### Diagnosis requirement on prescription

Of all the requirements needed to be written on a prescription, there is no requirement to include the diagnosis. Our project is to attempt in fixing WAC 246-871-050. The current minimum requirements on a prescription include patient name, patient address, drug name, strength, and dispensing quantity, patient directions for use, date written, prescriber’s name and DEA code if applicable, refill instruction, and provision for generic substitution. By adding diagnosis onto the prescription, it saves time for pharmacy personnel, prescriber, and patients. Additionally, it provides an extra safety check to protect the patient before dispensing as well as speeding up the processing time of the insurance claims.

**TKH Comments:** Because of historic opposition to requiring that prescribers note “intended use” or “notation of purpose” (the politically correct terms of art) on a prescription, you’ve several major challenges:

1. **Figure out where to put your requirement.** For instance, if you make the prescription that lacks the notation illegal, the patient and pharmacy have to sort out the problem, with phone calls & delays.
2. **Anticipate changes in technology that may ameliorate the problem.** For instance, could you mandate that all electronic prescription software include a mandatory field for “intended use”?
3. **Figure out how to deflect opposition of various prescriber groups, and other interested parties (“stakeholders”) such as the pharmaceutical industry – whose opposition derives from a concern that “intended use” will be used by fiscal intermediaries in therapeutic substitution schemes. Others raise privacy objections.**

### Schedule II Fill Restriction

Our group intends on addressing the issue of the duration of time a schedule II drug may be filled. According to RCW 69.50.308(d), schedule II drugs may be filled up to 12 months after the originally date the prescription was issued. This seems to be a lengthy duration considering most schedule II drugs are prescribed for the immediate management of severe pain. In addition, schedule III and IV drugs have a time frame of six months to be filled upon the original prescription date. The time frame allotted to schedule II drugs seems to be excessive and potentially detrimental to the patient’s health.

**TKH comments:** needs to be done. **Might be easier to change a WAC (Board could do it) than an RCW (requires legislation).**
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<th><strong>Introduction of a CPR certification requirement for WA state pharmacist licensure</strong></th>
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<tr>
<td>3</td>
<td>10/7</td>
<td><strong>WAC 246-869-220  Patient counseling required</strong></td>
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<td>Current law requires pharmacists to counsel patients on the use of drugs or devices. The extent of information provided remains within the purview of each individual pharmacist, who may provide any amount of counseling “that is reasonable and necessary under the circumstance to promote safe and effective administration of the medication and to facilitate an appropriate therapeutic outcome for that patient.” In our opinion, the current law is vague and difficult to interpret. We believe that patient safety is jeopardized when pharmacists do not convey at least a few important pieces of information. We also believe that setting a minimal standard for counseling will advance the profession of pharmacy and the practice of pharmaceutical care.</td>
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*TKH comments: as I mentioned in our discussion section, the current working was the product of protracted hearings and much angst. Your challenge will be:*

- **Be persuasive – what is your evidence that the current wording is inadequate?**
- **Be creative in your proposed remedies**
- **How will you deflect the criticisms of being more prescriptive in the WAC?**

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<th><strong>Mandatory Coverage for Off-Label Drug Use</strong></th>
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<td>5</td>
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<td>Currently, there are insurances that will only cover a medication if it is used for an FDA approved indication. There are some instances that may be life threatening to the patient in which a drug is used for an indication that is not approved and it is very helpful. We care about this issue because not having coverage of a medication (especially an expensive one), might lead to a patient not being able to take their meds for a life threatening condition because they cannot afford the medication. I looked on insurance sites to find a citation, but could not find anything that was specific enough to our subject. Thank you!</td>
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TKH Comment: I believe that if you contact the right folks (I’ve a list), you will find that insurers generally cover “reasonable & necessary” treatments. Sometimes, they will determine that an off-label use doesn’t meet this criterion, generally for reasons of safety, and deny payment. There have been some sensational and expensive lawsuits lost by insurers through denial of coverage; some of these do not seem to represent best science. Nonetheless, my impression is that current insurers look pretty carefully at evidence for/against an off-label use before denying coverage.

So ... what is your evidence that this is a problem? What part of the system do you want to fix?

We would like some advice, however. Although the above topic is interesting, we were wondering about maybe switching to a more pharmacy focused topic. Do you have any suggestions about the follow topics?

1) muscle relaxants should be changed to controlled prescriptions b/c of the potential for abuse.

TKH comment: Done for carisoprodol two years ago; draft WAC presently under review

2) all pharmacy employees should have CPR training before getting their license.

TKH comment: ok; receive, and renew on some schedule (maybe part of CE requirements)?

