to reduce dispensing errors. The extent and quality of counseling is not defined under the current legal structure. We hope to reduce dispensing errors by requiring pharmacists to show each individual new medication to patients during counseling. This will allow for patients to recognize their medication before leaving the pharmacy and for pharmacists to catch more medication errors.

II. Problem definition
Fifty-one million dispensing errors occur annually and sometimes result in serious adverse effects or death. They are also a serious liability issue for pharmacists. The trend of an increased workload per pharmacist is likely to exacerbate the problem during the decades ahead.

III. Language of proposed law
WAC 246-869-220   Patient counseling required.
.....The pharmacist shall present all new medication(s) and previous medication(s) that have changed strength, brand, or dosage form individually to the patient for a visual inspection upon dispensing of said medication(s), with the exception that a patient may opt to forgo such inspection at his/her own risk......

IV. Evaluation of alternatives
A. Evaluation criteria
Every pharmacy shall report medication errors caught during the show and tell process. Since it is assumed that these errors would have gone unnoticed without show and tell, the total amount of errors reported is equal to the improvement rate. This number can also be compared to the total prescription volume.

B. Alternatives to existing law
1) Make exception for mail-order pharmacies for alternative “showing” methods such as description of medication and/or picture of medication on the bottles.
   • This would require an investment in expensive software changes.

2) Exempt mail-order pharmacies or any prescriptions filled from pharmacies that provide mail-order services.
   • This would not be politically viable and give mail order pharmacies an unfair advantage.

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

Comment [2]: do you really want this? If the patient leaves without counseling, isn’t that as his or her own risk?
picture of medication on the bottles.

- This is the most viable option. It is flexible and accommodating for everyone.

C. Stakeholders
Stakeholders
Independent Pharmacy Owner
Retail Chain Pharmacy
Hospital or Institutional Pharmacy
Board of Pharmacy / NABP
Federal Agencies – CMS (patient safety)
Medical & Consumer Safety Organizations (NCCMERP)
Closed Door & Mail Order Pharmacy
National Pharmacy Associations (NCPA, APhA, etc)
State Pharmacy Associations (WSPA)

V. Conclusions
This law change will reduce medication errors, result in more pharmacist-patient counseling time, and allow the patient to become more involved in their medication therapy. However, it is unlikely to gather the political support necessary to become a law.

Group 4
Group Members: Andrea Eberly, Quyen Nguyen, Mai Linh, Jeff Loor, Geoff Meer, Jennifer Law, Nick Wyatt, Sareh Ghazanfarpour

OUTLINE

I. Introduction and summary
1. Language of the current law (or lack?? REFERENCE LAW) as it reads in the CFR (this is a national issue and will be addressed as such)—this causes problems in many levels of the healthcare system→ patients, prescribers and pharmacists. (reference some news articles or websites for ‘proof’ that this is a problem, perhaps two, look on lexis nexis, association site (AMA is good))
2. We propose a change to the law that makes CII prescriptions expire 90 days post prescribing date with a maximum of 2 refills with total quantity of medication prescribed to not exceed a 90 day supply. This removes undue burden from prescribers and still provides a framework for quality patient care (reference AMA site again for resolutions relating to schedule drugs and healthcare)

II. Problem definition
1. Describe the problem
[OVERALL? Reiterate issue with current law (mention we were concerned with the cost and time to patient, physician. Patient care being compromised? Too monitored and not monitored enough!) REFERENCE the law. (TO GROUP: ON a side note, should we try to get to suzallo or the law library or something to try to find old debates about CII legislation?? Federal law does not currently mandate a specific quantity limit on CII.]
i. Schedule II drugs—a potential for abuse and therefore argument is made for tighter control of prescribing (no more prescriptions for CIIIs that do not expire) REFERENCE: something supporting the abuse potential/ necessity of patients being monitored. Statistics of abuse? LOOK FOR REFERENCES (pain website, substance abuse website, association—AMA?, news media lexisnexis, etc) Think in terms of being a pharmacist, patient, prescriber. Perhaps list problems associated with being all three with current legislation

ii. Lack of refills makes it harder for patients to be compliant (cost of physician visit) REFERENCE average cost of visit to physician

iii. Is this a good use of prescriber time? (any REFERENCES on how much time physicians deal with CII ‘refills’ ← writing prescriptions for maintenance meds.

