Pharmacy Jurisprudence, L.L.C.

Our annual continuing education offering is written specifically for pharmacists and pharmacy technicians in all 50 states.

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2  DOJ Cases Against Pharmacists - 2016

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Contact Hour(s): 1.0 (or 0.1 C.E.U.’s)
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Select CE® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.
Program Title: DOJ Cases Against Pharmacists - 2016

Target Audience: All Pharmacists and Pharmacy Technicians

Expiration Date: February 1, 2020

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Accreditations: This CE activity is ACPE-accredited for 1.0 contact hour, or 0.10 C.E.U.’s, for pharmacists and pharmacy technicians under our trade name Select CE®.

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i) mail the Answer Sheet and the program fee to us. You will receive an Assessment Feedback mailed to you within 2 weeks. Checks or money orders are encouraged. Mail to: Pharmacy Jurisprudence or Select CE, P.O. Box 21186, Columbus, Ohio 43221-0186; or

ii) use the online test-taking website www.selectce.org. Follow the instructions on the website, using any major credit card to pay the program fee. Upon passing the test, you will receive immediate confirmation via email, and your Assessment Feedback will be sent
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A minimum score of 70% on the post-test is also required to earn credit.

Faculty: Patti Nussle, R.Ph., J.D., is 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. Robyn Satterfield, PharmD is our Peer Reviewer for this activity. Thanks Robyn!

Disclosure of Commercialism, Unlabeled Uses, Bias, Conflicts of Interest: Prior to the delivery of the content, we will disclose any commercial support, and we do so here: No commercial support was used for developing or presenting this program. All development, printing, mailing and internet costs, as well as ACPE accreditation fees, come solely from your program fees. No unlabeled uses of drugs are discussed in this program. Brand names are not used, unless the Department of Justice used the brand name of the drug in its publication and hence the brand name is used here too. Faculty Patti Nussle, Peer Reviewer Robyn Satterfield, and Select CE have no real, apparent, or potential conflicts of interest or financial relationships to disclose.

Objective: At the conclusion of this program, pharmacists should be able to describe at least 5 consequences of failing to comply with federal drug laws.

Objective: At the conclusion of this program, pharmacy technicians should be able to describe at least 5 consequences of failing to comply with 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.
Introduction

In this CE activity, we bring you 8 reports about pharmacy violations from the U.S. Department of Justice (DOJ). We tried to choose cases that are of interest to the practicing pharmacy professional. In a few cases, the nurse or physician was involved in the pharmacy violation.

It has been said that most fraud starts by accident. That is, by some minor lack of oversight a medication or money was not properly handled, and nothing happened. Nobody seemed to notice. Then the next time it happened, and again nobody noticed. And then, somehow, as time passed the oversight became a regular occurrence. From Girl Scout fundraising to pharmacy dispensing, the stories of fraud often start with an innocent oversight. We have no way to know how or why the pharmacists in the following DOJ cases first started in what the DOJ says are illegal activities. Yet these cases remind us to be vigilant in our pharmacy dispensing activities.

Northwest Alabama Pharmacy Owner Agrees to Plead Guilty to Obstructing Medicare Audit

Pledges to Pay $2.5 Million Penalty

BIRMINGHAM – The owner of two northwest Alabama pharmacies has agreed to plead guilty to obstructing a Medicare audit and to pay a $2.5 million penalty to the government.

The U.S. Attorney’s Office for the Northern District of Alabama charged RDL, 63, of Muscle Shoals, with one count of obstructing a 2012 federal audit of Medicare claims submitted by a pharmacy he owned. RDL, a registered pharmacist, owned Leighton Pharmacy Inc., which did business as Sheffield Pharmacy and Homecare in Sheffield, and Russellville Pharmacy in Russellville. At various times, according to the charge, RDL was the lead pharmacist at both Sheffield and Russellville. Prosecutors filed the charge by information in U.S. District Court, along with a plea agreement reached between RDL and the government.

“This case revolves around the falsification of documents in an effort to defraud Medicare, which exists to provide health care services for the elderly,” U.S. Attorney Joyce White Vance said.

