### Pharm 543 Evaluation Criteria

| Group Title                                                                 |   *
|-----------------------------------------------------------------------------|------*
| 1. Restriction on sales of pseudoephedrine – C-V "Meth Busters"              |   *
| 2 Prescription-Only Pseudoephedrine                                         |   *
| 3 Show and Tell at Dispensing                                               |   *
| 4 Expiration of Schedule II Prescriptions                                   |   *
| 5 Rescheduling of Clonazepam                                               |   *
| 6 Stating the "indicated use" on the prescription                          |   *
| 7 Label Requirements – description and picture                             |   *
| 8 Allow spacers to be dispensed without a prescription                      |   *
| 9 Reschedule tramadol                                                       |   *
| 10 Generic substitution at the discretion of the pharmacist                 |   *
| 11 Intern Hours                                                             |   *
| 12 Extension for CII partial fill completion                                |   *

**Overall Comments (tkh, aka “k” or “t” in comments below):**

1. Measuring pharmacy errors. This is a poor criterion for assessing change because there are relatively few errors reported to the Board, so observing a statistically different change will take awhile – probably several years.

   There are several alternatives. One, adopted by JCAHO for institutions under their purview, FDA for medical device manufacturers, a couple of health care quality assurance organizations (e.g., NCQA, Leapfrog Group), and California, is to make the individual organization responsible for implementing the policy, assessing the change and, in some instances, reporting the results.

2. Recall that there are other prescribers than physicians in WA.

3. Surveys and similar enterprises. My complaint falls in the "is the bang worth the buck?" territory. A problem with surveys is to have a response rate that is high enough to assure that the responses are unbiased. For instance, the survey that you folks complete each year is seen by some as potentially biased because the response rate is often less than 50%. Maybe a small proportion of students had a bad (or good?) experience and they complete the survey. Since the rest of the student may have had a different experience but they didn't complete the survey, the reported results are suspect. To do a survey correctly is very expensive. Sometimes this is the only method for gathering needed information and if this is the case, go for it (and get out your checkbook)! But there are often other measures. And part of the art of policy analysis is figuring them out.

4. Rescheduling issues. I've a concern that the eight criteria specified in RCW 69.50.201 may be difficult to defend. So be gathering information that will allow you to make a persuasive case for your planned change.

**Group 1: Decreased amount of pseudoephedrine/ephedrine dispensed**

(Meth Busters)
1. Technical feasibility

There are numerous factors that contribute to the diversion of pseudoephedrine/ephedrine for methamphetamine production (examples include supplies from over the border and out of state purchases). Because of this it would be hard to directly measure the outcome of our revisions, but these revisions will add into the overall decrease of pseudoephedrine/ephedrine diversion. Our intent is for this change to be a long term deterrent of pseudoephedrine/ephedrine diversion.

2. Political viability

Alternative to our revision include: doing nothing, make pseudoephedrine/ephedrine rx only, make pseudoephedrine/ephedrine a scheduled drug, pull the tablet form completely off the market, and enacting more stringent limitations on pseudoephedrine/ephedrine sales.

Reactions of various groups:

Manufacturers would not want to pull the drug off the market, and would probably disagree with repackaging, but that would be a better alternative. They may support the change of pseudoephedrine/ephedrine to rx only because they could supply the drug in larger quantities.

Pharmacy Staff are already required to log amounts of pseudoephedrine/ephedrine sold, this would be a small addition onto their duties. It would most likely be easier (therefore better accepted) for pharmacies to dispense the drug as rx only.

Prescribers would not want it to become rx only – this would increase the number of patients they have to see, when a pt can usually self treat for this condition. By the same token patients would not want to take the time or spend the money to see their physician for this problem. Although it will take longer to get pseudoephedrine/ephedrine in the pharmacy, the pt’s are benefited by the decrease of precursor substances available to the drug community.

Other groups impacted: firefighters, law enforcement, regulating agencies

Concession: possible give up the 60 day restriction.

3. Administrative operability

Because this law (minus our changes) is essentially already in effect (Jan 1, 2006) we feel that the Board of Pharmacy is capable of delivering this policy. As a law, the Board would have a commitment to uphold such law.

The Board has control over where and how much pseudoephedrine/ephedrine can be sold. The board has the ability to implement this law, but would not be able to fully enforce the law due to constrictions on money and staff.

Pharmacies and their staff will have to be relied upon to keep accurate records. Drug manufacturers will have to repackage the product.

