

Prescription Drug Diversion

Clinical Management and Protection

Kenneth Eakland, O.D.
Pacific University
College of Optometry

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Learning Objectives:

- What is drug diversion and why should it matter to optometrists
- What are the laws regarding drug diversion
- What is a provider's role in preventing drug diversion
- What are the strategies for prevention, detection, and response
- Reporting requirements
- HIPAA and Privacy Issues

Drug Diversion

Drug Diversion: General

- Involves the diversion of drugs from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary
- Basically, any act that results in a prescription medication or a precursor chemical being conveyed out of a legal distribution system
- This definition applies to controlled substances and non-controlled prescription drugs

Drug Diversion: General

- **Impact on your practice:**
 - Drug seekers see a multitude of health care professionals to obtain more of the prescription drugs they need to satisfy their need, and/or to sell at high profits on the street
- These drug seekers prey on doctors and their staff, in a relentless attempt to obtain drugs
- Optometry is not exempt!
 - It may be rare, but it can and does happen

Drug Diversion: General

- BUT drug diversion also occurs WITHIN Healthcare
 - By definition, diversion is a covert activity so statistics may not be accurate – it is likely underreported and under-detected
 - Various studies suggest an estimated one in 10 practitioners will fall into drug or alcohol abuse at some point in their lives, mirroring the general population
- Drug diversion by healthcare providers is a pervasive problem among healthcare institutions in the US
- Optometry needs to be aware...

Drug Diversion: Scope of the Problem

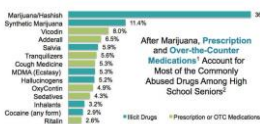


Drug Diversion: The Scope of the Problem

- Prescription drug abuse is nothing new
 - Prescription drugs are the second most abused drug of the past three or four decades
- Obtaining reliable statistics for prescription drug abuse is also difficult, with the most widely used program being that of the Drug Abuse Warning Network (DAWN)
 - Misuse of prescription opioids, CNS depressants, and stimulants is a serious public health problem in the United States
 - Estimated 18 million people (more than 6% of those aged 12 and older) have misused such medications at least once in the past year
 - Estimated 2 million Americans misused prescription pain relievers for the first time within the past year
 - Averages to approximately 5,480 initiates per day
 - Additionally, more than one million misused prescription stimulants, 1.5 million misused tranquilizers, and 271,000 misused sedatives for the first time

Drug Diversion: The Scope of the Problem

- Prescription drug abuse accounts for almost 30% of the overall drug problem in the United States, second only to the marijuana usage



About 1 in 9 youth

or 11.4 percent of young people aged 12 to 20 used prescription drugs nonmedically within the past year.¹



Drug Diversion: The Scope of the Problem

- Perceive that prescription drugs are not as addictive or as abused as common street drugs like cocaine, methamphetamine, and heroin
- Facts indicate that prescription drugs are every bit as addictive as the vast majority of street drugs

Drug Diversion: The Scope of the Problem

• Trends in Prescription Medication Abuse

Monitoring the Future Study: Trends in Prevalence of Various Drugs for 8th Graders, 10th Graders, and 12th Graders, 2010 (in percent)^a

Drug	Time Period	8th Graders	10th Graders	12th Graders
Any Prescription Drug	Past Year	-	-	[8.05]
Adderall	Past Year	2.50	3.10	3.90
Amphetamines	Past Year	4.20	5.20	[4.50]
Narcotics other than Heroin	Past Year	-	-	[2.70]
OxyContin	Past Year	1.20	2.00	1.70
Ritalin	Past Year	1.00	0.70	1.10
Tranquilizers	Past Year	2.40	3.40	3.40
Vicodin	Past Year	0.90	1.10	[1.10]

a. Data are based on self-reported use of drugs for the past year.

Drug Diversion: The Scope of the Problem

- Is drug seeking/drug abuse a problem in your practice?
- National Institute on Drug Abuse (NIDA) reports that more than half of primary care physicians report difficulty discussing misused prescription drugs and substance abuse
 - Optometry is much the same...

Diversion: Where

Diversion: Where

- Where are drugs diverted?
- Drugs are diverted from any site where they are stored, stocked, administered, prescribed, or dispensed!!

Diversion: Where

- Diversion of prescription drugs from medical sources into the illegal market may occur at any point in the distribution process, any site where they are stored, stocked, administered, prescribed, or dispensed!!
- Manufacturers
- Wholesale distributors
- Hospital
 - Doctors
 - Nurses
 - Ancillary staff
- Private Practices
 - Unscrupulous providers, duped providers, thief
- Patients
- Pharmacists
- Veterinarians

Diversion: When

Diversion: When

- When are drugs diverted?
 - When procedures are not followed
 - When records are not reviewed
 - When staff are too trusting or naïve
 - ANYTIME!