iv. Safety concern regarding having a prescription that does not expire for potentially dangerous and abused medications REFERENCE a news article or TWO that show this happening---Prof mentions Florida case involving fentanyl

v. DEA recommends mailing hardcopies—is this safe and secure? (REFERENCE mail theft stats) Practical? Cost of overhead on already burdened healthcare system? Stamps, person to fill the envelopes, write address, etc. (remember, faxing is not allowed—hard copy required before dispensing to patient—REFERENCE LAW)

2. Boundaries of the problem

i. Historical antecedents (Harrison narcotics act, Controlled Substance Act 1970—mention CIIIs and CIVs being regulated but CIIs largely ignored but for a 72 hour partial and no refills. REFERENCE THE NATIONAL LAW—the specific parts and really we should include some of the testimony regarding the original law as a reference (surely there had to be some debate going on about proper handling of CIIs—I highly doubt this was just some random oversight). Someone is going to have to go to the law library or suzallo—cannot remember which library he said this was in.

ii. New DEA regs (Federal Register / Vol. 70, No. 165 / Friday, August 26, 2005 / Notices) and the implications of this. Response from AMA?

iii. National level problem (may leave this out of paper as this was already mentioned in I.1.

III. Language of proposed law

1. Law in final language. Recommendation for change.

2. alternatives looked at, and rationale for rejection of the other two

IV. Evaluation of Alternatives

1. Technical feasibility

   i. Patient safety and decrease in abuse/adverse events (REFERENCE again the Florida case or another case of drug OD or something else suitably horrendous to show our point) Also REFERENCE any stats on CII prescription abuse, rehabilitation from drug abuse, and hospitalization from CII drug abuse← on our evaluations assignment, this was what our group said it would find for references, do we have any? If not, let’s get some) ALSO prof wanted to know if we were going from the patient safety/convenience side or the drug abuse side. With the current political climate I think we should go from the angle of decreasing abuse and patient harm. WE HAVE TO MAKE A CASE!!!

WE NEED CITATIONS TO SUPPORT ANY OF THESE CLAIMS
ii. Decrease in doctor visits, and time doctors spend writing prescriptions that they would have authorized a refill on had they been able (REFERENCE doctor stakeholder info (we have it))

iii. Patients would see/contact their prescriber every 90 days and hopefully this would prevent misdiagnosis/overmedicating etc (DO we have anything to back this up---or is this just our hope? Are we hurting our argument saying something for which we have no facts? Can we find facts or doctor opinions or something to back this up???)

2. Political Viability
   i. Background of actions taken in other states and outcomes of those actions---can we find any information about the testimony given in those states as for why these laws were passed/repealed??? This would strengthen our report (Oklahoma and California REFERENCE THE SOURCES—also this site mentions other states with more strict laws though it is outdated a bit http://www.medsch.wisc.edu/painpolicy/publicat/94appcs.htm

   ii. List groups with a stance on the issue and what current stance is (REFERENCE AMA, patient groups etc)

   iii. Mention 30 day limit brought to BOP before, but never went anywhere. Hypothesis for this?

   iv. Bring in information regarding the different stakeholders and their political power. Spending, lobbying, probably positions on our proposed change in legislation. (this will be a large section and I have a lot of references for this

3. Administrative operability
   i. Currently CIII and CIV are regulated, should not be a stretch to do the same with CII (RCW 18.64.005) (IS THERE FEDERAL LAW TO REFERENCE SINCE WE ARE LOOKING AT FEDERAL REGS?????)

V. Conclusions

IS ANYTHING MISSING? IS THE ORDER OF THE ARGUMENT ANY GOOD? PLEASE CHANGE WHAT YOU THINK WE SHOULD CHANGE IN ANOTHER COLOR AND SEND IT BACK TO ME SO I CAN FIX THINGS

**Group 5 Black Box Warning for the Benzodiazepines**

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

**I. Introduction and Summary**

Benzodiazepines are a class of sedative hypnotic medications with a high incidence of abuse in the illicit drug culture. While it had been established at the advent of their use that physiologic dependence is highly probably with chronic administration of benzodiazepines, it has been established that the risk of abuse is significantly higher among patients for whom benzodiazepines were prescribed. It can be deduced that increased prescriber awareness

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of the risks associated with prolonged use of benzodiazepines is necessary in reducing the
trend of abuse and dependence of benzodiazepines, and therefore action is necessary to
facilitate this increased awareness. Many options are available to disseminate pertinent
information to prescribers (such as rescheduling the general status of benzodiazepines from
C-IV to C-III, facilitating continuing education seminars about the negative potentials of
benzodiazepines, etc.), but the most feasible option is to implement a Black Box Warning
for all benzodiazepines emphasizing the risk of abuse and dependence associated with these
medications.

