Controlled Substance Prescribing: A Physician’s Guide

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Objectives

• Review schedules of controlled substances and their propensity for physical and psychological abuse and dependence
• Outline details of prescribing privileges with regards to federal and state law
• List required components of a prescription
• Explain a physicians role in South Carolina’s Prescription Monitoring Program
• Provide methods for providers to prevent diversion and explain the duty to report suspected diversion
## What is a Controlled Substance

<table>
<thead>
<tr>
<th>Schedule</th>
<th>Potential for Abuse</th>
<th>Current Accepted Medical Use</th>
<th>Abuse of Drug and Risk of Psychological and Physical Dependence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule I</td>
<td>High</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Schedule II</td>
<td>High</td>
<td>Yes</td>
<td>Physical and Psychological Dependence: Severe</td>
</tr>
<tr>
<td>Schedule III</td>
<td>Less potential than schedule I&amp;II</td>
<td>Yes</td>
<td>Physical Dependence: Low or Moderate Psychological Dependence: High</td>
</tr>
<tr>
<td>Schedule IV</td>
<td>Low as compared to schedule III</td>
<td>Yes</td>
<td>Physical and Psychological Dependence: Limited</td>
</tr>
<tr>
<td>Schedule V</td>
<td>Low as compared to schedule IV</td>
<td>Yes</td>
<td>Physical and Psychological Dependence: Limited</td>
</tr>
</tbody>
</table>

http://www.fda.gov/regulatoryinformation/legislation/ucm148726.htm
What is a Controlled Substance

• Medications that are commonly mistaken as non-scheduled:
  – Testosterone
  – Ketamine
  – Soma
  – Restoril
  – Desoxyn
  – Vyvanse
Prescribing Privileges

- A prescription for a controlled substance may be issued if a provider meets all of the following criteria:
  - Licensed by the S.C. Board of Medical Examiners, S.C. Board of Dentistry, S.C. Board of Veterinary Medicine Examiners, S.C. Board of Nursing, S.C. Board of Examiners in Optometry, or the S.C. Board of Podiatry Examiners
  - Authorized to prescribe under the type of license issued by the pertinent Board
  - Acting in the regular course of professional practice
  - Registered with Department of Health and Environmental Control (DHEC)
  - Institutional privileges must be granted
A prescription can only be dispensed or distributed for a medical purpose under the auspices of a 
bona fide practitioner-patient relationship.
# Prescribing Privileges

<table>
<thead>
<tr>
<th>Schedule 2</th>
<th>Days Supply, Expiration, Refills</th>
<th>MD Privileges</th>
<th>PA Privileges</th>
<th>APRN Privileges</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Days supply allowed: 31</td>
<td>Yes</td>
<td>- Must be listed in approved written protocol</td>
<td>No privileges in South Carolina</td>
</tr>
<tr>
<td></td>
<td>- Expiration of prescription: 90 days from time of issue</td>
<td></td>
<td>- Can prescribe 72 hours for new medication. MD must see patient as well</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Refills: Not allowed</td>
<td></td>
<td>- Can write refill for 30 days</td>
<td></td>
</tr>
<tr>
<td>Schedule 3-5</td>
<td>Days supply allowed: 90</td>
<td>Yes</td>
<td>Yes, if listed in approved written protocol</td>
<td>Yes, if listed in approved written protocol</td>
</tr>
<tr>
<td></td>
<td>- Expiration of prescription: 6 months from time of issue</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Refills: no more than 5 times. Cannot be refilled sooner than 48-hrs prior to time of prescription per daily dosage</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SC Code of Regulations, Controlled Substances 61-4; 1102, 1202-1204; Nurse Practice Act 40-33-34; F http://www.scapartners.org/?page=CIIPrescriptions
Issuing Prescriptions

• A prescription may be communicated to a pharmacist by an employee or agent of the practitioner
  – The decision-making process in whether to issue a prescription, what medication to prescribe, the dose, frequency, count, or refill quantity may not be delegated to a person not authorized to issue a prescription on their own