Diversion: What

Drug Diversion: What

- According to the Drug Enforcement Administration and the National Survey of Drug Use and Health Data, there are five drug classes with a high potential for diversion and abuse:
 - Opioids
 - Central nervous system stimulants
 - e.g., amphetamine, dextroamphetamine, methamphetamine
 - Central nervous system depressants
 - e.g., barbiturates, benzodiazepines
 - Hallucinogens
 - e.g., ketamine
 - Anabolic steroids
 - e.g., testosterone
- Source: Medicare Learning Network, "Medicaid Program Integrity: What Is a Prescriber's Role in Preventing the Diversion of Prescription Drugs," <https://www.cms.gov/Outreach-and-Education/.../Drug-Diversion-ICN901010.pdf>.

Most Commonly Diverted Prescription Medications

Generic	Brand	Classification
Hydrocodone	Vicodin, Vicodin ES, Lorcet, Lortab, Codiclear DH, Tussionex, Cogesic, Anexia	II Changed from III in Oct 2018
Alprazolam	Xanax	IV
Acetaminophen with codeine	Tylenol#3	III
Butalbital with codeine	Florinal with codeine	III
Propoxyphene	Darvon, Darvocet,	IV
Methylphenidate	Ritalin	II
Diazepam	Valium/Valmeperidine Demero	II
Oxycodone	Percodan, Percocet	II
Hydromorphone	Dilaudid	II
Carisoprodol	Soma	N/A

Diversion: Why

Drug Diversion: Why

- Prescription drugs are diverted because they have more reliable and predictable effects than street drugs
- Illegal narcotics may be "cut" with unknown diluents, or laced with toxic byproducts such as cyanide, stemming from unsanitary manufacturing techniques
- The results of taking a brand name drug are consistent and predictable, whereas the effects of crack or heroin may be different with each ingestion—even potentially lethal
- Abusers prefer the known potency and quality of prescription drugs manufactured by the regulated pharmaceutical industry

Drug Diversion: Why

- Financial Consequences of Drug Diversion
 - The estimated cost of prescription drug diversion and abuse to public and private medical insurers is \$72.5 billion a year
 - Much of which is passed to consumers through higher health insurance premiums
 - Additionally, the abuse of prescription opioids is burdening the budgets of substance abuse treatment providers, particularly as prescription opioid abuse might be fueling heroin abuse rates in some areas of the United States

Source: National Drug Intelligence Center, Drug Enforcement Administration, "National Prescription Drug Threat Assessment," <http://www.justice.gov/archive/ndic/pubs33/33775/33775p.pdf>

Diversion: Who

Diversion: Who

- Diversion of prescription drugs from medical sources into the illegal market may occur at any point in the distribution process:
 - Manufacturer employees
 - Wholesale distributors employees
 - Doctors
 - Nurses
 - Pharmacists
 - Ancillary staff
 - Patients
 - Burglars

Diversion: Who

- Patients - Doctor Shoppers:
 - The "doctor shopper" can be defined as a person who visits several different practitioners and presents with various maladies which are usually treated with a controlled substance, never informing any of the prescribers that he or she is being treated by another doctor
 - A doctor shopper is not always an unemployed, indigent person, they are well-dressed, well-educated, and speak very convincingly
 - They often hit multiple doctors, emergency rooms, 24-hour clinics, and pharmacies
 - A doctor shopper can earn a living by obtaining controlled substances and selling them on the street, usually keeping a supply of drugs for personal use

Diversion: Who

- Patients - Doctor Shoppers:
 - Most often the complaint will be for something very subjective, such as pain
 - Pain cannot be measured by objectively by a physician
 - Because pain cannot be quantified through clinical or laboratory tests, yet can impede healing and cause suffering, doctors are taught to trust patients
 - The doctor shopper exploits this trust
 - More experienced doctor shoppers keep detailed diaries regarding which pharmacies and doctors they have visited most recently in order to prevent the mistake of showing up "too early"

Diversion: Who

- **Patients - Doctor Shoppers:**
 - Law enforcement agencies who concentrate on prescription drug diversion on a full time basis are likely spending over 40% of their time investigating doctor shopping cases
 - Doctor shoppers typically are visiting multiple practitioners that can be doctors, dentists, and even veterinarians.
 - Example: Woman was visiting 69 doctors at one time, and having the prescriptions filled at over 21 different pharmacies in a three state area.
 - The majority of doctor shoppers are visiting between 5-10 practitioners
 - Health care fraud averages \$10-\$15,000 for each diverter per year
 - There is no accurate account of how many billions of dollars are lost as the result of prescription drug scams and the use of private and public health care insurers
 - This represents an enormous source of illegally gained prescription drugs in the United States each year
 - More on this later on how we are using technology to combat this!!

