Controlled Substance Prescribing and Diversion

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In 2010, approximately 38,329 unintentional drug overdose deaths occurred in the United States, \textit{one death every 14 minutes}.

Of this number, 22,134 of the deaths were attributed to prescription drugs. (75.2\%) 16,651 were attributed to opioid overdoses.

Prescription drug abuse is the fastest growing drug problem in the United States.
Drug-Induced Deaths vs. Other Injury Deaths (1999–2009)

Causes of death attributable to drugs include accidental or intentional poisonings by drugs and deaths from medical conditions resulting from chronic drug use. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all injury cause categories are mutually exclusive.
New Initiates 2011 – 12 years and older

Note: Numbers refer to persons who used a specific drug for the first time in the past year, regardless of whether initiation of other drug use occurred prior to that year.
Top Five Prescription Drugs Sold in the U.S. (2006-2011)

(By Number of Prescriptions Sold)

Source: IMS Health

- Hydrocodone/Apap
- Lipitor
- Amoxicillin
- Lisinopril
- Simvastatin
- Levothyroxine
- Azithromycin
- Amlodipine besylate
Poisoning Deaths:
Opioid Analgesics

Source: CDC/NCHS, National Vital Statistics System
ED Admissions Due to Non-medical use of Pharmaceuticals – SAMHSA 2011 Data

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<thead>
<tr>
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<th>2004</th>
<th>2011</th>
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<tbody>
<tr>
<td>Total</td>
<td>535,477</td>
<td>1,244,872</td>
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<tr>
<td>Adderall</td>
<td>2,303</td>
<td>17,272</td>
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<tr>
<td>Hydrocodone</td>
<td>39,846</td>
<td>82,480</td>
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<tr>
<td>Oxycodone</td>
<td>41,701</td>
<td>151,218</td>
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<tr>
<td>Alprazolam</td>
<td>46,528</td>
<td>123,744</td>
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"Parallel to opioid supply and nonmedical prescription drug use, the epidemic of medical drug use is also escalating with Americans using 80% of world’s supply of all opioids and 99% of Hydrocodone."

The population of the United States comprises 4% of the world’s population.
Presentation Objective

Role of DHEC Drug Control
Requirements of a valid controlled substance prescription
Practitioner inspections and common concerns
Controlled Substance Laws
Common methods of diversion
Role of DHEC Drug Control

SC Controlled Substance Act tasks DHEC with maintaining accountability of controlled substances in possession of those persons legally authorized to possess them.

SC Code Sec 44-53-480(b)
Role of DHEC Drug Control

Our goal is to achieve and maintain compliance with applicable laws and regulations through education.
Duties of an Inspector

Regulatory Duties
- Registrant inspections
- Accountability audits
- Education

Law Enforcement Duties
- Investigate and arrest for violations of SC Controlled Substance Act
References:

SC Code of Laws

Title 44 (Health), Chapter 53 (Poisons, Drugs, and Other Controlled Substances)

44-53-***

SC Code of Regulations

Chapter 61-4 (Controlled Substances)
Valid controlled substance prescriptions

SC 44-53-360. *Prescriptions*

(c) No controlled substances included in any schedule may be distributed or dispensed for other than a medical purpose. … No practitioner may dispense a controlled substance outside of a bona fide practitioner-patient relationship.
Valid controlled substance prescriptions (cont.)