II. Problem Definition
Benzodiazepines are commonly and safely used as treatment for anxiety and insomnia,
however the need to address the issue of benzodiazepine abuse in special populations (i.e.
history of addictive disorders such as alcoholics, intravenous drug users, and substance
abusers) is evident when data from the community are examined. 80% of benzodiazepine
abuse is associated with polydrug abuse and benzodiazepine-related Emergency
Department visits have increased 41% from 1995 to 2002. Polydrug abuse is often
intertwined with alcoholism and the most commonly abused psychoactive drugs in alcoholics
are benzodiazepines. Chronic use of benzodiazepines can also increase the abuse/addiction
potential of benzodiazepines.

III. Language of Proposed Law
We plan to petition the U.S. Food and Drug Administration (FDA) to implement a black box
warning regarding the risks of addiction in patients with a history of drug/alcohol abuse on
the benzodiazepine class of prescription drugs.

III. Language of Proposed Law (continued)
The petition will be in the format as indicated by the FDA. Black Box Warnings are the
strongest warning for medications issued by the FDA, and its effectiveness, depending on its
wording and presentation, has exhibited an effect in Emergency Departments and
behavioral changes of some prescribers.

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6 Poulos CX, Zack M. Low-dose diazepam primes motivation for alcohol and alcohol-related semantic

7 Johnson B, Longo LP. Addiction: part I. benzodiazepines - side effects, abuse risk and alternatives. In:
American family physician [Internet]. Leawood (KS); American Academy of Family Physicians; c2000

8 U.S. Food and Drug Administration [website on the internet]. Rockville: Food and Drug Administration;
Regulations and Submit Petitions. Available from:

9 Wagner AK, Chan KA, Dashevsky I, Raebel MA, Andrade SE, Lafata JE, Davis RL, Gurwitz JH,
Soumerai SB, Platt R. FDA drug prescribing warnings: is the black box half empty or half full?
Pharmacoepidemiol Drug Saf. 2005 Nov 18; [Epub ahead of print]

10 Weatherby LB, Nordstrom BL, Fife D, et al. The impact of wording in "Dear doctor" letters and in black
IV. Evaluation of Alternatives

A. Evaluation Criteria
The criteria used to evaluate possible alternatives include technical feasibility, political viability, and administrative operability.12

B. Alternatives to Existing Law
1) An alternative to a black box warning is rescheduling benzodiazepines from Schedule C-IV to C-III. This is a technically feasible, politically viable, and administratively operable alternative. However when implemented only at the State level and when considering likely measurable outcomes, this alternative becomes less feasible.

2) Mass mailings, including Dear Doctor Letters, are greatly dependent on appropriate presentation, concise and focused wording, and targeted intent towards a specific audience to have the greatest effect in adherence to the warning.8,13

3) Continuing education is a current fixture of most medical professions that has demonstrated mixed results regarding its impact on the knowledge and subsequent practice of healthcare providers. The major determinant of success of continuing education programs is the medium by which they are presented, such as lectures or interactive workshops.14

C. Stakeholders
Currently four stakeholders (Ron Jackson and Michaelene Kedzierski of Evergreen Treatment Center, Dick Morrison—Washington Board of Pharmacy investigator, and Saidee Whitehorn—a psychiatrist at Kwawachee Counseling Center) are in support of a petition to implement Black Box Warnings for all benzodiazepines. All manufacturers contacted have refused to comment. The FDA is unable to comment without presentation of data for a formal review. Five stakeholders have yet to respond.