Diversion: Who

- **Patients - Professional Patients:**
 - Use genuine illnesses or an obvious physical deformity to convince doctors to prescribe controlled substances
 - Are career patients who work for a middleman and are paid per prescription
 - Use any pre-existing condition that can be exploited to gain sympathy
 - Paraplegics and amputees often are used as professional patients
 - For example, amputees may abrade the stump to make it appear infected in order to obtain prescriptions for antibiotics and pain medications
 - They will ignore the antibiotic and only fill the prescription for the pain medication

Diversion: Who

- **Patients - Professional patients**
 - They know the medical aspects of their disease; use professional resource materials, such as the WebMD, or textbooks not generally accessed by other lay public; and exploit medical jargon or "buzzwords" that are familiar to clinicians
 - For example, the patient may complain of a migraine that is "intense, but has my usual pattern," meaning that treatment requires only medication and not diagnostic tests

Diversion: Who

- **Patients - Professional patients**
 - Try to persuade providers to diagnose by history
 - When tests are performed, they may try to make the results fit their alleged disease
 - May arrive with their own diagnostic reports from prior "workups."
 - In general medicine the usual complaints include: back pain, orthopedic problems, narcolepsy, headaches, carpal tunnel syndrome, sciatica, diabetic neuropathies, herpetic neuralgia, depression or anxiety, insomnia
 - In optometry reports have seen herpetic neuralgia, or self-induced conjunctival injuries (dilute monoethanolamine in Oven Off causes aggressive looking conjunctivitis)
 - **Attempt to control the interview and apply psychological pressure to health care providers**
 - They often refuse workups or leave before treatment is completed, if they perceive their drugs of choice will not be given
 - Can be overly talkative, polite, and friendly with staff, trying to evoke sympathy and manipulating them to dispense the right drugs

Diversion: Who

- **Patients - Entrepreneurs**
 - Are "street pharmacists" who obtain prescriptions for medications that can be resold for profit
 - They are engaged in a covert business activity that entails few risks and great rewards for minimal effort
 - Often refuse diagnostic testing, intramuscular injections, or medications for immediate consumption
 - They steal prescription pads; forge prescriptions; or call in prescriptions by phone, while posing as a prescribing doctor
 - They encourage providers to prescribe a maximum amount of pills or ask for a number that is easily converted to a greater one (for example, 10 can become 40 or 100 with a stroke of a pen)
 - They will also request that prescriptions be written separately (so they can selectively fill them) and discarding the ones for medications without street resale value

Diversion: Who

- **Patients - Entrepreneurs**
 - Potent extended-release medications, such as oxycodone (Oxycontin), that can be crushed and used for immediate effects, are especially sought (20\$ per pill!)
 - Often they express a preference for brand name drugs over generics because of street recognition as "the real thing"
 - They may even express a preference among drugs in the same class based upon resale value
 - High-dose hydrocodone/acetaminophen (Percocet) — with a street value of \$15 per pill versus oxycodone/acetaminophen (Vicodin) at \$10 street value per pill
 - Entrepreneurs are often hurried not wanting to spend time for diagnostic work up
 - They know exactly what they want, adamantly refusing alternatives

Diversion: Who

- Patients - Chemically Dependent Patients:
 - Often confused with criminal drug seekers
 - They are compulsive users of controlled substances and will often hoard a supply for fear of running out
 - Have a fear of withdrawal and will do anything necessary to prevent it
 - Visit other doctors at urgent care centers and emergency rooms to get the supply they need
 - They are less likely to sell drugs on the street, but they seek out substitute doctors when cut off or denied narcotics by their current doctor



Diversion: Who

- Doctors - Impaired Professionals:
 - Although the degree to which doctors, nurses, and pharmacists divert prescription drugs is uncertain
 - National Association of Drug Diversion Investigators (NADDI) reports:
 - Almost half of all diversion cases involve healthcare professionals
 - Among practicing pharmacists, it is estimated that 10% have problems with drug and alcohol dependence (other professions 'appear' to be about the same)
 - Healthcare providers divert in order to maintain their chemical dependence, or they will sell prescription medications on the black market for monetary gain

Diversion: Who

- Doctors - Criminal Practitioners
 - The vast majority of practitioners are honest members of their profession and seek to provide healing and comfort
 - Federation of State Medical Boards indicates that less than 1% of doctors in this country are ever sanctioned for anything, not just improper prescribing.
 - The very small percentage that do, these offenses typically involve an exchange of prescriptions for sex, street drugs, and ultimately, money

Diversion: How

Diversion: How

- How are drugs diverted?
- A partial list!
 - Theft
 - Record alteration
 - Prescription forgery
 - From "wastage"
 - Family sharing... "Some for you... some for "me"
 - Trading

Diversion Tactics: At the pharmacy

- Most scams take place during the evening or on weekends, when the pharmacist does not have an opportunity to verify the prescription with the prescriber

Diversion Tactics: At the pharmacy

- Forgeries:
 - Simply add refills, or to change the number of tablets



Diversion Tactics: At the pharmacy

- Fake Call-Ins:
 - Posing as a physician or physician's staff member, a drug seeker will telephone pharmacies requesting new prescriptions or add additional refills to an existing prescription



Diversion Tactics: At the pharmacy

- Prescription blanks:
 - Stolen out of doctors examination rooms
 - A person will travel from pharmacy to pharmacy and town to town forging prescriptions for controlled substances
 - With a scanner and color laser printer a prescription can be scanned and reproduced to create a perfect duplicate of the original
 - Some printed their own supply of prescription pads with a fictitious physician name, address, and phone number
 - When a pharmacist tries to verify the prescription by contacting the prescriber using the phone number listed on the prescription, the forger's accomplice will pick up on the other end and pretend to be the physician

Diversion Tactics: At home

- Family sharing of medications – nearly 60% of prescription medications used non-medically are obtained from family or friends:
 - Educate patients on the dangers of sharing their drugs with family and friends
 - Teach patients how to cope with pain without the use of medications
 - Stress that “doing prescription drugs” is the same as “using street drugs”

Diversion Tactics: At the provider

- One staff member calling in prescriptions for another staff member, both of who are responsible for phone verification of valid RX when the pharmacy calls
- Staff members calling in prescriptions for friends/family members
- Stealing and forging of blanks

NEVER PRE-SIGN BLANKS!!