Group #2: Prescription Only Pseudoephedrine

Elyse Tung, Leigh Brown, Angela Hitt, Vu Hoang, Jared Judd, Young Mi Kim, Karyn Moretsky, Shawn Hancey

- Technical feasibility
The intended effect of making pseudoephedrine a prescription drug through its rescheduling as a controlled substance is to reduce or eliminate the sale of pseudoephedrine for the production of methamphetamine in our country. We believe the right to reschedule pseudoephedrine, an immediate precursor of methamphetamine, in the same schedule as methamphetamine is outlined in the RCW 69.50.201 Enforcement of chapter -- Authority to change schedules of controlled substances. By regulating the access of pseudoephedrine, the production of methamphetamine 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. The policy of requiring prescriptions to gain access of pseudoephedrine would ascertain that that the product is made available only to those patients with proper and proven clinical indication for the medication. Therefore, 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 where this law is already taking effect, and would discourage any remaining methamphetamine producers in Oregon from resorting to Washington for methamphetamine precursor sources.

- Political Viability:

The proposed change would make an impact on three general parties; Medical personal (physicians, pharmacists, etc), manufacturers, and the general public. Highlighting an effort to increase public safety, three broad alternatives exist:

Removal from the market:  Few would support the complete removal of such a common drug.

Reschedule: The proposed change reduces the availability of the drug to the public, and would increase the cost. (Lower manufacturing volume leading to higher costs as well as increase medical costs due to required doctor visits to obtain a prescription) The three parties would generally support the trade-off between increased cost and increased public safety. The positive impact on the public would need to be clarified in order to gain support.

No change: Manufactures and the public may support due to the considerations above.

- Administrative operability

The Board of Pharmacy regulates the laws governing the practice of pharmacy so it is capable of delivering the policy of making pseudoephedrine a prescription only drug. The Board of Pharmacy is the main administrative system in Washington State that regulates over-the-counter pseudoephedrine sales. On May 11, 2005, state legislatures passed a law requiring requires customers to show ID showing they are at least 18 years old and limits the customer to two packages. It also requires all sellers to keep pseudoephedrine products in a location inaccessible to customers and require purchasers of pseudoephedrine to sign a log book in order for law
enforcement to track individuals that buy too much pseudoephedrine. This method of regulating and keeping track of pseudoephedrine sales is an administrative bottleneck in the existing system. It creates more work for already busy pharmacies. Keeping logs will not alert law enforcement if someone is going from one store to the next buying pseudoephedrine to make methamphetamine because the systems between pharmacies are not connected. It also does not go far enough in restricting the access of pseudoephedrine to those making methamphetamine. By making pseudoephedrine a prescription only drug, each time it’s dispense it will be logged like all other prescriptions and be regulated the same way as other prescription drugs. This would eliminate the task of keeping track of pseudoephedrine by all vendors except pharmacies, and pharmacies wouldn’t have to deal with log books and would treat pseudoephedrine like other prescription drugs. Since we would be regulating pseudoephedrine like other drugs, it would be very easy to do and cost efficient. By making pseudoephedrine prescription only it will also further limit its access to drug seekers. The Board of Pharmacy has the authority and capabilities to implement this policy with the approval of the governor and state legislature.

Group 3 Project Evaluation Criteria

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

1) Technical Feasibility—Decreasing the number of incorrect medications dispensed to patients is the main goal of 'show-and-tell' dispensing. The pharmacist participates in achieving the goal, by offering a visual inspection of the medication to the patient upon dispensing. Incorrect medication means a different medication than expected, a different medication, due to a change in manufacturer, than was previously dispensed, or another patient’s medication. Outcomes could be directly measured by randomly selecting pharmacies that would agree to implement this system on a trial run basis. During the 'show-and-tell' process these pharmacies can document the type of error that was caught and the total number or errors caught during a specified period (every few months). They would then implement the 'show-and-tell' method without any other changes to workflow to control for any variables. The effect of the trial can be evaluated after a 1-2 year trial period. The absolute change and the percent change in medication errors in relation to number of prescriptions filled and average number of errors would be calculated which could predict a trend in possible outcomes on a larger, state wide level. In terms of adequacy, any significant decrease in medication errors would be enough justification to pass such a regulation. The issue of medication errors cannot be fully alleviated by modifying one action in a multi-step process. But fine-tuning the process and introducing increased safety measures can reduce overall errors. The goal of 'show and tell' dispensing is not to completely resolve the problem of medication errors, but to become another step whereby medication errors can be systematically reduced.

1 http://www1.leg.wa.gov/House/Representatives/methbillsigning.htm
2) The main political opposition to our proposed law would be from mail order pharmacies that are unable to physically "show and tell." Other opposition might come from retail pharmacies that regularly mail out prescriptions to patients who live in remote areas. While it would be understandable to allow exceptions for medications that patients have received before (trading off an extra safety check for convenience), the challenge of performing "show and tell" on all new medications still remains. The only acceptable alternatives for a mail order pharmacy would some other form of patient "show and tell" that could be accomplished over the phone, on paper, or through the internet. For example, wording of the law could be changed to: "the pharmacist must insure that the patient or caregiver has the proper materials and instructions necessary to identify their medication." Other options might include allowing the patient to waive their right to being shown the prescription (although it could be argued that a patient of a mail order pharmacy would unfairly have this right automatically waived).