V. Conclusions
Evidence has shown that benzodiazepine abuse has remained unchecked and it is necessary to implement new policies that will foster increased awareness and monitoring of benzodiazepine prescriptions. In order for prescribers and policy makers to reassess current prescribing practices, the implementation of Black Box Warnings for all


benzodiazepines presents as the most feasible and viable option available to increase the awareness by the general population and all health care practitioners and ultimately decrease rates of benzodiazepine dependence, abuse, and misuse.15

**Group #6 < Intended Use written down on prescription>**
Members: Jens Frisvold, Erin Dennis, Hieu Le, Steve Hasslinger, Julia Coolman, Kellie Nakamura, Anne Mock, Nazleila Hojjati

I. Introduction and Summery
   a. Currently, Washington state law does not require prescribers to write an intended use on the prescription. This is a problem because oftentimes we, as pharmacists, are unaware of the condition for which the person is being treated. Knowing exactly why a person is getting a particular medication would greatly aid us in the process of counseling. We will be able to tell them what to expect from the medication regarding their particular problems.

II. Problem Definition
   a. The problem we are trying to solve with the law is to decrease medication errors that arise from not having the intended use available to pharmacists. An example would be counseling a patient correctly with medications that have multiple uses such as Digoxin which can be used either for cardiac irregularities or congestive heart failure, and some anticonvulsant medications that can be used for behavior problems or seizures.

III. Language of proposed law
   a. There is no existing law about writing the “indicated use” on paper prescriptions. The law should mandate the “indicated use” be written on every prescription by the primary health care provider. This will be very helpful to pharmacists in providing 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.

IV. Evaluation of alternatives
   a. Evaluation criteria
      i. Technical Feasibility
         The intent of the program is to give patients better healthcare by providing pharmacists with more information so that they can assure the safety, efficacy, and appropriateness of therapy. It will be very difficult to gather solid statistics on the efficacy of this measure; however a database could be set up for pharmacists to enter positive outcomes that have happened as a result of this program.
      ii. Political Feasibility
         Having the indicated use on prescriptions will clearly be beneficial to patients and pharmacists. At first, physicians might see this as extra work but, in the long term having this information available can greatly reduce medication errors which can ultimately decrease lawsuits against providers.
      iii. Administrative Operability
         It would be very feasible to add one extra line to prescription forms in most practice settings. With the introduction of electronic prescriptions it will be very easy to program in an extra line without having to waste old prescription pads.

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Alternatives to existing law

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.

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.

Alternative 3: Do nothing regarding the “indicated use” on prescriptions

c. Stakeholders

We interviewed a patient, a retail pharmacist, a hospital pharmacist, a member of the board of pharmacy, a member from DSHS, a Long Term Care representative, and a representative from the Washington State Medical Association and a media officer from JCAHO.

V. Conclusion

Stating the indicated use on the 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 a result, we would like to offer a state law that would require physicians to make the piece of information available.

Group #7

Madeleine Fry, Catharine Ulep, Chris Yocom, Caroline Kimani, Caroline Wu, Casey Lirot, Suejin Park, Dimay Wang

I. Introduction

We are proposing to add a mandatory medication description to prescription container labels. The existing law, WAC 246-869-210, does not require this information. This addition would increase both patient education opportunities and positive medication outcomes. Several other states, including Oregon, Wyoming and California have implemented similar laws.1, 2, 3

II. Problem Definition

Medication errors are one of the leading causes of preventable harm to patients “errors involving prescription medications kill up to 7,000 Americans a year.”4 Product labeling is considered one of the contributing factors to medication errors.5 By placing a description that includes the shape, color, and imprint of the drug on the prescription label many medication errors and patient confusion could be avoided. Research indicated memory is improved with the use of pictures and words in combination 6, 7.

III. Language of proposed law

WAC 246-869-210 Prescription labeling. To every prescription container, there shall be fixed a label or labels bearing the following information:

(1) All information as required by RCW 18.64.246, provided that in determining an appropriate period of time for which a prescription drug may be retained by a patient after its dispensing, the dispenser shall take the following factors into account:

(a) The nature of the drug;

(b) The container in which it was packaged by the manufacturer and the expiration date thereon;
(c) The characteristics of the patient's container, if the drug is repackaged for dispensing;

(d) The expected conditions to which the article may be exposed;

(e) The expected length of time of the course of therapy; and

(f) Any other relevant factors.

The dispenser shall, on taking into account the foregoing, place on the label of a multiple unit container a suitable beyond-use date or discard-by date to limit the patient's use of the drug. In no case may this date be later than the original expiration date determined by the manufacturer.

(2) The quantity of drug dispensed, for example the volume or number of dosage units.