Diversion Tactics: At the provider

- Using a False Name or Address:
 - Doctor shoppers will often refuse to give a home phone number or they will state that their number is disconnected
 - Multiple adults will share the same address and receive similar prescriptions for controlled substances
 - Asking for positive photo I.D. often catches this person by surprise, and they often quickly excuse themselves and do not return

Diversion Tactics: At the provider

- **On-call/Call-in Scam:**
 - The patient finds out which doctors in a group are on-call for each other
 - The patient then calls the on-call physician and states that he or she is a patient of another doctor in the group
 - The patient tells the on-call doctor that he has pain and needs medication until he can get into the office, or, he says that the medication is just not working for his pain, so he needs something stronger

Diversion Tactics: At the provider

- **Lost or Stolen Medications:**
 - "I dropped my medications down the toilet" or "I left my pills in my car and someone stole them"
 - "Traveling through town" or "luggage got lost"
 - In the event of theft of a controlled substance, local law enforcement officials must be contacted to conduct a complete investigation
 - A pharmacist must refuse to give any refills of the medications in question until the person presents proper documentation of the crime
 - Doctors should report but often they just rewrite a new Rx

Diversion Tactics: At the provider

- **Claims of Allergies:**
 - While there might be legitimate claims of allergy to a generic formulation in some cases, patients seeking to divert drugs will use this tactic to insist on having only the brand name dispensed to them
 - The branded product will produce greater revenue
 - When asked to describe the allergy, the patient will usually describe vague symptoms of discomfort or perhaps a rash, yet will refuse to accept an alternative substitute instead of the brand name medication

Diversion Tactics: At the provider

- **Overprescribing Doctors:**
 - Doctors will write prescriptions for reasons outside the scope of medical practice
 - A large amount of narcotics are prescribed for pain before other, nonaddictive alternatives are explored
 - Patients often pressure a physician into writing a prescription for a narcotic against the your better judgment
 - Drug-seekers often target older doctors with outdated medical knowledge and lax prescription-writing habits
 - A doctor will write a prescription simply to get an annoying or problematic patient out of the office

Characteristics of Overprescribing Physicians

- The American Medical Association describes four mechanisms-- the four "Ds"--by which a doctor becomes involved in overprescribing:
 - **Dated**
 - "Dated" refers to doctor who are out of date regarding knowledge of pharmacology and the differential diagnosis and management of chronic pain, anxiety, insomnia and addiction
 - Reports suggest that doctors are sometimes more out of date in their knowledge and less confident in their skills in these areas than they are in other areas of medical practice
 - Too busy to keep up with CME
 - Unaware of controlled drug categories
 - Only aware of a few treatments or medications for pain
 - Prescribes for friends or family without a patient record
 - Unaware of symptoms of addiction
 - Remains isolated from peers
 - Only education is from drug representatives

Characteristics of Overprescribing Physicians

- The American Medical Association describes four mechanisms-- the four "Ds"--by which a doctor becomes involved in overprescribing:
 - **Duped**
 - Physicians may be duped by patients
 - Doctors are generally a caring, trusting group of professionals who are trying to help their patients in an open and honest relationship based on mutual respect
 - Always assumes the best about his patients and is gullible
 - May be vulnerable to a manipulative patient
 - Leaves script pads lying around
 - Falls for lost medicine excuse -- fell into the toilet or sink
 - Complies with patients who only want specific medications (i.e., OxyContin or Percocet)
 - Co-dependent -- cannot tell patients "No" when they ask for narcotics

Characteristics of Overprescribing Physicians

- The American Medical Association describes four mechanisms-- the four "Ds"--by which a doctor becomes involved in overprescribing:
 - Dishonest (also called: Deliberate or Dealing)
 - Dishonest physicians are uncommon
 - There are a few physicians in every geographic area who are willing to write prescriptions for controlled substances in exchange for financial gain
 - Sells drugs for money, sex, street drugs, etc.
 - Office becomes a pill factory – full of drug seekers and known addicts who will likely sell drugs to others
 - Should be reported to the state board or other law enforcement agencies and appropriately investigated

Characteristics of Overprescribing Physicians

- The American Medical Association describes four mechanisms-- the four "Ds"--by which a doctor becomes involved in overprescribing:
 - Disabled
 - Disabled physicians are defined in this context as physicians with a medical or psychiatric disability, such as chemical dependency or a personality disorder
 - These doctors may be "loose" prescribers of controlled substances and may be less likely to confront patients who are abusing substances out of fear of turning suspicion on themselves
 - Often starts by taking controlled drug samples
 - Asks staff to pick up medications in their names
 - Uses another prescribers' DEA number
 - Calls in scripts in names of family members or fictitious patients and picks them up himself

