PHYSICIAN & PRESCRIBER INVESTIGATIONS

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PHYSICIAN and PRESCRIBER INVESTIGATIONS

- 30 years professional investigator
- 22 years drug law enforcement
- 19 years BNIDC
- 3 years patrolman / drug task force

- 10 years drug diversion unit
- 6 years supervisor
  - Drug diversion unit / Street supervisor

- 20 to 30 drug diversion lectures each year
  - Hospitals
  - Healthcare Associations
  - Universities
  - Allegheny County District Attorney / Bar Association
  - Law enforcement
    - Attorney General Agent Academy
    - Pennsylvania State Police Training Centers
Statistics on Prescribing

- Less than 40% of doctors receive training in medical school to ID Rx drug abuse or warning signs of diversion
- Average Primary Care Doctor should have 1,400 patients total and should see 20 patients per day
- Average Primary Care Doctor has 2,300 patients
- Two most frequently prescribed:
  - Hydrocodone
  - CR (Controlled Release) Oxycodone
- About 20% patients (non-cancer) receive Rx for Opioid
- 41% patients surveyed saw doctor for 16-30 minutes
- 32.8% saw a doctor for 11-15 minutes
- Based on these stats –
  The average doctor is giving 460 patients opioids every year

American Academy of Family Physicians, Article in Family Practice Management, Stanford Pain Management Center, Washington Post Article “how many patients should your doctor see each day” 5/22/2014
According to the National Center on Addiction and Substance Abuse at Columbia University (CASA)

- Almost half (47.1%) of the physicians who completed the CSA survey reported that patients often attempt to pressure them into prescribing CS.

- More than 40% of doctors said they DID NOT ask about prescription drug abuse when taking a patient’s history and one-third said they DID NOT regularly call or obtain records from the patient’s previous physicians BEFORE prescribing a CS or potentially addictive drug.

- CS medications contributed to 23% of the drug related emergency room mentions and was associated with one out of five emergency room deaths.

- 61.2% of physicians surveyed would like to obtain more education and training on prescribing controlled substance medications.
PHYSICIAN and PRESCRIBER INVESTIGATIONS

BETWEEN A ROCK AND HARD PLACE

PAIN

• Fifth vital sign – pressure from patients and hospital admin to control pain as an outcome measure.
• Complicates clinical outcomes / quality of life
• Patients often equate good care with more meds
• Opioid Epidemic makes it clear – too many physicians are prescribing too many opioids

COMPETING LEGAL PRESSURES;

• Federal & State pressure to decrease Rx’s
• Medical under prescribing
• Medical over prescribing
LEGITIMATE PHYSICANS vs. THE REST

- During 2015 – number of persons 12 or older used/abused opioids
  - 12,462,000 involving prescription pain relievers
  - 828,000 involving heroin.
  - **80% heroin users** admit **START with prescription drugs.**
    - *PA Medical Society*

- Legitimate doctors unknowingly become major source
  - 69.9% of abusers received narcotics from a doctor or family member who was prescribed medications

Sources: DEA, CDC 2017 annual surveillance report of drug-related risks and outcomes. PA Medical Society survey 2014. Medical-Legal Risks of Prescribing Pain Medications by Nabil Ebraheim, MD – Huffinton Post
LEGITIMACY OF PRESCRIPTIONS

DEA interpretation of CSA that C.S. can only be issued:

1. For a legitimate medical purpose
2. By a registered physician, acting -
3. Within the usual course of professional practice

MANY STATES REQUIRE AS MINIMUM STANDARDS:

• Physical examination
• Maintaining patient medical records
• Documenting condition / diagnosis / plan to treat
Pennsylvania Prescribing Requirements

- Prescribing controlled medications by any practitioner, or professional assistant under the practitioners direction, unless:
  1. In good faith, or
  2. Within scope of patient relationship, or
  3. In accordance with treatment principles by a responsible segment of the medical community

(35: 780-113 a14)

Felony - Narcotic C-II - 15 years / $250,000 fine
Non-narcotic C-II or any C-III - 5 years / $15,000
Pennsylvania Record CSA record keeping

- Refusal or failure to make, keep, or furnish any record, notification, order form, statement, invoice or information required under this act. (35: 780-113 a21)
  
