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Program Title: **Pharmacy Law Case Review**

Target Audience: Pharmacists, Pharmacy Technicians

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Faculty: Patricia Nussle, R.Ph., J.D., is the faculty for this CPE activity

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Objective: At the conclusion of this program, pharmacists should be able to restate the pertinent facts and court findings of at least 4 violations of state or federal drug laws.

Objective: At the conclusion of this program, pharmacy technicians should be able to restate the pertinent facts and court findings of at least 4 violations of state or federal drug laws.

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.

Questions? Just call us, text us, or email us: (614) 481-8711 or info@selectce.org.

As always, we want to know what you think. Please let us know.

Thank you! We truly enjoy serving you.

Introduction

In this CE offering, we highlight violations of state and federal drug laws from across the country. We selected these 8 cases because they deal with issues that many pharmacists and pharmacy technicians face on a daily basis - your pseudoephedrine log, the need for speed, mis-fills, pharmacy robberies and the like. While a court in, say, New Jersey, is not bound by what a state court in Iowa decides, we believe these cases should be instructive to you in meeting the objective of describing at least 5 violations of state and federal drugs laws.

Iowa - Pharmacy's PSE Log Used in Criminal Hearing[1]

Did you ever wonder if those pseudoephedrine logs are used for anything? In the case below, we see the logs maintained by each store (and also maintained in a master database by the State) used in court to convict a man of manufacturing methamphetamine.

Background Facts & Proceedings

The evidence presented in this case supports the following factual findings. One May night at about 3:00 a.m., police officers and firefighters responded to a report of a fire at a home in Des Moines. When they arrived they saw Mr. Q attempting to put out the fire with a garden hose. During an investigation officials determined the fire started as the result of manufacturing methamphetamine. Items used in the manufacture of methamphetamine were found in the home, such as empty pseudoephedrine packages, lithium batteries, muriatic acid, propane, and coffee filters. The residents of the home were Mr. Q and others.

Officers found a digital scale, an empty battery package, and empty pseudoephedrine packages in Mr. Q's bedroom. A magazine with pages ripped out was found in Mr. Q's room. Methamphetamine packaged in strips of paper, similar to that of the magazine, was found in a vehicle at the residence. Additionally, Mr. Q had black stains on his hands. There was evidence that stripping lithium from battery packs could lead to this staining.

One of the other residents of the home testified against Mr. Q at trial, indicating she bought pseudoephedrine for him so that he could, and did, manufacture methamphetamine.

A jury found Mr. Q guilty of conspiracy to manufacture methamphetamine, in violation of Iowa Code section 124.401(1)(b)(7) (2011); manufacturing methamphetamine, in violation of section 124.401(1)(b)(7); possession of lithium with intent to manufacture a controlled substance, in violation of section 124.401(4); and possession of a controlled substance with intent to deliver.. The district court sentenced Mr. Q to a total term of imprisonment of forty years..

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[1] STATE OF IOWA v. _____, No. 3-739 / 12-0739, Court of Appeal of Iowa, August 21, 2013; Appeal from the Iowa District Court for Polk County. Judge Mary Pat Gunderson.

Pharmacy Records.
Prior to trial the State indicated it intended to present as an exhibit an Iowa Pseudoephedrine Transaction Log (PSE Log) showing purchases of pseudoephedrine by Mr. Q and others.

Under section 124.212A of the Iowa Code, a pharmacy is required to enter information about each person purchasing pseudoephedrine in an electronic logbook. That information is kept in an electronic repository by the Governor's Office of Drug Control Policy (Office). The exhibit in this case contained information obtained from the Office's electronic repository.

Mr. Q objected to the exhibit on the grounds of foundation, hearsay, and the Confrontation Clause. The judge ruled during Mr. Q's trial that the State did not need to have a person from the Office testify about the records. Prior to trial, the court determined that under the Confrontation Clause, Mr. Q could question pharmacists who entered the type of information that went into the central repository. The State then presented the testimony of sixteen pharmacists, from each of sixteen different pharmacies in the Des Moines area, who testified about their general practice in obtaining information about people who purchase pseudoephedrine and putting that information into an electronic logbook. The information obtained from the Office showed either Mr. Q or other defendants had purchased pseudoephedrine at these sixteen locations.

Question 1:

Mr. Q was found guilty of, among other things:

a. purchasing excessive amounts of dextromethorphan to make methamphetamine;
b. falsifying the pseudoephedrine logs at 16 pharmacies;
c. possession of a controlled substance with intent to deliver;
d. lying to the pharmacy technician s about why he wanted to purchase the pseudoephedrine.