The Laws

To protect you and the patient

Prescribing Issues of Controlled Substances

- Drug Enforcement Administration
- www.dea.gov



- www.deadiversion.usdoj.gov



Federal Laws:

- Modern U.S. drug laws evolved from initial laws and treaties contained in the Harrison Narcotics Act of 1914
 - Defines 'what' can be sold and 'who' has the authority to prescribe
- The Controlled Substances Act of 1970, and its many subsequent amendments, mandates the strict regulation of controlled substances
 - The act delineates five specific categories or schedules based upon actual or relative abuse potential, related potential for individual or public harm, current knowledge of pharmacologic properties, and the scope and pattern of abuse of the substance or similar substances

Drug Enforcement Agency

- Who:
 - Mid-level practitioners (MLP) are registered and authorized by the DEA and the state in which they practice to dispense, administer and prescribe controlled substances in the course of professional practice
 - Examples of MLPs include, but are not limited to, health care providers such as nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, ambulance services, animal shelters, veterinarian euthanasia technicians, nursing homes and homeopathic physicians

Drug Enforcement Agency

- Who:
 - MLPs may receive individual DEA registration granting controlled substance privileges
 - However, such registration is contingent upon authority granted by the state in which they are licensed
 - Many states, including Oregon allow optometrist to prescribe a controlled substance medications

Drug Enforcement Agency

- Purpose of Prescription Issue
 - To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of sound professional practice
 - The practitioner is responsible for the proper prescribing and dispensing of controlled substances

Drug Enforcement Agency

- Purpose of Prescription Issue
 - A prescription for controlled substances which is not issued in the usual course of professional treatment is not a valid prescription
 - The individual who knowingly dispenses such a purported prescription, as well as the individual issuing it, will be subject to criminal and/or civil penalties and administrative sanctions
 - Legal charges:
 - Felony charges will include schedule 1 through 4
 - If the controlled substance is a schedule 5, then the prescription fraud is a Class A misdemeanor
 - Loss of license to practice
 - Financial penalties

Drug Enforcement Agency

- Purpose of Prescription Issue
 - Illegally obtaining a controlled substance, or possession of a narcotic without a prescription, is classified as a felony
 - A person using deceit, fraud, or forgery in an effort to obtain controlled substances will also, most likely, be charged with a felony

Drug Enforcement Agency

- Purpose of Prescription Issue
 - A prescription may not be issued in order for an individual practitioner to obtain a supply of controlled substances for the purpose of general dispensing to his/her patients
 - Prescription written for office stock is not valid

Controlled Substances Schedules:

- Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules
- These are updated and published annually in [Title 21 Code of Federal Regulations \(C.F.R.\) §§1308.11 through 1308.15](#)

Controlled Substances Schedules:

- Substances are placed in their respective schedules based on whether they have a currently accepted medical use in treatment in the United States, their relative abuse potential, and likelihood of causing dependence when abused

Controlled Substances Schedules:

- To prescribe, dispense, or administer controlled substances, you must be licensed in the state, and comply with applicable federal and state regulations
- You need to keep up on the specific rules governing controlled substances as well as applicable state regulations
- Each schedule has specific requirements on how the Rx can be transmitted, how many refills and duration of the prescription
 - You need to KNOW requirements!!!

Controlled Substances Schedules:

- Schedule I Substances
 - No Rx's
 - No medicinal uses
 - Lack of accepted safety for use under medical supervision
 - High potential for abuse
 - Can be obtained under special circumstances – VERY restrictive

Controlled Substances Schedules:

- Schedule II/IIN Controlled Substances (2/2N)
 - Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.
 - Requires a written prescription which must be signed by the practitioner
 - Examples of Schedule II narcotics include:
 - hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.
 - Examples of Schedule IIN stimulants include:
 - amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®)

Controlled Substances Schedules:

- Schedule II/IIN Controlled Substances (2/2N)
 - Refills
 - Refilling a Schedule II prescription is prohibited
 - Facsimile Prescriptions for Schedule II Substances
 - In order to expedite filling the prescription, a prescriber may fax the Schedule II prescription to the pharmacy
 - Requires that the original Schedule II prescription be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually dispensed

Controlled Substances Schedules:

- Schedule II/IIN Controlled Substances (2/2N)
 - In an emergency, a practitioner may transmit a prescription for a Schedule II controlled substance by telephone to the pharmacy, however, the prescribing practitioner must provide a written, signed prescription to the pharmacist within seven days

Controlled Substances Schedules:

- **Schedule III/IIIN Controlled Substances (3/3N)**
 - Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence
- Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with Codeine®)
- Examples of Schedule III non-narcotics include: benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as Depo®-Testosterone.

