7543 group topic	
Group	**Topic**
1	Mandatory new prescriptions pick-up inside pharmacy facility (home delivery excluded)
2	make it possible for prescriptions written by out-of-state PA's and ARNP's to be filled when within scope of practice
3	Schedule II prescription and prescriber identification and tracking
4	Notation of purpose on prescriptions
5	Waste management of unused and expired medications in community pharmacy [changed 071012]
6	Statewide drug-monitoring program
7	Establish enforcement criteria for illegible prescriptions
8	Clarify personal health information confidentiality requirements for HIPAA and WA state laws [modified 071012]
9	Define 60-day supply for medical marijuana
10	Improve emergency buprenorphrine access through collaborative practice agreements
11	Notation of purpose on prescriptions through enforcement of "legitimate medical purpose" requirements in RCW 69.41.040
12	Expiration date on C-II; federal petition

Note: if your topic has changed from the above, please notify Tom Hazlet.

Don William's Comments

Group Number	Comments in order of the Questions the groups answered
1. Drive Thru Counseling Issue	1. Remember, a WAC is a RULE and an RCW is a LAW. I believe that a Board rule will suffice for your purposes. Is there a study that the PI reporter was using as her source. If so, find it to see if the reporter interpreted it correctly. 2. The history of a law or rule is usually printed after the rule in the law book. The Counseling rule has actually been around since the mid-1970's. Sometimes if the Board is making multiple changes to a rule it will repeal the original rule and write a whole new one. The current rule was adopted in about 2004 (check the history further.) 3. The Board records will usually show counseling issues in the investigations related to medication errors. Most patients do not complain about lack of counseling. 4. While we currently stress counseling on new Rx, counseling on refills is equally important for chronic meds (e.g. diabetes, hypertension, etc.)

	5. You could ask the Board to have its investigators ask specifically if the prescription was picked up at the drive thru when they investigate a complaint. 6. If drive thru's are here to stay, what else can be done to make them safer. You have a good start.
2. PA/ARNP Prescribing	1. You may wish to track down some of the variances in Rx authority in the various states.. 2. Are there things that MOST states have in common? 3. I do not believe that the Puget Sound area pharmacies have as big a problem as the Vancouver WA area. You might check with pharmacies in that area. Also, talk to Medco in Spokane. As I remember, they were turning down these prescriptions from Oregon prescribers even though they were then transferring prescriptions to their automated pharmacy in Las Vegas. 4. I do not believe that you will find too many complaints at the Board of Pharmacy. When ARNP's or patients called about this issue, we did not accept it as a "complaint" since there was nothing to investigate. We just explained the law to the caller and offered to send them a copy. Therefore, your attempt to measure change using complaints, will not work. 5. Can you really substantiate your statement concerning "unnecessary emergency room visits and hospitalizations"?
3. Serial Numbers on Schedule II Rx	1. Why not include other Schedules? There is some evidence that when you tightly control Schedule II drugs, the abuse shifts to lower schedules. Also, could you require these Rx forms to be tamper-resistant like the new requirement for ALL Medicaid prescriptions effective 4/08? 2. Your statement concerning substance abuse beginning in 1970 is not accurate. The Federal Government first started controlling "narcotics" in 1914 with the enactment of the Harrison Narcotic Act. The CSA in 1970 added other abused drugs to the control plan. 3. You might look at NY, IL, and CA for states that have had special prescriptions for Schedule II drugs for many years. Also, it is the TX Department of Public Safety that operates their program not the Board. 4. See how the above states deal with attempts to copy their state-issued prescriptions and even theft of the prescription pads from prescribers. 5. I do not see how these prescriptions will increase patient waiting time.