SC 44-53-360.  *Prescriptions*

(h) A prescription, in order to be effective in legalizing the possession of a controlled substance and eliminating the need for registration of the recipient, must be issued for legitimate medical purposes. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding liability rests with the pharmacist who fills and ultimately dispenses the prescription.
(a) A prescription for a controlled substance to be effective shall be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice.
(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug dependent person for the purpose of continuing his or her dependence upon such drugs...
Prescribing for Family Members

Reg. 61-4 Section 1204

...A practitioner cannot usually acquire a valid practitioner-patient 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 controlled substances...(fiancé, close personal friend, paramour, etc)
Prescribing for Family Members

Reg. 61-4 Section 1204

...In the event of a bona fide emergency situation, 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.
Prescribing for Family Members

SC Medical Board *Examiner* (Winter 1999)

“The board feels that prescribing controlled substances for family members is outside the scope of good medical practice in South Carolina, except for a bona fide emergency situation where the health and safety of an individual may be at great detriment.”
Requirements of a Valid Controlled Substance Prescription

(1) Valid practitioner-patient relationship
(2) Treatment of a legitimate medical condition
(3) Practitioner acting in the usual course of professional practice
(4) Properly licensed and registered practitioner-LLR license, prescriptive authority, DHEC and DEA controlled substance registrations
Violation

SC 44-53-380 Prohibited acts B; penalties

(a) It shall be unlawful for any person:

(1) Who is subject to the requirements of Sections 44-53-280 to 44-53-360 to distribute or dispense a controlled substance in violation of Section 44-53-360;
(b) Any person who violates this section is punishable by a civil fine of not more than one thousand dollars; provided that, if the violation is prosecuted by an information or indictment which alleges the violation was committed knowingly or intentionally, such a person shall be deemed guilty of a felony and, upon conviction, shall be imprisoned for not more than five years, or fined not more than ten thousand dollars...
Controlled Substance Inventory

Must be conducted on May 1 of each year

Must indicate time of day

Must be readily retrievable for 2 years

Must have the name, address, and DEA number of the registrant
Controlled Substance Inventory

Must be maintained at the registered location
Must include all controlled substances on hand, including samples
Receipt Records

Must be noted with date received
Must be readily retrievable for 2 years
Controlled substance records must be kept separate from non-controlled substance records, and CII records should be separated from CIII, CIV, and CV records
Dispensing Records

Controlled substance dispensing records must be kept separate from patient chart.

Record must include the following information:

Drug name and strength
Date dispensed or administered
Patient name and address
Quantity dispensed or administered
RN or dispenser’s signature or initials
Practitioner’s initials

Must report dispensations to SC Prescription Monitoring Program.
Security

Controlled substances should be stored in a securely locked and substantially constructed cabinet.

Registrants should report any theft to DHEC Bureau of Drug Control.

Suggestions:
- Limit access to the locked cabinet
- Do a weekly count and denote on dispensing log
- Have a witness to all wastage and have both persons sign
Additional Key Items

Keep all prescription blanks in a secure place
Power of attorney
Documentation of all authorized controlled substance prescriptions in patient’s medical record
Some Common Problems

Failure to conduct May 1 inventory
Unable to locate receipt records
Incomplete dispensing records
Post-dated prescriptions (all prescriptions must be dated on the date written)
Some Common Problems

Pre-signed prescription blank (violation of SC Code 44-53-395(A)(1))

Controlled substances not stored in a secure location

Prescriptions issued outside of valid patient/practitioner relationship (44-53-380)

Stamped or electronic signature (SC Reg 1003)
Some Common Problems

Prescriptions issued outside of usual course of professional practice (44-53-380)

Excessive quantity (cannot exceed thirty-one days supply for C-II)

Faxed prescriptions for C-II that are not issued to terminal, LTCF, or home-infusion patients
Other Agencies

Drug Enforcement Administration (DEA)

SC LLR

Board of Nursing
Board of Pharmacy
Board of Medical Examiner
Commonly Diverted and Abused Controlled Pharmaceuticals

Schedule II Hydrocodone Products

Most commonly diverted and abused licit drug

Most often cited brands – Norco, Lortab, Lorcet, Vicodin

Oxycodone

Oxycodone is the drug of choice in most areas

Methadone
Common Diversion Methods

Legally obtaining drugs for medical condition

Stealing drugs from sick family members or befriending a patient who gets lots of C/S

Lying to physicians regarding pain level

Calling physicians after-hours and claiming to be a patient of his/her partner

Going to multiple practitioners and/or different pharmacies

Altering prescriptions that were legally issued
Common Diversion Methods (cont’d.)