• Dual liability of proper prescribing falls on prescriber and pharmacist
Issuing Prescriptions

• A valid controlled substance prescription includes the following
  – Full name and address of patient
  – Drug name, strength, dosage form, quantity prescribed, directions for use
  – Name, address, and federal registration number of the practitioner
  – Dated with day of issuance
  – Must be signed on the day when issued and signed in the same manner of which one would a legal document

**Preprinted prescriptions for any controlled substance are prohibited**
WRITTEN PRESCRIPTIONS

• Ink, indelible pencil, typewriter, or other mechanical means of printing MUST all be manually signed by the practitioner

• Prescriptions may be prepared by a secretary or agent for the signature of the practitioner, but the prescribing practitioner is responsible if the prescription does not conform in any way to laws and regulations

• Cannot have pre-signed blanks
ELECTRONIC PRESCRIBING

• An individual practitioner may sign and transmit electronic prescriptions for controlled substances provided the practitioner meets all of the following requirements:
  – The practitioner must comply with all other requirements for issuing controlled substance prescriptions
  – The practitioner must use an application that meets the requirements of 21 CFR part 1311
  – The practitioner must comply with the requirements for practitioners in 21 CFR part 1311

21 CFR, 1306
SC Code of Regulations, Controlled Substances 61-4; 1003
ELECTRONIC PRESCRIBING (cont.)

• If required components of a controlled substance prescription is altered during the transmission, it is deemed invalid, and cannot be dispensed by pharmacy

• To ensure the integrity of electronic prescriptions, the electronic application shall comply with current DEA regulations prior to use
Issuing Prescriptions

ORAL PRESCRIPTIONS

• Allowed for schedule 3-5 when called in by individual practitioner

• Allowed for schedule 2 medications, when called in by the individual practitioner, only in an emergency situation
  – Quantity must be limited to amount adequate to treat patient during emergency situation
  – Must submit a written prescription within 7 days to issuing pharmacy with “Authorization for Emergency Dispensing” and date of original order notated

21 CFR, 1306.11, 1306.21
Issuing Prescriptions

• Emergency Situation defined as:
  – Immediate administration of the controlled substance is necessary, for proper treatment of patient; and
  – No appropriate alternative treatment is available, including administration of a drug which is not a schedule 2; and
  – It is not reasonably possible for the prescribing practitioner to provide a written prescription to be presented to the person dispensing the substance, prior to the dispensing
Prescribing for Family Members

• “A practitioner cannot usually acquire a valid patient-practitioner relationship... with a member of his or her immediate family, due to the likelihood of the loss or vitiation of the objectivity required in making the necessary medical decisions in order to properly prescribe or dispense controlled substances”

• “The practitioner may not be able to acquire a sufficient practitioner-patient relationship with non-family members (i.e., fiancé or fiancée, close personal friend, paramour, etc.) if total objectivity in deciding to prescribe or dispense controlled substances cannot be maintained...”

• If a bona fide emergency arises, where great detriment to the health or safety of a patient may be involved, a practitioner may administer, dispense or prescribe limited amounts of controlled substances to any person until such time as another objective practitioner can be contacted.
South Carolina’s Prescription Monitoring Program (PMP)- *Scripts*

- **Purpose:** to improve the state’s ability to identify and stop diversion of prescription medications
- **All Schedule 2-4’s** dispensed in South Carolina
  - Includes mail order pharmacies and dispenses from doctor’s offices
- **Does NOT include** dispenses from:
  - Long term care and assisted living
  - Methadone clinics
  - Emergency Departments
  - Veterinarian (less than 5 days supply, except phenobarbital which is up to 31 days supply)
Prescription Monitoring Program

• Dispensers must report daily
  – 24-48 hour delay from actual dispensing date until data is available online