  Misdemeanors - 6 months / $10,000

- Furnishing of false or fraudulent material information in, or omission of any material information from any application, report, or other document required to be kept by this act. (35: 780-113 a28)
  
  Misdemeanor - 3 years / $25,000
C.S. Rx REQUIREMENTS

MUST be dated and SIGNED on the date ISSUED - NOT PRE-SIGNED

MUST be manually signed by the practitioner! - NO STAMPS, Ink or indelible pencil

MUST include patients full name and address

MUST practitioners full name and address AND DEA number
   DEA number CANNOT be pre-printed

MUST include;
   drug name
   strength
   dosage form
   quantity
   directions for use
   number refills (if any)
Dispensing in Good Faith

• Good Faith: Dispensing a drug for legitimate medical purpose in the usual course of accepted medical practice. U.S. v. Volkman 736 F.3d 1013 (6th Cir. 2013)

• Factors to be considered
  – Did prescribing practices exceed legitimate bounds
  – Was prescription for legitimate medical purpose
  – Were there excessive prescriptions
  – Dispensing prescriptions without any medical history, examinations or without seeing patient.
  – Falsification of patient records
  – Prescriptions issued in different or false names
  – Patients indicating they obtained merely to get high or other non-medical purpose
  – Providing drugs for incidental services unrelated to medical treatment

May require expert review of patient files.
EXCEPTIONS - DISPENSING

EMERGENCY
- Limit supply to the emergency time frame
- Immediate dispensing of C-II necessary for proper treatment
- C-II may be called in to RPH with written Rx within 7 days to pharmacy

E-SCRIBE
- Rx must be in conformity with requirements of CSA and 21 C.F.R. 1311
- The Pharmacy uses application that meets all requirements of 21 C.F.R. 1311.
- Third party audit to determine it conforms with DEA rules
- Designate which employees will have E-access
- Pharmacy must have logical controls in place
- Required notations on paper Rx’s, same electronically

FAXING C.S.
- Original must be presented before dispensed
  Exceptions,
  1. C-II narcotic C.S. compounded for direct administration to patient by injection. All normal requirements must be followed.
  2. Long Term Care Facilities – fax considered written
  3. Hospice Care program / physician to note on Rx it is for Hospice patient.

Schedules III – V prescriptions may be faxed as long as signed
SEQUENTIAL PRESCRIPTIONS (Do Not Fill Until...)
21 CFR 1306.12

- Sequential Rx’s up to a 90-day supply of a C-II are permitted
- Example: Writing 3 Rx’s to be dispensed every 30 days by the RPH (all Rx’s have same date of issuance)
  - Write one Rx for one-third of the total quantity of controlled substance to be prescribed
  - Write a 2nd Rx for one-third of the total quantity of controlled substance to be prescribed
  - Write DO NOT FILL UNTIL ____/____/______ on the 2nd Rx, with the date 30 days after the 1st Rx date of issue
  - Write a 3rd Rx for one-third of the total quantity of controlled substance to be prescribed
  - Write DO NOT FILL UNTIL ____/____/______ on the 3rd Rx, with the date 60 days after the 1st Rx date of issue

- DEA's regulations allow practitioners to provide individual patients with multiple prescriptions for a specific C-II, written on the same date, to be filled sequentially
- This combined effect of such sequential multiple prescriptions is that it allows a patient to receive, over time, up to a 90-day supply of that controlled substance

- 21 CFR 1306.14(e)
- A RPH cannot fill a Rx issued as one in a series of multiple Rx’s prior to the date written by the prescribing physician
EMERGENCY PRESCRIBING

SEQUENTIAL PRESCRIPTIONS
(Do Not Fill Until...)

NO EXCUSE FOR PRE-SIGNED PRESCRIPTIONS BECAUSE THE DOCTOR COULDN’T BE THERE!
Can doctors prescribe to themselves, family friends and colleagues?
Can Doctors prescribe to themselves, colleagues, family, neighbors, and friends?