Question 2:

Mr. Q's total prison term for being found guilty of all the offenses was:

a. 40 years;
b. 15-30 years;
c. 12 years;
d. 4-8 years.

Mr. Q appealed his case on many grounds, most notably by trying to get the PSE Log thrown out of court. The appeals court in Iowa ruled that the PSE Log was admissible under Iowa Rule of Evidence 5.803(6), the business records exception. On the issue of foundation, the court found the records were regularly kept in the course of business by each pharmacy and it was not necessary to bring anyone in from the Office for the records to be admissible. On the issue of the

Confrontation Clause, the appeals court noted that the PSE Log was not "testimonial" in nature, because the PSE Log would have existed even if Mr. Q was never criminally charged. The appeals court said:

> "The pharmacists who entered the information showing the sales of pseudoephedrine could not be considered witnesses against Mr. [Q] because there was no prosecution at the time the entries were made….They were simply workers with no axe to grind who performed their routine, ministerial tasks in a nonadversarial setting pursuant to a statutory mandate. The pharmacists were following their statutorily mandated duties, not attempting to generate evidence to use in a possible criminal prosecution at some point in the future. We conclude, because the records were nontestimonial in nature, the Confrontation Clause does not apply."

Question 3:

In Mr. Q's case, pharmacists who entered pseudoephedrine purchase information into the PSE Log:

a. could be questioned in court about their actions;
b. could not possibly remember each time a person signs the PSE Log, so could not be questioned in court about it;
c. could not be held responsible for the information they put in the PSE Log, so could not be questioned in court about it;
d. generally left this task to technicians, so could not be questioned in court about it.

Question 4:

In Mr. Q's case, the Iowa appeals court ruled that:

a. the pharmacists who entered the information into the PSE Log were workers with no axe to grind;
b. the pharmacists who entered the information into the PSE Log were following their statutorily mandated duties;
c. the PSE Log would have existed even if Mr. Q had never been criminally charged;
d. all of the above are true.

And so the PSE Log was admitted as evidence, and Mr. Q's guilty verdict on all charges except the conspiracy charge was affirmed.

Alabama - Where Everyone Knows a Mis-fill is Wrong[2]

In December 2010, Ms. M went to the pharmacy at the grocery store to refill her prescription for amlodipine, a medication used to treat hypertension. Ms. M had used this pharmacy to fill this prescription, as well as other prescriptions, for several years without incident. However, on this occasion, the refill Ms. M was given contained a mix of both amlodipine and furosemide pills. Both pills are apparently small, round, and white, and Ms. M, not noticing a difference in this refill, proceeded to ingest one pill from the container each day for approximately the next two weeks. During this time, she began experiencing physical problems including swelling on her face, tingling lips, hives, and painful scales and hyperpigmentation around her mouth and eyelids. Believing she was experiencing an allergic reaction to something, Ms. M treated these symptoms with Benadryl, an over-the-counter antihistamine.

After approximately two weeks, Ms. M returned to the pharmacy to fill another prescription. The assistant pharmacy manager approached Ms. M at that time and told her that her last amlodipine refill had accidentally been partially filled with furosemide. The assistant pharmacy manager further told Ms. M that the pharmacy could not account for approximately 10 or 12 furosemide pills and gave Ms. M the identification number printed on the furosemide pills. After returning home, Ms. M discovered approximately two furosemide pills among the pills remaining in her amlodipine refill vial. The assistant pharmacy manager subsequently telephoned Ms. M, told her not to take any of the pills, and offered to refill the prescription. Ms. M instead transferred the prescription to a different pharmacy and disposed of the remaining pills.

Ms. M thereafter consulted with her primary-care doctor, a dermatologist, and an allergist regarding the symptoms that she began experiencing after receiving the December 2010 refill from the pharmacy. She testified in a subsequent

Question 5:

This is an "application" question, rather than a straight-forward knowledge-based question. The assistant pharmacy manager's advice to Ms. M to stop taking any of the pills from the vial of co-mingled pills:

a. is required by federal law;
b. is required by state law;
c. is prohibited by privacy laws;
d. regardless of whether it is required by a specific law, is one way to put the patient's health and safety at the forefront in the midst of a difficult situation.