	6. It is more likely that the State would issue the Rx's rather than DEA. Do you intend that the numbered prescriptions be used along with an electronic Rx monitoring system? If so, describe it in more detail. While there could be a reduction in investigation of forgeries, there would probably be an increase in investigation expenses as a result of having more data so enforcement can identify doctor shoppers. How will this increase pharmacist's rapport with patients and prescribers?
4. Notation of Purpose on Rx & Label	1. Sounds good. 2. You may have to search for information to determine if anyone has studied the relationship between illegible Rxs and medication errors. 3. For resources you may want to include the WA State Medical Assn. (WSMA) in addition to AMA. 4. Since most errors do not get reported to the Board, you may need another marker to determine success. 5. I have heard about the MD's liability concerns but I have not seen evidence of this as a major problem. Have you? Also, how much of a real problem is the insurance concern about off label use unless they specifically prohibit something from being so used? 6. We have tried to use "notation of purpose" rather than "diagnosis" since the latter seems to scare physicians.
5. Requiring a private consultation area.	General comment: Your summary is much less detailed than other groups. 1. Have you decided what to propose? 2. Have you found out what alternatives pharmacies now use in order to come into compliance with HIPPA? How are they working? What should pharmacies do differently. 3. I do not believe that you will find very many complaints filed on this issue with the Board of Pharmacy. Those with which I am familiar have related to pharmacies dispensing prescriptions to the wrong patient along with printed information that tells the wrong patient for which condition the other patient is being treated.
6. Prescription Drug Monitoring Program	1.Most PMP's are structured to detect doctor and pharmacy "shoppers" who obtain CS

	illegally. Most of the programs set their screens at something like 5 doctors and 10 pharmacies in a particular time period. Your "recently obtained" criteria may be too strict. Some states put limits on when law enforcement agencies can review PMP reports. Do you wish to do so? 2. Good summary. 3. Good summary. 4. Have any of the current programs or the DEA reported on their results related to the criteria that you have described? 5. I suggest adding "patients" to your list of stakeholders. 6. The end of the 2nd paragraph should be "comply" not "apply.
7.Penalty for illegible prescriptions	General comment: Your summary is much less detailed than other groups. 1. A study on legibility of Rxs has been published by med students and docs from UW Med school. I believe that it was in Northwest Medicine??? 2. Need more detail. 3. Med errors have multiple causes is may be difficult to tease out those related to illegibility. 4. Pharmacist time on this issue is a good measure. 5. The "board of medicine" is officially the Medical Quality Assurance Commission.
8. Designation of Patient's Agents	1 & 2 Good summaries. 3. Could you revise RCW 70.02 rather than HIPPA. I am not sure Congress and DHHS want to deal with this issue again. 4. What kind of criteria are you thinking about. 5 & 6 Good summaries
9. 60 day supply of Medical Marihuana	Since you did not number your sections, my comments will be general. You might look at the history of control of marijuana. It goes back to the 1930's so it preceeded the CSA. Prosecutions will still occur if a person exceeds the amount of the drug that you (or the State) sets as the 60 day supply. Physicians who recommend the use of medical marijuana should be considered to be stakeholders. One physician Rob ???? was the prime person behind the initiative (see news articles.) He may have some thoughts.. Do you plan to include the "co-operative gardening" concept in your proposal? You do not have to amend the law (RCW 69.51) The legislature gave the Department of Health the authority to define a 60 day supply.

	You can act as if you were the Department.
10. Collaborative Practice for Buprenorphine	1 & 2 Good summaries. 3. Pharmacies that stock these drugs will probably be located close to the authorized prescribers. What liability issues are you preventing? Your proposal to separate the pharmacist from the company that they work for may be difficult. 4 & 5 Good goals and measurements.
11. Notation of Purpose	1, 2 & 3 Good summaries. 4. Be careful to separate "medical errors" from "medication errors" in your report. You may want to check with Group Health Pharmacies. Their electronic medical record requires that each prescribed drug must be associated with a diagnosis or health condition. For state issues, the Washington State Medical Assn. may be a more interested stakeholder than the national AMA.
12. Schedule II Rx expiration date	1. Last paragraph on page 1. "requires" would be a more appropriate term than "allows". Page 2 paragraph 2. Since prescribers are not allowed to "prescribe" methadone for addiction treatment, your example does not fit the problem that you are trying to fix. Paragraph 3 your fix should involve a RULE not a LAW! 2. No comment. 3.Can you relate the abuse of schedule II drugs with the lack of an expiration date on these prescriptions. It may be a reach. 4. You can solve this with a RULE you do not need to change a LAW. Can you determine how long the current lapse is between issuance and filling of schedule II Rxs.