- Yes. *Although self and family prescribing is discouraged by AMA*
- Must conduct minimum standards required by State Boards
- Must maintain patient records *as if any other patient*
- Legitimate medical purpose
- Within usual course of professional practice
- Must adhere to PDMP Requirements
Doctor / Patient relationship

What is the definition of a patient?
When does that occur?
- Cannot prescribe to non-patient
- Hard to define
- Factors to consider
  - Is person seeking legitimate medical treatment, services, etc.
  - Does doctor inquire about person’s medical concern, complaint or issue
  - Does doctor perform any type of physical examination, take vitals, medical history
  - Is there a logical connection between person’s medical concerns, examination, history and the treatment plan, including drugs prescribed?
Prescribing, administering and dispensing CS

**1. Initial medical history and physical exam**
- Done before prescribing CS unless emergency
- Other physicians report may be used if within 30 days
- Exam must include heart, lungs, B/P and body functions specific to complaint

**2. Re-Evaluations**
- Condition diagnosed, CS, expected results/side effects
- Chronic conditions shall be recommended to monitor effectiveness

**3. Patient Counseling**
- must be counseled regarding diagnosis and CS administered or dispensed. (outside hospital)
- Should be counseled on dosage levels, use instructions, frequency and duration of use and possible side effects

**4. Medical Records**
- Shall be recorded in patient file on each occasion; when prescribed administered and dispensed, name of CS, strength, quantity and date
Medical Records

(a) Shall be maintained for each patient
   • Identifying patient
   • Person making entry
   • Date of each contact
   • Pertinent clinical info
   • Diagnosis
   • Lab results and other diagnostics, corrective or therapeutic procedures
     – Including prescription drug orders, arising out of patient care

(b) Records shall be maintained 7 years from last entry
(c) Shall be confidential
(d) Shall provide a complete copy to patient, within reasonable time and charge a reasonable fee.

Sexual Misconduct
– Prohibited unless spouse
– 2 years after terminated as patient
Prescribing in accordance with treatment principles of a responsible segment of the medical community

- This prong typically requires expert testimony, which means $$$$$$$$

- Deviation from accepted medical protocols
  - Exceeding the MME
Examples of treatment deviations

- Practitioner prescribed controlled substances to patients and records showed:
  - No vitals taken or taken initially but not after
  - No urine tests
  - No physical examinations
  - No appropriate medical history
  - No monitoring patient pain levels or side effects
  - No treatment or pain management plan
  - Early refills with no explanation
  - Test ordered but no indication tests performed
  - Excessive amounts of controlled medications
GUIDELINES ON OPIOID PRESCRIBING

Three areas of recommendation

1. When to initiate or continue opioids for chronic pain

   - Non-pharmacologic and nonopioid therapy preferred
   - Opioids should outweigh risks to patients
   - Before start – treatment goals w realistic expectations
   - Only continue if clinically meaningful improvements outweigh pt. risk
GUIDELINES ON OPIOID PRESCRIBING

Three areas of recommendation

2. Opioid selection, dosage, duration, follow-up and Discontinuation
   • When starting, should prescribe IR’s instead of ER/LA
   • Start with lowest possible effective dosage
   • Caution in increasing dosages, carefully justify decisions to titrate to >90 mme/day
   • When for acute pain, low dosages, no quantity than expected need – 3 days often enough
   • Evaluate benefits and harms with patients within 1 to 4 wks from starting
   • Evaluate every 3 months or more frequently
   • If benefits do not outweigh harms, work w pts to taper/lower dosages or taper to discontinue
GUIDELINES ON OPIOID PRESCRIBING

Three areas of recommendation

3. Assessing risk and harms of opioid use
   • PDMP review every three months if not every prescription
   • Incorporate risk strategies such as history or concurrent benzo’s.
   • Offer naloxone when factors increase
   • Urine drug screens before start and during at least annually
   • Avoid prescribing benzo’s concurrently when possible
   • Offer or arrange evidence based treatments like buprenorphine or methadone w behavioral for pts w opioid disorder.
SECURITY REQUIREMENTS
Federal Regulation – Title 21, CFR Section 1307.71(a)

• Requires ALL registrants provide effective controls and procedures to guard against theft and diversion of controlled substances.

