

Pharmacy Practice Issues Update: Recent Changes and Trends in State Pharmacy Laws and Regulations

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Pharmacy Law and Regulatory Update

- **Provision of Pharmacy Services**
 - Immunizations
 - Collaborative Practice
 - Patient Counseling
- **Dispensing Cost-Effective Generic Drugs**
 - Generic “Carve Outs”
 - “Continuity of Care” Legislation
 - Chemotherapy Drug Parity
- **Issues Impacting Pharmacy Operations**
 - Disposal of Unused Drugs
 - Prescription Drug Monitoring Programs
 - Electronic PSE Reporting Logs
 - PSE as Rx-Only Product



Provision of Pharmacy Services



Provision of Pharmacy Services

- The national healthcare reform debate and recent public health emergencies have placed a greater demand on state laws and regulations that affect the provision of pharmacy care services.
- These include:
 - Immunizations
 - Collaborative Practice
 - Pharmacy Counseling



Collaborative Practice

- Collaborative practice agreements between pharmacists and physicians that permit pharmacists to manage and modify patient's drug therapy under a protocol.
- The Pharmacist must manage the protocol as directed by a physician.
- These agreements, generally, allow pharmacists to provide disease management services to patients for ailments such as diabetes, hypertension, and hyperlipidemia.



Collaborative Practice

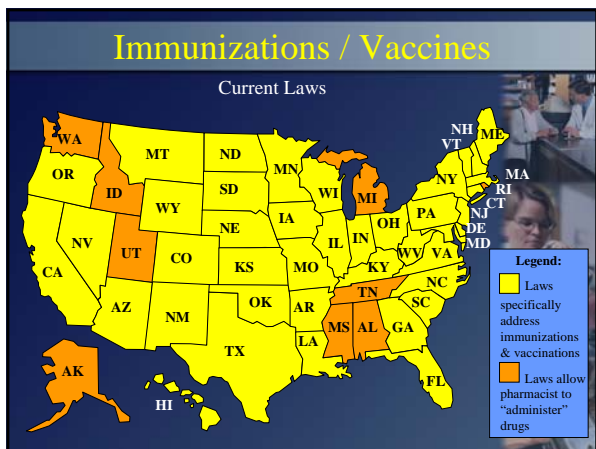
- **30 states** permit *community* pharmacists to enter into collaborate practice agreements with physicians.
- More states are expanding their laws defining pharmacy practice to permit pharmacists to engage in these activities.






Immunizations / Vaccines

- EVERY state permits pharmacists to administer immunizations and vaccines under certain conditions
- States are further expanding the lists of vaccines that pharmacists can provide, or are expanding the patient population to which pharmacists may provide vaccine services – such as the Herpes Zoster vaccine.
- H1N1 may have been a tipping point on this issue.




Patient Counseling

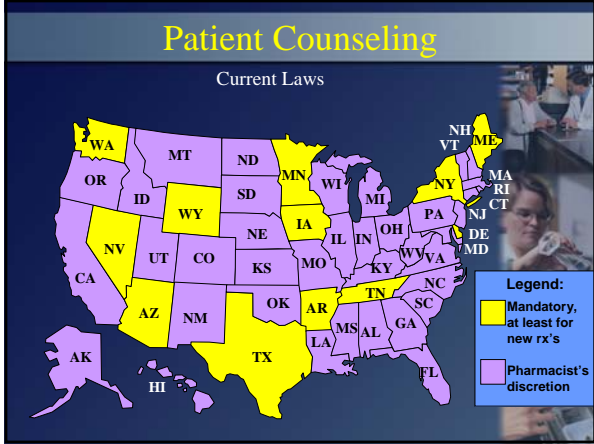
- By virtue of their education, pharmacists are medication experts and are the key healthcare provider to counsel patients and provide information on the safe and effective use of medications.
- Pharmacists have the professional judgment to determine what, when, where, and how counseling on appropriate medication utilization should be provided.



Patient Counseling

- Under OBRA '90, an *offer* to discuss the unique drug therapy regimen of patients must be made.
- Counseling must include *matters that are significant*, (in the professional judgment of the pharmacist) and include various general information pertaining to the drug prescribed.
- OBRA '90 established a benchmark to ensure that patients are sufficiently counseled according to uniform standards.





