

Pharmacy Jurisprudence, L.L.C.



For pharmacists in states with a pharmacy law continuing education (CE) requirement*, we offer our annual CE booklet free from commercial support.

Program Title: Consequences of Failing to Comply with Federal and State Drug Laws, with a Focus on Controlled Substances

Ohio Board of Pharmacy Program No.: 036-350-10-003-H03

ACPE Program No.: 487-000-10-003-H03-P knowledge-based activity or 487-000-10-003-H03-T knowledge-based activity

Target Audience: All Pharmacists, Nurses and Pharmacy Technicians

Release Date: September 3, 2010

Expiration Date: August 9, 2012

Accreditations: This continuing education activity is approved by the Ohio State Board of Pharmacy for 1.0 contact hours, or 0.10 C.E.U.'s, of continuing pharmacy education in Board-approved jurisprudence. This program is also accredited by ACPE for pharmacists and pharmacy technicians under our trade name Select CE®.



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Media: Enduring print material and **interactive test-taking at www.selectce.org.**

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Estimated Time to Complete the Activity: 60 minutes

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or

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A minimum score of 75% is required to earn a Statement of Credit.

Faculty: Patricia A. Nussle, R.Ph., J.D., is the founder of Pharmacy Jurisprudence and Select CE. She is also a healthcare attorney who has written and published continuing education programs in pharmacy law and nursing law for over 200,000 healthcare professionals since 2001.

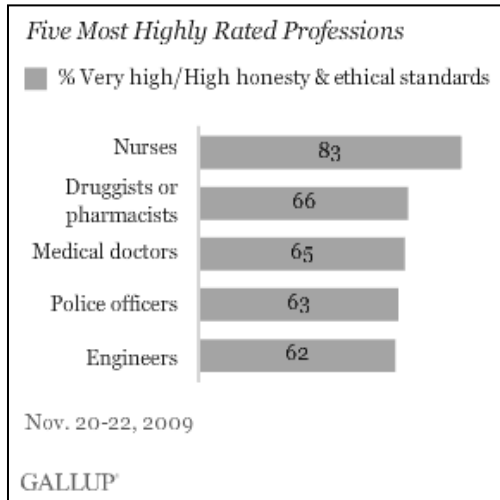
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Objectives: At the conclusion of this program, pharmacists and nurses should be able to recognize at least three consequences of failing to comply with federal and state drug laws regarding controlled substances.

Objectives: At the conclusion of this program, pharmacy technicians should be able to recognize at least three consequences of failing to comply federal and state drug laws regarding controlled substances.

Important Note: Colleagues, this is a continuing education program. It is not legal advice. Do not rely on this CPE program as legal authority. If you do have a legal problem or question, please consult an attorney experienced in pharmacy law matters to discuss your specific situation.

Nurses, pharmacists, and medical doctors enjoy the top three spots in a recent Gallup poll survey of honest professionals.¹ Each have close to two-thirds of Americans rating them highly.



For pharmacists, the high trust level is perhaps due in part to the steadily increasing educational requirements to become a pharmacist²:

1900's – apprenticeship

1950's – 4 year B.S. degree

1960's – 5 year B.S. degree

1970's – optional 2-year post-B.S. Doctor of Pharmacy degree

2000 – 6-year Doctor of Pharmacy degree is entry level degree

But sometimes pharmacists can do things to damage our individual and collective reputations. And when it happens, the stories often appear in the newspapers because we are such a highly trusted, highly educated and highly regulated profession.

We present to you recent stories of pharmacists and other healthcare professionals who have “done wrong” and are living the consequences. These are taken from publicly available news sources, and we have no intent to embarrass or harm the parties in the stories. But we believe we can and should learn from others. With that in mind, read on.

¹ <http://www.gallup.com/poll/124625/Honesty-Ethics-Poll-Finds-Congress-Image-Tarnished.aspx>

² <http://www.scribd.com/doc/12459523/Pharmacy-An-overview-of-one-of-the-worlds-most-trusted-professions>

Pharmacist Places False DEA Numbers on the Back of Oxycodone-Containing Prescriptions³

A 45-year old pharmacist practicing in Catonsville, Maryland, and the former owner of NatureCare Pharmacy agreed to pay \$500,000 to settle claims that he violated the Controlled Substances Act by providing false information and/or improperly dispensing prescriptions containing oxycodone.