[2] _____ v. Publix Super Markets, Inc., No. 1120522, Supreme Court of Alabama, August 16, 2013, Appeal from Jefferson Circuit Court (CV-11-903523); opinion by Justice Stewart.

deposition that the hives and facial swelling went away fairly quickly after taking Benadryl and undergoing a steroid treatment; however, she also testified that it took almost a year and microdermabrasion treatments before the hyperpigmentation and scales were resolved.

In October 2011, Ms. M sued her pharmacy, alleging that she had sustained injuries as a result of the pharmacy's negligent issuance of the wrong medication. The pharmacy denied causing Ms. M's injuries, asserted that her lawsuit was governed by the AMLA (Alabama's Medical Liability Act), and denied breaching any applicable standard of care. The pharmacy argued that Ms. M could not meet her burden of proof under the AMLA because she had not identified any expert witness who was qualified to testify that the pharmacist who filled the prescription had breached the applicable standard of care. Ms. M opposed the motion and…*argued that a pharmacy's negligence in dispensing the wrong medication was so apparent that a layperson could understand it without the assistance of expert testimony.* In January 2013, the trial court entered a judgment in favor of the pharmacy, holding that Ms. M had failed to timely identify any similarly situated individuals who could give expert testimony regarding the standard of care applicable to pharmacists licensed in Alabama.

Ms. M appealed, and the Supreme Court of Alabama ruled that:

> Although [Ms. M] identified two physicians she might call to give expert testimony, [the pharmacy] correctly argues that, because *those physicians are not pharmacists*, they are not qualified to give expert testimony regarding the standard of care applicable *to pharmacists* and whether that standard of care was breached in this case….
>
> It is possible, [the pharmacy] argues, that a manufacturer or distributor could have provided it with the commingled amlodipine and furosemide. We…note that [the pharmacy's] hypothetical is belied by the evidence in the record indicating that [the pharmacy] discovered the problem with [Ms. M's] refill and that a pharmacist told [Ms. M] that the pharmacy at which she had had the prescription refilled could not account for approximately 10 or 12 furosemide pills….
>
> …[W]e have previously stated that "'[p]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect.'" [case citations omitted]. For this and other reasons, the law requires them to be dispensed by licensed pharmacists as opposed to simply being purchased "over the counter." Any individual who has ever had a prescription filled has a general understanding of this fact. Accordingly, we agree with the rationale set forth in [other cases] and hold that it is unnecessary for [Ms. M] prosecuting an AMLA claim based on a pharmacy's filling his or her prescription with the incorrect medication to put forth expert testimony establishing the standard of care and a breach thereof because *the want of skill or lack of care in incorrectly filling a prescription is so apparent as to be within the comprehension of the average layperson without the assistance of expert testimony*.

After ruling that Ms. M does not need an expert pharmacy witness, the Alabama Supreme Court let the case proceed to trial.

Question 6:

Ms. M had physicians she could call as expert witnesses about her prescription mis-fill, but the court said that physicians:

a. *are* qualified to give expert testimony about what pharmacists should do;
b. *are not* qualified to give expert testimony about what pharmacists should do.

Question 7:

The court said that Publix's argument that a manufacturer or distributor could have co-mingled amlodipine and furosemide in the same stock bottle:

a. is impossible, because of the safeguards in place at the manufacturer and distributor levels;
b. was belied by evidence that Publix's pharmacist told the patient that the pharmacy was missing 10-12 pills of furosemide;
c. is possible, and is such a common occurrence that the jury believed it;
d. is possible, because Publix showed that it had happened in the past.

Question 8:

The Alabama Supreme Court stated that prescription drugs must be dispensed by a licensed pharmacist because:

a. the drugs are likely to be complex medicines, esoteric in formula and varied in effect;
b. it is required by law;
c. the drugs are relatively expensive;
d. both (a) and (b) are true.

Question 9:

The Alabama Supreme Court ruled in Ms. M's case that:

a. the average lay person can fill a prescription;
b. there was not much harm done to Ms. M in this mis-fill;
c. the want of skill or lack of care in incorrectly filling a prescription is so apparent as to be within the comprehension of the average lay person without the assistance of expert testimony;
d. the want of skill or lack of care in incorrectly filling a prescription is not apparent to the average lay person, and an expert pharmacist must called to testify about the correct standard of care of the average pharmacist.

