WORKSHOP C
Rational Prescribing and Drug Diversion

COPE Course 44082-EJ
Rational Prescribing and Drug Diversion

About Me...
Native Memphian
2001 SCO Graduate
Primary Care Residency 2004
Joined SCO faculty in 2008
Started teaching Systemic Pharmacology I and II in 2011
Master's Degree in Pharmacology and Toxicology in 2013
  - Michigan State University
Teaching Drug Diversion Course since 2010

What Will I Learn Today?
Legal Factors of Prescribing
Most Commonly Prescribed Controlled Substances
State Efforts to Decrease Abuse of Controlled Substances
  - TN Prescription Safety Act
Tennessee Chronic Pain Guidelines
Rational Prescribing and Prescription Delivery
Tips to Avoid Prescription Errors
Legal Factors of Prescribing

Legal Factors (USA)
U.S. Government recognizes two classes of drugs
- OTC
  - Can be self-administered by the layman for self-limited conditions and for which labels can be written for lay comprehension
  - Represent half of all drug doses consumed by the American public
- Rx Only
  - Require a prescription from a licensed prescriber

Who Are “Licensed Prescribers”?
Prescribing privileges are controlled by the state licensing boards
- Delegated powers by the state legislatures
Professions with prescribing privileges:
- Physician
- Dentist
- Podiatrist
- Veterinarian
- Optometrist
- Nurse Practitioner or Midwives
- Physician’s assistants
- Pharmacists
“Limited” Scope

Optometrists in Tennessee are limited (somewhat)
- Prescriptions MUST be “in the course of professional practice, or in good faith to relieve pain and suffering, or in good faith to diagnose and treat conditions or diseases of the eye or eyelid”
- Can be broad interpretation
- Recommend no prescription without supporting documentation

Varying Responsibility

Licensed Prescriber
- Granted authority to prescribe “Rx Only” medications

Pharmacist
- Authorized to dispense prescriptions based on a prescriber’s order and the medication order is appropriate and rational for the patient.

Nurses
- Authorized to administer medications to patients subject to a prescriber’s order

Government Control

While the individual state legislatures have the right to control who can prescribe/dispense, it is the federal government who controls the labeling and distribution of drugs.

Prescription drugs are controlled by the United States Food and Drug Administration
FDA
Established in 1906
- Pure Food and Drug Act
- Additional legislation through the years has given additional responsibilities
Oversees the drug evaluation process in the USA and grants approval for marketing of new drug products
- Must show through rigorous testing that a drug is “safe and effective” for a specific use

Labeled and Unlabeled Use
The FDA approves a drug only for the specific uses proposed and documented by the manufacturer in its New Drug Application.
- Labeled use = Approved Use
  - Set forth in package insert
- Off-labeled use = use of a medication in the treatment of any unapproved condition in which the drug may be useful
  - NOT restricted by FDA regulations
  - Use caution – courts may consider the package insert as a complete listing of the safe uses of the medication

Controlled Substances
Title II of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970
- Federal Controlled Substances Act
- Regulates each step of the handling of controlled substances
  - Closed system
  - Enforced by the DEA
Physicians must be authorized to prescribe controlled substances by the jurisdiction in which they are licensed and registered with the DEA
DEA Number

What is it?
- Number assigned by the DEA for the purposes of tracking controlled substances
- 2 letters followed by 7 digits
- Required to be on the written prescription

How do I get one?
- Apply online at www.deadiversion.usdoj.gov
- Cost is around $731
- Must be renewed every 3 years

Controlled Substances

Common Classes of Controlled Substances

Opioids
- “Pain Pills”
Benzodiazepines
Barbiturates
Opioids

Examples
- Codeine
- Heroin
- Hydrocodone
- Meperidine (Demerol)
- Methadone
- Morphine
- Oxycodone
- Tramadol (Ultram)*

Opioids

Indications
- Relief of Pain (from any source)
- Most common optometric application would be in treatment of severe corneal or orbital injury
  - Corneal abrasion
  - Corneal burn
  - Laceration
  - Use your judgment…
- Other uses…
  - Anesthesia (not true anesthesia)
  - Antidiarrheal
  - Antitussive
  - Treatment of addiction

Opioids

Mechanism of Action
- Bind to opiate receptors in the spinal cord
  - Decrease conduction of pain signal to the brain
- Also bind to opiate receptors in the brain
  - Cause sedation and euphoria
Side Effects of Opiates

Physical Dependence

- Very common
- Withdrawal response:
  - Irritability, insomnia, nausea, vomiting, diarrhea, chills alternating with flushing, sweating, muscle cramps, pupil dilation
  - NOT life threatening
  - Addict may delay treatment for addiction in order to avoid
  - Less intense for methadone withdrawal
  - "relaxed withdrawal"
Side Effects of Opiates