Controlled Substances Schedules:

- **Schedule IV Controlled Substances**
 - Substances in this schedule have a low potential for abuse relative to substances in Schedule III
- Examples of Schedule IV substances include: alprazolam (Xanax®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), carisoprodol (Soma®), temazepam (Restoril®), and triazolam (Halcion®)

Controlled Substances Schedules:

- **Schedule V Controlled Substances**
 - Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics
- Examples of Schedule V substances include: cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®), and now in some states gabapentin

Controlled Substances Schedules:

- **Schedule III-V Substances**
 - A prescription for controlled substances in Schedules III, IV and V issued by a practitioner may be communicated either orally, in writing or by facsimile to the pharmacist and may be refilled if so authorized on the prescription
 - Refills
 - May be refilled if authorized on the prescription
 - The prescription may only be refilled up to five times within six months after the date of issue
 - After five refills or after six months, whichever occurs first, a new prescription is required
 - A patient is permitted to request a refill of an existing Schedule III-V controlled substance prescription in person, by sending an e-mail, or by telephone

A Provider's Role in Preventing Drug Diversion

Drug Abuse Risk Management

To protect you and the patient

Risk Management: In General

- A basic clinical survival skill in situations in which patients exert pressure to obtain a prescription drug is to say "no" and stick with it
- Maintaining a current knowledge base, documenting the decisions that guide the treatment process and seek consultation are important risk-management strategies that improve clinical care, outcomes and protect you from the law

Risk Management: Keys

- You should not fear disciplinary action from state regulatory or enforcement agencies for prescribing controlled substances for legitimate medical purposes in the usual course of professional practice
- When you prescribe controlled substances can optimize risk management by implementing a few basic safeguards

Risk Management: Cardinal Principles

- Maintaining a Current Knowledge Base
 - Review your pharmacology, including pharmacokinetic and pharmacodynamic properties, drugdrug interactions and signs of intoxication and withdrawal
 - Be aware of the epidemiology of abuse and appropriate treatment indications and contraindications
 - Be able to perform basic alcohol and drug addiction screening assessments

Risk Management: Cardinal Principles

- Write (RX) Right
 - Careful charting and documentation are essential when initiating a controlled drug regimen
 - It is important to document clearly in progress notes the diagnosis, the clinical indications, the expected symptom end points and the treatment time course
 - A medication flow chart is useful to monitor refills, symptoms and time course, or chronicity of prescribing
 - Develop practice policies for calling in refills and cross-coverage prescribing

Risk Management: Cardinal Principles

- Write (RX) Right
 - Writing prescriptions in a manner that decreases tampering and keeping prescription pads under close control
 - When writing prescriptions, you should make every effort to do the following:
 - Prescribe the exact amounts to carry through to the next appointment and no refills
 - Write out the number dispensed, ex: "twelve" instead of using the number "12"
 - Consider instituting a one-doctor/one-pharmacy treatment plan with the patient. Tell the patient that only one doctor in the practice will prescribe medication, and prescriptions will be telephoned to only one pharmacy



Risk Management: Cardinal Principles

- Consultation
 - Consultation with peers and others with specialized expertise can clarify the decision-making process, thereby raising the level of clinical care and strengthening the your position in administrative or legal actions

Risk Management: Cardinal Principles

- Informed Consent
 - Informed consent can be considered as an alliance-building process
 - When a controlled substance is being considered as a treatment option, patients should be informed of the potential for physical dependency and the possibility of mild to moderate rebound effects even with gradual tapering
 - You should carefully review the benefits and risks of the chosen medications, as well as other treatment choices

Risk Management: Cardinal Principles

- **Duty to Warn Liability**
 - The so-called "driving cases" are a special example of a specific "duty to warn"
 - Failure to inform patients of the risk of driving while taking a medication, such as a benzodiazepine, may lead to a claim of negligence against the prescribing doctor
 - An increased risk of driving errors occurs mainly after the initial dose of a benzodiazepine or following an increase in the dosage
 - Driving errors may occur with significantly increased frequency if a patient is also consuming alcohol
 - Given the liability risks, doctors should apprise patients of these concerns and document this in the medical record

Risk Management: Cardinal Principles

- **Third-Party Liability**
 - States have become aggressive in prosecuting doctors over opioid deaths from reckless prescribing habits
 - Los Angeles-area doctor was recently convicted of second-degree murder for prescribing painkillers that killed three patients, and he was sentenced to 30 years to life in prison
 - Oklahoma doctor was charged with second-degree murder in the overdose deaths of at least five patients from prescription painkillers and other drugs
 - The doctor had prescribed more than 3 million doses over a 5-year-period
 - In 2010, she had prescribed for a 47-year-old patient a total of 450 painkillers, muscle relaxants, and anti-anxiety drugs – the so-called addict's holy trinity
 - The patient died 6 days later
 - MANY more examples in the news!!
 - KEY: These doctors did NOT follow USUAL and CUSTOMARY prescribing guidelines!

