Washington State Department of Health
Pharmacy Commission

Christopher Humberson, R.Ph.
Executive Director
Pharmacy Quality Assurance Commission
Financial disclosures

I have no financial interests to disclose regarding the presentation material.
Pre-Test Questions

1. Can I fill a prescription for hydrocodone from a naturopathic physician?
2. Does a prescription for a chronic pain opioid medication require a diagnosis by the prescriber?
3. I can start my drug Take Back program before any approvals?
4. Washington pharmacies are subject to the 5% rule on drug transfers.
5. I can delegate my PMP account access to my technician.
Prescription Requirements for Chronic Pain Medications

WAC 246-919-850 through 246-919-863

Rules that govern the use of Opioid medications in the treatment of chronic non-cancer pain.

The rules instruct the physician to “include indication(s) for medication use on the prescription and require photo identification of the person picking up the prescription in order to fill.” (WAC 246-919-854)
Collaborative Drug Therapy Agreements

CDTA’s (WAC 246-863-100/110, RCW 18.64.011)

A CDTA is an agreement between a prescriber and a pharmacist. It allows the pharmacist to prescribe within a specific protocol authorized by the doctor for a specific period of up to two years.

This can include controlled substances PROVIDED that the pharmacist has their own separate DEA number. You may not use the provider’s number for controlled medication prescriptions on a CDTA.
Prescriptions for Controlled Substances

What can be changed on a C-II prescription?

The prescription must have the patient name, drug (brand or generic), and be signed by the practitioner.

In Washington State, everything else can be changed after contacting the practitioner and annotating on the prescription that the practitioner was contacted by the pharmacist.

2008 policy letter from DEA states “follow your state regs/policy”.

Multiple prescriptions for up to a 3 month supply may be written at the same time, if written on separate prescription blanks.
Electronic Prescribing of Controlled Drugs

Senate Bill 5416 redefined out law to mirror federal law (21 CFR 1311)

The law also establishes that a Schedule II CS may not be filled more than six months after the prescription is issued.

Federal law has allowed electronic prescription since 2010.

Federal requirement that a third-party auditor verify that the software meets DEA security requirements, this is for both sending and receiving software. The third-party auditor will provide certification to each registrant if the software meets the requirements.

If a pharmacy does not have certification, then they must require a “wet” signature on all controlled substance prescription
f) Emergency refills—If the prescriber is not available and in the professional judgment of the pharmacist an emergency need for the medication has been demonstrated, the pharmacist may dispense enough medication to last until a prescriber can be contacted - but not to exceed 72 hours' supply. The prescriber shall be promptly notified of the emergency refill.

The pharmacy commission, in coordination with DEA, has developed guidelines for patients displaced by governor declared emergencies. The Commission has a guidance document on this issue. E.g. Eastern Washington Fires
Washington State Drug Takeback Programs

Review and approval of program by Commission prior to implementation.

Pharmacies that modify their DEA registration and meet DEA criteria can now take back controlled medications in approved receptacles.

Responsible pharmacist’s job to ensure program policies and procedures are followed.

Cannot take drugs back directly to pharmacy personnel behind the counter.
Disposal of Controlled 1 Substances
Marijuana 2013- HB 1808

Concern related to pharmacies coming in contact with marijuana from patients.

Cannot be placed in TakeBack program receptacle

If you find, contact local law enforcement officer for proper disposal.
Naturopathic Physician Rx’s WAC 246-836-210

Naturopathic physicians can currently:

Prescribe all legend drugs with the exception of Botulinum Toxin;

Prescribe codeine and testosterone products that are contained within class III, IV, & V

They cannot prescribe any class II drugs or other controlled substances.
Compounding Medications in Washington

Compounding of controlled drugs must be patient specific pursuant to a prescription.

Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States pharmacopeia as it applies to nonsterile and sterile administered products.

Pharmacies cannot compound controlled substances for practitioner’s, 21USC802(10)(15) & (27)
2015: Optometrists and Hydrocodone
SSB 5293

This legislation permits an optometrist to write for a seven day supply of hydrocodone products. This is the only Class 2 medication they have authorization to prescribe in Washington State.

This is currently in rulemaking by the regulatory board.
PMP Rules Update for Delegation of authority

The current rule allows for “licensed health care practitioner authorized by a prescriber” to access information as a delegate.

Work is under way to amend rule to allow, “Prescribers and Pharmacists,” delegation authority.

Any health professional licensed by the department can have a delegate account. (New rule language will include Pharm Techs)

Same registration process for the delegate.

