Legal Aspects of Opioid Prescribing
South Carolina Medical Association
2018 SCMA Annual Meeting

Stephen P. Williams, BA, JD
Vice-President & Chief Operating Officer
New Horizon Family Health Services, Inc.
Greenville, SC
Presentation Objectives

• Know SC legal requirement to register with SCDHEC as a controlled substance provider
• Know federal requirement to register with DEA
• Know requirements of the SC SCRIPTS program
• Know rules about original and refill prescriptions for controlled substances
• SCBME requirements for pain management
Requirement to Register with SCDHEC as a Controlled Substance Prescriber

• SC Code of Regulations R61-4(106). Persons Required to Register. Every person who manufactures, distributes, prescribes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance shall obtain annually a registration...
Federal Requirement to Register with Drug Enforcement Administration

• As part of the DEA Diversion Control process, DEA registration to prescribe controlled substances is predicated on successfully completing all of the requirements imposed by the state in which the practitioner will conduct business and obtaining a state license

• DEA Practitioner registrations must be renewed every three years
Controlled Substances Monitoring Program

• New South Carolina law effective May 19, 2017
• "Section 44-53-1645; A practitioner, or the practitioner's authorized delegate, shall review a patient's controlled substance prescription history, as maintained in the prescription monitoring program, before the practitioner issues a prescription for a Schedule II controlled substance. If an authorized delegate reviews a patient's controlled substance prescription history, the practitioner must consult with the authorized delegate regarding the prescription history before issuing a prescription for a Schedule II controlled substance. The consultation must be documented in the patient's medical record."
SC SCRIPTS Program

- **SCRIPTS** (South Carolina Reporting & Identification Prescription Tracking System), is 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.
Which Drugs are Included in the Tracking System?

- Controlled Substances Schedules II, III & IV (i.e., OxyContin®; Percocet®; Vicodin®; Klonopin®; Xanax®; and Valium®)
What are the Uses for SCRIPTS Reports?

- A **SCRIPTS** report provides information for schedules II-IV controlled substance 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.
Is it Safe to Say that a SCRIPTS Report is Complete and Accurate?

• **SCRIPTS** does not warrant any report to be accurate or complete. The Report is based on the search criteria entered and the data entered by the dispensing pharmacy or practitioner. It also depends on the timely submission of data from the dispensing pharmacy or practitioner.
What Can Occur to Those Who Do Not Report or Disclose SCRIPTS Confidential Information?

- Dispensers who fail to report will be subject to a two thousand ($2,000) dollars fine and/or two (2) years imprisonment. Authorized users who knowingly disclose their account user information or breach confidentiality of the information will be subject to a ten thousand ($10,000) dollars fine and/or ten (10) years imprisonment.
Original and Refill Prescriptions for Controlled Substances

• SECTION 44-53-360. Prescriptions.

(a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, or in emergency situations as prescribed by the Department by regulation, no controlled substance included in Schedule II may be dispensed without the written prescription of a practitioner. Prescriptions shall be retained in conformity with the requirements of Section 44-53-340. No prescription for a controlled substance in Schedule II may be refilled.
Legitimate Medical Purpose

• (c) No controlled substances included in any schedule may be distributed or dispensed for other than a medical purpose. No practitioner may dispense a Schedule II narcotic controlled substance for the purpose of maintaining the addiction of a narcotic dependent person outside of a facility or program approved by the Department of Health and Environmental Control. No practitioner may dispense a controlled substance outside of a bona fide practitioner-patient relationship.
Schedule III, IV and V Refills

• (d) Unless specifically indicated in writing on the face of the prescription that it is to be refilled, and the number of times specifically indicated, no prescription may be refilled. The indication of "PRN" or "ad lib" or phrases, abbreviations, or symbols of like meaning shall not be construed as to exceed five refills or six months, whichever shall first occur. Preprinted refill instructions on the face of a prescription shall be disregarded by the dispenser unless an affirmative marking or other indication is made by the prescriber.
Limit on Quantity of Pills per Prescription

• (e) Prescriptions for controlled substances in Schedule II with the exception of transdermal patches, must not exceed a thirty-one day supply. Prescriptions for Schedule II substances must be dispensed within ninety days of the date of issue, after which time they are void. Prescriptions for controlled substances in Schedules III through V, inclusive, must not exceed a ninety-day supply
Pain Management Contracts

• Now considered as passé standing alone
• See the Mid 2017 Joint Statement from Boards of Medicine, Dentistry, Nursing and Pharmacy:
• http://www.llr.state.sc.us/pol/Medical/pdf/FINAL%20Joint%20Revised%20Pain%20Management%20Guidelines%20August%202017.pdf