(3) The following statement, "Warning: State or federal law prohibits transfer of this drug to any person other than the person for whom it was prescribed."

(4) A black and white pictorial and written description of dispensed drug containing shape, color, and identifying imprints on tablets or capsules.

(4) The information contained on the label shall be supplemented by oral or written information as required by WAC 246-869-220. 8

IV. Evaluation of Alternatives

A. Evaluation Criteria

The technical feasibility of this law is not a challenge, as several other states have already implemented similar laws and we know the technological ability to create labels with a description are currently available.

There are some worthwhile alternatives to our proposed labeling requirements on all prescription drugs. To ease the transition as well as budget concerns for smaller pharmacies, the initiation of this proposal could be mandated in a stepwise fashion. Pharmacies and government officials may find the alternatives more feasible and achievable initially, while advancing toward the ultimate goal of the proposition.

The BOP has the ability to deliver this policy by simply revising the WAC labeling section, and the administrative committee would have complete authority to enforce the proposal.

B. Alternatives to existing law

1. 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.

2. 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.

3. 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

Comment [18]: can you provide information from the experience of these other states?
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.

C. Stakeholders
The overwhelming response from stakeholders was in support of this change in law. Points of concern from several stakeholders included the cost to local pharmacies in upgrading computer systems to support the law.

Conclusion
Washington State is very innovative with respect to the practice of pharmacy and patient care and it is time to move forward with patient empowerment and adopt a law such as the one we have proposed.

References:

Group 10 Generic Substitution

I. Introduction and Summary:
Brand name medications cost about 30% more than their generic, and this number rises to 70% when more than one generic for it hits the market. Underutilization of generics, which are available for more than half of brand drugs sold in the U.S., costs patients

upwards of $9 billion a year.\textsuperscript{17} The intent of this proposal is to simplify the prescription process to guarantee patients are receiving the most cost effective treatments. We propose to change the two-line system to a simplified one-line format.

II. Problem Definition
According to a National Association of Chain Drug Stores (NACDS) study, 20% of a pharmacist's time is spent resolving third party insurance claims, and 5.4% of this is dealing directly with resolving conflicts due to insurance restrictions, communicating the problem to the patient, and resubmitting the claim.\textsuperscript{18} Today, the conflict regarding generic use revolves around economics. Manufacturers try to protect their patents for as long as possible and then rely on brand loyalty to maintain revenue. While brand manufacturers at times suggest there are quality or bioequivalence inequalities, this position is opposed by generic manufacturers, the pharmacy profession, and the FDA.\textsuperscript{19}

III. Language of proposed Law

\textbf{RCW 69.41.120 Prescriptions to contain instruction as to whether or not a therapeutically equivalent generic brand name drug may must be substituted dispensed—Out-of-state prescriptions—Form—Contents—Procedure.} Every drug prescription shall contain an instruction on whether or not a therapeutically equivalent generic drug may be substituted in its place, unless substitution is permitted under a prior-consent authorization.

If a written prescription is involved, the prescription must be legible and the form shall have two signature lines at opposite ends on the bottom of the form. Under the line at the right side shall be clearly printed the words “DISPENSE AS WRITTEN”. Under the line at the left side shall be clearly printed the words “SUBSTITUTION PERMITTED”. The practitioner shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the practitioner on one of these lines. If a written prescription is involved, the prescription must be legible and the form shall have one line for signature. No prescription shall be valid without the signature of the practitioner. In the case of a prescription issued by a practitioner in this state or another state that uses a one-line prescription form or variation thereof, the pharmacist must, if possible, substitute a therapeutically equivalent generic drug unless otherwise instructed by the practitioner through the use of the words “dispense as written”, words of similar meaning, or some other indication. At any time, if patient prefers brand, brand may be dispensed. If the prescription is from a state that uses a two line system, the pharmacist shall follow the instructions indicated by the signature line (dispense as written or substitution allowed).

If an oral prescription is involved, the practitioner or the practitioner’s agent shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug may

\textsuperscript{17} Haas MD MSPH, Jennifer S; Phillips PhD, Kathryn A; Gerstenberger MS, Eric P; Seger PharmD, Andrew C. "Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000.” Annals of Internal Medicine 142 (2005): 891-897.