Psychological Dependence (addiction)
- Very common
- Compulsive drug use with strong craving for the drug
- May be so strong will commit crime in order to obtain

Contraindications to Opiate Use

In certain situations, use of opiate receptor agonists should be used with great care
- Shock
- Head injuries
- Opiates can increase intracranial pressure and add to increased intracranial pressure caused by the injury itself
- Obstetrics
  - Systemically can prolong labor
  - Hard on baby
- Emphysema/asthma
- Opiate reduces respiratory rate

Opiate Prescribing Tips

Tylenol #3 (acetaminophen 300 / codeine 30)
Lortab 5 (acetaminophen 300 / hydrocodone 5)
- Now schedule II

Dosage
- 1-2 by mouth every 4-6 hours for pain
- Limit number to 2-3 days supply
- NO refills
Benzodiazepines and Barbiturates

Examples
- Benzodiazepines
  - Alprazolam (Xanax)
  - Diazepam (Valium)
  - Eszopiclone (Lunesta)
  - Zolpidem (Ambien)
- Barbiturates
  - Phenobarbital

Benzodiazepines and Barbiturates

Indications
- Sedative
- Reduce Anxiety
- Anti-epileptic
- Sleep induction
- Anesthesia

Optometric Use
- Reduction of pre-surgical anxiety (benzodiazepines)
- Treatment of eyelid spasms?
  - Sleep induction (keep eye closed)

Important Note
- Benzodiazepines and barbiturates are NOT analgesics
  - Do not reduce the perception of pain
- Often used as an additive agent in anesthesia and analgesia but NOT effective in pain relief
Benzodiazepines and Barbiturates

Mechanism of Action
- Similar for both
- Bind to different sites on the GABA receptor
  - Increase affinity of GABA neurotransmitter to receptor
  - Enhances inhibitory affect of GABA

Benzodiazepine Side Effects

Tolerance
- Reduced effectiveness is noted with long term use
- Reduced sensitivity to drug, NOT more rapid elimination
- Chronic use of alcohol and/or barbiturates causes a reduced sensitivity
  - "cross-tolerance"
Benzodiazepine Side Effects

Dependence
- Abrupt discontinuation leads to signs of withdrawal
- Anxiety, insomnia, irritability, involuntary muscle twitches (opposite of effects of drug)
- Gradual discontinuation (taper) required

Abuse
- Cause mild excitation or arousal at low doses
- Low intensity – abuse is uncommon

Benzodiazepine Side Effects

Common
- Amnesia
- Often a desired effect (medical procedures)
- Daytime sedation
- Continuation of effect
- Disinhibition
- Some reports of “bizarre” behavior and hallucinations
- In the absence of other drugs, benzodiazepine overdose is NOT lethal

Barbiturate Side Effects

Dependence
- Abrupt discontinuation leads to signs of withdrawal
- Anxiety, insomnia, and irritability

Abuse
- At low doses cause mild excitation or arousal
- Recreational abuse is relatively unusual
Barbiturate Side Effects

Common
- Sedation
- Addiction
  - Highly addictive
- Hypotension with IV use
  - Can be lethal in overdose even in the absence of any other drugs
  - In part due to drug-induced, decreased sensitivity to plasma carbon dioxide concentration
  - Decreased respiratory activity

Benzodiazepine Prescribing Tips

For anxiety or muscle spasms
- Diazepam 2-10 mg bid-qid
- TAPER dose if long-term use

For induction of sleep
- Zolpidem 5 mg at bedtime
  - Pt must have a full 7 hrs to devote to sleep

I do not recommend using barbiturates in any clinical situation that is likely to come up in optometric practice
Carisoprodol (Soma)
Centrally acting spasmolytic
- Gives alteration in pain perception and sedation
Not well-understood
- Thought to act on the brainstem
Indicated for the relief of acute muscle spasm
Can cause significant sedation as well as confusion and visual hallucinations
No true optometric indication

Drug Schedules
Controlled substances are divided into schedules based on abuse potential
- Individual states CAN have additional schedules
- TN schedules same as Federal
Schedule I
- Substances with no accepted medical use in the U.S.
  - Heroin, LSD, Peyote, Mescaline, THC, etc.
  - Many states have legalized the medical or non-medical use of THC
  - Still illegal Federally!