Prescribers manage (link and un-link) delegate accounts to their main account to make requests on their behalf.
# Prescriptions Dispensed ‘12 – ‘14

*Rank by most recent year*

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>2014 RX</th>
<th>2013 RX</th>
<th>2012 RX</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCODONE/ACETAMINOPHEN</td>
<td>2,775,054</td>
<td>2,814,288</td>
<td>3,007,054</td>
</tr>
<tr>
<td>OXYCODONE HCL</td>
<td>1,043,239</td>
<td>962,909</td>
<td>927,899</td>
</tr>
<tr>
<td>OXYCODONE HCL/ACETAMINOPHEN</td>
<td>847,054</td>
<td>854,344</td>
<td>922,408</td>
</tr>
<tr>
<td>ZOLPIDEM TARTRATE</td>
<td>791,303</td>
<td>834,515</td>
<td>916,823</td>
</tr>
<tr>
<td>ALPRAZOLAM</td>
<td>645,435</td>
<td>638,556</td>
<td>657,064</td>
</tr>
<tr>
<td>LORAZEPAM</td>
<td>644,463</td>
<td>457,689</td>
<td>644,306</td>
</tr>
<tr>
<td>DEXTROAMPHETAMINE/AMPHETAMINE</td>
<td>580,426</td>
<td>518,964</td>
<td>475,749</td>
</tr>
<tr>
<td>CLONAZEPAM</td>
<td>528,338</td>
<td>518,349</td>
<td>529,671</td>
</tr>
<tr>
<td>METHYLPHENIDATE HCL</td>
<td>423,117</td>
<td>414,548</td>
<td>412,848</td>
</tr>
<tr>
<td>MORPHINE SULFATE</td>
<td>336,520</td>
<td>328,015</td>
<td>333,717</td>
</tr>
<tr>
<td>TRAMADOL HCL</td>
<td>308,524</td>
<td>____</td>
<td>____</td>
</tr>
</tbody>
</table>
PMP Trends in Washington

PMP Interconnect: 30 states now connected. WA are still challenged with interoperability and technical issues.

Challenges with Oregon PMP Database: Prohibited by Oregon statute from sharing. Not accessible unless you also register with Oregon directly as out of state providers.

How is patient file listed? For accuracy, does patient file have nicknames, or shortened names or initials?
Controlled Drug Paperwork requirements

Biennial Inventories: Need to be at one point during the inventory day. Beginning or end.

During inspections Commission inspectors examine of all relevant invoicing, CSOS, and C222 forms for completion at the site.
Non-prescription transfer of drugs
WAC 246-879-010(10) (e)

- Wholesale distribution” means distribution of prescription drugs to persons other than a consumer or patient, but does not include:
  - The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, “emergency medical reasons” includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.
  - Cannot sell to offices or other pharmacies otherwise.
Hospital Transfer of Drugs to Ambulance Services

Recent 2015 legislation HB 1625 allows for transfer of drugs by hospital pharmacies to ambulance services.

Must follow specific protocols established by Medical Program Director and via approved EMS protocols.

Drugs must be transferred from license to license, not loaned.

Must be located in county of service or adjacent county.
2015 Clinic possession of Drugs

SSB 5460 2015

Medical clinics owned or operated within a hospital system may possess drugs by transfer of drugs from the hospital pharmacy to the clinic by:

A clinic having a Health Care Entity license and following HCE regulations on drug security and storage and appropriate DEA licensing.

Clinic being licensed under the hospital pharmacy license (all regulations pertaining to hospital pharmacy apply and reflect on the main license). Work in progress to determine fee and process.

Have a single prescriber take responsibility for clinic medications under their license. (hospital cannot transfer to prescriber’s license; wholesaler license required)
90 Day supplies of Prescriptions Medication

SSB5459 (Effective July 28, 2013)

This law allows, a pharmacist (in his or her professional judgment) to dispense up to a 90-day supply of a drug (except controlled substances) when a prescription is for an initial quantity of less than 90-day supply with refills. The prescription must meet the following conditions:

- The patient has completed an initial 30-day supply or the prescription continues the same medication previously dispensed in a 90-day supply.
- The total quantity of doses does not total more than the prescriber authorized including refills; and
- The prescriber hasn’t specifically said it is medically necessary to dispense in the initial amount followed by refills.
- The pharmacist shall notify the prescriber of the quantity of dosage units dispensed.
Answers to questions

1. Can I fill a prescription for hydrocodone from a naturopathic physician?

NO, they are restricted from prescribing class 2 drugs
Answers to questions

2. Does a prescription for a chronic pain opioid medication require a diagnosis by the prescriber?

YES, per the pain regulations for the five prescriber boards and commissions
Answers to questions

3. I can start my drug Take Back program before any approvals?

False, You must first change your DEA registration and follow all established DEA regulations. In addition, you must have pharmacy commission approval for your plan prior to implementation.
4. Washington pharmacies are subject to the 5% rule on drug transfers.

True, however in Washington State, it is based upon total dollar sales, versus total units.
Answers to questions

5. I can delegate my PMP account access to my technician.

Not yet, but rule work is progressing to allow this practice.
QUESTIONS ??

Contact Information

Chris.humberson@doh.wa.gov
360-236-4853

Commission E-mail Address :
WSPQAC@doh.wa.gov