Using stolen prescription blanks
Generating Rx blanks on computer or making photocopies
Calling in their own prescriptions for controlled substances
Diversions by employees or pharmacists (for personal use/profit) [Reg 61-4-410]
Armed robberies and/or break-ins of pharmacies, drug wholesalers or physicians’ offices
Suggestions: patients requesting controlled substances

Don’t call in controlled substance unless you have valid practitioner-patient relationship and can verify legitimate medical need

Ask the patient to come to office for evaluation

Contact the pharmacy

Advise the patient that state law requires pharmacy to document picture identification before dispensing.
Doctor Shopping

Ask direct questions about other health care providers that patient may be seeing and other medications patient is receiving; document responses.

Written “sole-provider” contracts can be very useful in most settings.

Use resources that are available.
Applicable Laws

44-53-390(A)(3): Illegal to obtain controlled substance by fraud, forgery, deception, or subterfuge.

44-53-395(A) (3): Illegal to withhold information that a medication of like therapeutic use was obtained from another practitioner during a concurrent time period.
Prescription Forgery

Commonly due to stolen or photocopied prescription blanks.

Increase in scanned or computer-generated forgeries.

Large number of fraudulent telephoned prescriptions for C-III and C-IV, especially alprazolam and formerly hydrocodone, now tramadol.
Suggestions to prevent forgeries

Use prescription blanks that are difficult to photocopy or scan into computer.

Always secure prescription pads/paper.

Do not leave prescription blanks in exam rooms.

Never sign blank prescriptions!
Altered Prescriptions

- Altered quantity
- Altered refills
- Altered dates, including “do not fill until” dates
- Altered medication strengths
- Medications added at bottom of prescription
Suggestions to prevent prescription alteration

Write out quantity in numerals and spell out alphabetically.

Line or zero out refills if none authorized.

Line out unused portions of prescription or write total number of rx on script.
Diversion of Controlled Substances by an Employee

Do not say anything to the employee; obtain as much information as possible without causing any suspicion.

Contact your local law enforcement agency or SC DHEC Bureau of Drug Control.

Reg 61-4-406(a) - prohibits any registrant from employing a person with a felony record related to controlled substances to have access to controlled substances.
When to Contact Drug Control

Suspicion of forged, altered, or fraudulent controlled substance prescriptions

Deception or misrepresentation made by patients to obtain controls

Suspected “doctor-shopping” activity
Requires **pharmacist or practitioner dispensers** to electronically or manually (waiver) submit information regarding each controlled substance (CII, CIII & CIV) prescription dispensed.
A **SCRIPTS** report provides information for scheduled prescriptions a patient has had filled for the specified time period, as well as the prescriber who prescribed them and the dispenser who dispensed them. The report should be used to supplement a patient evaluation, to confirm a patient’s drug history or document compliance with a therapeutic regimen.

- **SCRIPTS** is updated daily

- **SCRIPTS** includes CII, CIII, & CIV Rxs
“Dispenser” does **not** include:

- Hospital pharmacies that distribute controlled substances for inpatients, or dispenses controlled substances at time of discharge; however, hospital outpatient pharmacies **must** report

- Hospital emergency rooms/departments (less than a 48-hour supply)

- Practitioners who **administer** controlled substances

- VA inpatient or outpatient pharmacies

- Most long-term care and assisted living dispensers

- Wholesale distributors
PMP REPORTS - Who may receive them?

- A practitioner or pharmacist for providing treatment to a bona fide patient
- A state, federal, or local law enforcement, or prosecutorial official for a specific drug related investigation involving a designated person
- LLR Boards
- DHHS regarding a Medicaid recipient
- Subpoena by a grand jury

REMINDER: Reports cannot be shared with anyone (raw data).
Visit us at: www.dhec.sc.gov/scripts

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