Schedules
Schedule II
- Substances that have a high abuse potential with severe psychic or physical dependence liability
- Contains certain narcotic, stimulant, and depressant drugs
- Handwritten Rx only (or eRx), NO refills
- Example:
  - Oxycodone (percocet, percodan, tylox)
  - Hydrocodone (loratab, vicodin)
- Reclassified as of October 6, 2014
Schedules

Schedule III
- Substances with abuse potential less than those in Schedule I and II
- Due to widespread abuse, many state legislatures place anabolic steroids on schedule III status
- Can be called in, limited refills
- Examples:
  - Codeine (Tylenol #3)

Schedule IV
- Substances with abuse potential less than those in schedule III
- Examples:
  - Barbital
  - Phenobarbital
  - Diazepam (Valium)
  - Lunesta, Ambien, etc

Schedule V
- Consist of certain preparations containing limited amounts of certain narcotic drugs generally for the antitussive and antidiarrheal purposes
- Can be sold OTC by a pharmacist
- Usually "behind the counter" but a prescription is generally not needed
Prescription Orders for Controlled Substances

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.

- Documentation is key!

It is illegal for a physician to prescribe a controlled substance for themselves

- Legal (but questionable) for other prescription meds
- For family members: written record must exist for prescription of controlled substances

Execution of the Order

Prescriptions for controlled substances must be dated and signed on the day of their issuance

Full name and address of patient is required along with the printed name, address and DEA number of the practitioner

- Signed the way one would sign a legal document

Preprinted orders not allowed and presigned Rx blanks are prohibited by federal law

Oral Orders

Schedule III through V may be called in

Schedule II prescriptions may be telephoned to a pharmacy in emergency situations

- Immediate administration is necessary
- No appropriate alternative treatment is available
- It is not reasonably possible for the physician to provide a written prescription prior to the dispensing
Refills

Schedule II may not be refilled for any reason

Schedule III and IV
- Refills may be issued either orally or in writing
- Not to exceed five refills or six months after issue date

Schedule V
- No restrictions on number
- If no refills are noted at time of issuance, a new prescription must be made

Dispensing Controlled Substances

Pharmacy or other dispensing entities must also be registered with the DEA
- Must still have a physician’s order

May call to verify information on the written prescription
- Patient’s name can NOT be changed
- It is legal to dispense a 3 day supply without phone verification
- Balance must be dispensed within 72 hours

Internet Dispensing

It IS legal to obtain controlled substances from an internet pharmacy
- They are required to obtain original written form prior to mailing
- MAJOR cause of concern for the DEA
- Considering ways of controlling diversion
Drug Abuse Prevention

What is Prescription Drug Abuse?

Prescription drug abuse is the intentional use of a medication:
- without a prescription;
- in a way other than as prescribed; OR
- for the experience or feeling it causes.

Approximately 7.0 million persons were current users of psychotherapeutic drugs taken non-medically in the US in 2010 (2.7% of US population)
- Pain relievers - 5.1 million
- Tranquilizers - 2.2 million
- Stimulants - 1.1 million
- Sedatives - 0.4 million


What Fuels Prescription Drug Abuse?

Patient Factors Driving Abuse
- Misconceptions about their safety
- Increasing environmental availability
- Varied motivations for their abuse

Health Risks
- Opioids
  - Addiction, overdose, heightened HIV/Hepatitis risk
- CNS Depressants
  - Addiction and dangerous withdrawal symptoms, overdose
- Stimulants
  - Addiction and other health consequences

Statistics from a National Perspective...

Prescription painkiller overdoses killed nearly 15,000 people in the US in 2008. This is more than 3 times the 4,000 people killed by these drugs in 1999.

In 2010, about 12 million Americans (age 12 or older) reported nonmedical use of prescription painkillers in the past year.

Nearly half a million emergency department visits in 2009 were due to people misusing or abusing prescription painkillers.

It is estimated that 20 percent of people in the United States have used prescription drugs for nonmedical reasons.

Nonmedical use of prescription painkillers costs health insurers up to $72.5 billion annually in direct health care costs.

http://www.cdc.gov/vitalsigns/PainkillerOverdoses/index.html

Statistics from a Tennessee Perspective...

Tennessee-Specific CSMD Data (1/1/03 – 12/31/10)
- One-third of TN population filled an opioid prescription each year
- 2.5 fold increase in overdose deaths (422 to 1059 per year)
- 1.3 fold increase in prescription rates (108.3 to 142.5 per 100 population per year)
- Increased risk of death:
  - 4 or more prescribers
  - 4 or more pharmacies
  - More than 100 milligram morphine equivalents (MME)


Statistics from a Tennessee Perspective...

