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Pharma Diversion
.com

“ Contact us before DEA or ”

Carlos M. Aquino

Compliance Consultant &
Founder

LAW ENFORCEMENT

and

PAIN MANAGEMENT

PHARMA DIVERSION DISCLAIMERS

- We Do Not Represent Law Enforcement
- We Do Not Speak on Behalf of Law Enforcement
- Read the DEA & State Regulations

My Experience

24 Years with Philadelphia
Police

(Last 10 years assigned to DEA Task
Force)

12 Years with PFD DEA
Diversion

(8 as an Investigator & 4 as a
Supervisor)

PURPOSE OF THIS TRAINING

- Discuss Concerns of Law Enforcement
- Importance of a Good Patient Chart
- Review of Patient Agreement and Treatment Plan
- Regulations for Purchasing and Prescribing CS
- Care of Prescription Pads

“ A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.”

Law Enforcement

(DEA, FBI and the Attorney General's Office)

Focus on Legitimacy of a Prescription
and

Physician

(Physician Treating the Patient)

Focus on a Legitimate Treatment Plan

95% RULE

- 95% of Patients will take their Medication as Directed
- 5% Some Form of Diversion of Medications

HEARTBURN PATIENTS

Look for Misuse, Abuse & Diversion

- Substance Abuse Patients
 - Doctor Shoppers
- Patients with Diversion History
 - Patients that Don't Keep Appointments
 - Out of State Patients

REFERENCE MATERIAL & WEBSITES

Model Policy for the Use of Controlled Substances for the Treatment of Pain

Federation of State Medical
Boards of the United States,
Inc.

Adopted as Policy May 2004

Managing Chronic
Pain
with Opioids in Primary Care

written by:

Nathaniel P. Katz, M.D.
Bill H. McCarberg, M.D.
Lori Reisner, PharmD.

WWW.PAINEDU.ORG

– Designed for Pain Management

WWW.PAINACTION.COM

– Designed for Patients with Pain

Contact: Synne Wing Venuti, MSW

Direct Line: 617-614-0423

PAINEDU.ORG

Screener and Opioid Assessment for Patients with Pain (SOAPP)

– Brief paper and pencil tool to facilitate assessment and planning for chronic pain patients being considered for long-term opioid treatment

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Current Opioid Misuse Measures (COMM)

- Brief paper and pencil tool to help identify whether a patient may be exhibiting aberrant behaviors associated with misuse of opioid medications

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Other Forms

- Brief Pain Inventory
- Patient Agreement
 - Low Literacy Agreement
- Neuropathy Pain Scale

PATIENT CHARTS

INITIAL EVALUATION

- Conduct a Medical History
- Establish the Nature & Intensity of Pain
 - Conduct a Physical Examination
- Review the Current & Past Treatments
 - Evaluate Co-Existing Disease or Condition
- Study the History of Substance Abuse
 - Limit the Initial Prescription (no more than 10 days of medication)

PATIENT AGREEMENT

- Unannounced Urine/Serum Screening
- Reasons for Discontinuing the Treatment
- Consultation with a Family Member
- Inspection of CS Prescriptions
- Patient Storage of CS Prescriptions
- Identify Pharmacy Used by Patient
- After-Hour Calls from Patients

Good Medical Chart

- Initial Evaluation
- Patient Medical History
- Referral Letter (Pain Management)
- Medical Tests and Evaluations
 - Pain Level Evaluations
 - Detail Treatment Plan
 - Independent Evaluation
- Patient Agreement & Drug Screening
- Prescribed Drugs and Instructions

METHADONE & FENTANYL PRESCRIPTIONS

- Great Potential for Abuse/Overdose
 - Educate Your Patient on Use
 - Discuss Rx Directions
 - Discuss Abuse Potentials
- List the Pharmacy Used by Patient
 - Document in Chart

MEDICAL RECORD

- Signed Patient Agreement
- Documented Treatments with Results
- List of Prescribed Medications & Instructions
- Independent Evaluation of Treatment
- Review of Patient Chart by Medical Director
- Electronic Records



PRESCRIPTIONS

ELECTRONIC PRESCRIPTION

- Effective June 1, 2010
- Schedules II through V
- Requires State Approval
- Software to Meet the DEA Requirements
 - Required for Pharmacy & Physician
 - Electronically Signed & Receive by Pharmacy
- It Archives the Prescription

Title 21, Code of Federal Regulations Section 1311

DEA C-II 90 DAY POLICY

- 3 Signed Prescriptions
- Dated on Date of Visit
 - 2 Rx Will Note

“Not to be Filled Until (Post Date)”

- Post Date should be the 28th Day
- Provided that the Multiple Rx does not Create an Undue Risk of Diversion

Title 21 Code of Federal Regulations Section 1306.12

“Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances.”

TITLE 21, CODE OF FEDERAL REGULATIONS SECTION 1306.12

“Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.”

“A prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner’s agent to a pharmacy via facsimile equipment, provided that the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substances”

“Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner.”

Title 21, Code of Federal Regulations Section 1306.05

Schedules III, IV, or V prescribed only pursuant to either a written prescription signed by a practitioner

or

a facsimile of a written, signed prescription transmitted by the practitioner or the practitioner's agent to the pharmacy

or

pursuant to an oral prescription made by the individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Section 1306.05 except for the signature of the practitioner

“BREAKTHROUGH PAIN”

is pain that comes on suddenly for short periods of time and is not alleviated by the patients' normal pain suppression management. It is common in patients who commonly have a background level of pain controlled by medications, but the pain periodically "breaks through" the medication. The characteristics of breakthrough pain vary from person to person, including the duration and possible causes.

“BREAKTHROUGH PAIN”

- Limit the amount on the prescription
 - Educate the Patient on its Use
 - Review the Treatment Plan
 - Will be a Source of Diversion
- Establish a Policy for Breakthrough Pain

PURCHASING CONTROLLED SUBSTANCES FOR OFFICE USE

- Need DEA Registration at Each
Location

Title 21, Code of Federal Regulations Section 1301.12 (a)

- Maintain Dispensing Records

Title 21, Code of Federal Regulations Section 1304.03 (b)
& (d)

- Maintain Inventory Records

Title 21, Code of Federal Regulations Section 1304.11
(e)(3) & 1304.22(c)

RECOMMENDATIONS

Perpetual Inventory for Dispensing in Office

- Date CS Dispensed
- Patient Name or Identifier
 - Name of Drug
 - Amount Dispensed
- Amount Available Before Dispensing
- Amount Available After Dispensing
- Initial's of Person Doing the Dispensing

Electronic Format is Recommended

- Treat Them Like a Loaded
Weapon
- Use Carbonless Copy
- Sequentially Numbered Rx
- Maintain Copy in Patient
Chart
- Limited Access & Secured



Q & A

Thank You

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