New Jersey - Pharmacist Prosecuted for Early Fills of a C-II[3]

Defendant, on five occasions while performing duties as a pharmacist, dispensed [oxycodone] in excess of the amount prescribed by a patient's physician. He explained that the patient had misplaced her pills and he made up the shortfall, subsequently subtracting from her next prescription the amount of pills he initially advanced to her. He submitted an application for admission to PTI. The Salem County Superior Court Criminal Division Case Management Office notified defendant that his application for admission into PTI had been rejected because he had been charged with "the sale or dispensing for Schedule I or Schedule II narcotics." The Prosecutor would not consent to defendant's entry into PTI, and defendant appealed to the Superior Court.

Some background about PTI: In New Jersey, PTI (Pre-Trial Intervention Program) provides defendants, generally first-time offenders, with opportunities for alternatives to the traditional criminal justice process of ordinary prosecution. PTI seeks to render early rehabilitative services, when such services can reasonably be expected to deter future criminal behavior. PTI strives to solve personal problems and ultimately to deter future criminal or disorderly behavior by a defendant. [4] Most states have some form of a pre-trial intervention program, and healthcare providers with first time offenses are often good candidates for such rehabilitative programs rather than face criminal courts.

[3] STATE OF NEW JERSEY v. _____., No. A-4461-10T3, Superior Court of New Jersey, Appelle Division, February 26, 2013.
[4] http://www.judiciary.state.nj.us/criminal/crpti.htm

However, in this case, the Prosecutor saw the pharmacist's conduct as too egregious to be eligible for PTI. He noted that the pharmacist's actions did not reflect one transaction but at least three known instances where the patient had been given the pills without the requisite prescription and that the pharmacist acknowledged this conduct on his part had been ongoing for at least three months. Pharmacy technicians had observed suspicious behavior by the defendant pharmacist, including personally filling this patient's prescriptions and his constant counting of the [oxycodone] pills, which the technicians found to be abnormal, as well as leaving the pharmacy with the customer and sitting in the car with her. It was also suspected [but not proven] that defendant manipulated pharmacy records and, on at least one occasion, forged a prescription. From these facts, the Prosecutor contended defendant's actions did not "implicate a single transaction in which a heartfelt pharmacist wanted to help a suffering customer." The Prosecutor explained that he viewed defendant's conduct as a "profound deviation from ethical standards."

The pharmacist appealed, saying that he qualified for PTI. On appeal, the appeals court explained that the Prosecutor is given "extreme deference", and a defendant such as this pharmacist has a heavy burden when seeking to overcome a prosecutorial veto of his admission into PTI…. In order for a defendant to overturn the prosecutor's denial of his admission, he must "clearly and convincingly establish that the prosecutor's refusal . . . was based on a patent and gross abuse of his discretion . . . ."

In this case, the pharmacist was not able to clearly and convincingly show that the prosecutor abused his discretion. Therefore the denial of PTI stood. This means the case against the pharmacist proceeded to trial in criminal court.

Question 10:

The suspicious actions of the N.J. pharmacist included:

a. personally filling the patient's prescription;
b. "constant counting" of the oxycodone pills;
c. leaving the pharmacy and sitting in the patient's car with her;
d. all of the above were considered to be suspicious actions by the N.J. prosecutor.

Question 11:

In the opinion of the local prosecutor, the N.J. pharmacist who advanced some oxycodone to a patient, and then subtracted those pills from her next prescription:

a. took care of the patient, and that was the most important thing;
b. engaged in an unfortunate but technical violation of the law;
c. engaged in conduct that is a profound deviation from ethical standards;
d. revealed a heartfelt pharmacist trying to help a suffering customer.

New Jersey - When the Patient Changes Quantity From "10" to "100" on the Rx

Pharmacists and technicians are always alert to potentially forged prescriptions. But what happens when a patient forges his prescription, pharmacy personnel call police, and the person is arrested? The case that follows is one example.

In 2009, while investigating a complaint about a fraudulent prescription, two police officers entered the Rite Aid where a patient was waiting to have his prescription filled and motioned him to come outside so they could speak with him. The officers' investigation was motivated by a telephone call to police that a fraudulent prescription had been submitted. The pharmacist contacted the doctor who wrote the prescription and discovered that the amount of medication written by the doctor did not match the amount on the prescription submitted by the patient to the pharmacy. The original prescription had been written for ten Darvocet® pills but the ten had been changed to one hundred.

The patient was arrested, and at his hearing the police officer testified that he did not exert any physical control over the patient during the questioning. Once outside the store, he advised the patient that the prescription he presented to the pharmacist "was fraudulently doctored by putting another zero" after the number ten. The patient then admitted that he did change the number because he did not want to keep coming back to the pharmacy because he has chronic back pain.