"Obstructing a Medicare audit is something the OIG takes very seriously," OIG Special Agent Derrick Jackson said. "Submitting documentation to Medicare to substantiate that tablets or capsules were utilized when, in fact, bulk pharmaceutical powders were actually used is straight-up fraud."

The Sheffield and Russellville pharmacies operated as both compounding and retail pharmacies. A compounding pharmacy is one that prepares customized medications for individual patients, usually by mixing ingredients in order to create a prescription. The two pharmacies sold compounded prescriptions to patients in Alabama and other states.

According to the information and plea agreement, RDL obstructed a 2012 audit of the Sheffield pharmacy’s claims for Medicare reimbursement on compounded prescriptions as follows:

CVS/Caremark Inc. administered prescription drug claims for Medicare Part D and served as an auditor on Medicare’s behalf. Part D prohibited reimbursement to pharmacies for compounded medications made using bulk pharmaceutical powders. Russellville and Sheffield nonetheless sought Part D reimbursement after February 2009 for compounded medications, primarily topical pain creams, made from bulk powders. The pharmacies, however, used the billing code for the tablet or capsule form of the ingredient.

In response to the 2012 audit, RDL caused Sheffield to submit falsified and misleading documents stating that medications in tablet or capsule form were used as ingredients for the compounded prescriptions.

The maximum penalty for obstructing a federal audit is five years in prison and a fine of $250,000 or twice the amount improperly gained through the defendant’s conduct.
Wisconsin Pharmacist Charged with Health Care Fraud & Identity Theft

Madison, Wis. - John W. Vaudreuil, United States Attorney for the Western District of Wisconsin, announced that MJ, 55, Janesville, Wis., was arrested without incident by agents from the U.S. Department of Health and Human Services and the U.S. Postal Inspection Service.

MJ was charged in a 46-count indictment returned by a grand jury in Madison. The indictment charges MJ with health care fraud, making false statements in a health care fraud audit, and identity theft. Each of the 39 health care fraud charges carries a maximum penalty of 10 years in federal prison; the false statements charge carries a maximum penalty of five years in federal prison; and the six identity theft charges each carries a mandatory penalty of two years in federal prison.

The indictment alleges that MJ devised a scheme to defraud Medicare and Medicaid from approximately January 2008 to March 2014. During this time period, MJ was a licensed pharmacist, and the owner and president of Kealey Pharmacy and Home Care, Inc. Kealey Pharmacy was a retail pharmacy providing, among other things, prescription drugs to customers. Kealey Pharmacy was reimbursed for these prescriptions.

Question 1:

Using the billing code for the tablet or capsule form of the ingredient, rather than the bulk powder that was actually used in compounding a pain cream, can result in:

a. a charge of obstructing a federal audit;

b. 5 years in prison and a fine of $250,000;

c. 5 years in prison and a fine of twice the amount improperly gained by the wrongful conduct;

d. all of the above can be true.

in a number of ways, including reimbursement payments under Medicare and Medicaid.

The indictment alleges that MJ submitted false and fraudulent claims to Medicare and Medicaid obtaining reimbursement for medication that was not, in fact, provided to beneficiaries. The indictment also alleges that MJ created false prescription orders for medication and submitted claims for reimbursement for medication pursuant to these false prescription orders. The indictment alleges that MJ caused the payment of approximately $1,000,000 by Medicare and Medicaid to him during the time period of the fraud.

The indictment also alleges that MJ lied in August 2013 in his responses to an audit being conducted by the Wisconsin Department of Health Services of paid Medicaid claims for the period from January 2010 to December 31, 2011. Finally, the indictment charges that MJ used the

**Question 2:**

An ________________ is merely an accusation and a defendant is presumed innocent until and unless proven guilty.

a. acquittal;
   b. indictment;
   c. indication;
   d. exoneration.

**Question 3:**

Using the DEA number and National Provider Identifier of two physicians to create false physician prescription orders to support claims to Medicaid and Medicare can result in a charge of:

a. grand theft;
   b. identity theft;
   c. theft in office;
   d. prescription theft.
DEA number and National Provider Identifier of two physicians to create false and fictitious physician’s prescription orders to support the submission of false claims to Medicare and Medicaid.