Political opposition may also come from long-term care facilities or in-patient hospitals in which the pharmacist is not physically present to show the medications to the patients. If the show-and-tell at dispensing process is not supported politically to make amendments to the current dispensing guidelines, then individual pharmacies can offer additional counseling sessions to provide this service to their patients. Pharmacy owners can also decide whether the show-and-tell process would increase customer satisfaction and encourage their employees to include this during counseling. The Board of Pharmacy, pharmacy associations, hospital and retail pharmacies, pharmacy owners, and patients are groups that are affected by the show-and-tell at dispensing process. To gain support from these groups, how this process will affect patient safety, business, and the pharmacy profession will need to be considered. Another alternative would be to provide a description of the medication for the patients. This would allow all pharmacies to give the same information for patients, whether patients receive their medications through mail-order or directly from a pharmacy.

4) The Board of Pharmacy (BOP) has authority over patient counseling regulations in Washington State. Administering the "show and tell" program will be within the scope of power of the Board and help decrease dispensing errors with minimal financial burden. Individual pharmacies and pharmacy employees will be responsible for reporting errors. The Board of Pharmacy will be responsible for monitoring the errors caught by the "show and tell" program and enforcing the requirement to visually show the prescription to be dispensed. To do this, voluntary surveys can be placed in pharmacies for patients to fill out stating whether or not they received a full consultation. Pharmacies with multiple reports of noncompliance can be disciplined and/or fined by the Board. This regulation falls in the domain of BOP and it is within their authority to implement it.

Group 4- Expiration of CII Prescriptions

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

Technical feasibility (effectiveness, adequacy)
The idea behind shortening the C-II expiration deadline is to make sure that patients on these medications are being seen on a regular basis and that the patients are taking the medications for the intended purpose for which it was prescribed. The best indicators of the effectiveness of the policy is the change in number of drug abusers (stats on CII prescription abuse, rehabilitation from drug abuse, and hospitalization from CII drug abuse) and in the number of doctor visits for CII prescriptions. Since the drug abusers have so many other ways to gain the drug, the effect of the program on reduction of number of the drug abusers would be indirect. The influence of this policy on improving the patient care is direct. Since patients have to see their MDs to renew their CII prescriptions, their health conditions will be monitored prior to each CII RX, and thus decrease the chances for misdiagnosis and preventable adverse reactions. Eventually by observing a higher quality of patient care we can trace back the changes to the program. The changes would be considerable in a long term.

**Political viability**

This policy has had a great deal of variability from a political perspective. Certain states such as Oklahoma are very punitive, limiting the lifetime of CII prescriptions to 5 days. Other states had other variance in laws, such as a recently repealed law in California which limited lifetimes to 14 days. Most states do not have any specific laws on the books any longer, or have never had any laws on the books, and as such they default to the standard prescription lifetime of one year.

Most groups would argue that the decision should be left to the states, as is the situation right now. Some groups would support a shorter lifetime, specifically groups which tended to be patient-care advocates like pharmacists and nurses. Other groups, specifically many medical associations, would probably tend to oppose a shorter lifetime as they would argue that it infringes on their ability to treat as they see fit. It is unknown how various legal lobbies would react. Most Pharmacy Benefit Managers (PBMs) would tend to support such restrictions, as they would be able to more aggressively control their formularies and further reduce their costs.

This issue has recently been brought up in California, where a law that required pink "triplicate" copy CII prescriptions and 14-day lifetimes was repealed several years ago. The law did not stand up to public and lobby scrutiny due to what was believed to be undue hardship placed upon patients and physicians, who had to regularly rewrite CII prescriptions which expired due to many reasons beyond the control of the patient. It is interesting that the 5-day lifetime in Oklahoma has thus far stood up to scrutiny, though it is regularly challenged.

There is considerable spread among various stakeholders as to what they believe the appropriate lifetime of a CII prescription could be. In such a situation, trying to hammer out a compromise would be complicated and a lengthy time investment. Previously, lifetimes of 30 days have been proposed in the State of Washington and have not been successfully passed into law. It is possible that a compromise could be reached that was unsuccessful before, though the various organizations and lobbies which would impact such a bill are all influential and negotiations would not be trivial.

**Administrative operability**

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Comment [t10]: So, is your emphasis patient safety or substance abuse prevention (as in "drug cop")? Which will be more politically acceptable?

Comment [t11]: Your arguments will be more persuasive with lots of specifics supported by citations.

Comment [t12]: Evidence? This is a long reach!

Comment [t13]: be sure to provide citations to support your observations.
Measuring the length of time between the acquisition of a CII prescription and dispensing may prove difficult, but not impossible. Since pharmacies don’t normally calculate and keep records of these time intervals, a board member may need to audit these prescriptions which will require more funding and more personnel. If adopted, this statute would provide the administration with authority to limit the expiration of CII prescriptions to 90 days.