Dispensing Cost-Effective Generic Drugs



Dispensing Cost-Effective Generic Drugs

- Affordable healthcare includes dispensing cost effective generics
 - Patient’s quest for safe affordable and cost effective treatments
 - Growing national healthcare costs
 - Current Economic Status
 - State Budget Crisis



Generic Substitution “Carve Out” Bills

- Legislation that would require pharmacists to perform additional administrative actions in order to engage in safe substitution of approved generic drugs:
 - Written notice to prescriber and/or patient
 - Consent of prescriber and/or patient
- Targets specific classes of drugs:
 - Anticonvulsant drugs
 - Immunosuppressant drugs



Generic Substitution “Carve Out” Bills

In 2009:

- As of August 2009, bills introduced in **13 states**.
- Bills would prohibit pharmacist from interchanging anticonvulsants and/or immunosuppressant drugs, brand or generic, without prior notification of and/or signed informed consent of interchange from prescriber and patient.



Generic Substitution “Carve Out” Bills

Run contrary to FDA’s position:

- Generic drugs **meet** FDA’s rigorous approval process and are interchangeable with brand-name drugs under all approved indications and conditions of use.
- Orange book ratings represents FDA determination of therapeutic equivalence, thus products evaluated as therapeutically equivalent (A rating) can be expected to have equivalent clinical effect whether the product is brand innovator drug or generic equivalent.
- FDA does not recommend treating any one class of drugs separately.



Generic Substitution “Carve Out” Bills

Additional concerns with “carve out” laws:

- Existing state substitution laws already give prescribers ultimate authority to prohibit or allow generic substitution.
- Medicaid’s requirement for dispensing generic unless prescriber has indicated on the prescription Dispense as Written “DAW”.
- Creates barriers to patient access to equally effective generic products at time when patients and the nation are looking to control rising healthcare costs.



Disposal of Unused Drugs

- **Federal government guidelines** advise consumers to mix their unwanted drugs with an undesirable substance such as coffee grounds and place them in containers into their household trash, and advises that certain controlled substances be flushed.
- **DEA** does not permit pharmacies to take back controlled substances from consumers – only authorized law enforcement may do so.



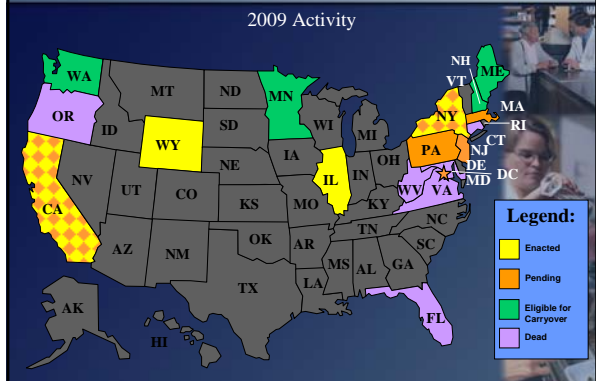
Disposal of Unused Drugs

- Legislation has been introduced in a number of states to create programs for consumers to dispose of unwanted and expired drug products
- Proposals offer different approaches for consumers' return of their unwanted drugs
 - consumer mail back program
 - using the state waste management system
 - in store disposal container



Disposal of Unused Drugs

2009 Activity



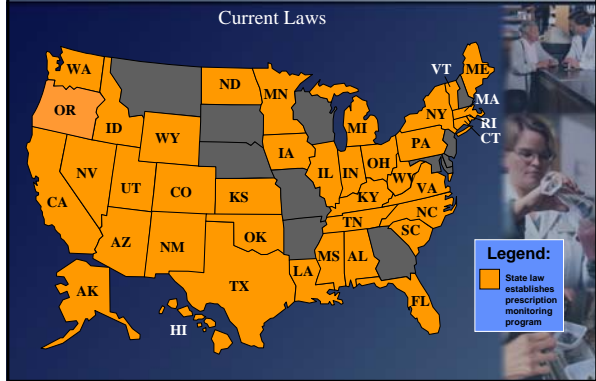
Prescription Drug Monitoring Programs

- Prescription drug monitoring programs allow states to monitor the prescribing and dispensing of controlled substances.
- Pharmacies submit controlled substance prescription information to states.
- **Currently, 39 states have laws for prescription monitoring programs.**



Prescription Drug Monitoring Programs

Current Laws



Prescription Drug Monitoring Programs

- Federal funding available since **2003**
- Currently, there are **two sources** for states to obtain federal grants:
 - Harold Rogers Grant Program
 - National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER)



Prescription Drug Monitoring Programs

Harold Rogers Grant Program

- Under Department of Justice (Bureau of Justice)
- Permits states to establish their own requirements with regard to controlled substances schedules monitored, information sharing, and accessibility/availability to the program data.
- Harold Rogers Grant Program has been funded for many years now has issued state grants from 2003 through present.