Risk Management: Cardinal Principles

- **Documentation of the Decision-Making Process**
 - When providing care to a patient you should document not only what was done but also how that action was chosen
 - Any treatment protocol that deviates from the community standard of care should be carefully considered and voluntarily chosen by the patient, and explicit documentation of this should be included in the medical record

Risk Management: Cardinal Principles

- **Avoid Prescribing Medications in Isolation From Other Therapies**
 - Controlled substances can be used safely and effectively when part of an overall treatment plan that is carefully monitored
 - Periodic review of the course of treatment should occur at reasonable intervals and include input from multidisciplinary staff or consultants
 - Remember narcotic analgesics, sedative-hypnotics and psychostimulants are effective and justified in a wide range of conditions
 - Remember the potential for misuse and abuse of these agents is a key to avoiding the paradox of overprescribing them to high-risk patients and underprescribing them to the majority of patients with conditions that would be improved by their use

Risk Management: Cardinal Principles

- **Medical Records are CRITICAL!**
 - You should keep accurate and complete records to include:
 - The medical history and physical examination
 - Diagnostic, therapeutic and laboratory results
 - Evaluations and consultations
 - Treatment objectives
 - Discussion of risks and benefits
 - Treatments
 - Medications (including date, type, dosage, and quantity prescribed)
 - Instructions and agreements
 - Periodic reviews
 - Records should remain current and be maintained in an accessible manner and readily available for review



A Provider's Role in Preventing Drug Diversion

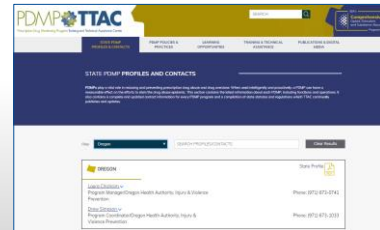
Prescription Drug Monitoring Programs
To protect you and the patient

Prescription Drug Monitoring Programs

- 49 states have operational PDMPs that have the capacity to receive and distribute controlled substance prescription information to authorized users
 - Only Missouri is not fully operational
- Electronic database – collects designated information on substances dispensed
 - Impact:
 - New York required prescribers to consult their state's database before prescribing pain medications, the percentage of patients with multiple provider episodes (receiving prescriptions from five or more prescribers or filling prescriptions at five or more pharmacies in a 3-month period) dropped 75%
 - Following Kentucky's mandate on enrollment and use of its PDMP went into effect overall dispensing of controlled substances in the state declined 8.5 percent in the first year

Prescription Drug Monitoring Programs

<http://www.pdmpassist.org/content/state-profiles>



Prescription Drug Monitoring Programs

- Healthcare providers and pharmacists must apply to the PDMP for an account to access information from the system
- Access is granted to individuals only—not to clinics
- To apply for an account, go to enrollment website specific for your state and follow the account request procedure listed



Prescription Drug Monitoring Programs

- Benefits – inform, intervene, investigate (per AMA)
 - Access a patient's prescription history for opioids and other controlled substances quickly during the patient encounter
 - Determine whether patients have received opioids and other controlled substances from other providers/dispensers
 - Evaluate and manage patients with persistent pain more effectively
 - Create alerts when a patient reaches certain thresholds
 - Identify the need to counsel the patient
 - Identify other prescribers to help coordinate care and follow-up activities

Clinical Dilemma

To Treat or Not To Treat

Dilemma: Desire to Treat vs. Fear of Sanction

- Reports from state medical boards indicate that allegations of controlled-substance overprescribing are the leading cause of investigations of doctors and of actions against doctors' licenses
- This sets up an unfortunate paradox for doctors:
 - Desire to relieve pain, anxiety and other discomfort verses fear of creating addiction, of being investigated by law enforcement or licensing authorities, and/or of being "scammed" by the occasional patient who abuses opioid analgesics, sedative-hypnotics or psychostimulants

Dilemma: Desire to Treat vs. Fear of Sanction

- These competing concerns often leave doctors feeling ambivalent and uncomfortable about prescribing controlled substances, to the detriment of the majority of patients who suffer legitimate illnesses and are often left undertreated or feeling stigmatized

Dilemma: Desire to Treat vs. Fear of Sanction

- REMEMBER: Most patients who take prescribed narcotic analgesics, sedative-hypnotics or stimulants use them responsibly, as directed
- Doctors' concerns about possible legal, regulatory, licensing or other third-party sanctions related to the prescription of controlled substances may contribute significantly to the undertreatment of pain syndromes and anxiety disorders

Dilemma: Desire to Treat vs. Fear of Sanction

- Pain and somatic manifestations of anxiety are two of the most common reasons that people consult a doctor, yet frequently these problems are inadequately treated
- Failure to provide relief from pain and anxiety disorders exacts an enormous social cost from lost productivity, needless suffering and excessive health care expenditures

Dilemma: Desire to Treat vs. Fear of Sanction

- For optometry:
 - USE narcotics when INDICATED AND when APPROPRIATE
 - YOU WILL NOT CREATE AN ADDICT!
 - Withholding opioids out of fear, harms your patients
- Make sure only Rx for pain directly related to the eye
 - Review laws in your state
 - Many states, 72 hrs max!