United States Attorney Rod J. Rosenstein said, “Pharmacies and pharmacists who fill bogus prescriptions for controlled substances, especially invalid prescriptions for the highly addictive Oxycontin and Oxycodone related drugs, must be held accountable for their actions. This settlement is further proof that the United States will not tolerate the diversion of highly addictive controlled substances.”

The federal Controlled Substances Act requires pharmacists and pharmacies to dispense controlled substances pursuant to valid prescriptions and to maintain complete and accurate records of the distribution of controlled substances in a pharmacies’ possession. The Act authorizes the imposition of up to \$10,000 per violation of the record keeping requirements and \$25,000 for each occasion a pharmacy or pharmacist dispenses a controlled substance without a valid prescription.

According to the settlement agreement, the government contends that between March 18, 2002 and November 1, 2004, Pharmacist Cheung and NatureCare pharmacy committed multiple violations of the Controlled Substances Act by dispensing Oxycontin® and oxycodone-related products without a valid prescription; and

Question 1:

The federal Controlled Substance Act authorizes the imposition of up to _____ per violation of its record-keeping requirements.

- a. \$1,000;
- b. \$10,000;
- c. \$25,000.

Question 2:

The federal Controlled Substance Act authorizes the imposition of up to _____ for each occasion a pharmacy or pharmacist dispenses a controlled substance without a valid prescription.

- a. \$1,000;
- b. \$10,000;
- c. \$25,000.

³ http://www.justice.gov/usao/md/Public-Affairs/press_releases/press07a.htm

from March 21, 2003 to October 6, 2003 placed false DEA numbers on the back of 246 dispensed prescriptions, including prescriptions for Oxycontin®, Percocet®, Endocet® and Roxicet®, in order to avoid detection by the federal Drug Enforcement Administration.

Later, the Maryland Board of Pharmacy took action against his license. After considering the evidence, the Board and Mr. Cheung reached a consent agreement in which Mr. Cheung was suspended from the practice of pharmacy for two (2) years, and then placed on probation for another five (5) years.

Nursing Home Medication Administration Records (“MAR’s) Included Under “Drug Records” Law

Nurses, pharmacists, technicians, aides or anyone who places false notations in a patient’s MAR or other proof-of-use records regarding controlled substances can be found guilty of violating state laws regarding processing of drug documents.

In Ohio, the law states that [n]o person shall knowingly make a false statement in any prescription, order, report, or record required by Chapter 3719...of the Revised Code.⁴ Chapter 3719 is Ohio’s Controlled Substances Act.

In this case, a nurse who worked in a nursing home took controlled substance medications intended for the patient, and falsified the MAR to make it appear as if the patient received the medication, when in fact the patient did not. Instead, the nurse took the medications for herself. She was charged with theft of drugs and also with illegal processing of drug documents. She did not contest the theft charge. But the second charge she contested, acknowledging that she was a “person” under the law, but that the MAR’s of the nursing home where she worked were not required “records” under the Controlled Substance Act.

Question 3:

In Ohio, the law that no person shall knowingly make a false statement in any prescription, order, report or record required by the state’s Controlled Substance Act applies to:

- a. only licensed people, such as pharmacists and nurses;
- b. only un-licensed people, such as nursing students;
- c. any person.

Chapter 3719 is Ohio’s Controlled Substances Act. The General Assembly enacted Ohio’s Controlled Substances

⁴ Ohio Revised Code 2925.23(A)

Act in an attempt to regulate controlled substances in the state. One goal of the Act is to control the abuse of prescription drugs. To help achieve that goal, R.C. 3719.07 requires certain recordkeeping of those who prescribe, manufacture, and distribute controlled substances.

In this case, the Ohio Supreme Court reasoned that the record-keeping law applied to the records in the nursing home, which means the nurse's falsification of the patient's MAR is a violation of Ohio's drug offense laws:

“Without a requirement of recordkeeping for the delivery of controlled substances, the record would stop before the drugs reached the patient if the patient lived in a nursing home. We believe that the General Assembly specifically included nursing homes within the ambit of R.C. 3719.07 to make them responsible for keeping records of the drugs they handle. The high quantity of drugs present in a nursing home, the often reduced awareness of the residents for whom they are prescribed, and the ease with which prescription pills could otherwise be pilfered are factors necessitating the keeping of records of drugs delivered within nursing homes.”⁵

2-Year Prison Sentence for Ordering and Receiving Counterfeit Prescription Drugs⁶

A licensed pharmacist will spend two years in prison, although he did not actually dispense any medication wrongfully. Instead, what he did was order and receive counterfeit and misbranded medications.