In 2010, evidence showed that in Tennessee, there were enough prescriptions dispensed to represent:
- 51 hydrocodone for EVERY Tennessean greater than 12 y/o
- 22 alprazolam for EVERY Tennessean greater than 12 y/o
- 21 oxycodone for EVERY Tennessean greater than 12 y/o

Statistics provided by the Tennessee Department of Mental Health and Substance Abuse Services.
Sources of Prescription Opioids

<table>
<thead>
<tr>
<th>Source</th>
<th>1-29 days (low risk)</th>
<th>30-99 days</th>
<th>100-199 days</th>
<th>200-365 days (high risk)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Given by a friend or relative</td>
<td>54.4%</td>
<td>61.9%</td>
<td>48.5%</td>
<td>26.4%</td>
</tr>
<tr>
<td>Prescribed by 1 or more physicians</td>
<td>19.7%</td>
<td>17.9%</td>
<td>19.5%</td>
<td>27.3%</td>
</tr>
<tr>
<td>Stolen from a friend or relative</td>
<td>4.9%</td>
<td>5.3%</td>
<td>4.6%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Bought from a friend or relative</td>
<td>11.3%</td>
<td>7.6%</td>
<td>15.6%</td>
<td>23.2%</td>
</tr>
<tr>
<td>Bought from a drug dealer or other stranger</td>
<td>4.2%</td>
<td>2.1%</td>
<td>5.3%</td>
<td>15.2%</td>
</tr>
<tr>
<td>Other</td>
<td>5.5%</td>
<td>5.3%</td>
<td>6.4%</td>
<td>5.0%</td>
</tr>
</tbody>
</table>


Behavior of Drug Seekers

Challenge is to distinguish between legitimate pain complaints and drug seekers
- Every socioeconomic status
- Any age
- Any gender

Patients become drug seekers for many reasons
- Developed as progression of disease
- Poorly managed pain
- Tolerance
- Unrecognized addiction
- Untreated depression

Behavior of Drug Seekers

Common Characteristics
- Unusual behavior in the waiting room
  - Complaints of “excruciating pain” to receptionist or tech but do not appear in distress while waiting for doctor
  - Extremes in attitude
  - Hostile assertiveness
  - Excessive politeness
  - Vague or evasive answers to medical history questions
  - Use medical jargon

ProAssurance Medical Risk Management Advisor, Third Quarter 2006 – Vol 14, Issue 3
Behavior of Drug Seekers

Methods to obtain controlled substances
- Repeated visits with pain complaints
- Walk-ins
- Request late afternoon appointments
- Especially Fridays
- Refuse trips to ER when calling after-hours
- Request drugs by name
- “Loose” original prescription
- Refuse work-ups
- Alter prescriptions
- Change refill numbers

Managing Drug Seekers

Document ALL medications taken by or prescribed for a patient
- Including samples
Limit refills on pain medications
- I prefer NO refills
Write prescriptions for limited quantity
Keep prescription pads secure
- Do NOT pre-print DEA number
Don’t rely on previous diagnosis

TN Prescription Safety Act

Tennessee Public Chapter Number 880
Signed into law by Governor Haslam on May 9th, 2012
Joint effort between the TN Departments of Health, Mental Health, Safety and the Governor’s Office
Input provided by healthcare providers, professional associations, and other stakeholders

http://health.state.tn.us/boards/ControlledSubstances/faq.shtml
TN Prescription Safety Act

Important New Definitions:

"Dispenser" means a pharmacist, a pharmacy, or any healthcare practitioner who is licensed and has current authority to dispense controlled substances.

"Healthcare practitioner" means:
(A) A physician, dentist, optometrist, veterinarian, or other person licensed, registered, or otherwise permitted to prescribe, distribute, dispense, or administer a controlled substance in the course of professional practice;
(B) A pharmacy, hospital or other institution licensed, registered, or otherwise permitted to distribute, dispense, or administer a controlled substance in the course of professional practice;

"Healthcare practitioner extender" means any registered or licensed healthcare professional, and up to two (2) unlicensed persons designated by the prescriber or dispenser, who act as agents of that prescriber or dispenser. The prescriber or dispenser shall be responsible for all actions taken by their agents pursuant to this act.

Tennessee Prescription Safety Act

Established a database to monitor the prescription and dispensing of controlled substances
- For prescribers with DEA numbers AND dispensers
  - Must be in practice currently
  - More than 15 calendar days per year
  - Should have registered by January 1, 2013
  - Register at www.tncsmd.com

Who MUST to be registered in the database?

Effective January 1, 2013: All prescribers with DEA numbers who prescribe controlled substances and dispensers in practice providing direct care to patients in Tennessee for more than fifteen (15) calendar days per year shall be registered in the controlled substance database.

