

A Pharmacist's Corresponding Responsibility & Louisiana's Prescription Monitoring Program

Pharmacy Diversion Awareness Conference

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Discussion Guide

- The Rule & The Reason
- Case Study
- Prescription Monitoring Program

The Rule

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a ***corresponding responsibility*** rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act ([21 U.S.C. 829](#)) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
[21 CFR 1306.04(a) + LAC 46:LIII.2747.E]

Valid Physician-Patient Relationship

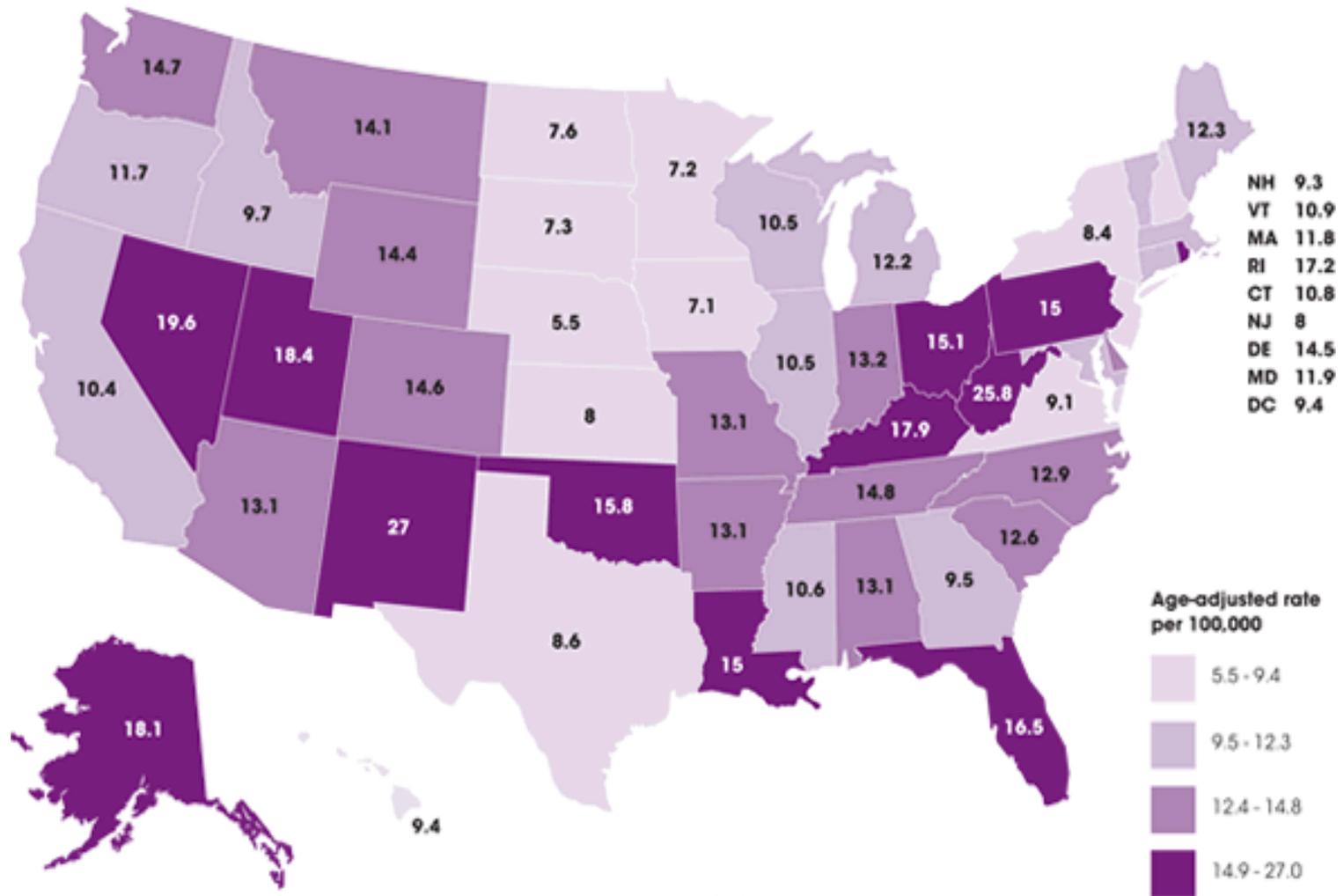
Physician establishes valid relationship by:

- verifying that the person requesting the medication is in fact who they claim to be;
- conducting an appropriate examination of the patient;
- establishing a diagnosis through the use of accepted medical practices, *i.e.*, a patient history, mental status, examination, physical examination and appropriate diagnostic and laboratory testing;
- discussing with the patient the diagnosis, risks and benefits of various treatment options; and
- insuring the availability for appropriate follow-up care.

Issuance of prescription, along with rationale for use, shall be documented in patient medical record.

[La. Board of Medical Examiners, May 2000]

Drug Overdose Rates by State, 2008



Case Study

- Pharmacy in Lafitte, LA.
- Population of 1,500 – “not on the way to anywhere.”
- 2008 inspection – multiple CDS infractions noted. Inspector cautioned pharmacy about TX prescriptions and discussed corresponding responsibility with pharmacists.

Case Study

- During all of 2009, pharmacy purchased 32,900 tablets of oxycodone – 307th in state.
- During all of 2009, pharmacy dispensed 223 prescriptions for 22,457 oxycodone tablets – 187th in state.
- During 1st three months of 2010, pharmacy purchased 147,300 tablets of oxycodone – 3rd in state.
- During 1st three months of 2010, pharmacy dispensed 755 prescriptions for 121,238 oxycodone tablets – 1st in state.

Case Study

- Supplier reported purchases to DEA and cut off all CDS sales to pharmacy in April 2010.
- Of the 3,912 prescriptions dispensed from January 1, 2010 to April 14, 2010:
 - > **3,048** (78%) were from TX prescribers, and of this number, 30% were for oxycodone products.
 - > 183 (21.5%) were from LA prescribers, and of this number, 3% were for oxycodone products.

Case Study

Multiple problems with TX prescriptions:

- > Prescriptions written by MD after they had already surrendered their DEA registrations;
- > Prescriptions written by NP who have no legal authority in TX to prescribe C-II drugs;
- > Prescriptions written on invalid prescription forms (TX requires CDS prescriptions on special forms).
- > Prescriptions contained stamped signatures or phrase “electronically signed.”

Case Study

- Patients told pharmacist they came to his pharmacy because no one would fill their prescriptions. Owner said he didn't know why no other pharmacy would fill the prescriptions. Relief pharmacist refused to fill the TX prescriptions.
- Patients never used insurance and paid cash, with some prescriptions costing up to \$3,000.
- Pharmacist said patients came to his pharmacy because his prices were cheaper, but price check revealed they were cheaper than no other pharmacy.

Case Study

- Pharmacist stated his practice to call prescriber to verify prescription: he provided name and birth date, and office recited drugs on prescription.
- Telephone records indicate frequency of calls didn't match prescriptions, and further, average duration of calls were less than one minute.

Case Study

- Pharmacist stated he only filled prescriptions for LA residents.
- Records reflect valid nonresident driver licenses along with newly-issued LA identification cards – mostly same day as prescription fill date.

Case Study

- Board suspended license of the pharmacist owner for an indefinite period of time, and further, conditioned any reinstatement application upon (1) at least 10 years of active suspension, and (2) payment of a \$15 fine for each of the 3,048 invalid prescriptions from TX prescribers. Also prohibited any access to the prescription department of his pharmacy.

Case Study

- Board suspended the pharmacy permit and CDS license for 5 years, stayed the execution of the suspension, then placed the permit and CDS license on probation for 5 years, and further, assessed a fine of \$35 for each of the 3,048 invalid prescriptions from TX prescribers. Board also prohibited access to prescription department by pharmacist owner.

Case Study

- On appeal, pharmacy argued vagueness of “corresponding responsibility” as well as severity of sanctions.
- Court affirmed all aspects of the Board’s decision.
- Appeal court’s written decision contains some useful information.

