



CE PRN

PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

● ABOUT WFPA ● LESSONS ● TOPICS ● ORDER ● CONTACT ● MCA EXAM REVIEWS

“Annual Law Lesson---Regulating Compounding” February 2013

The regulatory implications of compounded drugs are significant. It is impossible for drugs compounded by a pharmacist to be approved by the FDA, as this approval process takes years and the patient needs the drug within hours or minutes. With this as the basis, we present the annual lesson that reviews a concept related to pharmacy law and its impact on pharmacy practice.

1. Describe the historical evolution of compound as an essential component of pharmacy practice.
2. Discuss the authority that the FDA has over licensed pharmacists.
3. List the factors that are considered by the FDA to differentiate between compounding & manufacturing.
4. Describe how USP 797 may have led to centralization of compounding among large-scale pharmacies.



This is a subscription program. To get continuing education credit, you must subscribe to the program, or pay fee for individual lessons.

Future topics include:

- Cultural Competency & Sensitivity Pertaining to Adherence
- Pertussis Update
- Medication Errors-Update
- Superficial Fungal Infections
- CRE Infection
- STD's---Update & Review
- Latent TB Treatment
- Restless Leg Syndrome



PHARMACY CONTINUING EDUCATION FROM WF PROFESSIONAL ASSOCIATES

HAVE YOU RECEIVED YOUR 2012 CE CREDITS? IF YOU HAVE QUESTIONS, PLEASE CONTACT US.

MISSING A LESSON? GO TO OUR WEBSITE & DOWNLOAD WHAT YOU NEED (www.wfprofessional.com). WE NO LONGER HAVE REPRINTS AVAILABLE.

WHEN YOU SEND IN QUIZZES, ALWAYS KEEP A COPY. EMAIL OR FAX ANSWERS. FAX # IS 847-945-5037. OR SEND A CONVENTIONAL EMAIL WITH YOUR ANSWERS. ([INFO@WFPROFESSIONAL.COM](mailto:info@wfprofessional.com)). HAVE YOU RECENTLY MOVED? PLEASE NOTIFY US.

DON'T FORGET CPE MONITOR---IT'S A REALITY.

This lesson provides 3 hours (0.3 CEUs) of credit, and is intended for pharmacists in all practice settings. **The program ID # for this lesson is 707-000-13-002-H03-P. Pharmacists completing this lesson by February 29, 2016 may receive full credit.**

To obtain continuing education credit for this lesson, you must answer the questions on the quiz (70% correct required), and return the quiz. Should you score less than 70%, you will be asked to repeat the quiz. Computerized records are maintained for each participant.

If you have any comments, suggestions or questions, contact us at the above address, or call 1-847-945-8050. **Please write your ID Number (the number that is on the top of the mailing label) in the indicated space on the quiz page** (for continuous participants only).

CPE MONITOR IS HERE. Since May 1, 2012, we have been electronically transmitting your CE credits to **CPE MONITOR**. So, if you have not signed up with **CPE MONITOR**, do it now. We must have your **CPE MONITOR ID# & your birthdate (day & month only)**. Always, continue to send quiz answers to us like in the past. **YOUR CE CREDIT IS STILL BASED ON YOUR SENDING IN THE QUIZ ANSWERS TO US.** In December, 2012, you'll receive a hard copy, paper, Credit Statement from us for 2012. Beginning in 2013, you'll ONLY download your Credit Statements from the **CPE MONITOR** site. **NO PRINTED CREDIT STATEMENTS FROM CE PROVIDERS.**

All opinions expressed by the author/authors are strictly their own and are not necessarily approved or endorsed by W-F Professional Associates, Inc. Consult full prescribing information on any drugs or devices discussed.

CE PRN® (ISSN 0199-5006) is owned and published by W-F Professional Associates, Inc. CE PRN® is published eleven times per year, monthly, January through November. Subscription rate is \$110.00 per year. © 2013 by W-F Professional Associates, Inc. All rights reserved. None of the contents of this publication may be reproduced in any form without the written permission of the publisher.

PHARMACY LAW UPDATE---REGULATION OF PHARMACY COMPOUNDING

Compounding occurs in a pharmacy when a pharmacist prepares a pharmaceutical product extemporaneously and dispenses it to a patient, rather than dispensing a product that has been acquired, either directly or indirectly, from an FDA-regulated manufacturer. There is a long history of pharmacist compounding. In fact, one of the commonly used icons of pharmacy is a picture of a mortar and pestle; the tools pharmacists use to prepare many compounded products. As long as 4,000 years ago, there is historical evidence of a class of individuals who prepared medications for ailing persons pursuant to the directions of another class of diagnosticians who determined what medication was appropriate. There is also historical evidence from many centuries ago of written directions for product preparation, and this is thought to be one of the indications supporting the practice of compounding as essential to the pharmacy profession.

The continued popularity of compounding reflects the need by patients to have uniquely prepared prescriptions that have been determined by their physician to be necessary and appropriate, even though these products are not commercially available. For example, pediatric or geriatric patients who cannot swallow a solid dosage form may need a liquid, a dissolvable lozenge, or a rectal suppository to deliver the drug to their system. Patients who have allergies to dyes, preservatives, or fillers in commercial products may need a pharmacist to create a dosage form that omits these allergens. When a commercial product is in short supply or is unavailable, a pharmacist can often compound one for use in continuing therapy rather than have that therapy be interrupted or discontinued.