Question 4:

Conspiracy to introduce into interstate commerce counterfeit and misbranded drugs netted a Texas pharmacist:

- a. a big fine;
- b. a 2-year prison sentence;
- c. nothing, because he did not actually dispense the drugs.

James George, 50, a licensed pharmacist and owner of Lifeway Pharmacy in San Jacinto, Texas, was sentenced to two years in federal prison, without parole, for conspiracy to introduce into interstate commerce counterfeit and misbranded Cialis® and Viagra®.

George was convicted by a jury's verdict following a two-day trial during which the United States proved that George had ordered counterfeit and misbranded pharmaceuticals from China via the internet and arranged for the drugs to be shipped to him at his home in Texas.

⁵ *State v. Peeler*, 99 Ohio St.3d 151, 2003-Ohio-2903

⁶ <http://www.justice.gov/criminal/cybercrime/georgeSent.htm>

The investigation that led to George's indictment began when Immigration and Customs Enforcement (ICE) inspectors at the Dallas-Fort Worth Airport examined a large package that had arrived from China with shipping documents identifying its contents as health food. Inspectors found that contrary to its label, the package contained large quantities of the pharmaceutical drugs known as Viagra and Cialis. ICE special agents assigned to the airport were notified of the discovery and continued the investigation.

Suspecting the pharmaceutical drugs were counterfeit, ICE agents notified Pfizer Pharmaceuticals, the manufacturer of Viagra, to verify the authenticity of the drugs. Checking the lot numbers, Pfizer confirmed the drugs were counterfeit. Eli Lilly, the manufacturer of Cialis, also confirmed the Cialis tablets were counterfeit.

After contacting George by telephone and making arrangements to deliver the package to George at his pharmacy, special agents with the FDA, posing as delivery personnel, made a delivery of the package containing 1,000 counterfeit Cialis tablets and over 4,500 counterfeit Viagra tablets to George. The agents immediately arrested George for ordering and receiving the counterfeit medications.

While George was serving his federal prison term, his pharmacist's license was revoked by the Texas State Board of Pharmacy.

New Hampshire Pharmacist Pleads Guilty and Surrenders His License for Four Unlawful Schedule III Fills Over 2 Years⁷

John F. Reilly, a 59-year-old pharmacist, pled guilty to unlawfully dispensing and misbranding controlled substances.

On four separate occasions in 2005 and 2006, Reilly dispensed quantities of Schedule III controlled substances, including Vicodin®, to a customer of a Wal-Mart pharmacy in New Hampshire who did not have a valid prescription for the drugs. It is unclear from the record whether Mr. Reilly dispensed unauthorized refills, or unauthorized original fills. After the offenses were committed, Reilly voluntarily surrendered his pharmacist license to the State of New Hampshire.⁸

Reilly will be sentenced on or after July, 2010. The maximum prison term for unlawful dispensing of controlled substances is five years. The maximum prison term for unlawfully misbranding controlled substances is one year.

⁷ http://www.justice.gov/usao/nh/press/april10/MI_Reilly.html

⁸ <http://www.nh.gov/pharmacy/aboutus/documents/min200712.pdf>

Pharmacist Sentenced to 6 Years in Prison for Conspiring to Fill 621 Forged Oxycodone Prescriptions⁹

Pharmacist Ketankumar Arvind Patel, age 48, owner of the Medicine Shoppe in Reisterstown, Maryland, was sentenced April 9, 2010 to six years in prison followed by three years of supervised release for conspiring to distribute tens of thousands of pills of oxycodone to a drug dealer. Judge Motz also entered an order that Patel forfeit \$400,000.

According to Patel's plea agreement, the investigation began when a drug dealer advised DEA agents that since July 2007 Patel had been filling fraudulent prescriptions for Oxycontin® and Percocet® at his pharmacy. The drug dealer had obtained blank prescription pads, and would fill out multiple false prescriptions in different patient and physician names for Oxycontin® and Percocet®. The drug dealer says Patel instructed him how to write fake prescriptions to avoid detection from the DEA, insurance companies or any other authorities. From July 2007 to March 2009, Patel filled approximately 621 prescriptions, for different patient's names and several different physician names. Among all pharmacies in Maryland, his Medicine Shoppe ranked 18th in the purchase of 80 mg oxycodone products.