You are advised that an indictment or charge is merely an accusation and that a defendant is presumed innocent until and unless proven guilty.

New York Pharmacist Sentenced to 43 Months For Medicare And Tax Fraud³

Defendant Caused $2.7 Million in Losses to Government Health Care Programs and Underreported His Income By Over $2.6 Million

AB, a New York pharmacist who operated pharmacies in Bronx, Queens, and Rockland counties, was sentenced to 43 months’ imprisonment to be followed by three years of supervised release. As part of the sentence, he was ordered to forfeit $2.7 million in criminal proceeds, pay $2.7 million in restitution to Medicare and Medicaid, and pay $736,000 in restitution to the Internal Revenue Service.

On May 25, 2016, AB pleaded guilty to committing a health care fraud scheme and filing false tax returns. From January 2011 to December 2012, he fraudulently billed Medicare and Medicaid approximately $2.7 million for prescription medications that he never dispensed to patients. AB used some of these proceeds to buy pharmaceutical products for his pharmacies. He also falsely claimed over $2 million in personal expenses as business expenses on his tax returns. Through this scheme, he caused a tax loss of $736,192.80.

To prove its case, the government used AB's computer hard drives, seized during two audits of his pharmacies, and compared the dispensing records on the pharmacy hard drive to the wholesaler's records of purchases.⁴

E.D.N.Y. Docket No. 15-CR-103

⁴ https://casetext.com/case/united-states-v-barrett-56
Palm Harbor Oncologist Convicted of Buying Cancer Medications From Foreign Sources and Defrauding Medicare

Tampa, Florida – A federal jury today found AN (61, Palm Harbor) guilty of 17 counts of receipt and delivery of misbranded drugs, 12 counts of smuggling goods into the United States, 11 counts of health care fraud, and 5 counts of mail fraud. She faces a maximum penalty of 20 years in federal prison for each mail fraud and smuggling offense, 10 years’ imprisonment for each health care fraud count, and 3 years for each count of receipt and delivery of misbranded drugs. Her sentencing hearing is scheduled for February 16, 2017.

According to testimony and evidence presented at trial, AN, a licensed physician in Florida, was the head doctor, owner, and operator of East Lake Oncology (“ELO”), a cancer treatment clinic. Beginning in at least May 2009, she ordered, and directed others at ELO to order, drugs from foreign, unlicensed distributors, including Quality Specialty Products (“QSP”). The drugs sold to ELO by QSP and other foreign, unlicensed distributors were not FDA-approved. In fact, QSP had reportedly sold counterfeit versions of a chemotherapy medication that did not have the key ingredient in the drug. AN learned of this news from other sources.

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Question 4:

To prove that a pharmacy billed for prescription medications that were never dispensed, the U.S. government can:

a. seize computer hard drives of a pharmacy's dispensing records;
b. compare the pharmacy's dispensing records to the pharmacy wholesaler's records of medication purchased;
c. both a and b;
d. neither a or b.

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yet continued to have QSP drugs administered to patients. When QSP shut down, AN switched to buying drugs from another foreign, unlicensed distributor. Many of the drugs were shipped directly to ELO from a location outside the United States, usually from the United Kingdom. The packaging and documents shipped with the drugs showed that they were manufactured and packaged for distribution in foreign countries, such as Turkey, India, and Germany. Additionally, some of the packaging for the drugs was in foreign languages, without any English translation.

Unbeknownst to patients, these misbranded drugs were then administered at ELO. After administering these drugs to patients, ELO submitted claims for reimbursement to Medicare. In submitting those claims, AN falsely represented that the FDA-approved versions of the drugs had been administered, when she knew that unapproved and misbranded versions had been given to patients. In so doing, AN intended to generate profits from the difference between the Medicare reimbursement rates for the FDA-approved drugs and the discounted prices of the misbranded versions of those drugs purchased from foreign distributors.