Mindy's Comments on Homework 2

Group	Comments
1	Nothing was cited in section 3- Fact Base. Be careful that you don't make the assumption that patient counseling = patient compliance unless you can justify this association with facts. Has it been shown that there is an association between increased average time pharmacists spend with patients and patient compliance/ decreased medication usage errors? It's important that you first establish this aspect.
2	Well-written.
3	No references, citations? To make your case for this proposal, would expect to see some facts: Why is the issue at hand really an issue? Also

	suggest thinking more about some ways to measure the impact of your proposal.
4	Nice job addressing "off-label" use, please continue to think about this important aspect throughout and how to address it. I would encourage you to think more about patient privacy issues from the patient's perspective. Yes, HIPAA is important. But, may there be other consequences (social, perhaps) of having patients go into pharmacies with a sheet of paper in essence, declaring: "I am getting treatment for HIV" or "I am getting treatment for herpes infection." Also see comments for Group 11.
5	Topic has since changed.
6	Please cite all statements made to be facts: Sentence 1/Section 1. Sentences 1-3, Section 2. These statements are key to your proposal—how do we know these statements are true?
7	Same comments as to Group 3. How do you know that illegible prescriptions continue to be a problem? Some recent facts and figures?
8	Well- written.
9	Suggest re-thinking how you evaluate the change affected by your proposal—making a statement about 0 prosecutions is very absolute. Does that mean that if 1 prosecution occurs, your proposal is not effective? Any other ways to measure change? Also, your very last statement in this document does not make your proposal convincing – so one doesn't get busted by the local police, but one may get busted by the Feds. . .
10	Well-done, especially Question 3.
11	Should the statement: "Minimizing medication errors can decrease overall costs" be cited? How do you know this? This will be one of your primary justifications for your proposal- be sure to sufficiently establish your fact base. Need to address off-label usage. See comments for Group 4.
12	Be careful to cite all statements made to be facts. Section 3 is well-done.

Josh's Comments on Homework 2

Group	Comments
1	-You assert that some patients are leaving pharmacies "uninformed and uneducated on the proper administration and warnings of their medications", I don't doubt this reality, but do you have any research studies/sources to support this concept? Any data on impact of drive-through pharmacies specifically? -You state "The objective is to provide evidence to the Washington State Board of Pharmacy describing medication errors resulting directly from poor patient consultation received through the drive-thru window, propose guidelines outlining adequate counseling on prescription medications, and outline which prescription medications require counseling", how do you intend to come across this type of evidence? It seems like this would require a research study involving substantial investment of time and money. Does your group intend to collect this data, or is this something that the stakeholders will carry out? -Will likely to be tough to convince pharmacy owners to get rid of drive-through windows because they have already invested in the infrastructure to support that mode of filling prescriptions, and the patient population might value convenience over safety (is there any research evidence to indicate how patients feel about this?).
2	-Good exploration of the history of the issue -Will this change expose pharmacy owners to additional liability without a commensurate increase in revenue?