According to RCW 18.64.005, the Board of Pharmacy has full power to regulate practice and enforce laws assigned. Similar to the way expiration of CIII and CIV prescriptions are monitored, the same regulation can be implemented for CII. The existing administrative system has the capability to implement this program. In addition to the Washington State Board of Pharmacy, the system must rely on the cooperation of physicians, pharmacists, and other health care providers.

**Group 5 Rescheduling of Clonazepam**

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

**Technical Feasibility**

By rescheduling Clonazepam to a C-III status from a C-IV status, and thus increasing the general awareness of health care professionals and the general public as to the potential for abuse, misuse, and dependence potential associated with Clonazepam, it is feasible to achieve the long term purpose of this rescheduling project which is to decrease the current levels of nontherapeutic administration, misuse, and abuse of Clonazepam. The effectiveness of this policy can be measured indirectly by surveys that assess prescriber awareness, the number of prescriptions written, and the change in street price for Clonazepam (which has been correlated to the level of misuse of a drug). By legally acknowledging the potential risk of abuse of Clonazepam through the Washington State Board of Pharmacy by rescheduling this narcotic, the intended purpose of this action can be accomplished to a significant degree by instantly obligating health care professionals involved in Clonazepam use statewide to elevate their awareness and caution in prescribing, dispensing, and administering this drug which will then echo extensively through the health care system over the long term. Besides this direct effect, other positive changes associated directly with this action include: decreased access to Clonazepam as a "street-drug", increased caution by patients in self-administration of Clonazepam, and an increased effort by pharmaceutical entities to develop less addictive medications that will mimic intended effects of Clonazepam. Comparing resulting effects of measures mentioned above before and after implementation of this policy would indicate the adequacy of rescheduling Clonazepam. In addition, comparing the degree of resulting use in state compared to other states with similar statistics may provide a control group to assess the adequacy of this new policy. As mentioned already, while the general change in awareness of Clonazepam and its negative properties would be fairly rapid, the effects resulting from this change at the user level may take a longer period of time to be felt, but would be long term as with the improved awareness.

**Economic and Financial Possibility**

Effects on society by rescheduling of Clonazepam: (+ is positive effect, - is negative effect)

<table>
<thead>
<tr>
<th>ITEM</th>
<th>PATIENT</th>
<th>PRESCRIBER</th>
<th>PHARMACIST</th>
<th>MANUFACTURER</th>
</tr>
</thead>
</table>

Comment [t14]: What is your evidence that C-IV \( \rightarrow \) C-III will make any difference?

Comment [t15]: You've already heard my rant about surveys. See "overall comments" at top

Comment [t16]: Be sure that data are available to support your comparisons. I’m guessing that it may be hard to come by, which then raises the “who will pay” question. Be sure to build in technical support costs/talent if necessary. Also, be sure to support your arguments with credible citations (i.e., not newspaper stuff).
Reclassification (on bottles, in computers, etc.) | N/A | - | - | - | -
Misuse, abuse, addiction | + | + | - | - | -
Theft and other related crimes | + | + | + | + | +

**Political viability**
The rescheduling of Clonazepam is an important task required in order to raise awareness among health care providers as to the risks associated with use of this medication. If this policy were not to be accepted or implemented by the Washington State Board of Pharmacy (BOP) there are two alternative actions that can be taken. One alternative is to raise awareness by issuing a warning to health care providers regarding the potential for addiction. The other alternative is to not reschedule Clonazepam at all. Health care providers and the BOP may accept the proposed rescheduling because it may prevent or reduce diversion and abuse. Alternatively they may feel that it is unnecessary because they are already aware of the potential for addiction and abuse. Drug manufacturers may find rescheduling unacceptable due to financial costs of new labeling and potential profit loss due to decreased sales. A benefit to the manufacturers of Clonazepam is that they will be seen as more reputable companies that are patient-centered and not profit driven. A possible concession may be to provide a tax break or actual monetary contribution to subsidize labeling costs. Patients using Clonazepam may not find rescheduling acceptable for fear of being labeled as a potential abuser or that the added restrictions may make it more difficult to obtain their medication. Patients would just need to be reassured that the rescheduling is being done to ensure their protection and for the general public’s safety and welfare.