\textsuperscript{19} Ascione, FJ; Kirking, DM; Gaither, CA; Welage, LS. "Historical overview of generic medication policy.” Journal of the American Pharmacy Association (Washington) 41 (2001): 567-577.
be substituted in its place they request brand by stating "dispense brand only" or words of similar effect. The pharmacist shall note the instructions on the file copy of the prescription. The pharmacist shall note the manufacturer of the drug dispensed on the file copy of a written or oral prescription.

IV. Evaluation of alternatives
A. Evaluation criteria
We will talk about technical feasibility (Quantitative measures of time and money saved pre and post implementation would be advantageous. Methods to test for effectiveness and adequacy over time are also needed.), economic and financial feasibility (Illinois Blue’s Health Plan stated that patients could save $40-60 per prescription by using generic and NACDS showed substantial savings in time could be expected after switching to a one-line system,20,21 ), political viability (The legislature and prescriber associations would need persuasion. Policy makers, in looking out for their constituents, would call for adequate quality and cost controls. Prescribers would want to know that they were not giving up autonomy.), and administrative operability (In order to evaluate how much authority the administrative system has to implement this law, one needs to look at the structure and process of changing existing laws.).

B. Alternatives to Existing law
We will include 3 alternatives, including our proposed law of: Make generic substitution mandatory except when objected by a prescriber’s handwriting on a prescription to "dispense brand only". This will save time and money when brand drugs become newly available as generics.

C. Stakeholders
We will summarize key points from each interview and find public statements from organizations we could not get a response from. For example: Don Williams, Executive Director of WA Board of Pharmacy, states that, "Pharmacists are in a better position than prescribers to make these decisions.”

V. Conclusions
A pharmacist’s primary concern should be providing the best healthcare possible to patients. Helping patients afford their medications so they can actually take them is part of that role. If costs can be lowered and therapeutic medication usage increased, then this must be done.

Group 11
Stacie Chen, Rebecca Goodwin, Chris Rogge, Kelly Philophant, Tuyen Haynh, Amy Thomas, Julie Sun

  1. Introduction and Summary
      a. The current process for interns in the state of Washington does not provide a sufficient framework to ensure that a quality preceptor:intern relationship is maintained and a beneficial experience is obtained for the intern that enables them to further their professional career.

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b. In addition the process (in particular the forms) required for interns and preceptors needs a set of guidelines to assist in the promulgation of this new definition and the gathering of data to accurately assess the experience.

c. Our goal is to define the preceptor:intern relationship, empower the board to maintain certain standards amongst preceptors through guidelines submitted to the Code of Revisors office, and enact a more suitable method of gathering evaluative data.

II. Problem Definition

a. The expectations for the pharmacy intern and preceptor are currently vague and do not provide a sufficient framework to guide the internship experience. RCW 18.64.080 states that the internship, "shall include such instruction in the practice of pharmacy as the board by regulation shall prescribe". Many fellow classmates have expressed concern regarding their internship. Some students have preceptors that they only see once a month and are never under direct supervision of. Other students are upset that many times internships feel more like jobs than learning experiences. If a balance of the two could be accomplished this would be advantageous for both preceptor and intern.

III. Language of proposal

a. To amend RCW 18.64.080 by including a definition of the preceptor:intern relationship that would be proposed as follows:

i. Add the definition here.

IV. Evaluation of Alternatives

a. Evaluation Criteria

i. Currently the forms required by the board of pharmacy for interns to submit their hours are not sufficient for gathering evaluative data. The forms need to be more detailed in order to guide the thought process of interns in relaying valuable information about preceptors and sites. We are proposing a new form that would be available online and would allow for the gathering of data through a computer generated system that would alleviate cost and time that is currently devoted to the current forms. It would take time to generate enough data to be considered useful but the end result would greatly benefit the preceptor, intern and the Board of Pharmacy.

b. Alternatives

i. The proposed change may dissuade pharmacists from wanting to become preceptors. If this was to occur it might be advantageous to look into offering more incentive to preceptors through the use of yearly CE credits. Although this is most likely not a viable solution.

ii. Currently the evaluations are only due at the end of the four years in order to submit your 700 hours to the Board of Pharmacy. We propose that these forms be required to renew licensure for the intern.

iii. In order to give preceptors a better framework for adhering and implementing addendum to the RCW we will propose a new set of guidelines to help with the transition. These guidelines will adhere to the Department of Health guidelines for guidelines and will be within the Board of Pharmacies powers of duty through RCW 18.64.003 (3).

