Legal Considerations for Pharmacists Providing Immunizations

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Outline

• Scope of Pharmacists’ Involvement
• Legal Authority for Pharmacists to Administer Immunizations
  – Texas Regulations
• General Principles in Pharmacist Liability Cases
• Compounding Issues
Scope of Pharmacist Involvement

- American Pharmacists Association estimates over 80,000 pharmacists will be certified by end of this year.
- Walgreens has 16,000 certified immunizers (most pharmacists) and in past 6 weeks administered 4 million seasonal flu vaccines (1 million in 2008).
Scope of Pharmacist Involvement

- Walgreens estimates could provide 19 million H1N1 vaccinations if they have access to it.
- State law restrictions are a problem.
  - Only adults or children over a certain age
Pharmacists’ Authority to Administer Immunizations & Vaccinations

- Now authorized in 50 states and D.C.
- Usually under a protocol or collaborative practice agreement with a physician
- Requirements vary by state
  - Training
  - Order of a physician
  - Types of immunizations
  - Age restrictions
  - Notification requirements
Texas Occupations Code
Sec. 554.052

• Became effective 9/1/99
• Authorized Texas Board of Pharmacy to develop rules to allow pharmacist administration of vaccinations and immunizations under protocol with a physician.
• Originally required referral from physician required if under 14 years of age.
• Amended in 2009 to allow for patients over 7 years old without a referral.
Board of Pharmacy Rule
295.15

• May be done within a pharmacy or other location specified in protocol but not where patient resides other than nursing homes/hospitals
• Specific requirements for written protocol
• Pharmacist Certification requirements
• Physician supervision requirements
• Notification requirements
  – Patient’s Primary Care Physician
  – Protocol Physician
Prep Act

- Immunity from Liability includes qualified persons who prescribe, administer, or dispense countermeasures.
- Pharmacists are included as they are licensed both when dispensing a covered product or administering a covered product.
General Principles in Pharmacist Liability Cases

- Clear legal duty established with respect to dispensing (mechanical) functions.
- Emerging legal duty with respect to cognitive (non-dispensing) functions.
Pharmacist Liability in Texas

• Dispensing Errors

• Duty to Warn
  – Morgan v. Wal-Mart (30 SW 3d 455 Tex. App. – Austin, pet. denied)

• Drug Therapy Management or as Provider of Immunizations
  – No case law
  – Likely to be treated similar to Physician’s Assistant or Advanced Practice Nurse
  – Key is adhering to protocol
Applicability of Tort Reform

- Heath Care Liability Claim
  - Includes cause of action against health care provider
- Health Care Provider
  - Includes a pharmacist
- Pharmacist
  - Means one licensed …who for purposes of this chapter perform those activities limited to the dispensing of prescription medicines which result in health care liability claims and does not include any other cause of action that may exist at common law against them, including but not limited to causes of actions for the sale or mishandled or defective products.
Compounding Issues

• Compounding – part of practice of pharmacy and regulated by states
• Manufacturing – exceeds scope of pharmacy practice and is regulated by FDA.
• FDA Compliance Policy Guideline lists 9 factors FDA considers in making determination if a pharmacist is engaged in manufacturing.
Compounding Issues

- Compounding commercially available products is one factor.
- Texas law allows compounding of a commercially available product if:
  - The product is not reasonably available from normal distribution channels in a timely manner to meet patient needs.
  - The pharmacist maintains documentation that the product is not available due to a shortage.
  - The prescribing practitioner has requested the pharmacist to compound a product under specific conditions.
Tamiflu® Compounding

- Unique in that the package insert for the product specifically allows pharmacists to compound an oral suspension from 75mg capsules when the commercially available oral suspension is not available.
- “This compounded suspension should not be used for convenience or when FDA-approved Tamiflu® for Oral Suspension is available.”
ISMP Medication Safety Alert

- Alert issued Oct. 22, 2009 regarding the risk of dosing errors with pharmacy-compounded Tamiflu®.
- The compounded product results in a concentration of 15 mg/ml while the commercial product is 12 mg/ml.
- If a prescriber does not specify the dose in mg, but uses ml expecting the commercial product, this could result in an overdose.