**Question 5:**

Purchasing medications manufactured and distributed in foreign countries, from a distributor that is not licensed to distribute the medications in the United States, means that:

a. the use of the medication will definitely harm a patient;

b. the medications are not FDA-approved;

c. the medications should not be billed to Medicare or Medicaid;

d. both b and c are true.
CleanSlate Addiction Treatment Centers Settle Allegations of Unlicensed Prescribing and Improper Suboxone® Billing

BOSTON – The U.S. Attorney’s Office reached a $750,000 civil settlement with CleanSlate Centers, Inc. and Total Wellness Centers, LLC d/b/a CleanSlate, to resolve allegations that the two companies, which together operate opioid addiction treatment centers in Massachusetts and other states, improperly prescribed buprenorphine (Suboxone®) for addiction treatment and improperly billed Medicare.

CleanSlate operates 17 clinics, offering treatment to individuals addicted to opioids, including heroin and prescription painkillers, through medication and counseling. The medication, buprenorphine, is a Schedule III controlled substance that also can be used to treat pain.

Until recently, only a physician could prescribe buprenorphine for addiction treatment. Congress modified the law in July 2016, allowing nurse practitioners and physician assistants to prescribe buprenorphine for addiction treatment, provided they meet certain training and state-law licensing requirements. In Massachusetts, those requirements have not yet been established.

“We are committed to investigating healthcare providers engaged in improper billing and prescribing,” said Special Agent in Charge Phillip Coyne of the U.S. Department of Health and Human Services – Office of Inspector General (HHS-OIG). “Working closely with the DEA, the Office of Inspector General will continue the fight against the deadly and destructive opiate epidemic to protect public safety as well as the federal health care programs intended to care for vulnerable Americans.”

The settlement resolves two sets of allegations. First, the government alleged that, from March 2012 to February 2014, CleanSlate clinics routinely contacted pharmacies representing that physicians had prescribed buprenorphine for patients when, in fact, only midlevel practitioners had seen the patients. Days later, after patients had already picked up their medication from the pharmacies, part-time physicians employed by CleanSlate for as little as six hours per month accessed the

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6 https://www.justice.gov/usao-ma/pr/cleanslate-addiction-treatment-centers-settle-allegations-unlicensed-prescribing-and
patients’ electronic medical records. After reviewing the patient visit information, the part-time physicians signed the prescriptions, backdating them to the visit dates. These actions violated the Controlled Substances Act and regulations issued by the DEA.

Second, the government alleged that, from June 2010 to April 2016, CleanSlate repeatedly billed Medicare for patient visits using physicians’ identification numbers when, in fact, the patients saw midlevel practitioners and no physicians were on clinic premises to supervise those practitioners. Had CleanSlate properly billed under the midlevel practitioners’ identification numbers, Medicare would have paid less. These actions violated HHS’s rules for billing Medicare and violated the False Claims Act.

Upon learning of the prescribing and billing violations, CleanSlate cooperated fully with the federal investigation. It has appointed a new management team and has begun the process of hiring at least one full-time physician at each of its clinics. In addition, CleanSlate has implemented a new system under which only doctors can prescribe buprenorphine, and they do so electronically, thereby ensuring that no prescription is issued until after a doctor has reviewed the patient visit information.

Question 6:

A physician, who signs buprenorphine prescriptions written by mid-level practitioners and back-dates his/her prescription signatures to match the dates of the patient visits days earlier, is guilty of:

a. violating the Controlled Substances Act;
b. violating the Narcotic Substances Act;
c. harming the patient;
d. harming the mid-level practitioner.
Pharmacist Sentenced to 4 Years for Illegally Distributing Approximately 100,000 Oxycodone Tablets, Medicare Fraud, and Money Laundering

LJ was sentenced November 29, 2016 by U.S. District Judge Jed Rakoff to four years in prison for illegally distributing 100,000 tablets of oxycodone, Medicare fraud, and money laundering. LJ pled guilty on July 28, 2016.

Manhattan U.S. Attorney Preet Bharara said: “Through her pharmacies in Queens and Brooklyn, [LJ] dumped 100,000 illegally diverted oxycodone pills into the City’s streets. Driven by greed, [LJ] abused her pharmacy license, helping to fuel the opioid abuse epidemic that is ravaging too many of our communities. For her crimes, [she] will spend four years in prison and forfeit her ill-gotten gains.”