New licensees shall have up to thirty (30) calendar days after notification of licensure to register in the database.

Authorization for dispensers to check the database:
A dispenser or pharmacist conducting drug utilization or medication history reviews who is actively involved in the care of the patient but not authorized to dispense controlled substances
A dispenser having authority to dispense controlled substances to the extent the information relates specifically to a current or a bona fide prospective patient to whom that dispenser has dispensed, is dispensing, or considering dispensing any controlled substance

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml
TN Prescription Safety Act

When MUST the database be checked?

Prescribers: Beginning April 1, 2013, all prescribers or their designated healthcare practitioner's extenders, unless otherwise exempted (next slide), shall check the controlled substance database prior to prescribing all opioids and benzodiazepines* at the beginning of a new episode of treatment and at least annually when that prescribed controlled substance remains part of the treatment.

Dispensers: Beginning January 1, 2013, before dispensing, a dispenser shall have the professional responsibility to check the database if the dispenser is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance identified by the committee as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes.

*Subject to change: The committee may require a check of the database for additional Schedule II-V controlled substances identified by the committee as demonstrating a potential for abuse.

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

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When are prescribers NOT required to check the controlled substance database?

- Patients currently receiving hospice care
- Medical specialty determined by the committee to not be required to check the database (none currently)
- Non-refillable prescriptions as part of treatment for surgical procedure performed in a licensed healthcare facility
- Quantity does not exceed a single, seven (7) day treatment period and does not allow for refills
- The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68 or a mental health hospital licensed under title 33 (Addison Sharp)

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

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When are dispensers NOT required to report to the CSMD?

- Drugs administered directly to the patient
- Drug samples
- Any drug dispensed by a licensed veterinarian; quantity dispensed is limited to amount adequate to treat a non-human patient for a maximum of 48 hours
- DEA-registered narcotic treatment programs (21 CFR 1304.24)
- Drugs dispensed by a licensed healthcare facility; quantity dispensed is limited to amount adequate to treat patient for a maximum of 48 hours

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml
TN Prescription Safety Act

Mandatory dispenser reporting to CSMD:
Information in the database shall be submitted by a procedure and in a format established by the committee, at least once every seven (7) days for all the controlled substances dispensed during the preceding seven (7) day period.
Dispensing reports are not required to be filed electronically. If filing reports electronically presents an undue hardship, the committee may waive electronic reporting requirements for a period of up to two years.
Controlled substance information to be reported to the database:
- Prescriber identifier
- Dispensing date
- Patient identifier
- Substance dispensed
- Quantity dispensed
- Strength dispensed
- Estimated days supply
- Dispenser identifier
- Date prescription issued
- New or refill
- Source of payment
- Other relevant information

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

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Designation of Healthcare Practitioner Extenders by practitioners:
The extenders must act under the supervision of a licensed prescriber or dispenser. A licensed or registered health care professional designated by the prescriber or dispenser and up to two (2) non-licensed staff members can access the database.
As of January 1, 2013 designated extenders can register at www.tncsmd.com and will need specific information from their supervising practitioners.

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

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Electronic prescriber and dispenser access to CSMD mandated:
Each person or entity operating a practice site where a controlled substance is prescribed or dispensed to a human patient shall provide for electronic access to the database at all times when a prescriber or dispenser provides healthcare services to a human patient potentially receiving a controlled substance.
A violation is punishable by a civil penalty not to exceed one hundred dollars per day assessed against the person or entity operating the practice site.

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml
TN Prescription Safety Act

Limitations on Disclosure of Information:
Any prescriber, dispenser or healthcare practitioner extender receiving patient specific information pursuant to subdivision (a)(1), (a)(2), (a)(3), or (a)(4) shall not disclose the information to any person other than:

The patient to whom the information relates for the purpose of adjusting the patient's treatment plans or counseling the patient to seek substance abuse treatment;

Other dispensers or prescribers who are involved or have a bona fide prospective treatment in the treatment of the patient, or dispensers or prescribers identified by the information for the purpose of verifying the accuracy of the information; or

Any law enforcement personnel to whom reporting of controlled substances being obtained in a manner prohibited by §53-11-401, §53-11-402(a)(3) or (a)(6) and required by §53-11-309, or any agent of the prescriber who is directed by the prescriber to cause a report to law enforcement to be made in accordance with §53-11-309(a) and (d).

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

TN Prescription Safety Act: Effective?

