

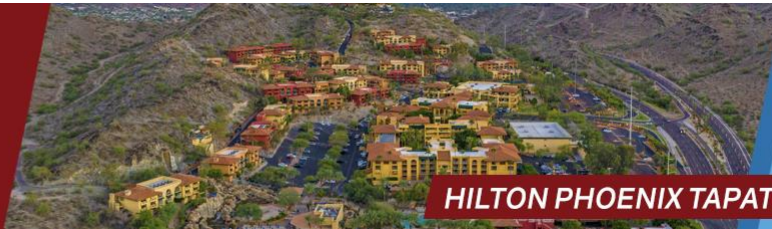
Red Flags: Variability in State Laws & Rules

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American
Society for
Pharmacy
Law

**DEVELOPMENTS
IN PHARMACY LAW
SEMINAR DPL XXXV**



**NOVEMBER
07-10**

HILTON PHOENIX TAPATIO CLIFFS RESORT 2024

Conflict of Interest Disclosure

I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.



Learning Objectives

- At the completion of this activity, the participant will be able to:
 - Identify nomenclature used in state-controlled substances acts regarding diversion by prescription
 - Identify nomenclature used in state pharmacy and medical practice acts regarding diversion by prescription
 - Discuss the variability of language used regarding “red flags”
 - Describe directives provided regarding diversion by prescription
 - Provide recommendations for pharmacy association government affairs divisions to utilize in working with DEA and DOJ
 - Propose language revisions to be included in the Federal Controlled Substances Act which would impact state practice acts



Assessment Questions

1. The DEA Pharmacist's Manual includes the term "red flag."
 - a. True
 - b. False
2. DEA utilizes the term "red flags" to mean anything that would alert a reasonably prudent pharmacist to issues regarding a certain prescription or a series of prescriptions.
 - a. True
 - b. False



Assessment Questions

3. In the Holiday CVS case, DEA must prove
 - a. A controlled substance was dispensed by the pharmacy.
 - b. A red flag was or should have been recognized at or before the time the controlled substance was dispensed.
 - c. The red flag was not resolved conclusively prior to the dispensing of the controlled substance.
 - d. All of the above



Opioid Epidemic

- Increase in deaths associated with opioid overdoses
- Multidistrict and individual municipality litigation against
 - Manufacturers
 - Distributors
 - Pharmacies



Legal Precedent for Red Flags

- Holiday CVS – Red Flags Test
 - DEA must prove
 1. The registrant dispensed a controlled substance.
 2. A red flag was or should have been recognized at or before the time the controlled substance was dispensed; and
 3. The question created by the red flag was not resolved conclusively prior the dispensing of controlled substances.
- East Main Street Pharmacy
- Jones Total Healthcare Pharmacy



Pharmacist's Manual

- The term “Red Flag” is not used in this reference
- Documentation per se not specified; however, documentation is the only way to determine if a red flag has been resolved
- “Think in ink!”

United States Department of Justice
Drug Enforcement Administration
Diversion Control Division
www.DEAdiversion.usdoj.gov



Pharmacist's Manual

An Informational Outline of the
Controlled Substances Act



State Controlled Substances Acts

- Follow federal CSA rules
- Many states more stringent (Texas)
- Varying detail in state statutes & rule language
- Some “prescriptive” with detailed language regarding **red flags** and **documentation**



Project Goals

- Identify what nomenclature/terminology is used
 - In state-controlled substances, pharmacy, and medical practice acts and associated rules and regulations
- Develop recommendations for pharmacy association governments affairs divisions to utilize in working with DEA and DOJ to propose language changes to be included in the Federal Controlled Substances Act and subsequent changes to state practice acts



Methodology

- Reviewed respective state laws and rules for all states, the District of Columbia, and Puerto Rico
- Documents were reviewed for the following:
 - Where **red flags** mentioned in state laws?
 - Was the term “**red flag**” defined?
 - Was diversion mentioned in the state’s law?
 - Was the directive to “not dispense the prescription” stated?



States with Red Flags Mentioned & Defined in Statutes or Rules

Texas



Massachusetts



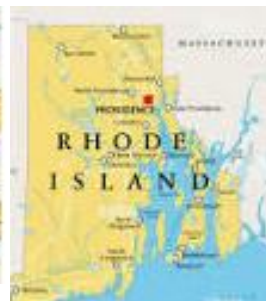
States with Red Flags Mentioned in Other Documents



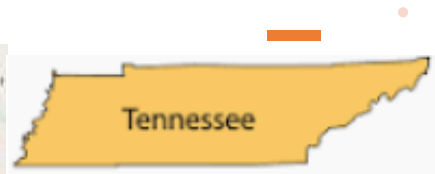
ARIZONA



PENNSYLVANIA



RHODE ISLAND



TENNESSEE



VERMONT



Diversion Mentioned

Alaska	Indiana	Nevada	South Carolina
Arizona	Iowa	New Hampshire	South Dakota
Arkansas	Kansas	New Jersey	Texas
California	Louisiana	New Mexico	Vermont
Colorado	Michigan	North Carolina	Wisconsin
Connecticut	Mississippi	North Dakota	
Idaho	Missouri	Oklahoma	
Illinois	Nebraska	Oregon	



Not Dispensing Directive

- Alaska
- Arkansas
- Colorado
- Nevada
- Oklahoma
- Oregon
- Texas



Observations

- Reference to federal statutes
- Reference to NABP video and other materials
- Included in non-statutory and/or role language
 - FAQs
- Reference to DEA Pharmacist's Manual



Conclusions & Recommendations

- “Red Flag” nomenclature mentioned in very few states
- Types of red flags mentioned; however, term not used in language
- Concerns regarding inclusivity of all types of red flags that may exist
 - What if one is not included in the statute or rule?
- Language could be broadly included CSA



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