**Administrative operability**
The Board of Pharmacy has the authority to reschedule Clonazepam based on RCW 69.50.201, which states “The state board of pharmacy shall enforce this chapter and may add substances to or delete or reschedule substances...” It appears that under subsection 2d of RCW 69.50.201, the state board is not only capable, but also fully authorized to reschedule controlled substances even if that action would be contradictory to federal law. The state board of pharmacy will be willing to back the rescheduling of Clonazepam according to parts iii, iv, v, vi, and vii of subsection 1 of RCW 69.50.201 if it can be shown that Clonazepam more closely resembles a CIII than a CIV in regards to the criteria listed above. Finally, the state board of pharmacy can readily implement this rescheduling according to subsection 2b of RCW 69.50.201. Controlled substances are a highly regulated area of pharmacy, therefore once rescheduling is approved, the new status of Clonazepam would be forced to be recognized by law. Manufacturers and prescribers would have to recognize this rescheduling. The ability to demonstrate the impact of rescheduling Clonazepam could present a “bottleneck” in the system slowing the progress of this policy. An alternative “bottleneck” effect that might occur beyond the rescheduling of Clonazepam would be implementation of its new scheduled status and appropriate precautions taken by both prescribers and pharmacists. Manufacturers might also try to slow the process due to alterations they would have to make to packaging of their product. We believe that the administration would back our policy, however as previously stated we have the burden of proof. Since our primary goal is to raise awareness of the addiction potential of Clonazepam, a somewhat intangible goal, some might view it as hard to measure the impact and effects of this policy. However, we will be able to clearly demonstrate that awareness has in fact increased.
Group 6; Evaluation Criteria – “Indicated Use”

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. This would allow at least some perspective on the benefits of the program. Once implemented, our project should reduce medication errors that occur in pharmacies. This reduction in error should coincide with the implementation of our program into pharmacy practice. To trace the changes that our project might make we will have to get the number of medication errors occurring in Washington before our program is implemented and after it is implemented and compare the two numbers. By using the numbers for the whole state we will reduce the risk of skewing data with results of single pharmacies that may have implemented another program to reduce errors. As long as no other large-scale program to reduce medication error is implemented we should get a good idea of what impact our program has had.

Stating the “indicated use” on the prescription has a direct impact on health care system. If pharmacists are aware of the patient’s diagnosis, they can provide better and more effective counseling. Also, in some cases, they might be able to prevent drug-disease interactions and contraindications. This directly results in the improvement of the patient’s health. However, the positive effects can not be seen in short term; this is a gradual, ongoing improvement that can be recognized on a long term basis.

Political Viability

If the “intent of use” law is not supported by lawmakers, one alternative could be to talk to policy makers at community hospitals, and suggest the “intent of use” be written on all prescriptions from their hospital. This way if the patient chooses to fill their prescription at a community pharmacy instead of the hospital pharmacy, the community pharmacist can still verify a correct dose and strength for the condition being treated. At this point, including the “intent of use” on a prescription would be voluntary, but the importance of patient safety and quality of care is stressed, prescribers may choose to follow suit. If a prescriber feels the inclusion of indication is a violation of patients’ privacy, they may opt to omit this portion of the prescription. Board of pharmacy and pharmacists most likely will favor this law because it will decrease the rate of medication errors. Citizens may vote for this law if they understand that pharmacists are not trying to invade their privacy, but rather be more involved in their health care. The “intent of use” law is meant to provide the best possible health care to every patient by pharmacists. With the “intent of use” written on each prescription, the patient, the pharmacist, and the provider benefit from this extra step. Medical errors are more easily caught, with more “eyes” verifying the right dose and strength of a drug. If these intentions are clearly defined to the public and health care providers,
the law is more likely to gain support. This law will also allow prescribers and pharmacists to have a better relationship with one another. A trade-off for a physician having to spend more time writing out the indication on the prescription would be less medical errors, with an increase in the quality of patient care. Fewer medication errors also means less lawsuits against providers.

Administrative Operability

They have the power and authority to implement such a measure and the biggest concern with our proposal is that it can be argued that it violates HIPAA policies. This concern can be addressed with the fact that even without an indicated use, a person’s privacy is put in jeopardy when a doctor writes the name of the drug on a prescription. From the name of the drug, other people besides the patient may be able to tell what condition they are being treated for. One other note of concern would be compliance from the doctors, and we are working out some data on this one. However, I think if we stress the potential usefulness of indicated use, many prescribers would find that benefits outweigh risks, and privacy, though important, is only relevant if we can help the patient as best we can.

The Department of Health controls the licensure and discipline of health professionals in the state of Washington, including both physicians and pharmacists; it therefore has the power to compel professionals to comply with regulations upon penalty. The cooperation of individual physicians would be required, making the backing of associations of prescribing professionals within Washington State invaluable. Administratively, omission of an indication must take a lower priority than many more egregious violations of pharmacy law. When combined with high frequency of prescription-writing and current prescriber attitudes, the scale of this proposed law makes its enforceability fairly low. Most members of the proposing group agree that this omission does not warrant major sanctions on non-compliant prescribers. It is true that the administrative system has the capability to implement our suggestion of revising the law to include the requirement of a written indication to be included on a paper prescription. However, the answer to the question of whether the administrative system is willing to back us up is unknown. We will bring up our suggestion, make our arguments regarding this case, and see whether or not the administration is willing to negotiate with us. We are committed to this assignment and know that bringing forth this idea is both important and would be technically easy to implement. We hope that administrative authorities will be able to understand and cooperate with our views. The simple answer to the question of whether or not the BOP is capable of implementing our proposal of indicated use is yes.