	-How will the system change be funded, how will it function in a logistical sense? -Is this a large problem today? Do you have data about prescriptions denied or pharmacy time invested in verifying credentials? -You say"interviewing pharmacists in the greater Puget Sound area will provide data in regards to the loss of time and economic opportunities resulting from prescription denial as well as the consequences the current law has on patient care", are local pharmacies systematically collecting this data (i.e. if they have it, is it valid)?
3	-#3-good use of using other states laws to guide your process. Are there are any socio-political similarities/differences between WA and TX that would make the TX law more or less likely to be adopted here? -A new drug monitoring system would likely be very expensive to implement, and change management could be a major issue (in terms of employee training, altering existing policies/procedures, etc.)? Have you considered any strategies to mitigate push-back? -#4-you state "once installed the rates of schedule II fraud will be better recorded and then be able to measured", do you have any evidence to support this assertion (e.g. from TX experience)? -Good idea, but think about cost involved and potential stakeholder resistance. Use a forcefield analysis to think about how to manage these forces.
4	-You state "The Washington State Department of Health, the National Coordinating Council for Medication Error Reporting and Prevention and the American Medical Association, among other organizations, all recommend writing a notation of purpose on prescriptions", how will you utilize these stakeholders to implement your policy? -You state "Prescribers may oppose the initiative because they feel that it subjects them to increased liability, but this should not be an issue if the prescriber is practicing evidence-based medicine", is it possible for prescribers to always practicve evidence based medicine? Given the lack of evidence in many medical realms, this might not be construed as a valid argument. -Will there be any incentives/assistance in terms of implementing notation of purpose processes? -Is there evidence to support the idea that notation of purpose will reduce a significant number of medication errors?
5	-You state "goals are to increase patient privacy and to reduce pharmacy variability in establishing patient privacy standards", not entirely clear how you intend to go about this. I recall that you were going to create an isolated area 7ft away from other people, is this still the intention? -Who will resist this policy? How will you address their concerns? -What is the cost involved in implementing your policy? -Do you have data showing that patients care about this issue?
6	-#2-Good use of evidence - You state, "The goal will be to reduce death and hospitalization rates, due to misuse or abuse of controlled substances, by 40% in two years", is this realistic? Is the data collection infrastructure in place to collect/evaluate this data? -You state "the benefits are dependent on many factors and may not be immediately measurable", tough to sell this type of thing to stakeholders who are investing in the program. They will likely want to see a definitive return on investment…
7	-You state that the intention is to "Compile a database of actual medication errors or near-errors", what is a "near error"? Is a "near error" actually an error? How will you define a "medication error"? - You say you wan tto "reduce illegible prescriptions being written by 50% in two years", is this realistic? Are you basing this objective on any existing effort (i.e. has any state, organization, country attempted this?)? -Do you think physicians will resist this effort? How would you address their concerns?
8	-What are the draw-backs of explicitly defining a list of those able to pick up prescriptions?

	-Who will resist this change? How can you address their concerns? -Will there be any financial incentives/assistance issued by the state to aid in the cost of changing the current system (e.g. tax-break, etc.)?
9	-If you achieve your goal of "no ambiguity in the law", how will the pro-medical marijuana stakeholders feel about it? Do they have an interest in legal ambiguity? -Seems like the central issue is determining the stakeholders on either side of the policy and creating a policy that both can live with. Think about the forcefield analysis demonstrated in class. How will you address the stakeholders on either side of the policy?
10	-Good evidence in bullet 3 under "question #1" -"Question 3", bullet 1-will a brief survey to several pharmacies yield information that will be valued by policymakers? Will likely need to find VERY convincing data in order to support your point through this approach. -"Question 3", bullet 4- Though you say you are only looking to "authorize an emergency fill", the law would have to be crafted in a very rigid manner, otherwise this could turn into a slippery slope with drug being dispensed in non-emergency situations. How will you define "emergency"? -Will MD's feel that you are encroaching on their scope of practice? If they do feel this way, how could you address their concerns?
11	-You state, "44000-98000 deaths annually may occur in hospitals each year due to medical errors", would notation of purpose address a majority of these deaths, or are many of them due to other reasons? -Will the increased implementation of computerized physician order entry (CPOE) in hospitals already address this type of issue, at least in a hospital setting? May want to look up info on CPOE. -Who might resist this policy? How would you address their concerns?
12	-What is the rationale for a 90 day expiration period? (i.e. why 90 and not 30, 180, etc.) -Who might resist this policy and how would you address their concerns?

Tom's Comments

Group	Comments
1	Suggest getting some background information on the most recent change in WAC 246-869-220: Karan Dawson (here at UW), the WSPA folks, and Donna Docktor (Sand Point Clinic) were heavily involved in the discussions. Note: you don't need to convince legislators to changes the WAC, just the Board. As I mentioned in a discussion with your group, I suspect that the Board will have received few if any complaints of the sort you would like, so you should pursue other avenues. Perhaps your own experience is "good enough". Some frank discussions with management folks with chains that have drive-through set-ups will be important.
2	Probably older history in WA; might want to check newspapers, maybe State Register, etc. for older history. As this is a problem that impacts other states, please check with your UPPOW rep to see what APhA etc., has done about this. Might also check with national chains, perhaps NACDS, and the association for independents (whose name escapes me just now); also check with the associations representing PAs and ARNPs.