The patient was charged with two counts: (1) forgery in violation of state law by altering a Darvocet prescription from ten to one hundred pills (count one); and (2) attempting to obtain a controlled dangerous substance by fraud in violation of state law (count two).

The customer eventually pled guilty to attempt to obtain a controlled dangerous substance by fraud (count two), and the forgery count was dismissed. He was subsequently sentenced to two years probation, contingent on serving thirty days in county jail, with an option to apply to the corrections labor assistance program in lieu of jail time.

Question 12:

A patient who manually changes the quantity of controlled substance on his prescription from 10 to 100 can expect:

a. to be charged with forgery;
b. to be charged with attempt to obtain a controlled substance by fraud;
c. mandatory jail time;
d. both (a) and (b) are true.

Georgia - Policy of Speed Does Not Justify Punitive Damages for a Prescription Mis-Fill[5]

In this case, a patient's prescription for citalopram was filled with both citalopram and warfarin by a pharmacy technician. The pharmacist then visually verified the prescription vial's contents. But it was the patient who noticed the vial contained two (2) differently shaped tablets. He then took the pills, was hospitalized, and sued in federal court for both compensatory (the costs which he incurred to make him "whole" again) and punitive (an amount to punish so as to deter future conduct) damages.

The pharmacy asked the court to take the possibility of any punitive damages away, essentially arguing that no one did anything so egregious as to justify any possible punitive damages. The court's discussion about punitive damages prompted us to include this case in this CE offering, because rarely do we get to see a federal judge comment about the practice of pharmacy. This case can also help pharmacists and technicians understand why its employer has certain policies and procedures in place to prevent mis-fills.

In the case below, the pharmacy is the Defendant and the injured patient is the Plaintiff. What follows is quoted from the federal judge:

A. Legal Standard

> [State] law provides that punitive damages may be awarded only in such tort actions in which it is proven by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences.
>
> [State law further provides that] "punitive damages cannot be imposed without a finding of some form of culpable conduct." [citation omitted]. "Something more than [the] commission of a tort is always required to impose punitive damages…. Negligence, even gross negligence, is inadequate to support a punitive damage award….There must be aggravating circumstances or outrage, such as spite, malice, or a fraudulent or evil motive on the part of the defendant, or such a conscious and deliberate disregard of the interests of others that the conduct may be called willful or wanton….In this sense, conscious indifference to consequences means an intentional disregard of the rights of another, knowingly or willfully.

[5] _____, Plaintiff, v. WAL-MART STORES EAST, L.P., Defendant. No. CV 212-042 United States District Court, S.D. Georgia, Brunswick Division. August 2, 2013. ORDER by Judge Lisa Wood.

B. Application

The record lacks any clear and convincing evidence that Defendant's alleged improper filling of Plaintiff's prescription was intentional, malicious, willful, wanton, or made with conscious or deliberate indifference to the consequences. The record also lacks clear and convincing evidence that Defendant acted with an entire want of care. To the contrary, the record indicates that Defendant implemented processes, policies, and procedures in an attempt to eliminate such errors and that those processes, policies, and procedures were inadequate to stop the allegedly misfilled prescription. With respect to the particular employees who filled Plaintiff's prescription, the record only suggests that they made an error or errors in completing their tasks. The record does not demonstrate a clear pattern of misfilling errors, much less a pattern of malicious, willful, or wanton actions related to misfilling prescriptions.

At most, Defendant's actions in failing to prevent Plaintiff's allegedly misfilled prescription demonstrate gross negligence…That is insufficient to sustain a claim for punitive damages pursuant to [state law].

Plaintiff asserts that Defendant had "a corporate policy of acceptance of errors." ….In particular, Plaintiff directs the Court to Defendant's policy to coach, suspend, and train employees who commit errors when filling prescriptions….Plaintiff also directs the Court to evidence that Defendant focuses on "speed" when filling prescriptions…..Such policies do not demonstrate intentional, malicious, willful, or wanton misconduct. Nor do such policies demonstrate an entire want of care or deliberate indifference to their consequences. By contrast, Defendant's policies demonstrate an attempt to avoid the precise error that allegedly occurred here. While the evidence does demonstrate that Defendant emphasized speed when filling prescriptions, the evidence also demonstrates that Defendant simultaneously emphasized accuracy. See, e.g., Dkt. No. 46-11, at 30-31 (noting that "both accuracy and speed are required"). Thus, even after construing the evidence in Plaintiff's favor, the Court cannot say that there is any evidence supporting a theory that Defendant's policies showed willful misconduct, malice, wantonness, or an entire want of care.