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) Technical feasibility (effectiveness, adequacy)

In order to measure the effectiveness of our program we can compare the amount of dispensing errors, or the amount of time/money spent on resolving errors before and after implementing the program. These comparisons should be done within each pharmacy, and we expect to see results of positive outcomes for the pharmacies that have implemented the program. In order to control for secular trends we could do a time series comparison and not just a before and after
comparison. A reduction in medication errors is a direct result from our program. By including description/picture on label we are adding three more checkpoints in the filling process: a new check for the technician when filling the medication, a new check for the pharmacist at the final check before the medication is given to the patient, and a new check when the patient is being counseled (during the show and tell, medication can be compared to the picture). All these checks will greatly reduce the number of patients leaving with the wrong medication. Also, an indirect benefit lies in the fact that the patient is empowered in his autonomy to have the opportunity to check that the medication in the vial is indeed the correct medication. This is especially important for customers of large chain retail pharmacies, where it is common to see switching of drug manufacturers, and thus the color, shape and imprint of the medications changes on a frequent basis; it would be comforting to patients to have a label that confirms the medication is the same through a picture. If our program is implemented, the changes will be long term. There are many costs involved in our program. Many pharmacies will have to upgrade their technologies in order to support this change. Drug companies will have to create downloads for their medications, and these downloads will have to be updated by someone every time a new medication goes on the market.

2) Political viability

There are some worthwhile alternatives to our proposed labeling requirements on all prescription drugs. A large proportion of medication errors and problem solving time is spent in the pharmacy are due to sound-alike and look-alike drugs, so as a trade off we can implement a stepwise program that includes as one of the steps this labeling requirement for the medication error-prone drugs only. To ease the transition as well as budget concerns for smaller pharmacies, the program will start with the basics of requiring just auxiliary labels with the required description, then in a few years move onto having this required information to be printed on the prescription label. Pharmacies and government officials may find these alternatives feasible. Additionally there would be support from technology companies in setting up this task like developing software and having training sessions on how and why the labeling program is important.

3) Administrative operability

The BOP has the ability to deliver this policy by simply revising the RCW labeling section, and the administrative committee would have complete authority to enforce the proposal. The software, computer, and printer capabilities are available. To monitor the use of this program the BOP could add it to their inspection list. Other associations involved in promoting patient care and assessing medical errors would benefit in bring the law into effect. Other groups that need to be relied upon are the manufacturers. We have to make sure they are willing to cooperate in providing the pictures/descriptions. They could be forced to provide them, or pharmacies won't be able to dispense their products. This might be a problem because if not all states have this as a law/regulation, pharmaceutical companies might just stop selling their products to Washington pharmacies because they have to provide picture/descriptions with their products.

Group 9 Rescheduling Tramadol

Holly Dirks, Gigi Wong, Amy Little, Adam Mccown, Robert Siegfried, Michael King, Pavel Mitin
Technical Feasibility:

The rescheduling of tramadol will reduce adverse drug reactions as well as abuse. This can be measured by comparing the reports from surveillance programs such as Medwatch and DAWN from both before and after the drug was a controlled substance. Changes in the real world will be related directly to the rescheduling of tramadol as it will be more difficult to gain access to and to abuse. The change should be long term as tramadol will be controlled from here on out. This rescheduling should help reduce the abuse problems but not completely eradicate it.

Political Viability:

This policy should be acceptable to law makers, pharmacists, and prescribers. One alternative to rescheduling tramadol is to start a state wide surveillance program to further monitor the abuse potential of tramadol in Washington. We could also send another dear doctor letter or hold conferences to try to educate prescribers on the potential of abuse associated with tramadol.

Administrative Operability:

The Board of Pharmacy has the authority to reschedule drugs as noted in WAC 69.50.210. The Board has control to monitor controlled substances. In addition to the Board of Pharmacy, prescribers and pharmacists will be relied upon to follow protocol for dispensing controlled substances.

Group 10 -- Evaluation Criteria – Generic Substitution

Fran McGaugh, Jasmine Chase, Melvin Wang, Whitney Stoffel, Michael Fallon, Thu Dang, Ching Chow

Technical feasibility (effectiveness, adequacy)

The change with implementing our proposal would be both long term and short term. While substitution may start occurring immediately, it will also in the future as name brand drugs go generic each year. The desired effect is to save pharmacists, insurers, patients, and providers both time and money. A measure of how much time and money are being possibly wasted with the current system would be needed in order to make an accurate comparison post implementation. Some possible ways to test the effectiveness and adequacy over time are listed below. An annual review of the same scope that was done initially may be most effective to allow enough time to measure change in practice.

1. Count the number of prescriptions coming in on new pads and how many providers are writing, “dispense as written” or something to signify such.
2. Tally the amount of money spent out of pocket on brand medications that are generically available to patients before and after implementation.
3. Observe/poll pharmacists to see if their time spent consulting providers or dealing with insurance decreased.
4. Compile stats on any medication errors from dispensing the wrong “brand/generic” version since implementation.
5. Obtain before and after totals of money spent on generically available brand name drugs before and after implementation.