According to the allegations in the Indictment and the civil Complaint, and other information in the public record:

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Question 7:

Billing Medicare under a physician's identification number in situations in which the physician is offsite and the patient is not seen by the physician but instead is seen by a mid-level practitioner:

a. results in Medicare paying more than it would have;
b. results in a violation of the False Claims Act;
c. violates Medicare billing instructions;
d. all of the above are true.

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https://www.justice.gov/usao-sdny/pr/pharmacist-sentenced-4-years-illegally-distributing-approximately-100000-oxycodone
Between in or about March 2010 and October 2015, LJ owned and operated two pharmacies in Queens and Brooklyn doing business as “Chopin Chemists.” During that time period, at these pharmacies, LJ knowingly distributed approximately 100,000 tablets of oxycodone based on fraudulent prescriptions, including prescriptions made out in the names of famous luxury brands, such as Coach and Chanel. In addition, LJ used the proceeds of that illegal narcotics trade to help finance the purchase of a multimillion-dollar home. Finally, LJ deliberately overbilled Medicare by more than $500,000, submitting reimbursement claims for medication that she never actually distributed to patients. In addition to the prison term, LJ was also directed to forfeit $800,000 and to pay restitution of $520,000.

**Question 8:**

LJ was guilty of illegally distributing oxycodone and also Medicare fraud because she:

a. filled prescriptions for oxycodone made out in the names of luxury brands such as Coach and Chanel:
b. billed those prescriptions to Medicare;
c. neither of the above are true;
d. both of the above are true.

**Former Owner of Miami Based Pharmacy Convicted at Trial of $700,000 Medicare Fraud Scheme**

The former owner of a Miami based retail pharmacy was convicted, following a three-day trial, for his participation in a scheme that involved the fraudulent submission of approximately $700,000 dollars in false billing to Medicare.

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AA, 54, of Miami, was convicted of three substantive counts of health care fraud. AA faces a maximum possible sentence of ten years in prison for each count of conviction. AA is scheduled to be sentenced on January 27, 2017, by United States District Judge James I. Cohn in Fort Lauderdale.

Evidence presented at trial showed that, for less than six months in 2014, AA owned a retail pharmacy called La Gloria Pharmacy, in Miami. During that time, AA stole approximately $700,000 from Medicare Part D, by stealing the identities of doctors and Medicare beneficiaries and billing for prescription drugs he never purchased nor dispensed. The beneficiaries testified at trial that, although La Gloria Pharmacy had submitted claims for prescription drugs in their names, they had never heard of La Gloria Pharmacy, never received the drugs for which the pharmacy had submitted claims, and had never been treated by the doctor listed in the claim. The doctors testified that, although their names were listed as the prescribing physician in La Gloria Pharmacy’s claims submissions, they had never treated, nor prescribed medication for, any of those beneficiaries.

Related court documents and information may be found on the website of the District Court for the Southern District of Florida at www.flsd.uscourts.gov or on http://pacer.flsd.uscourts.gov.

Question 9:

AA owned a pharmacy for less than 6 months, and was found guilty of submitting claims to Medicare Part D for prescriptions that doctors said they never wrote and patients said they never received. AA faces:

a. up to 2 years in prison on each count;
b. up to 5 years in prison on each count;
c. up to 10 years in prison on each count;
d. up to 20 years in prison on each count.
Former Walgreens Clinical Pharmacy Manager Pleads Guilty to $4.4 Million TennCare Fraud Scheme

Author's Note: In a departure from the cold, hard facts that we aim to deliver to you, I will admit this case breaks my heart. It does because it is so easy to see how this pharmacist could well have had the patient's best interests in mind, but did not understand how serious her actions were. Also, once a pharmacist or technician deviates from the employer's standard operating procedures, then the typical employer does not support the employee and often the employee is terminated and left to defend themselves alone in court. Finally, CMS now advises state Medicaid agencies to do some of what this pharmacist did, and that is to ignore liver scarring as a criterion for reimbursing for this class of drugs.