3) all immigrants should have completed their immunizations 1 year after being admitted into the U.S.

TKH Comment: I’d be surprised if this wasn’t already covered somewhere else, especially for children. I don’t know this area of regulations, though.

Title: Classifying Pseudoephedrine as a Schedule 5 drug

What Law are you attempting to fix?

We are attempting to fix Washington State laws regarding the scheduling of drugs.

Why do we care about this issue?
Washington State has one of the highest rates of crystal-meth use in the nation. Classifying Pseudoephedrine as a schedule 5 drug may aid in the amount of crystal-meth produced. This law was recently passed in Oklahoma and the amount of meth labs decreased significantly thereafter.

*TKH Comments: I believe that you are contacting Dick Morrison to determine the current status of WA\BOP activities regarding pseudoephedrine.*

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<td><strong>10/4</strong></td>
<td><strong>RCW 69.50.208</strong></td>
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|   |   | For our law project, we are proposing the rescheduling of clonazepam from schedule four to schedule three by showing that it fits the schedule three tests of moderate to low physical dependence with the concurrent use of opiates. We intend to show its consistent abuse with heroin addicts for an additive effect. This project is important because of its opportunity to reduce the potential for heroin addicts to misuse clonazepam.

*TKH Comments: See “RCW 69.50.201 Enforcement of chapter -- Authority to change schedules of controlled substances” for the rules on what you will need to do to defend a change of schedule to a more stringent one that in federal regulations. Some issues you will need to sort out:
  * is the proposed remedy proportional to the problem?
  * what evidence do you have that changing the schedule will “fix” the problem
  * if it becomes hard to get clonazepam, what are the next candidates? Might you be making things worse? This is the “unintended consequences” theme.*

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<td><strong>8</strong></td>
<td><strong>10/4</strong></td>
<td><strong>Managing Methadone Misuse &amp; Minimizing Mishaps</strong></td>
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<td>Methadone is a commonly used narcotic. It is used both for pain treatment and the management of withdrawal symptoms. There several common and severe adverse events associated with methadone use; toxicity and respiratory depression. There is no current legislation managing the use of methadone in this manner. Our recommendation is to establish a regulation requiring prescribers to list patients on a state registry of methadone patients and to perform periodic evaluations of patient samples to ensure that levels of methadone are within the therapeutic range and to promote patient safety.</td>
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<td><strong>TKH Comments:</strong></td>
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<td>1. <em>Having spoken to one of your team members, I think I understand some of the issues you are attempting to address. As I mentioned, there is a good deal of baggage with methadone use specifically, because it is employed in opiate detox programs for which there is a separate body of law as well as pain management.</em></td>
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<td>2. <em>Is legislation needed, or does the Board already have the authority to do what you want? You mention both, so I’m not clear which you want.</em></td>
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<td>3. <em>What is the evidence of misuse or unsafe use?</em></td>
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<td>4. <em>Is the extent of misuse sufficient to justify establishing a registry (very expensive, privacy issues)</em></td>
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<td>5. <em>How would registry information be used to correct the problem?</em></td>
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9 10/4  Revision of Schedule II Prescription Expiration Date

We are attempting to fix the following law:

Uniform Controlled Substances Act – RCW 69.50.308 Prescriptions

3d) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule III or IV, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written or oral prescription of a practitioner. Any oral prescription must be promptly reduced to writing. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times, unless renewed by the practitioner.

Due to omission of Schedule II drugs in the above law, these prescriptions are good for 1 year from the date written; the current law for schedule III-IV drugs is for six months. We believe schedule II drugs need a stricter regulation to be consistent with the schedule III-IV drugs. This will require more proactive patient monitoring and may assist in reducing unjustified prescription use.

*TKH: I suspect that this could be done in WAC, which would be much easier. The trick is: what is the “correct” length of time?*
Because we are concerned about the regulation of natural and herbal supplements in retail pharmacies, we wanted to make sure patients were being screened for supplement use and educated on interactions between natural supplements and other drugs. While looking through the minimum required information in patient records, we also noticed that the law says nothing about screening for OTC’s or other legend drugs. Therefore, we propose to add the clause: "Any current medications including OTC's and natural supplements" as a new lettered item in sections 1 and 2. This clause could also be added into WAC 246-875-030 sections 1 and 2.

TKH Comment: Seems reasonable on its face. Devil in the details issues that come immediately to mind:

- how will you obtain the information?
- how will you keep the information up-to-date?
- will the drug-drug interaction software be useful in detecting interactions ....

