

Dispensing Laws:

Laws, Rules, and Public Policy that Govern the Dispensing of Medications

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Faculty

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Objectives

- **Define the public health nurse's role as a medication dispenser**
- **Distinguish between the role of the Nurse and the role of the dispenser**
- **List laws, rules, regulations and public policy affecting dispensing**

Objectives

- **Identify liability issues as they apply to the dispensing of medication**
- **List methods to provide medication information to the patient or caregiver**

Factors That Affect Nurse Dispensing In ADPH

- **Alabama State Board of Pharmacy Dispensing Policy and Law**
- **ADPH Nurse Dispensing Protocol**
- **Federal Dispensing Law**

Factors That Affect Nurse Dispensing In ADPH

- **National Public Policy**
- **Federal Law and Public Law differentiated from State Policy and Protocol**
- **Liability issues**

Citations: Controlled Substances

- **State Law**
 - Code of Ala. § 20-2-1, et seq.,
Federal Register- 21 CFR § 207.10,
 - 21 CFR Part 208, Subpart A , and
 - 21 CFR §314.70(b)(3)(ii) (21 CFR 314.70(b)(3)(iii) and § 601.12(f) and (21 CFR 601.12(f)

Citations: Controlled Substances

- **Code of Federal Regulations**
 - 21 CFR Parts 1300 to End, and 201, 208, and 209 RIN 0910–AC35
- **Liability pursuant to laws**

Definition: Legend Drug

- **A Legend Drug is - any drug, injection, powder, ointment, IV, vaccine, tablet, capsule, or in any other delivery form that includes the following on the label:**
 - **The Words: Caution: Federal Law Prohibits Dispensing Without A Prescription,**
Or
 - **The Words: RX ONLY**

Citations: Legend Drugs

- **OBRA 90-(P.O.101-508)**
- **Alabama Administrative Code-**
 - **R. 420-7-2 and 34-23-1, et seq.**
- **Public Policy**
 - **Healthy People 2010-Medical Product Safety (Part 17)**
- **Liability pursuant to laws**

Definition of Dispensing

- **Definition of Dispensing 680-X-2-C: To sell, distribute, administer, leave with, give away, dispose of, deliver, or supply a drug or medicine to the ultimate user or their agent**

Alabama State Nurse Dispensing Law

- **Alabama Code: 1975 § 34-23-11b**

State Nurse Dispensing Law

- (b) A registered nurse in the employment of the State Health Department or a county health department may, in the provision of health care services, dispense legend drugs as provided in this section under the standing orders...

State Nurse Dispensing Law (con't)

... or direct supervision of a physician licensed to practice medicine in this state and pursuant to procedures established by the Board of Pharmacy and implemented by a pharmacist licensed to practice pharmacy in this state.

State Nurse Dispensing Law (con't)

- The nurse may dispense the legend drugs for the treatment of tuberculosis, sexually transmitted diseases, family planning, hypertension, and other programs if approved by the State Board of Pharmacy (meningitis & pertusis)

State Nurse Dispensing Law (con't)

- The dispensing of the drugs shall meet all labeling, packaging, recordkeeping and counseling requirements of a prescription
- The Board of Pharmacy shall have the responsibility to inspect the site where the dispensing occurs

State Nurse Dispensing Law (con't)

- The authority granted to a registered nurse pursuant to this subsection shall not apply to controlled substances as defined in Chapter 2 of Title 20

Counseling Provisions

- Counseling on the drug(s) as opposed to lifestyle or the condition
- Counseling according to set standards (About The Drug)
 - OBRA 90- Medicaid
 - Public Law 104-180 Counseling Guidance
 - FDA Counseling Guidance

OBRA 90

- Public law
- Set standards for counseling on drugs
- Primarily for pharmacists and Medicaid
- Applies to all dispensers
- Sets standards for drug utilization review
- Liability created

Counseling Provisions In Alabama

- See Handout: 680-X-2-21
 - Sets Standards for Counseling

Synopsis of Counseling Provisions

- Counseling should be oral and written on all new prescriptions
- ADPH nurses included in state law

Elements of Written Counseling Summarized & Included On PILS

- What is the medicine?
 - Give uses, indications
- What should I tell my Health Care Provider before I take this medicine?
 - List conditions

Elements of Written Counseling Summarized On PILS (con't)

- How should the medicine be taken?
 - Give directions Rx What to do if a dose is missed?
- What may interact with this medicine?
 - List drugs that interact both OTC

Elements of Written Counseling Summarized On PILS (con't)

- What side effects may occur?
 - List side effects and what to do about them

Elements of Written Counseling Summarized On PILS (con't)

- **Side effects statement verbatim: Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 (this is new starting on Jan. 1, 2009)**

–Delayed for 6 Months

Elements of Written Counseling Summarized On PILS (con't)

- **What should I watch for while taking this medication?**
 - List special items pursuant to this drug (see example isoniazid PIL)
- **How do I store the medication?**

Liability

- **Law is clear about provision of written and oral counseling and standards are set**
- **Liability is created if patient not counseled and has health problem as a result**
- **Providing PILS is one way to lessen liability**

Steps To Legal Dispensing

- **Similar to nurses right of medication administration**
- **Provide the correct medication,**
- **Properly labeled,**
- **To the correct patient**
- **Along with the required standardized drug information either orally, in writing or both**