LEGISLATIVE AND REGULATORY UPDATE

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TENNESSEE BOARD OF PHARMACY

DISCLOSURE INFORMATION

2014 LONG TERM CARE SEMINAR
AUGUST 27 & 28, 2014
REGGIE DILLIARD, D.Ph.

**I have no financial relationships to disclose**

**I will not discuss off label use and/or investigational use in my presentation**

LEGISLATIVE AND REGULATORY UPDATE

Objectives for today’s session:
- Gain an understanding of new laws and rules affecting pharmacy
- Be able to discuss proposed rule changes and how they affect long term care practice
- Learn common Board issues and suggestions for remaining compliant
- Understand Controlled Substance issues

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Public Chapter 872: ID Bill
- Applies to CII-IV opioids, benzodiazepines, zolpidem, barbiturate, or carisoprodol in quantities greater than 7 day supply

Public Chapter 906: Pseudoephedrine Limits
- Limits purchase to 5.76 gm in any consecutive 30 day period and...
- 28.8 gm in any one year period
- Daily limit did NOT change (still 3.6gm/day)
- Purchaser must be 18 years of age or older

Public Chapter 1011: Controlled Substance Reporting
- Changing the required timeframe for reporting to the controlled substance database to once per business day (p7) (effective date January 1, 2016).

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Public Chapter 623: Prescribing and Dispensing of Opioid Antagonists
- Allows prescribing and dispensing of opioid antagonists to at-risk persons, their family members, or their friends (effective date July 1, 2014).

Public Chapter 832: Collaborative Practice
- Effective 7/1/14
- Board currently promulgating rules

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Public Chapter 989: Traffic-Control Signals
- Clarifies that drivers can run yellow lights as long as their front tires cross the stop line before it turns red!
- Affects those pharmacists and technicians that can’t get to work on time
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CURRENT LICENSEES AS OF 7/1/14:
- Pharmacists 10693
- Technicians 17823
- Pharmacies 2491
- MWD 1945
- Researchers 260
- Medical Sales Reps 42

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• Permanent Compounding Rules
  *Public Hearing held 7/7/14
  *Sent to Attorney General 7/8/14
  *Arrived at Attorney General’s office to become effective 10/9/14

1140-07-.02 (4)-Revised(4) Any licensed pharmacy which compunds high-risk or batch sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of sterile products compounded and dispensed during the previous quarterly period and any other information as required by USP standards the Board of Pharmacy

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• COMPOUNDING, cont’d
  - Discussion of need for clarification of “inpatient vs. outpatient” and tracking of lot numbers

We are continuing to work with pharmacies to bring them into compliance with U.S.P. 797 standards and hope to have all in compliance by the end of 2014

Common Complaints Heard by Board

- Unregistered/expired technicians
- Diversion/theft
- Misfills
- Alleged discounts (usually controlled substances)
- Failure to counsel on new prescriptions
- Rude or unprofessional conduct
- Failure to counsel on pseudoephedrine sales
- Alleged HIPAA violations
- Copay, insurance issues
- Professional privilege tax

Don’t shoot the messenger!

Chapter 1140-14
Proposed Long-Term Care Pharmacy Practice Site Rules

Chapter 1140-14
Proposed Long-Term Care Rules

• Security
  - If a long-term care pharmacy practice site is located within a long-term care facility, a pharmacist must be accessible within that long-term care facility
  - When a pharmacist is not present at the long-term care facility, the pharmacy practice site must be kept closed and securely locked.
Chapter 1140-14
Proposed Long-Term Care Rules

- Controlled Drugs
  - Record of the destruction of controlled substances previously dispensed to or for patients and returned to the dispensing pharmacy or destruction shall be maintained and records shall include:
    - Identification of patient
    - Drug name, strength, dosage form, and quantity
    - Date and method of destruction
    - Identification of authorized personnel witnessing the destruction and its record

- Emergency and Home Care Kits
  - A pharmacy technician holding an active registration and employed by the pharmacy may restock and reseal the emergency kit with items prepared and checked by a pharmacist at the pharmacy.
  - Nurses as agents of a physician
    - Form must be submitted to DEA for control substances

- Automated Dispensing Systems in Long-Term Care Practice Sites
  - Each pharmacy using automated dispensing systems shall register each automated dispensing device, and its physical location, with the Tennessee Board of Pharmacy. Each pharmacy shall be responsible to pay a registration fee for each automated dispensing device.
  - Any automated dispensing device containing controlled substances must be registered with the DEA.