c. Stakeholders

i. Jeff Rochon (WSPA) – support

ii. Terri O'Sullivan (UWSOP Director of Experiential Learning) – support

iii. Stan Weber (UWSOP Associate Dean of Professional Education) – support

iv. Gail Caballe (Retail Preceptor from Bartell's) – support, neutral
v. Hospital preceptors (Group Health) – support, neutral
vi. Independent preceptors – support, neutral
vii. UWSOP or WSU pharmacy students – support

V. Conclusions
a. The Board of Pharmacy has not undergone a revision of the preceptor:intern relationship for about 10 years. Due to the increase in complaints from some students regarding their internship experiences it is advantageous for the Board of Pharmacy to wrestle with this issue and bring standards to a new level. By defining the relationship and implementing a set of guidelines to be followed by the preceptors it will allow interns to have experiences that will further their professional careers and provide pharmacy sites with well-equipped employees. The crucial step in the process is the revamping of new forms that will allow interns a forum to discuss their internships and in the long will provide valuable data for the Board of Pharmacy to use.

Group 12, Extension of C-II Partial Fills
Group Members: Ashley Bean, Amy Chang, Morgan Hutchings, Rachel Schreffler, Kathleen Thornton, Kelli Watari, Jeff White

I. Introduction and Summary <summarize the problem with existing law and your proposed alternative>
   The problem with the law as it is written now is that it is too restrictive. Patients who are in pain cannot go all over town looking for a pharmacy that has enough of the medication in stock to fill the entire prescription if the original pharmacy is low on stock, and most people cannot afford to have another doctor’s visit to get another prescription. The alternative to this that we are proposing is to extend the 72 hour limit to a seven day limit, which should give every pharmacy enough time order and receive the remaining balance of the that C-II prescription.

II. Problem definition
   The time constraint of this law is a concern for many pharmacies. Issues with stock, inconvenience, new information, additional appointments, etc. burden the pharmacist, patient, and prescriber in this situation.

III. Language of proposed law
   The law that currently exists explicitly limits the period in which partial fills of C-II substances to 72 hours or less. (§1306.13) We suggest that the language is amended to allow the completion of partial fills within seven days.

IV. Evaluation of alternatives
   A. Evaluation criteria
      The amount of complaints from pharmacists, physicians, and patients may be measured to evaluate the effect of this law change, however, this may be unreliable and unpredictable. Surveying random populations would conclude similarly. The implementation of this new law would allow for a decrease in costs regarding pharmacies. When evaluating the political criteria, we find that there is no reason to have a short time limit and also a change from 72 hours to 7 days is not drastic. The DEA, not the Board of Pharmacy, has jurisdiction over this issue.

   B. Alternatives to existing law
Alternatives to the existing law would be to take away the time limit completely, allowing partial fills to be completed at a patient's convenience, increasing the time limit from 72 hours to 7 days to allow more time for all parties involved, but still keeping safe limits, or completely restricting the law and refusing to fill partial C-II prescriptions at all. We believe our best option is to extend the law from 72 hours to 7 days.

C. Stakeholders

1. Pharmacists: Two out of 3 supported the change, believing it would improve patient care. The one that did not see the 72 hour limit as an obstacle and thought extending it would make the completion less of a priority.¹,²,³

2. CII prescriber: did not see the 72 hour limit as a problem but agreed that our change was reasonable if warranted.⁴

3. APhA-ASP (student) - recognized our concerns as valid, but remains undecided.⁵

4. APhA - would support if members expressed concerns, but since have not heard such concerns, APhA has not found a need to change this law.⁶

V. Conclusions

It is easy not to think about an issue such as this, because “it never happens at my pharmacy.” There will however come a time when it is an issue, and following the code of the law will not provide the best patient outcomes that we are looking for. In order to provide optimum care for our patients the time limit of 72 hours needs to be amended to 7 days. In this way, we can provide health care in a timely and cost effective manner.

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2. Rei-Kirby Janice, RPh, Personal Interview. 04 November 2005
3. Hoy Ellen, RPh, Personal Interview. 04 November 2005
4. Lagerberg Steven, MD, E-mail Interview. 31 October 2005; 21 November 2005
5. Long Aaron, Personal Interview.