Comment [t28]: Specific evidence for either?
Comment [t29]: Probably not for medwatch (especially if the use was illicit); DAWN has some methodological problems – discuss with Don Williams, get a description of how it works
Comment [t30]: you are incurring some data gathering and other costs. Be sure to include provisions for this if you keep this. Who will be responsible for carrying this out? Can they do it?
Comment [t31]: These are interesting measures. But they will cost. Who pays? Who analyses the results?
6. Poll providers to see if these changes have saved them time on the telephone to insurance and pharmacists, and if the new law has positively impacted their practice.

**Economic and Financial Feasibility**

Implementation costs pertaining to the one line system are at a minimum, if any at all. The small cost of a cosmetic change for a written prescription is minute in comparison to the amount of time wasted on contacting physicians for miscellaneous reasons. The economic and financial possibilities of this change are **limitless**. Instead of waiting on hold with a physician’s office, pharmacists and other staff members have time to work with patients on more important issues such as counseling and answering medical questions. In addition, the implementation of this system assures patients savings with generic equivalent medications and allows pharmacies more profitability from dispensing them; insurance companies also benefit from this plan from less expensive, but still effective medications on their formularies.

**Political viability**

Proposed policy changes must survive the political test: if a policy will not be supported by decision makers, officials or voters, it has little chance of being adopted or implemented. What alternatives are available? What will be acceptable to various groups? What concessions will have to be made to gain support for each option? Do you have trade-offs in order to secure agreement on an alternative?

The legislature, medical associations, and drug companies would all need persuasion. Policy makers would need to be satisfied that adequate quality and cost controls were in place. Medical associations would need urging that they were not giving up control. Drug companies would fight the measure vigorously. Many people still believe (helped by drug companies) that brands work “better” than generics. This would have to be addressed with FDA data and education campaigns.

A few concessions/trade-offs to meet quality controls include:
1. Use of FDA’s “orange book” in deciding generic equivalency
2. Strong Board of Pharmacy enforcement policies and penalties

A few concessions/trade-offs to meet cost controls include:
1. Pass 60% or greater of cost savings onto consumer
2. If more than one generic substitution product available dispense cheapest
3. If available generic not in stock, sell brand product at generic price
4. If Rx written “d.a.w.” consult that available generic could save money

A few concessions/trade-offs to appease prescribers include:
1. Narrow therapeutic range lists that are off limits to substitution
2. Prescriber not liable for substitution errors
3. Instructions on the Rx form for how to request brand only dispensing
4. A “check box” somewhere on the Rx form to request brand only dispensing

**Administrative operability**

In order to evaluate how much authority the administrative system has to implement this law, we need to look at the structure and process of changing existing laws. The Board of Pharmacy regulates laws pertaining to pharmacy practices and our proposal to have mandatory generic substitution will fall under the Board’s regulations. However, external organizations such as pharmaceutical companies would potentially influence the execution of the proposal. The new policy would involve pharmacists in improving the delivery of cost-effective healthcare and enhancing our goal for patient-centered care. All benefits from this program will

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*Comment [t32]: Wow. As in infinite? Probably better to come up with some specifics supported by citations.*

*Comment [t33]: see RCW 69.41.130
Savings in price to be passed on to purchaser. Unless the brand name drug is requested by the patient or the patient's representative, the pharmacist shall substitute an equivalent drug product which he has in stock if its wholesale price to the pharmacist is less than the wholesale price of the prescribed drug product, and at least sixty percent of the savings shall be passed on to the purchaser.*

*Comment [t34]: very generous, but you are liable to go broke*

*Comment [t35]: how is this different from existing stuff?*
contribute to our patient’s well-being by increasing their autonomy to choose the most appropriate medical therapy.

**Group 11 – Evaluation Criteria – Intern Hours**

**Technical Feasibility**

Measurement of our policy’s effectiveness will be highly subjective. We will have to rely on the perceived impact as judged by preceptors and interns. Measurement might occur through evaluation forms similar to those currently used in which the intern evaluates the quality of both the experience and the preceptor, and the preceptor evaluates the benefits/accomplishments of the intern.

We hope to see a direct impact in the improvement of learning experiences during the internship through quality preceptor-intern relations and a more structured intern program.

Change will be long-term, because it will require that several groups of student pharmacists complete their intern experiences under our new guidelines.

Our proposal of more specific guidelines and improved monitoring/reporting systems for the internship experience could significantly improve the situation. The goals of Preceptors and interns will inevitably deviate from the board’s guidelines. No feasible policy can overcome this. Our policy will clearly inform all parties of expectations and make deficient experiences more visible. The existing problem will be adequately, but not completely, fixed.

Proving that a change is due to our policy and not a secular trend is near impossible. Causation is always difficult to prove. Nonetheless, measuring key variables (see last week’s assignment) before and after the policy is adopted will help to show its effectiveness.