With respect to Plaintiff's misfilled prescription, Plaintiff asserts that Defendant took only seventeen (17) seconds to visually verify the contents of Plaintiff's prescription bottle. Plaintiff further asserts that this was less than the average time of thirty (30) seconds that is typically consumed by a visual verification step. See Dkt. No. 48, at 5. Plaintiff maintains that this "warp-speed visual verification" demonstrates "an entire want of care in verifying the contents" of Plaintiff's prescription bottle. See id. at 6. However, taking approximately half of the time of an average visual verification does not demonstrate an entire want of care by clear and convincing evidence. At most, the

speed of the verification step demonstrates that a jury may find that Defendant's employee was negligent, possibly even grossly negligent, when verifying the bottle's contents for seventeen (17) seconds rather than thirty (30) seconds. There is no evidence that the shortened visual verification step constituted intentional misconduct, malice, willfulness, or wantonness. Nor is there clear and convincing evidence that the employee acted with an entire want of care when completing her task.

Because there is no clear and convincing evidence that Defendant's "actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences," Defendant's motion for summary judgment on Plaintiff's claim for punitive damages is GRANTED.

The case then proceeded to trial, with any possible punitive damages removed.

Question 13:

When the judge in the citalopram/warfarin misfill case applied the legal standard for punitive damages to the facts at hand, she found:

a. the Defendant/pharmacy emphasized speed when filling prescriptions, but also simultaneously emphasized accuracy;
b. the technician's actions in filling the prescription vial with 2 different pills were intentional, malicious, willful, wanton, or made with conscious or deliberate indifference to the consequences;
c. the pharmacy technician acted with an entire want of care;
d. the pharmacist did a "warp-speed" visual verification.

Question 14:

The judge in the citalopram/warfarin mis-fill case said the pharmacy and pharmacist's actions in failing to prevent the patient's allegedly mis-filled prescription demonstrate, at most:

a. misdemeanors;
b. intent to place the wrong pill in the vial;
c. gross negligence;
d. malice.

Question 15:

When the judge in the citalopram/warfarin mis-fill case applied the legal standard for punitive damages to the facts at hand, she found:

a. the pharmacist's visual verification was done at "warp speed";
b. the pharmacist's 17-second visual verification that did not catch a mis-fill fell short of the 30 seconds that is required to verify the contents of a prescription vial;
c. the pharmacist acted with an entire want of care;
d none of the above are true.

Question 16:

When the judge in the citalopram/warfarin mis-fill case examined the store's policy to coach, suspend, and train employees who commit errors when filling prescriptions, she found:

a. by keeping employees who commit mistakes employed and requiring them to undergo a suspension with coaching and training demonstrates an attempt to avoid the precise error that allegedly occurred here;
b. the policy had no relevance;
c. the policy is in violation of state law;
d. the policy encourages prescription filling errors.

Alabama - Kickbacks for Referring Factor Patients[6]

This is a federal kickback case involving "factor" medication, which is an expensive medication used to treat hemophilia.

If you find yourself thinking that the whole topic of federal kickbacks is outside of the practice of pharmacy, or is far too complicated to understand, consider what the federal appeals court stated in this case involving drug kickbacks:

> We [hold] that "[the Anti-Kickback statute] is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct…. Rather, **the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal.**

As keepers of our nation's drug supply, pharmacists and pharmacy technicians handle drugs, money, and patients on a daily basis. Despite the court's quote above, it is possible to fail to grasp the concept that paying people…or giving people something of value…to come and buy medications from your pharmacy is a kickback, and that it is illegal.

We include this particular case because it has been so widely discussed in pharmacy circles, because it was decided by a federal appeals court which is only one step below the U.S. Supreme Court, and because the lessons to be learned here apply to pharmacists, pharmacy technicians, and anyone who owns or operates a pharmacy.

The following is taken directly from a long court of appeals decision. Again, we have tried to take out the legal jargon. To the extent any of the remaining legal terms distract you, just ignore it. You can still pass the post-activity quiz.

First we'll give you the long but lively story directly from the court records, and then discuss the Anti-Kickback Statute and how it relates to this practice of pharmacy.