Survey of over 900 CSMD Users:

71% of respondents have changed a treatment plan after viewing a CSMD report

73% of respondents are more likely to discuss substance abuse issues or concerns with a patient

57% of respondents are more likely to refer a patient for substance abuse treatment

79% of respondents feel that the CSMD is useful for decreasing doctor shopping

72% of respondents indicated it takes 10 seconds (on average) for the CSMD to return a patients report

2014 CSMD Report

Milligrams of Morphine Equivalents (MME)

More than 9.8 billion milligrams of morphine equivalents (MME) were dispensed in TN in 2013

- Over 1,900 milligrams of morphine equivalents per adult in Tennessee
- Over 1,500 milligrams of morphine equivalents per person in Tennessee

Opioids and Benzodiazepines

71% of all prescriptions dispensed in TN in 2013

- 13,140,812 total
2014 CSMD Report

In 2013:
Number of registrants increased by 56.8% (34,802)
240% increase in the number of patient reports requested (4.49 million)
Number of high-utilization patients ("provider shoppers") identified in the CSMD has steadily decreased

Drug Trends:
- 0.7% increase in the number of overall prescriptions reported to the CSMD
- 0.4% decrease in the number of opioid prescriptions
- 3.6% decrease in the number of BZD prescriptions

Adapted from the CSMD 2014 Report to the 108th General Assembly, TDH, CSMD Advisory Committee

Addison Sharp Prescription Regulatory Act

Public Chapter 430: Provisions regarding requirements for certain controlled substances and requirements for pain clinics:
- 10/1/2013: No opioid or benzodiazepine prescription may be dispensed in greater than 30-day supply.
- 5/16/2013: Exempts prescribers from checking CSMD before prescribing controlled substances for patients in hospitals, nursing homes, and mental health hospitals.
- 7/1/2014: Prescribers must have two hours of CE related to controlled substances biennially.

Additional Regulation of Pain Management Clinics

Certain provisions became effective on May 16, 2013, and other provisions became effective on October 1, 2013.

Chronic Pain Guidelines

Purpose is to "define appropriate treatment of chronic pain" and to "avoid addiction and adverse outcomes"

Guidelines available at:

"Long term goals of appropriate pain management are to improve symptoms, function, and overall quality of life while minimizing adverse effects, addiction, and overdose deaths"
Chronic Pain Guidelines

Key Principles — Section I: Prior to Initiating Opioid Therapy
1. A patient having been prescribed opioids by a previous provider is not, in and of itself, a reason to continue opioids.
2. Reasonable non-opioid treatments should be tried before opioids are initiated. Opioids should be initiated only after other reasonable, appropriate and available treatments for the pain condition have been considered.
3. All minors/pregnant women should have a urine drug test administered by the appropriate women’s health provider.
4. The provider should discuss a birth control plan to prevent unintended pregnancy with every woman of childbearing age who has reproductive capacity when opioids are initiated.
5. The patient’s medical history, physical examination, laboratory tests, imaging results, electro-encephalograms, testing, and/or any other information regarding the plan of care, should be documented in the medical record prior to initiating opioid therapy.
6. Chronic pain shall not be treated by the use of controlled substances through telemedicine.

Chronic Pain Guidelines

Key Principles — Section II: Initiating Opioid Therapy
1. A patient should be prescribed a maximum of four doses of a short acting opioid per day. If a provider deems it necessary to do otherwise then he/she shall clearly document the medical reasons for this decision.
2. Prescribers who are not pain medicine specialists shall not prescribe methadone for a chronic pain condition. (See Pain Medicine Specialist Appendix)
3. The patient shall not prescribed buprenorphine in the form of trans or sublingual buprenorphine for chronic pain condition.
4. Benzodiazepines should be generally avoided in combination with chronic opioid therapy. When the opioid dose reaches 120mg/day or if the benzodiazepine is being used for sedation, the patient should be referred to a mental health professional to assess necessity of benzodiazepine medication.
5. Buprenorphine/benzodiazepine combinations should be avoided for the treatment of chronic pain.
6. Should treatment deviate from recommended guidelines, the reasons shall be documented in the medical record.

Chronic Pain Guidelines

Key Principles — Section III: Treatment With Opioid Therapy
1. All chronic opioid therapy should be provided by a single provider or practice and all prescriptions should be filled in a single pharmacy, unless the provider is informed and agrees that the patient can go to another pharmacy for a specific reason.
2. Opioids should be used at the lowest effective dose.
3. A provider should not use more than one class of agents concurrently. If a provider deems it necessary to do so then the medical reasons shall be clearly documented.

Documentation of the discussion of the five A’s (assessment, activities of daily living, adverse side effects, aberrant drug-taking behavior and effect) at initiation of chronic opioid therapy and at follow-up visits shall be included in the medical record.