After becoming an informant for the DEA in March 2009, the DEA had the drug dealer tape-record controlled purchases of oxycodone made with fake prescriptions and DEA funds. Phony prescriptions were also used by a separate Department of Health and Human Services undercover agent to purchase Xanax® from Patel on May 21, 2009 and June 5, 2009.

In total, Patel sold approximately 34,000 oxycodone pills to the drug dealer between July 2007 and March 2009 for approximately \$400,000. The total weight of the oxycodone sold was approximately 4.4 pounds.

Question 5:

The maximum prison term for unlawful dispensing of controlled substances is:

- a. 1 year;
- b. 2 years;
- c. 5 years.

Question 6:

The maximum prison term for unlawful misbranding of controlled substances is:

- a. 1 year;
- b. 2 years;
- c. 5 years.

⁹ http://www.justice.gov/usao/md/Public-Affairs/press_releases/press08

UCLA Healthcare Employee Sentenced for HIPAA Violations¹⁰

HIPAA now has teeth. A former UCLA Healthcare System employee who admitted to illegally reading private and confidential medical records, mostly from celebrities and other high-profile patients, was sentenced to four months in federal prison.

Question 7:

In Pharmacist Patel's case in Maryland, the testimony of a drug dealer -who stole prescription pads and forged prescriptions – that Mr. Patel instructed him on how to write prescriptions, helped land Mr. Patel in prison.

- a. Yes;
- b. No.

Huping Zhou, 47, of Los Angeles, was sentenced on April 27, 2010.

Zhou pleaded guilty in January to four misdemeanor counts of violating the federal privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA). Zhou specifically admitted to knowingly obtaining individually identifiable health information without a valid reason, medical or otherwise. Zhou is the first

person in the nation to be convicted and incarcerated for misdemeanor HIPAA offenses for merely accessing confidential records without a valid reason or authorization.

Zhou, who is a licensed cardiothoracic surgeon in China, was employed in 2003 at UCLA Healthcare System as a researcher with the UCLA School of Medicine. On October 29, 2003, Zhou received a notice of intent to dismiss him from UCLA Healthcare for job performance reasons unrelated to his illegal access of medical records. That night, Zhou, without any legal or medical reason, accessed and read his immediate supervisor's medical records and those of other co-workers. For the next three weeks, Zhou's continued his illegal accessing of patient records and

Question 8:

Accessing confidential medical records without a valid reason or authorization is a violation of:

- a. federal privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA);
- b. federal privacy provisions of the Health Information Privacy and Patient Protection Act;
- c. no state or federal law, as long as the information is not sold or published.

¹⁰ <http://www.justice.gov/usao/cac/pressroom/pr2010/079.html>

expanded his illegal conduct to include confidential health records belonging to various celebrities. According to court documents, Zhou accessed the UCLA patient records system 323 times during the three-week period, with most of the accesses involving well recognized celebrities.

There is no evidence that Zhou improperly used or attempted to sell any of the information that he illegally accessed.

Question 9:

Accessing confidential medical records without a valid reason or authorization can earn a healthcare employee:

- a. a misdemeanor charge;
- b. 4-month prison sentence;
- c. both.

I Million Tablets of Hydrocodone – No Legitimate Medical Purpose¹¹

A physician who operated a clinic in Duarte, California and dispensed more than 1 million tablets of hydrocodone and oxycodone, directly out of his office, was sentenced in April 2010 to 48 months in federal prison.

According to court documents, from January 2005 until his arrest on February 10, 2009, Dr. Daniel J. Healy prescribed and dispensed huge amounts of prescription painkillers to patients he typically did not examine.

In fact, no single doctor in the nation purchased more tablets containing hydrocodone than Dr. Healy did in 2008.

Special Agents with the Drug Enforcement Administration found that in 2008 Healy ordered more than 1 million hydrocodone tablets – more than any other individual physician in the nation. In contrast, the average pharmacy in the United States orders approximately 100,000 hydrocodone pills each year, meaning that Healy himself ordered nearly 10 times more hydrocodone in 2008 than the average American pharmacy. In the City of Duarte, Healy ordered

¹¹ <http://www.justice.gov/dea/pubs/states/newsrel/2010/la041410.html> and http://mobile.latimes.com/inf/infomo?view=page7&feed:a=latimes_1min&feed:c=localnews&feed:i=53386066&nopaging=1

nearly three times more hydrocodone during 2008 than the CVS, Wal-Mart, Target and City of Hope Hospital pharmacies *combined*.

