Who Regulates Controlled Substances?

DHEC is a regulatory agency with the goal of achieving and maintaining compliance with applicable laws and regulations through education.

The Bureau of Drug Control regulates the dispensing and administration of controlled substances. This is done through:

- Audits
- Inspections
- Educational Programs
- Investigations

SC Controlled Substance Act tasks DHEC with maintaining accountability of controlled substances in South Carolina – SC Code Sec. 44-53-480(b)
DHEC Drug Control Inspectors

DHEC Drug Control Inspectors requirements:

- Licensed pharmacists
- Minimum of three (3) years working experience in pharmacy practice
- Complete SC Criminal Justice Academy training and become a commissioned law enforcement officer

Duties of an inspector:

- Regulatory
- Registrant inspections
- Accountability audits
- Education
- Law Enforcement
- Investigations/Arrests
What is the Problem?

750-1000 complaints received annually from:

- health care professionals
- concerned citizens
- state and local agencies
- inspectors

450+ result in arrest and prosecution

30% Oxy
25% HC
10% Adderall

36% of all arrests are health care professionals
Arrests

FY 2016

• +450
  • 36% HCP (Nurses and Pharmacy techs most often)
  • Obtaining CS
  • Theft
  • Attempt/Conspiracy
  • Unlawful Distribution
  • Record Keeping
  • Doctor Shopping
  • Trafficking

“Get me a hundred milligrams of Oxycontin... And pick up something for this guy while you’re at it.”
Registrants - manufacture, possess, distribute, prescribe, administer, dispense

- Currently + 24,000
  - Pharmacies
  - Hospitals, Methadone Clinics
  - Practitioners (physicians, dentists, vets, NPs, PAs, podiatrists, optometrists)
  - EMS
  - Animal Shelters/Humane Societies
  - K9 units
  - Detention Centers/Prisons
  - Clinics, Hospice, Surgery Centers
  - Manufacturers, Distributors
These deliveries of OxyContin to pharmacies are getting ridiculous!
Pharmacy Inspections

- **Inventory**
  - Readily retrievable
  - Date/time
  - Signature of responsible individual that can attest to the completeness and accuracy

- **Purchase Records**
  - Readily retrievable
  - Date/qty received
Pharmacy Inspections

• Dispensing Records (Administration Records)
  • Three files
  • Patient name/address complete
  • Drug/strength/directions
  • Practitioner name/address
  • Date written
  • Pharmacist dispensing indicated on Rx
  • Rx signed
  • Refill requirements are met
Pharmacy Inspections

• **Security**
  - Access by unauthorized individuals
  - Notification of theft/loss

• **Identification for Controlled Substance Rx**s
  - Date dispensed
  - Rx number
  - Type/number of ID
  - Verified and initialed by pharmacy employee
Common Issues Found During Inspections

- Inventory – Not completed; no date/time/signature
- Invoices – No date of receipt noted on invoice
- Rx Records – wrong practitioner, fax requirements, early refills
- IDs – missing information; no employee initials; state not noted in the ID number
  - **Train Staff on Visual Verification**
- Rxs issued/filled outside of scope of practice (in SC, NPs **CANNOT** prescribe CIIs)
- Repeated loss/thefts – **no later than 30 days of discovery**
- Corresponding liability
- Preprinted/post dated Rxs
WE FOUND A FEW PILLS HERE AND A FEW PILLS THERE. HERE PILLS, THERE PILLS—EVERYWHERE THESE LITTLE PILLS. WORD ON THE STREET WAS RIGHT... OL’ MCDONALD RAN A PHARM.
Administrative Action

• Notice of Conference
  • to permit any person against whom criminal and/or civil action is contemplated under the Act an opportunity to present his or her views and his or her proposals for bringing his or her alleged violations into compliance

• Order to Show Cause
  • Denial
  • Suspension
  • Revocation
Loss by diversion due to repeated thefts, etc.

- Any registrant who suffers repeated losses of controlled substances by theft due to break-ins, employee theft, mysterious disappearance, or other than through an armed robbery shall be deemed to be providing inadequate security for such controlled substances.
SC PMP Program -

• intended to improve the state's ability to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances where there is a valid prescriber-patient or pharmacist-patient relationship.
SC PMP Program -

• CII-CIV prescriptions dispensed in SC are uploaded daily by the dispensing pharmacy/practitioner

• An authorized user (practitioner/pharmacist/delegate) logs into the SCRIPTS database and queries their patient.

• The practitioner/pharmacist uses the SCRIPTS report to make informed healthcare decisions.
SC PMP Program -

- Quality of dispensing data is essential and is dependent on the accuracy and completeness of information provided by the dispenser
  - Legal name
  - Accurate DOB
  - Correct practitioner

The slightest error or omission may impact how a patient receives care
Questions