**Political Viability**

Our change in law is so straightforward that we don’t feel there are any alternatives available. For interns, we hope their internship experiences will be more valuable and that new updated evaluation forms will provide a better way to evaluate preceptors and intern sites. These changes may increase the work load for preceptors, but will provide better guidelines for preceptors to establish higher quality internships. In the event that a preceptor does not want to use the ACPE guidelines, the preceptor can develop his/her own guidelines that must be approved by the board.

**Administrative operability**

The Washington State Board of Pharmacy is not capable of enforcing the proposed changes in our intern policy that we are proposing due to a lack of a definition of the pharmacist:intern relationship.

It would be advantageous to also propose a revision of RCW 18.64.005 (3) to give more detail in regards to the board of pharmacies powers and duties over this new policy. This would allow the board of pharmacy more control over the enforcement of the intended policy.
The most important group/individual that must be relied upon is the preceptor. The board should not only require a willingness for each preceptor to serve as a preceptor, but also be reliable to establish a training process/program. This program should include check points where the preceptor will present and evaluate the intern’s progress and learning to be submitted to the board. Furthermore, each preceptor must agree to give immediate personal and direct physical supervision to assigned intern to assure the quality of the interning experience. (AR BReg 02-01-005)

One of the main organizational limitation to this goal is that there is a lack of time and money invested in making sure that preceptors do this. For example, retail pharmacies concentrate strongly on the business aspect and may not allow preceptors the time for such projects which could possibly force preceptors to devote personal off-the-clock time to work. This could deter many potential preceptors from the commitment.

However, the existing (or proposed) administrative system does have the capability to implement the program being that they have the authority to establish the qualifications for the licensure of pharmacy interns. With strict enforcing and time to adjust, pharmacies will want to comply to the program if they want to have interns and future pharmacists.

**Group 12: Extension for CII partial fill completion**

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

**Project Evaluation Criteria**

1. **Technical feasibility (effectiveness, adequacy)**

   This criterion measures whether the policy or program outcomes can achieve their purpose. How will you know if the policy has had/will have its intended effect (effectiveness)? To what degree does the proposed action accomplish the objectives set forth? Can changes in the real world be traced back to the program, or they are the result of other factors (sometimes called “secular trends”)? For example, did you see a reduction in medication errors because of your program, or because of some separate activity? Is the impact direct (it addresses the stated objective) or indirect (creates an impact not associated with the program)? Will change (if any) be short term (for 1-2 years) or long term (>2 years)? Adequacy relates to how completely the program resolves the problem.

   We have discussed as a group measuring responses of complaints to the board from patients, pharmacists, and physicians about the hassles of running out of time to complete a partial fill in less than 72hrs. This is a feasible way to measure effect; however it may not be the best way to track effect of the changed rule. The results may or may not reflect the changes in the law specifically because of the unreliability and unpredictability of people writing letters to the board. A better way to measure change might be to create a randomized survey of physicians and ask how many
repeat prescriptions they have to write as a result of this time limitations of this law. This, although a possible better alternative, would be a very hard survey to conduct.

- **Economic and financial possibility**

  This criterion (beyond the scope of this course) assesses whether the costs of implementing the program are justified by the degree of improvement in the problem. If you have any comments on your perception of the implementation costs, please include them. Not required.

  Implementing this program would decrease costs to pharmacies in regards to their ordering processes.

- **Political viability**

  Proposed policy changes must survive the political test: if a policy will not be supported by decision makers, officials or voters, it has little chance of being adopted or implemented. What alternatives are available? What will be acceptable to various groups? What concessions will have to be made to gain support for each option? Do you have trade-offs in order to secure agreement on an alternative?

  The law is already established, we are just trying to amend the law. Why 72 hours? Did those making the law take into account the average amount of time to order a schedule II narcotic? Proposal to change the law and extending the window from 3 days to 5 days is not an outrageous request when one actually looks into the process at hand. However, it may be hard to change the law to a more lenient standard; it is may be difficult to argue that a less stringent law may be necessary.

- **Administrative operability**

  Is the existing administrative system (e.g., the Board of Pharmacy or Department of Health) capable of delivering the policy or program? How much control does the administrative system have? What other groups/individuals must be relied upon. Are you aware of administrative bottlenecks in the existing system? Are there organizational limitations? Specifically, will the administrative system have the authority to implement the policy? That is, have you crafted the statutes/regulations correctly? Is there institutional commitment? That is, is the administrative system willing to back your program? Does the existing (or proposed) administrative system have the capability to implement you program?

  The Board of Pharmacy in Washington has no say over our request because the law that we are challenging is a federal law. Consequently we must work with the DEA instead of the Washington state authorities. Parties that may be interested in

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Comment [t39]: this is an advantage of the petition process requires the agency to defend its practices

Comment [t40]: petition will likely be seen as adversarial
amending this law include physicians associations, drug companies, and wholesale retailers.