Background

Defendants Jeff Vernon and Chris Vernon were executives of MedfusionRx, LLC ("Medfusion"), which is a specialty pharmacy that fills prescriptions for, among other things, factor medication. Specialty pharmacies dispense critical, somewhat rare, and expensive medications, and they also provide certain health care services to their clients, including infusion

[6] UNITED STATES OF AMERICA, Plaintiff-Appellant, v. CHRIS VERNON, Defendant-Appellee. UNITED STATES OF AMERICA, Plaintiff-Appellee, v. BUTCH BRILL, Defendant-Appellant. UNITED STATES OF AMERICA, Plaintiff-Appellee, v. JEFF VERNON, Defendant-Appellant. Nos. 12-13267, 12-13266, 12-13311 United States Court of Appeals, Eleventh Circuit, July 26, 2013.

and educational services. As a specialty pharmacy, Medfusion filled prescriptions for medications used to treat long-term, serious diseases, including hemophilia.

Their dispensing of factor medication, especially to Medicaid recipients, was a profitable, and indeed, lucrative business for Medfusion. In order to gain more factor medication business, Medfusion made sizable payments to individuals and businesses if they would refer their hemophiliac clients to Medfusion for prescription filling. Specifically, Medfusion paid 45-50% of its profits on filling factor medication prescriptions to the individual or business that referred that client to Medfusion for prescription filling. Those kickback payments for referrals form the basis of the charges against former chief financial officer Chris Vernon and former chief executive officer and pharmacist Jeff Vernon.

Meanwhile, Butch Brill worked for a business that received those kickback payments. Butch Brill was convicted of conspiring with others, including his estranged wife Lori Brill, to increase the kickback payments he received by committing health care fraud. Specifically, the conspirators falsified records in order to justify the ordering of more factor medication than was necessary.

Medfusion was a successful business. It is undisputed that between 2005 and 2010, Medfusion grew from $12 million in sales to over $200 million. Medfusion supplied drugs in 45 states and had physical locations in 4 states.

Factor medication is expensive. It was not uncommon for factor medication to cost between $50,000 and $200,000 per patient, per month. In 2010, Alabama Medicaid spent $23 million paying for factor medication for 90 patients. Alabama Medicaid reimburses providers, like Medfusion, for recipients' prescribed medications.

In 2008, Alabama Medicaid implemented a new formula for paying specialty pharmacies like Medfusion for factor medication. Under this new formula, Alabama Medicaid reimburses a specialty pharmacy the average sales price, plus six percent, for a factor medication prescription. For each unit of factor medication dispensed, Alabama Medicaid also paid the pharmacy a "furnishing fee" which, between 2008 and 2010, rose from 15 to 18 cents per unit. A single dose of factor medication might consist of approximately 3,000 units. Thus, in 2008, a specialty pharmacy received a furnishing fee of $450 for filling a prescription for just one dose of factor medication, and in 2010, the specialty pharmacy received $540 for one dose of factor medication. The furnishing fee was meant to cover the patient services provided by specialty pharmacies. Additionally, each time a specialty pharmacy filled a factor medication prescription, Alabama Medicaid also paid that pharmacy a "dispensing fee" which covered various administrative costs.

Here, given the high reimbursement rates, Medfusion paid large sums to individuals simply for referring hemophiliac patients to Medfusion for filling their prescriptions. Medfusion recruited co-defendants Lori Brill (through her company Hemophilia Management Specialties ("HMS")) and Leroy Waters to refer their clients to Medfusion for prescription filling. In turn, HMS/Lori Brill and Waters received 45-50% of any profits Medfusion earned from the referred clients.

This referral arrangement was lucrative for both parties. In just one year, between September 2007 and October 2008, Medfusion earned a net profit of $451,988.61 from filling factor medication prescriptions for Lori Brill's clients alone and paid her $203,394 of that sizable yearly profit.

The record further showed that in the 22-month period between November 2007 and August 2009, Medfusion paid a total of $369, 371 to Lori Brill's company HMS, consisting of: (1) $50,000 in 2007; (2) $195,203 in 2008; and (3) $124,168 in 2009.

The Vernons fully knew that Medfusion was making sizable payments to Lori Brill/HMS. And key in this case was the fact that Lori Brill/HMS was not performing any work or services for Medfusion other than referring clients for prescription filling. (If they had been performing other work or services, and could show the value of those services was close to what they were paid, the outcome of this case would likely have been very different.)

The Anti-Kickback Statute

The federal Anti-Kickback Statute is the basis for the charges against both Vernons. To make this phrase easier to understand, break it down into its single words. "Anti'" means "against", and "kickback" means a negotiated bribery. As a pharmacist or technician when you hear the term "federal Anti-Kickback Statute", you should immediately think about the federal government and its desire to work against negotiated bribery.