There is no known law in Washington requiring pharmacists or pharmacy students to be educated in Natural or Herbal Products. We were also interested in making a Natural and Herbal Supplements course required curriculum in the two state Schools of Pharmacy as well as adding herbal questions on the NAPLEX. However, we weren’t sure how this fit into existing law. Any advice?

TKH Comment: The Board defers to the accrediting organization (AACP?), which, in turn, has curricular suggestions. UW is embarking on its decadal curriculum review real soon now, and you could propose a curriculum revision. If you want to go in this direction, I suggest that you schedule a meeting with Stan Weber, me, Don Williams (if available) and Gary Elmer to define your project. Or you could try to get the curricular requirements amended. Dana Hammer may know about this, as may Don Williams and Stan Weber. The content of NAPLEX is defined by (as I recall), by representatives from schools of pharmacies, Boards of Pharmacy, professional organizations, etc. They formulate “content areas” to guide question writers. The “content areas” get revised every so often. Perhaps there is a way you could petition to have the “content areas” amended to include what you want. I believe that Don Williams may have further wisdom.

One final idea would be requiring places that sell natural and herbal supplements (ie. retail pharmacies) to display a warning sign in that section that would caution patients to speak to a pharmacist before taking any
supplements. Our concerns were primarily potential drug interactions with supplements and general lack on information about these products. But again, this seems like it would entail creating a new law—is this a satisfactory project?

**TKH Comments:**
- what about non-pharmacies where these products are available?
- if they really are “unsafe”, should they be on the market? With some tongue-in-cheek, I’d suggest taking on the Dietary Supplement & Health Education Act, the current loophole through which most of these products slide

| 11 | 10/4 | **Schedule II RX Fill Expiration Change** |

We propose to change the current Schedule II RX fill date on an original prescription from 12 months to 6 months. When a script has a long-term expiration date, such as 12 months, we believe there is a potential for drug abuse for many reasons. Second, there is a potential for forgery if multiple scripts are given at one time to a patient by the provider. Third, patients who are on consistent narcotic therapy should be continuously evaluated by the provider to assure positive patient outcomes. Fourth, schedule III and IV have fill expiration dates of 6 months, so logically it should follow that schedule II should have the same or more regard. Fifth, the Washington law does not clearly state a specific fill expiration date for schedule II drugs. Sixth, other states such as Hawaii have stricter regulations to fill a schedule II RX within 72 hours. And last based on our experience, it is not practical to write scripts for more than 6 months, as we have only seen schedule II drugs given for 3 to 4 months.

Reference: CFR 1306.11 Doesn't specifically state time restrictions on filling a CII script.

**TKH: See comments for Group 2. If you both select the same topic, I will try to guide you to different aspects so you complement rather than overlap.**

In the case that this subject matter has been covered by previous classes, we would like to mention our second choice, which is MTMS. MTMS, or medication therapy management services, is mentioned in Part D of the recent Medicaid bill passed by congress. It provides pharmacists the ability to bill for pharmacy services. The definition of MTMS was worked upon by members of APhA at the last national meeting, and was just recently under open comment review.
One unfortunate part of MTMS is that it states pharmacists by name as being able to provide these services, but does not limit services to pharmacists. That is, another health care provider, such as a nurse, could bill for pharmacy services, to Medicaid. We feel that this is unethical, especially in cases of medication management, because pharmacists are the health care providers that are drug specialists, not MDs or nurses. For example, we feel that if a patient calls a 1800 nurse consulting line on their medications, the patient might not get the most appropriate medication evaluation, and therefore patient outcomes will be compromised.

For this reason it is our suggestion that MTMS be rewritten to state that only pharmacists can bill for pharmacy services.

*TKH Comments: I personally have some problems with using law to restrict another profession’s activities if the other profession is competent to provide the service. You are pursuing an opportunity to comment on proposed regulations. Are there aspects where you can comment favorably, areas where you could show pharmacist’s unique contributions to patient care? This is an interesting opportunity! You will probably want to read the sections of the Act giving CMS authority for the proposed regulations.*

### Clarification of the role of the pharmacist in the offering of patient counseling

In the Washington state Pharmacy Lawbook 2003, WAC 246-869-220, it is unclear that the pharmacist is the only individual in the pharmacy that can make the patient counseling offer. The law does not address the role of technicians and assistants in offering the provision of patient counseling by a pharmacist. This need for clarification arises from the disparity between the law and the actual practice of pharmacy. The other issue of concern is if the offer for counseling by a pharmacist is required for refills in addition to new prescriptions. We care about this issue because personal pharmacist licensure is in jeopardy due to misunderstanding of the law.

*TKH Comments: go for it!*