  - If the automated dispensing system uses removable cartridges or containers to hold drugs
    - The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the PIC

  - A pharmacist verifies the cartridge or container has been properly filled and labeled
  - The individual cartridges or containers are transported to the remote site in a secure, tamper-evident container
  - The automated dispensing system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated dispensing system.
  - All drugs to be stocked in the automated dispensing system shall be delivered to the remote site by the provider pharmacy.

  - The filling/stocking of all medications shall be completed by a pharmacist or pharmacy technician under the direct supervision of a pharmacist, except:
    - If the automated dispensing system uses removable cartridges or containers to hold drugs
    - The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the PIC

  - A record of medications filled/stocked shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.
  - The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system.
  - The automated dispensing system shall provide a mechanism for securing and accounting for wasted or discarded medications in accordance with existing state and federal law.
Chapter 1140-14
Proposed Long-Term Care Rules

- Automated Dispensing Systems in Long-Term Care Practice Sites
  - The Board shall maintain a list of registered automated dispensing devices, including physical address and number of devices located at each physical address.
  - Registrations must be renewed every two (2) years.

REGULATORY UPDATE

A State Comparison: Annual Prescriptions per Capita 2013

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<th>Rank</th>
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REGULATORY UPDATE

Governor Haslam’s initiative:

**PRESCRIPTION FOR SUCCESS**
1. Decrease the number of Tennesseans that abuse controlled substances
2. Decrease the number of Tennesseans who overdose on controlled substances
3. Decrease the amount of controlled substances dispensed in Tennessee

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Prescription for Success, cont’d

4. Increase access to drug disposal outlets in TN.
5. Increase access and quality of early intervention, treatment and recovery services.
6. Expand collaborations and coordination among state agencies.
7. Expand collaboration and coordination with other states.

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Five of seven initiatives directly apply to the Controlled Substance Monitoring Database

The CSMD is a useful tool for prevention of abuse and to alert and prevent patient risk of harm and overdose

All pharmacists and prescribers should be using the database regularly as part of normal drug utilization review

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Controlled Substance Monitoring Database has become a valuable asset to determine abuse and dispensing and prescribing patterns that might be red flags.

The Database has become the centerpiece for the Governor’s efforts to control prescription abuse and overprescribing/dispensing.

Continual upgrades are being made to alert to patient risks and abuse.

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Some enhancements:
- Alerts for average daily Morphine Equivalent Dosage
- Database easier to use and faster
- User reports readily available
- Laws changed to allow enhanced usage by prescribers
- Looking yearly at top 50 prescribers and dispensers
- State sharing

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TENNESSEE CLINICAL PRACTICE GUIDELINES FOR MANAGEMENT OF CHRONIC PAIN
- In draft form waiting for approval from all involved regulatory boards.
- Expected to be released within a few months
- Goal is to set guidelines for initiation, continuation, and withdrawal of opioid therapy
CHRONIC PAIN GUIDELINES - cont’d

- These guidelines also address women’s health issues and the Neonatal Abstinence Syndrome
- Recommended morphine equivalent dosage (speed bump-not a block)
- Proper usage of the CSMD to monitor patient therapy and prevent abuse
- When should a patient be referred to a pain specialist

WHAT IS THE PHARMACIST’S RESPONSIBILITY AS DEFINED IN CFR 1306.04(a)?

WHAT ARE RED FLAGS?

https://www.dropbox.com/s/jbjem2olb2qcmfy/TENNESSEE-redflag.mp4

POTENTIAL RED FLAGS ??????????

- Many customers receiving the same combination of prescriptions (cocktail)
- Many customers receiving the same strength of controlled substances
- Many customers paying cash for their prescriptions
- Prescriptions resulting in therapeutic conflicts

POTENTIAL RED FLAGS – cont’d

- Many patients with the same diagnosis
- Individuals driving long distances to visit physicians and/or to fill prescriptions
- Patients coming into the pharmacy in groups, each with the same prescriptions from the same physician
- Constant requests for early refills
- Multiple Red Flags could be a reason to deny

WHAT DO I DO AS A PHARMACIST NOW?

- UTILIZE CSMD
- USE COMMON SENSE
- USE YOUR EDUCATION AND TRAINING
- BE A PART OF THE SOLUTION NOT THE PROBLEM
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• DO NOT FEAR THE BOARD OF PHARMACY
• USE US AS A RESOURCE
• WE WOULD RATHER EDUCATE YOU ON HOW TO DO IT RIGHT THAN FIND OUT YOU ARE DOING IT WRONG

BIG RED FLAG!!

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Questions?

THANK YOU!