Reporting Drug Diversion Requirements



Reporting Drug Diversion Requirements

- Why many don't report:
 - Uncertainty or disbelief
 - Turning a blind eye
 - Hoping the problem will go away – isolated event
 - Concern about what getting involved will mean for them
- Failure to report enables the diverter

Reporting Drug Diversion Requirements

- Prescribing physicians should be familiar with federal and state prescribing laws - most stringent law takes precedence
- Must report theft of controlled substances to DEA immediately
- Reporting a patients that you believe is diverting:
 - Maybe/Maybe not
 - <https://www.mdedge.com/psychiatry/article/77198/practice-management/should-you-report-patient-who-misuses-prescription/page/0/1>
 - Local law enforcement -- some states mandate reporting of crime (Ohio)
- Other reporting:
 - State licensure board -- mandatory if you suspect doctor
 - Possibly the State Medicaid fraud control unit
 - Possibly FDA/Office of Criminal Investigation
 - Possibly the Office of the Inspector General (OIG)

HIPAA and Privacy Issues

Reporting a Crime and Privileged Information

- Information communicated to a physician in an effort to procure unlawfully a prescription drug is not privileged communication
- The physician no longer is bound by the physician-patient relationship
- However, the physician is not obligated to report the criminal behavior

HIPAA and Privacy

- Under 45 C.F.R. §164.512, a covered entity may disclose PHI without receiving permission of the individual for national priority purposes including:
 - Disclosure required by law
 - Public health activities
 - Health oversight activities
 - Law enforcement
- Under §164.506, disclosures are also allowed for treatment, payment, and health care operations.
 - Health care operations include (i) quality assessment and improvement activities, including case management and care coordination, and (ii) fraud and abuse detection and compliance activities.

HIPAA and Privacy

- In disclosing dispensed prescription drug data pursuant to 45 C.F.R. §164.512(b), (d), (f), or health care operations under 45 C.F.R. §164.506, a covered entity must limit the PHI to that minimally necessary to accomplish the intended purpose of the use, disclosure or request. 45 C.F.R. §164.502(b)(1).
- You are not authorized to turn over the patient's entire chart!

Summary....

SUMMARY: Controlled Substances Prescribing:

- Controlled substances may be prescribed, administered, or dispensed only for a legitimate medical reason
 - Scope of practice applies – KNOW YOUR LAW!!!
- Optometrist Keys facts:
 - Prescriptions are patient specific- NO prescription can be written "For Office Use"
 - DEA registration numbers are individual, not issued for a clinic

SUMMARY: Controlled Substances Prescribing:

- Optometrist Keys facts:
 - Can not post date a prescription
 - All Rx's signed & dated on day issued
 - CAN write on Rx "Do not fill before (date)"
 - E.g., Vicodin #20, 1 refill not before.....
- Must sign own Rx's
 - Stamps are not allowed

SUMMARY: Controlled Substances Prescribing:

- Optometrist Keys facts:
 - Must put patient name & address on Rx
 - Must indicate in writing if generic substitution is prohibited.
 - Must give directions for use
 - Should give indication for use
 - Must include prescribers address
 - Must include DEA number
 - Write both numbers and words for quantity: (30)(thirty) tablets
 - Never leave refill space blank
 - Write none, if you are allowing the write the number one, etc.

SUMMARY: Controlled Substances Prescribing:

- Pharmacist's Responsibilities
 - There is a corresponding responsibility on the pharmacist to ensure all the required information is on the original prescription
- What you leave off... expect a phone call for the information

Remember Who the Drug Seekers Are:

- Drug seekers are not necessarily drug abusers or drug addicts
- The DEA estimates that the street value of controlled prescription medications is second only to cocaine
- Many drug-seekers intend to sell or barter most or all of the prescription medications they obtain

Remember Who the Drug Seekers Are:

- Controlled prescription medication abuse accounts for one-third of the U.S. drug problem
- Drug-seekers are not just derelicts and dead-enders
 - Anyone, regardless of gender, income, race, ethnicity, health or employment, is a potential abuser and/or seeker of prescription medications
- Six million Americans were using prescription drugs recreationally each month
 - This is a greater number than heroin, crack and powdered cocaine users combined

Remember Who the Drug Seekers Are:

- Misunderstanding about the potential for addiction leads doctors to under prescribe pain medications
- Patients, also fearing addiction, will refuse pain medication when it is indicated
 - In fact, in optometry, the potential for addiction or abuse is low when medications are used as indicated and administered per prescription or protocol

Remember Who the Drug Seekers Are:

- Not all drug-seekers are faking symptoms
- They may have a legitimate complaint
- Over time, they have become physically dependent or tolerant to prescribed pain medication, and in order to complete daily life tasks, they feel compelled to seek larger doses or additional pain medications

Remember the Red Flags:

- Clinic Calls
 - Demand to be seen immediately
 - Usually a late Friday appointment
 - Calls or presents after regular clinic hours
- Clinic Interaction
 - Presenting complaints
 - Pain related
 - Demands
 - Must have a specific drug right away
 - Alternative are not acceptable
 - Other medications do not work
 - Medication allergy
 - Lost or stolen prescription
 - Vague about medical history
 - Traveling through town or visiting
 - No primary medical provider
 - Refuses lab tests or changes test

Remember the Guiding Principles:

- If are prescribing medications appropriately, you will consider three important factors:
 - The severity of the patient's symptoms
 - The patient's reliability in taking medication as directed (compliance)
 - Whether a drug with less potential for abuse would provide equivalent benefits

Finally Remember:

- First: Protect your patient
 - Do no harm
- Second: Protect yourself
- Be aware,
do the right thing,
and help your patients!

Thank You!!