Prescription Drug Monitoring Programs

- FY 2008, 16 states plus Guam received **\$5.9 million** in Harold Rogers grant funding:

- Planning grants (of up to \$50,000) were awarded to: FL, GA & MO
- Implementation grants (of up to nearly \$400,000) were awarded to: GU & MN
- Enhancement grants (of up to \$400,000) were awarded to: AL, CO, IL, IN, KY, ME, MA, ND, OH, RI & WV
- Training and technical assistance grant (of \$670,000) to MA

- FY 2009 grant awards will be announced by September 30th

Source: US Bureau of Justice, <http://www.ojp.usdoj.gov/BJA/grant/prescrindrugs.html>



Prescription Drug Monitoring Programs

National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER)

- Under the Department of Health and Human Services (SAMHSA)
- **To be eligible for grant funding, NASPER requires state collect data for C II-IV prescriptions and be capable of sharing information and prescription data with other states.**
- Although the 2005 authorized \$60 million for the NASPER program through fiscal 2010, no funding was appropriated until the 2009 stimulus bill.



Prescription Drug Monitoring Programs

- Recent state PMP trends:
 - Attempts to **expand program** scope to require reporting of “**drugs of concerns**” and/or OTC products (**PSE**)
 - Attempts to mandate “**real-time**” reporting of PMP data
 - Attempts to decrease reporting days from 30 days to 7days
 - Attempts to mandate that pharmacies have “internet access” for mandated data base review.



PSE - Is it still an issue?



METHAMPHETAMINE

Shake and Bake or One Pot



Fertilizer (white rocks)
Pseudoephedrine
Fuel
Lithium Battery
Household Lye
1 CAP FULL WATER



Shake and Bake



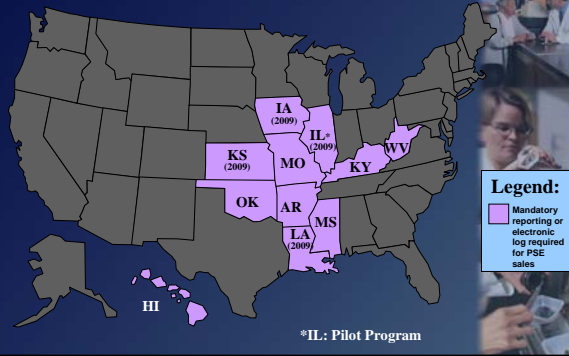
Electronic PSE Logs

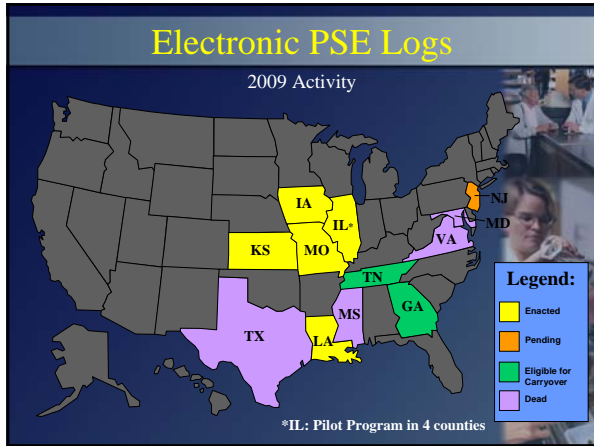
- Combat Methamphetamine Act (CMEA) of 2005 allows retailers to log PSE sales in an electronic or manual log.
- Pressure to stop “smurfing” has resulted in legislative activity to require retailers to record PSE sales in electronic logbooks.
- To date, laws requiring electronic reporting of PSE sales enacted in **8 states**.



Electronic PSE Logs

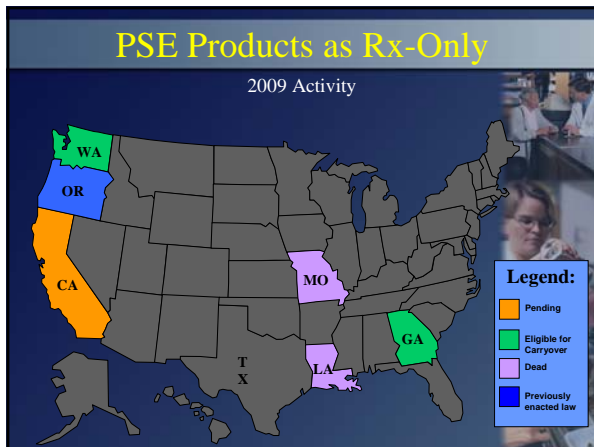
Current Laws





PSE Products as Rx-Only

- **OR** scheduled PSE as C-III in 2006
- Interest from other states to change their PSE laws to require a prescription.
- In 2009, **5 states** considered making PSE available only upon prescription.



The Future Rule of Three

In order to advance healthcare reform and maximize patient outcomes - our profession, regulators and legislators should:

- 1) Maximize the bandwidth of practitioners
- 2) Expand the practice boundaries
- 3) Foster practice site innovations



Questions