  – Factors used to determine adequacy of security affecting practitioners;
    • Location security needs
    • Type of building and office construction
    • Type of storage (safe, vault or steel cabinet)
    • Public access to facility
    • Registrant’s monitoring system (alarms and detection system)
    • Local police protection

  – Registrants should not employ an agent or employee who has access to CS:
    • Any person convicted of CS Felony
    • Any person denied, revoked or surrendered for cause a DEA registration
Safeguards for Prescribers

- In addition to security controls, practitioners can utilize additional measures to ensure security. These include:

1. Keep all Rx blanks in a safe place where they cannot be stolen
2. Write actual number in addition to giving a number
3. Use Rx blanks only for writing Rx order & not for notes
4. **Never sign Rx blanks in advance**
5. Assist RPH when they phone to verify
6. Contact DEA to furnish suspicious Rx activity
7. Use Tamper-Resistant Rx pads
49 Pa. Code 18.158 (a) 3 & 4, (b) 3
Prescribing and dispensing drugs

a (3) Initial visit –
• 72 hour dose.
• Notify physician ASAP not longer than 24 hours.
• 30 day supply if approved by supervising physician for ongoing therapy
• Rx must clearly state initial or ongoing therapy

(4) only Rx or dispense for patient of sup. Physician

b (3) Supervising Physician is prohibited from signing Rx blanks.
PHYSICIAN ASSISTANT (continued)

49 Pa. Code. 18.158 (d) Recordkeeping

P. A. must keep in patient medical record;
Copy of Rx, including refills, in ready reference file with;
- Name
- Amount
- doses
- date of Rx
- PA name

P. A. shall report orally or in writing to S. Physician within 36 hrs drug prescribed or dispensed when S. Physician not present and basis for each decision

Same rules apply to PA’s in State Board of Osteopathic Medicine
What is normal at a Doctor’s office?

- **Red Flags**
  - Office location
  - Office setting
    - Lawn furniture for chairs
  - Open one day a week
  - Open only on weekends
  - No office staff
  - No medical equipment
  - Office staff is family
  - Office staff are former addicts????
  - Cash only
  - No vitals
  - Unsupervised urine screens
  - Doctor meeting off site
  - One drug consistently prescribed to EVERYONE

- Dr. West was convicted of 35 PS 780-113(a) 12 after writing prescriptions for Quaaludes in the names of 35 people who either didn’t even live in the county or had never received the prescriptions. Dr. West was obtaining the Quaaludes for his own personal use.

- The Superior Court upheld the conviction in this case based on the fact that Dr. West wrote the prescriptions and presented them to the pharmacy himself. The pharmacy trusted that, since Dr. West was a physician, he would provide the medications to the patients listed on the prescriptions.

- This was a deliberate scheme to deceive the pharmacist.
Gathering DATA

**Covert**
- Background Data
- Undercover
- Confidential Informants

**Overt**
- Search Warrant(s)
  - Patient records
  - Office observations
  - Residence
  - Computer
  - Cell phones
- Interviews
  - Staff
  - Patients
PHYSICIAN and PRESCRIBER INVESTIGATIONS

COVERT ACTIONS

1. Run PDMP report
   - Prescriber and
   - Patients
2. Forge alert (later)
3. Dept. State Professional License Report
4. Criminal History search
5. JNET search
6. Fincen
7. Clear Report
8. Obtain PDMP access report on prescriber
Expert Witness

- Challenging aspect of prescriber cases
- Generally handled by the prosecutor
- Rarely any in the bullpen
- Expensive
- Do not like to eat their own
- Tribe mentality
- For every expert you obtain, defense will have 10
Finding an Expert Witness

- Should be of similar discipline as defendant
- Better if not from the immediate area
- Responsible segment of the medical community
- Networking
- Associations
- Internet companies
- If new, be upfront about everything
  - Length of time to contract
  - Length of time it takes for court action
  - Defense will be aggressive
- Do your homework on the expert
- Interview his/her practice habits
- Get report first
- Do not coach on results

Better if honest and fair even if it works against your case
PHYSICIAN and PRESCRIPTOR INVESTIGATIONS

BUREAU OF NARCOTICS
INVESTIGATION and DRUG CONTROL

CAREER IMPACT in Pennsylvania

Automatic 10 year license suspension on conviction or plea

FELONY – DRUG ACT (CSDDCA)

ALL PRACTITIONERS – doctors, pharmacists, nurses, etc.

Title 35: 780-113 a14
1. Good faith
2. Doctor patient relationship
3. Treatment principles responsible segment of medical community

Title 35: 780-113 a30 – Delivery of a controlled substance including constructive delivery

Title 35: 780-113a12 – Illegally obtaining a C.S.
Thank You

Questions?

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