United States District Judge Manuel Real agreed with the government's assessment: "Dr. Healy was in this for the money, I don't think there's any question about that."

On July 6, 2009, Healy pleaded guilty to one count of knowingly and intentionally distributing the prescription painkiller oxycodone outside the usual course of professional practice and without a legitimate medical purpose.

Question 10:

The average American retail pharmacy dispenses approximately _____ tablets containing hydrocodone each year.

- a. 10,000
- b. 100,000
- c. 250,000

Question 11:

Prescribing and dispensing from his office over 1,000,000 hydrocodone tablets in a year netted a California physician.

- a. 4-year jail sentence;
- b. \$150,000 fine;
- c. both.

Healy attracted the attention of federal authorities when an informant reported that Healy was dispensing controlled substances in exchange for cash payments, according to court documents. The informant reported that "patients" could obtain any amount of nearly any kind of painkillers they wanted from Healy, and then use the pills themselves or sell them for profit. In many instances, Healy accepted cash payments for manufacturer bottles of narcotics containing as many as 500 pills.

According to DEA informants, Healy either did not examine or made only cursory examinations of "patients" who directly received drugs or obtained prescriptions. A criminal complaint filed last year said that Healy was known to inquire whether his "patients" wanted a "party size" or a "family size" bottle of narcotics.

Dr. Daniel J. Healy, 53, was sentenced to prison by United States District Judge Manuel Real. In addition to the four-year prison term, Judge Real ordered Healy to pay a \$150,000 criminal fine. Following his release from prison, Healy will be on supervised release for 10 years, and he is required to perform 500 hours of community service during each of those years.

Idaho Pharmacist Fired For Tackling Armed Robber¹²

A northern Idaho pharmacist who tackled a gun-toting robber and received a special award from the city of Coeur d'Alene has been fired for violating company policy.

Jerry Gunderson says he was dismissed from the Shopko pharmacy in November 2009 because he resisted the robbery in violation of company policy.

A Shopko spokeswoman at the company's corporate office in Green Bay, Wis., declined to comment.

On Nov. 18, 2009 Gunderson chased after the gunman who police say had just stolen six bottles of anti-anxiety prescription medicine and then tackled him near the entrance of the store.

Police arrested the man and Gunderson later received a Citizen Appreciation Award from city leaders.

Gunderson tells the Coeur d'Alene Press he has since found another job at a different pharmacy.

Question 12:

Tackling a robber who is stealing controlled substances from your pharmacy might be a violation of:

- a. state law;
- b. federal law;
- c. your company's policy.

¹² Information from: Coeur d'Alene Press, <http://www.cdapress.com> and <http://www.kivitv.com/global/story.asp?s=11704876>

Return this **ANSWER SHEET** with the **\$15.00 Program Fee** payable to:

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ANSWER SHEET: Consequences...Focus on Controlled Substances

Expiration Date: August 9, 2012

Circle the answer for each question (questions are imbedded in the program).

- | | | | | | | | |
|----|---|---|---|-----|---|---|---|
| 1. | a | b | c | 7. | a | b | |
| 2. | a | b | c | 8. | a | b | c |
| 3. | a | b | c | 9. | a | b | c |
| 4. | a | b | c | 10. | a | b | c |
| 5. | a | b | c | 11. | a | b | c |
| 6. | a | b | c | 12. | a | b | c |

13. For Pharmacists: After completing this program, I am able to recognize at least 3 consequences of failing to comply with federal and state and federal drug laws regarding controlled substances: Yes No

13. For Technicians: After completing this program, I am able to recognize at least 3 consequences of failing to comply with federal and state and federal drug laws regarding controlled substances: Yes No

13. For Nurses: After completing this program, I am able to recognize at least 3 consequences of failing to comply with federal and state and federal drug laws regarding controlled substances: Yes No

14. This program was an effective way for me to learn: Yes No

15. I liked the program's format: Yes No

16. This program fostered my mental participation: Yes No

17. This was a "user-friendly" way for me to learn: Yes No

18. I could sense some commercialism in this program: Yes No

If yes, please describe: _____

19. The faculty quality was: Great OK Needs to Improve

20. The learning material quality was: Great OK Needs to Improve

21. How long did it take to complete this program? _____

22. What other topics would you like to see? _____

23. Comments welcome! _____

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