Case Study

- Prior case law from 1979:

“Standing alone, the phrase ‘corresponding responsibility’ is not crystal clear, but when read in context the regulation gives adequate notice of prohibited conduct.”

- Prior case law from 1984:

“The regulation is not irrational. The regulation does not place an unduly heavy burden on the pharmacist. Proof is required that the pharmacist had reason to believe that the prescription was not issued in the usual course of medical treatment.”

Case Study

Reasons to believe prescriptions not valid:

- Lafitte is 375 miles from Houston, and 'is not on the way to anywhere.'
- 2008 warning about TX prescriptions.
- Oxycodone purchases for 1st three months of 2010 exceeded by 4x purchases for all of 2009.
- 78% of CDS prescriptions dispensed written by TX prescribers.
- Patients with prescriptions from LA prescribers lived near the pharmacy; patients of TX prescribers did not.

Case Study

Reasons to believe prescriptions not valid:

- 111 of the TX prescriptions were written after the prescribers had surrendered the DEA registrations.
- Many of the prescriptions not valid because prescription form did not meet TX requirements.
- No one else would fill the TX prescriptions, not even his relief pharmacist.
- TX patients never sought to use insurance; all paid with cash or credit cards.

Case Study

Reasons to believe prescriptions not valid:

- Louisiana identification cards presented by patients with nonresident driver's license; address did not match address on prescription.

Transcript from conclusion of trial:

Q: “ Today, do you think it was right to fill these?
Now that you know more information, do you think it was right?”

A: “Yes.”

Prescription Monitoring Program

- Database of prescription transactions for CDS and drugs of concern dispensed to LA residents by all pharmacies licensed to do business in the state.
- Funded by \$25 fee paid by all pharmacies license by the Board as well as all the prescribers with authority for controlled substances (~ 18,000 accounts).
- No fee for queries.

Prescription Monitoring Program

- Prescribers and dispensers must register with the Board to obtain access privileges to the database – short online webinar and notarized proof of identity required, but no fee.
- Program complies with all HIPAA requirements; further, PMP law has criminal penalties for improper access or improper disclosure of PMP information.
- New law gives prescribers and dispensers permission to assign delegates; required rule should be ready by end of the year.

Prescription Monitoring Program

Practitioner Access (as of June 30, 2013)

- Prescribers – 3,652 (25% of 14,444 in state)
- Dispensers – 2,249 (44% of 5,148 in state)

Practitioner Queries (January – June, 2013)

- Prescribers – 406,897 (71% of total)
- Dispensers – 168,933 (29% of total)

Queries (average) – 3,550 per day

Prescription Monitoring Program

- PMP law requires all dispensers to report all eligible prescription transactions.
- PMP law does not require prescribers or dispensers to query the program data (except in licensed pain management clinics).

Prescription Monitoring Program

- Given the relative ease of access, the potential benefits of use, and the adverse consequences for failure to use the information, it may soon be a standard of practice.
- There are discussions underway suggesting the law be changed to require mandatory use of the data by prescribers and dispensers.
- To require a query for every patient every time would not be realistic. Is there a middle ground?

Prescription Monitoring Program

When a pharmacist becomes aware of a patient:

- Receiving CDS from multiple prescribers;
- Receiving CDS for more than 12 consecutive weeks;
- Abusing or misusing CDS (overutilization, appears intoxicated, unfamiliar patient requesting drug by street name, color, or markings);
- Requesting dispensing of prescription from prescriber located outside pharmacy's usual geographic patient population; or
- Presenting prescription when patient resides outside pharmacy's usual geographic patient population.

Corresponding Responsibility & Prescription Monitoring Program

- The pharmacist dispensing a prescription for a controlled substance has a corresponding responsibility to ensure the prescription is dispensed for a legitimate medical purpose in the usual course of a patient's treatment.
- The prescription monitoring program provides valuable information to the dispensing pharmacist and assists the pharmacist in fulfilling his corresponding responsibility.
- Be part of the solution, not part of the problem.

Final Review

- The Rule & The Reason
- Case Study
- Prescription Monitoring Program

Final Review

Questions?

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