Patients on opioid doses of 100mg MME or greater should be referred to a pain specialist for a consultation and/or management. If a provider cannot make the required consultations as outlined above, then he/she shall clearly document why not.
Chronic Pain Guidelines

Tier 1: Non-Pain Medicine Specialists

- All providers who wish to treat patients requiring less than 120 milligram morphine equivalent daily dose (MEDD) shall:
  - Hold a valid Tennessee license issued by their respective board through the Department of Health and a current DEA certification.
  - Attend Continuing Education pertinent to pain management as directed by their governing board.
  - Recommend, but does not require, that providers have completed three years of residency training and be ABMS board eligible or board certified.

- All providers wishing to treat patients requiring 120 MEDD or more shall consult with a Pain Medicine Specialist.
  - Providers treating patients with ongoing opioid therapy (prescribing of 120 MEDD for more than six months in any calendar year) shall obtain at least one annual consultation with a Pain Medicine Specialist.
  - Patients with more complicated cases may require more frequent consultation.

Chronic Pain Guidelines

Morphine Equivalent Dose (MED)

"Equipotent dose of any opioid in terms of morphine" As MED increases, the likelihood of any side effects increases, therefore identifying at-risk patients is a crucial first step towards improving patient safety.

MED Conversion Formula:

\[
\text{Drug Strength} \times \text{Drug Quantity} \times \text{Morphine Equivalent Multiplier} = \text{Day Supply}
\]

Chronic Pain Guidelines

Tier 2: Pain Medicine Specialists shall hold

- ABMS subspecialty certification in Pain Medicine under the boards of Anesthesia, Neurology, Psychiatry and Physical Medicine & Rehabilitation and:
  - An unencumbered Tennessee license and,
  - The minimum number of CME hours in pain management to satisfy retention of ABMS certification.
  - Any exceptions to this must be approved by the respective regulatory board.

- ABPM diplomate status by 7/1/2016 and:
  - Unencumbered Tennessee license and,
  - The minimum number of CME hours in pain management to satisfy retention of ABPM diplomate status.
  - Any exceptions to this must be approved by the respective health-related licensing and regulatory board.
  - Current pain medicine specialists who are qualified to take the ABPM exam may continue to practice as a pain medicine specialist until 7/1/16, when diplomate status will be required.
Public Chapter 820

women shall be criminally charged with “…an assaultive offense for the illegal use of a narcotic drug while pregnant, if her child is born addicted to or harmed by the narcotic drug… or for criminal homicide if her child dies as a result of her illegal use of a narcotic drug taken while pregnant.”

“…a woman actively enrolled in an addiction recovery program before the child is born, [shall] remain in the program after delivery, and successfully complete the program, regardless of whether the child is born addicted to or harmed by the narcotic drug.”

Effective April 28, 2014

Public Chapter 622

Authorizes prescriber, healthcare practitioner extender or dispenser who may place a copy of a patient’s report obtained from the database pursuant to this section in that patient’s medical records. Once placed in a patient’s medical records, any copy of a patient’s report obtained from the database pursuant to this section shall be subject to disclosure on the same terms and conditions as medical records defined under §§ 63-2-101 and 63-1-117.

Effective July 1, 2014

Public Chapter 623

Defined as “opioid antagonist” as naloxone hydrochloride (FDA-approved for the treatment of a drug overdose)

Authorizes a health care practitioner to prescribe an opioid antagonist in the following circumstances if the practitioner is:

- licensed to do so
- acting in good faith
- and the prescription is for a person at risk of experiencing an opiate-related overdose, or for a family member, friend, or a person who is in a position to assist a person at risk of experiencing an opiate-related overdose

Authorizes an individual who receives an opioid antagonist that was prescribed under this bill, to administer it to another person if individual has a good faith belief that the other person is experiencing an opioid related overdose, and the individual exercises reasonable care in administering the drug.

Authorization is granted ONLY after the person administering the medication exhibits competency by completion of an online overdose education program.

Effective July 1, 2014
Doctor Shopping

If Doctor Shopping is suspected based on a review of patient’s records:

Any physician, dentist, optometrist, veterinarian, pharmacist, advanced practice nurse with a certificate of fitness, or physician assistant who has actual knowledge that a person has knowingly, willfully and with intent to deceive obtained or attempted to obtain a controlled substance must report that information within five (5) business days to the local law enforcement agency.