Group	Comments
	Comment on footnotes: be sure that they can be interpreted. http://www.blackwell-synergy.com/doi/pdf/ … gives me an error. I anticipate that there will be few complaints to the Board, so be thinking about some different metrics.
3	Suggest focusing on public health issues rather than police/regulatory activities for project. For instance, the Pharmanet program in BC (a common profile system available to all pharmacists in BC, + some others) provides a good deal of clinical information. Seethe PharmaNet web site http://www.bcpharmacists.org/PharmaNet/tabid/85/Default.aspx You may wish to contact Suzanne Solven at the BC College of Pharmacists Pharmanet contact -- Suzanne.Solveen@bcpharmacists.org; 604-676-4202 – though wait until I hear back from her; I'll let you know. I would try to find information experts at the various Boards that have implemented tracking systems and find out how they use the information, and any problems they have encountered in information acquisition and evaluation. Keep in mind that the information is useless (hence expensive) unless someone actually does something with it. So a question is: how has the tracking process changed something? Also, if you need someone who really knows the issues with billing, data switches and the like, contact Ryan Hansen -- rhansen@u.washington.edu See comments for Group 6
4	See also comments for group 11. Given the various prescribers' prior objections to doing the logical thing, your challenge is to figure out a way to make is so desirable that they will do it anyway (or the reverse), recognizing that you are not in a political position (generally) to overcome their objections..
5	… out of sequence. I'll look forward to future updates re waste management.
6	See comments for group 3. Well written and nicely referenced! I'm a bit concerned about focus. As with Group 3, could you change the

Group	Comments
	focus so that you have a "advance public health" spin rather than "jail the bad guys"?
7	Note requirement for "well referenced". Paying attention to the history of the existing law should help identify proponents and opponents. Your skill will be required to craft a fix what will provide buy-in by the prior opponents, etc.
8	So I'm a bit confused. Maybe a sequence issue. Do you still intend to produce some sort of document that shows the various age thresholds for various state and federal laws impacting protected health care information disclosure? The notion of "fraud" is mentioned: "deceit, trickery, sharp practice, or breach of confidence, perpetrated for profit or to gain some unfair or dishonest advantage" [Random House Unabridged]. It isn't clear to me where you are encountering fraud.
9	Good start! As your project is following a somewhat different path than others, please set up a meeting with me so we can map future homework submissions.
10	I wonder if contacting the buprenorphrine manufacturer would help – Reckitt Benckiser Pharmaceuticals Inc. Seems to me that they would be interested. Suggest getting a contact through Group Health, or contact them directly at 877-782-6966. Also, contact Tim Fuller at the Board – tim.fuller@doh.wa.gov – about collaborative agreements.
11	See also comments for group 4. It seems to me that there is (or should be) some theory of law that could be used to force the "legitimate purpose" issue onto the prescription. So, I've sent the following to two law school faculty listed in the administrative law section: I teach a required pharmacy law and ethics course for pharmacy students. One of the course requirements is for student groups to identify some area of law governing pharmacy practice that appears "broken" and to propose a "fix" following a standard policy analysis format. A recurring issue is a disconnect between prescriber intent and what is communicated via prescription (however delivered, whether written, verbal, electronic, etc.) that could be resolved if the prescriber somehow indicated the intended use -- "notation of purpose" is the current term-of-art. Prescribers object to a requirement of such notation for a host of reasons such as increased liability, HIPAA violations, etc. PhARMA has historically objected because insurers may interfere if the intended use differs from their reimbursement guidelines. To those of us on the receiving end, the objections seem trivial compared to the consequences in medication errors and processing

Group	Comments
	delays. One of this year's groups wants to pursue an issue of logic. RCW 69.41.040 requires, in part, A prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. They ask how they may know the legitimacy of the prescription without knowing its intended use and want to pursue this line of thinking for their project. And if legislative intent is that this linkage be established, how best to effectuate their intent? If I've got your project wrong, please let me know. I report back when I get a response.
12	Be sure you can defend your 90-day selection; have an exemption policy in place for the circumstances that several faculty have described – patients with extremely painful episodic diseases such as kidney stones, migraine, etc. Also be sure that your scheme will accommodate chronic disease states such as ADHD. Do you plan of a federal petition? I hope so.