Next, think about what you as a taxpayer do *not* want to pay for. You do not want to pay a kickback, or a bribe, for a patient to use one particular pharmacy instead of another.

The Anti-Kickback Statute, found in 42 U.S.C. § 1320a-7b(b), entitled "Illegal remunerations, " has two subsections: 1320a-7b(b)(1) and 1320a-7b(b)(2). One subsection gets at the person paying the bribe; the other subsection addresses the person receiving the bribe.

The two subsections are effectively the two sides of the same illegal kickback coin when federal funds are used to pay for goods or services: subsection (b)(1) criminalizes the soliciting or *receiving of the kickback* and subsection (b)(2) criminalizes the offering or *paying of the kickback*.

To convict the Vernons of violations of the Anti-Kickback statute, the government needed to prove that each (1) knowingly and willfully, (2) paid money, directly or indirectly to HMS/Lori Brill, (3) to induce her to refer individuals to Medfusion for the furnishing of factor medication, and (4) the factor medication was paid for by federal funds (e.g., Medicaid).

The federal government was able to prove to a jury each of the elements of the crime. As a result, pharmacist Jeff Vernon, Medfusion's CEO, was found guilty and sentenced to 180 days at a halfway house, 3 years' probation, and a $1.7 million fine.

Butch Brill (who referred patients and received some of the payments) was sentenced to 15 months' imprisonment, followed by 3 years' supervised release, with no fine.

Non-pharmacist Chris Vernon did not dispute that Medicaid paid Medfusion for furnishing factor medication and that, in turn, Medfusion paid 45% of its profits to Lori Brill/HMS. But his position was that the Medfusion payments to Lori Brill/HMS were simply routine business checks, and there was nothing illegal about it.

Question 17:

The federal Anti-Kickback Statute criminalizes:

a. paying a kickback when federal money is used;
b. receiving a kickback when federal money is used;
c. providing services at market value when federal money is used;
d. both (a) and (b) are true.

Question 18:

The court found Chris Vernon guilty of violating the Anti-Kickback Statute because he fully knew that:

a. Medfusion was making sizable payments to Lori Brill/HMS;
b. Lori Brill/HMS was not performing any work or services for Medfusion other than referring clients for prescription filling;
c. Lori Brill/HMS was providing home delivery and educational services, and the value of these services was reflected in the amount she was paid;
d. both (a) and (b) are true.

The jury convicted Chris Vernon of the substantive provisions of the Anti-Kickback statute involving payments to Lori Brill. After an arduous set of court motions and appeals, in which a judge threw out the jury's verdict and then another judge reinstated it, the Vernons sold their Medfusion business.

Question 19:

At least one federal appeals court judge has found that:

a. the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal;
b. the Anti-Kickback Statute is a highly technical financial regulation;
c. the Anti-Kickback Statute is a highly technical tax regulation;
d. the Anti-Kickback Statute poses a danger of ensnaring persons engaged in apparently innocent conduct.

Question 20:

Chris Vernon's payments to Lori Brill/HMS were simply routine business checks and thus proved that he was not violating the federal Anti-Kickback Statute:

a. True;
b. False.

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ANSWERS: Pharmacy Law Case Review

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1.	a	b	c	d	11.	a	b	c	d
2.	a	b	c	d	12.	a	b	c	d
3.	a	b	c	d	13.	a	b	c	d
4.	a	b	c	d	14.	a	b	c	d
5.	a	b	c	d	15.	a	b	c	d
6.	a	b			16.	a	b	c	d
7.	a	b	c	d	17.	a	b	c	d
8.	a	b	c	d	18.	a	b	c	d
9.	a	b	c	d	19.	a	b	c	d
10.	a	b	c	d	20.	a	b		

21. After completing this program, I am able to restate the pertinent facts and court rulings of at least 4 violations of state or federal drug laws: YES SOMEWHAT NO

22. This CE activity met my educational needs: YES SOMEWHAT NO

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24. The learning material was useful: YES SOMEWHAT NO

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26. The learning assessment (the post-test) was appropriate: YES SOMEWHAT NO

27. The test questions were relevant to the CE activity: YES SOMEWHAT NO

28. The test questions were at an appropriate level of difficulty: YES SOMEWHAT NO

29. The activity was presented in a fair and unbiased manner: YES SOMEWHAT NO

30. If you perceived any bias or commercialism, please describe, or want to make any other suggestions, please tell us:_____