GREENEVILLE, Tenn. – On Oct. 25, 2016, AR, 33, pleaded guilty to one count of healthcare fraud contained in a federal information, before the Honorable J. Ronnie Greer, U.S. District Judge. AR was the former Clinical Pharmacy Manager at the Walgreens Specialty Pharmacy located in the Holston Valley Hospital in Kingsport, Tenn.

Sentencing has been set for Jan. 30, 2017. AR faces a potential sentence of up to 10 years in prison, a fine of up to $250,000, and supervised release of up to three years.

In a detailed plea agreement on file with the U.S District Court, AR admitted that between October 2014 and April 2016, she falsified prior authorizations, medical lab reports, and drug test results for at least 51 Hepatitis C patients who had prescriptions for the expensive Hepatitis C drugs of Sovaldi®, Harvoni®, Viekira Pak®, or Daklinza®. These patients had health insurance through TennCare, which does not pay for Hepatitis C prescriptions for patients who abuse illicit substances or who have limited or no scarring of the liver. The patient’s authentic medical lab reports and drug tests showed that they failed to meet TennCare

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eligibility requirements. However, AR admitted to replacing disqualifying information regarding levels of liver scarring and illicit substance abuse on the authentic records with qualifying information, and then submitting the altered records to TennCare. She also admitted to fabricating allergies on the prior authorization forms of some of these patients so they could receive the most expensive Hepatitis C drug, Harvoni®.

As a result of AR’s conduct, TennCare paid at least $4,400,000 to purchase Sovaldi®, Harvoni®, Viekira Pak®, and Daklinza® prescriptions for these 51 patients, which they would not have paid if true and accurate prior authorizations, drug test results, and medical lab reports pertaining to these patients had been submitted.

**Question 10:**

AR pled guilty to falsifying the prior authorizations, lab reports, and/or drug tests for 51 patients to enable them to meet clinical criteria for expensive drugs to treat chronic hepatitis C. The effect of her actions includes:

a. the Medicaid agency paid at least $10 million to purchase the medications for these patients;
b. AR faces a potential prison sentence of up to 10 years in prison;
c. AR caused significant harm to her patients;
d. AR faces a potential fine of up to $1 million.
Return this ANSWER SHEET with the $15.00 Program Fee payable to:

Pharmacy Jurisprudence, LLC
P.O. Box 21186
Columbus, Ohio 43221-0186

NAME: ____________________________   Pharmacist? Yes/No
ADDRESS: ____________________________   Technician? Yes/No
CITY, STATE and ZIP: ____________________________
EMAIL: ____________________________
NABP e-Profile #: ____________________________   Month and Day of Birth: ____________________________

ANSWERS: DOJ Cases Against Pharmacists - 2016
Expiration Date: February 1, 2020

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

1. a b c d  6. a b c d
2. a b c d  7. a b c d
3. a b c d  8. a b c d
4. a b c d  9. a b c d
5. a b c d  10. a b c d

11. For Pharmacists: After completing this program, I am able to describe at least 5 consequences of failing to comply with federal drug laws: Yes No
12. For Pharmacy Technicians: After completing this program, I am able to describe at least 5 consequences of failing to comply with federal drug laws: Yes No
13. This CE activity met my educational needs: Yes No
14. The author was organized in the written materials: Yes No
15. The learning material was useful: Yes No
16. The teaching and learning methods (case format, questions embedded in the program) fostered active learning and were effective: Yes No
17. The learning assessment (the post-test) was appropriate: Yes No
18. The test questions were relevant to the goals of the CE activity: Yes No
19. The test questions were at an appropriate level of difficulty: Yes No
20. The CE activity was presented in a fair and unbiased manner: Yes No
21. If you perceived any bias or commercialism, please describe: ____________________________

22. How long did it take you to complete this program? ____________________________
23. Thank You! Other comments are welcome, including any gaps in your knowledge regarding pharmacy law or patient safety that we can help fill in with our next CE activity: ____________________________

NAME: ____________________________   Pharmacist? Yes/No
ADDRESS: ____________________________   Technician? Yes/No
CITY, STATE and ZIP: ____________________________
EMAIL: ____________________________
NABP e-Profile #: ____________________________   Month and Day of Birth: ____________________________

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