The reporting form can be found at the following link:

Call your nearest law enforcement agency or fax the report to 423-267-8983. Additional questions, call the Meth and Pharmaceutical Task Force at 423-752-1479.

http://health.state.tn.us/boards/Controlledsubstance/faq.shtml

Rational Prescribing and Proper Prescription Delivery

Rational Prescribing

Should base your prescription writing on a series of steps

1. Make a specific diagnosis
   - Can be dangerous to prescribe in order to satisfy a patient’s psychological need for therapy
2. Consider the implications of the diagnosis
   - Understand the disease process and prescribe accordingly
Rational Prescribing

3. Select a specific therapeutic objective
   - Chosen for each pathophysiologic process defined in previous step
   - For example: do you wish to reduce pain, reduce inflammation or halt the disease process
   - Your prescription decisions may differ
4. Select a drug of choice
   - Suggested by the therapeutic objective
   - Must consider patient factors such as allergy, age, other diseases, etc

Rational Prescribing

5. Determine the appropriate dosing regimen
   - Largely determined by the pharmacokinetics of the drug
6. Devise a plan for monitoring and determine the therapeutic end-point
   - Follow-up is important to determine effectiveness and to determine the appropriate stopping point
7. Plan a program of patient education
   - May be most important step
   - Improves compliance

Written Prescriptions

Traditional Method
   - Most often on pre-printed forms
Must be Tamper-Resistant
   - Pantograph or Watermark designed to prevent copying
   - Uniform, non-white background color OR quantity check-off boxes
   - Security features listed on the form
   - Can be on the back
Written Prescriptions

Other requirements
- Full name and address
- Both the patient AND the prescriber
- Prescriber phone number
- Date
- DEA number (if controlled substance)
- Refill instructions
  - Even if zero
  - Signature
  - In ink
  - Include last name and professional degree

Written Prescriptions

Other tips
- Be specific, i.e. “one tablet by mouth”
- Include any formula used to calculate dose
  - So pharmacist can check your math!
- Avoid “use as directed”
- Abbreviations are accepted but it is recommended to write out the directions in English

Verbal Prescriptions

Most prescriptions can be called in
- Must give same information as on written form
- Can be called in by office staff
- Limitations on controlled substances

Do not forget to document any prescription that is called in from alternate locations
Alternative Delivery Systems

Fax
- It IS legal to fax a prescription
- Must be legible
- Contains same information as written Rx
- Limitations on controlled substances
- Tamper-proof paper will come through as “void”
  - Pharmacist must verify

Alternative Delivery Systems

Electronic submissions
- E-prescribing
- Supported by many EMR systems
- Prescription goes straight to pharmacy from your medical record
- Medicare has incentive program for those practicing E-Prescribing
- May soon be required for full payment

E-prescribing Rules

Must be transmitted from your office to the pharmacist
- Do not email!
Transmissions must include:
- Prescribers telephone
- Time and date of transmission
- Pharmacy name
- Electronic signature
- Name of prescribers agent (if any)
Prescribing Errors

7000 Americans die each year due to preventable medication errors

- Cost of approximately $21 billion in wasteful healthcare spending

"Prescribing Medication Errors is a $21 Billion Opportunity" National Priorities Partnership, December 2010

Prescribing Errors

Numeral and Measurement System

- Multiple systems have historically been employed (avoirdupois, apothecaries’ and metric) and been combined with Roman and Arabic numerals
- All orders should be written using metric measurements
- Arabic (decimal) numerals are preferable to Roman numerals
- Use leading zeros (0.125mg)
- Avoid trailing zeros (5 mL instead of 5.0 mL)

Prescribing Errors

Abbreviations

- Many commonly used medical abbreviations are derived from Latin phrases
- No longer the international language of medicine
- There is NO standardized or “official” list of medical abbreviations recognized by health-care associations
- Practitioners often create their own
- Some organizations are recommending that abbreviations not be used at all
- Or at least create a standard list
Prescribing Errors

Omission of Information
- One or more components of the prescription missing
  - No strength/concentration
  - No dosing information
  - No signature
  - Pharmacist can call to verify but that takes time away from two patients

Omission in the Record
Errors of omission are more common in hospital orders and patient records (we see it all the time!)
- Instructions like “resume pre-op meds”, “continue eye drops” or “use medications as instructed”
- Assumes that accurate record of meds or instructions is available
- Can lead to medication errors if the patient calls for further instructions and the person taking the call can not tell what the medication instructions are

Prescribing Errors

Handwriting
- Poor penmanship will compound the likelihood that there will be harmful errors
- Wastes time and resources
- Cited as the second most frequent type of malpractice claim
- Print orders carefully or use pre-printed forms
Clarity!
Ambiguity of Intent
• Must be clear
• Example:
  Azithromycin 1500mg over 3 days
  Azithromycin 1500mg days 1-3
  Azithromycin 500mg once a day for 3 days
• Avoid omitting information for the sake of expediency

Any Questions?

Thank You!