• Physician Use:
  – Registration for practitioner and practitioner’s delegate available at https://southcarolina.pmpaware.net/login
  – Evaluate prescription history prior to writing prescription on every patient
  – Practitioner delegate can run report for provider if registered through Scripts
  – Additional information available by contacting scripts@dhec.sc.gov or by telephone at (803) 896-0668
Prescription Monitoring Program

• Physician Use:
  – To assess if patient is drug-seeking or doctor shopping
  – Supplemental information for drug screens
  – To assess compliance with medication
  – Avoid therapeutic duplication or interactions
  – Do not provide report to patient, can only discuss report with patient if concerns arise
  – Do not query anyone except your own patients
Diversion

• Controlled Substances (CS) are at high risk for diversion
• Diversion at healthcare facilities can compromise patient safety
• What qualifies as diversion?
  – The theft of medications, including waste, from patients or healthcare facilities for personal use
  – Theft or selling of a prescription
  – The use of a prescription for recreational purposes or any use not intended by the prescriber
Diversion

• Reasons for diversion
  – Occupational factors for healthcare providers (HCP)
    • Access and availability
    • Knowledge of medication dosing, side effects, etc.
    • Physical and emotional demands of the job
  – Providing medications for friends or family
  – Financial gain
    • Selling prescriptions or actual controlled substances is a crime and will be prosecuted

Duty to Report

• Loss or theft
  – Investigations are required in the event of a loss or theft
  – Copy of the investigations are to be signed by responsible supervisor and filed with the institution’s controlled substance records
  – Appropriate action must be taken to prevent recurrence

• Employee reporting
  – If knowledge or suspicion of diversion is known by an employee it is mandatory to report to your respective supervisor
    • “Failure to report can be considered in determining feasibility of continuing to allow an employee to work in a drug security area, or with access to controlled substances”
Duty to Report

• Reporting to DHEC
  – Regional DHEC Bureau of Drug Control Officers should be contacted anytime diversion or inappropriate prescribing practices are suspected
  – DEA 106 must be filled out anytime there is an unexplained loss or theft of controlled substances
  – Failure to proactively report concerns can lead to extensive audits and fines down the road
Diversion Prevention: Writing Prescriptions

• A prescription for a controlled substance may not be written for any person(s) who is narcotic drug dependent for the purpose of continuing his/her dependence upon such drugs.
• Ensure days supply prescribed accurately reflects if presenting problem is acute versus chronic.
• Write out number and word for quantity of medication prescribing.
• Do not pre-sign prescription blanks.
• Circle name on prescription pad to ensure accurate information is entered into PMP by pharmacist.

http://www.ccwjc.com/Forms/Chronic%20Pain/Proper%20Prescription%20Writing.pdf
Diversion Prevention: Writing Prescriptions

• Circle “zero” for refills and cross out other refill numbers
• Use gel ink pens as ink is more deeply imbedded into the fibers of the paper, making the prescription less prone to tampering
  – UniBall 207 pen deemed tamper-resistant
• Consider keeping copies of prescriptions written on file for comparison when needed
• Keep prescription pads and e-scribing paper stored in a secured area with limited pre-defined access

http://www.ccwjc.com/Forms/Chronic%20Pain/Proper%20Prescription%20Writing.pdf
Diversion Prevention: Security of Medications

• When administering a partial dose or titratable dose ensure the remaining medication is disposed of in a non-recoverable manner or secured in between administrations

• Outpatient Practices
  – Ensure controlled substances are stored under double lock and key (with restricted access) or in an automated dispensing cabinet
  – Ensure inventory of controlled substances is taken by two capable individuals
  – Compare purchase invoices with intake of stock controlled substances
Summary

• Controlled substances are at high risk for diversion
• Providers must do their part to prevent diversion through prescribing practices, SCRIPTS utilization, and appropriate medication handling
• Suspected diversion must be reported in a timely manner and process changes must be put in place to deter such activity in the future