CLARIFICATION OF DEFINITION

Reconstitution of a powdered pharmaceutical product with a suitable diluent pursuant to the directions in a manufacturer's labeling is not compounding. This is a common occurrence with pediatric antibiotics dispensed in a community pharmacy, or with intravenous drugs in a hospital setting. However, the mixing of a drug in a way not described in the product's official labeling is usually considered compounding. This could mean that an intravenous admixture with more than one drug would be considered a compounded product, as could small volume injectable products, or chemotherapeutic agents. Physicians may order a combination of drugs for a patient, due to that patient's unique needs, and it is impossible for a commercial manufacturer to anticipate what a patient may need at any particular time.

RISKS

There are risks with compounded products as there are with all drugs. Those compounded as sterile formulations for injection, inhalation, or ophthalmic application may become contaminated with bacteria, fungi, or other pathogens. Compounded drugs for pediatric or elderly patients may cause problems that were not anticipated due to the frailty of the patient. Long acting compounded products may release their drug at a rate or extent that differs significantly from what was planned and predicted. Yet these risks must be placed in perspective, as even FDA-approved and commercially produced products have significant risks. The withdrawal from the market of many approved commercial pharmaceutical products due to safety concerns over the past several decades demonstrates that requiring and obtaining FDA approval does not always assure product safety.

REGULATORY FACTORS

The regulatory implications of compounded drugs are significant. It is impossible for drugs compounded by a pharmacist to be approved by the FDA, as this approval process takes years and the patient needs the drug within hours or minutes. Thus, compounded drugs are necessarily unapproved new drugs. This is a potential regulatory violation if an agency, such as the FDA, interprets the law to require approval of all new drugs, with no exception for drugs compounded pursuant to a prescription for a specific patient. It is also unlikely that a compounded drug will be accompanied by labeling as extensive as a drug package insert, which is required for commercially prepared drugs, and this omission raises the possibility of a misbranding violation. It is also uncommon for compounded drugs to be mixed under conditions that comply with current Good Manufacturing Practices, leading to the potential for an adulteration violation. Because compounding pharmacists cannot consistently comply with the new drug, misbranding, and adulteration provisions of the Federal Food Drug & Cosmetic Act (FDCA), they must be exempted from them for their compounding activities in order to be legal.

Traditionally, compounding has been regulated by the states, with only high-level oversight by the FDA to assure that a small-scale local pharmacy operation does not build up to the level that is the equivalent of a high-volume multistate manufacturing business. The general rule has been that a physician may prescribe a compounded drug for that physician's patient, and a pharmacist may compound the drug pursuant to a prescription, as long as the drug is dispensed by the pharmacist directly to the patient. The risk of error is small when the scale is small. Physicians treating patients who have received compounded medications prescribed by them are likely to attribute an unexpected outcome to the possibility of improper compounding, since they know the drug was compounded. On the other hand, an error with high-volume compounding may lead to many bad outcomes since far more patients received the erroneously prepared drug, and physicians may not be aware that the drug was compounded if the pharmacy is assuming the role of a manufacturer.

During the 1980s, the FDA began to collaborate with state regulators to limit the risk posed by high-volume state licensed compounding pharmacies that the FDA felt were essentially doing what large manufacturers would do, but without the oversight that the FDA provides for manufacturing. The agency did not want to "throw out the baby with the bathwater," because they recognized that there is an important role for legitimate extemporaneous compounding by state-licensed pharmacies filling prescriptions from local physicians for their regular patients. The FDA began to consider formalizing a standard of practice for pharmacy compounding that would establish a safe-harbor for legitimate compounding while clearly making it illegal to conduct a large national manufacturing business that could hide behind a state pharmacy license.

By the early 1990s, the FDA had committed to adopting a Compliance Policy Guide (CPG) for pharmacy compounding. Published in 1992, that CPG stated, "FDA believes that an increasing number of establishments with retail pharmacy licenses are engaged in manufacturing, distributing, and promoting unapproved new drugs for human use in a manner that is clearly outside the bounds of traditional pharmacy practice and that constitutes violations of the Act." Without listing activities that were considered clearly illegal (because the agency lacked authority to issue such a list) the FDA provided a list of nine factors that it would consider in determining whether a pharmacy practice had crossed the line from compounding into

manufacturing. These nine factors were:

- Soliciting business (e.g. promoting, advertising, or using salespersons) to compound specific drug products, product classes, or therapeutic classes of drug products.
- Compounding regularly, or in inordinate amounts, drug products that are commercially available in the marketplace and that are essentially generic copies of those commercially available, FDA-approved drug products.
- Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-approved facility.
- Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
- Using commercial-scale manufacturing or testing equipment for compounding drug products.
- Compounding inordinate amounts of drugs in anticipation of receiving prescriptions in relation to the amounts of drugs compounded after receiving valid prescriptions.
- Offering compounded drug products at wholesale to other state-licensed persons or commercial entities for resale.
- Distributing inordinate amounts of compounded products out of state.
- Failing to operate in conformance with applicable state laws regulating the practice of pharmacy.

To say that the issuance of this Compliance Policy Guide (CPG) was controversial would be an understatement. Some pharmacists claimed that it was vague and that terms like "inordinate amount" should be specifically defined. Other pharmacists claimed that the FDA lacked the authority to treat the list as an enforceable substantive rule. In a lawsuit against the FDA, a group of pharmacists challenged CPG, contending that its development did not properly meet the notice and comment procedural requirements that apply to a legally enforceable rule. The court ruled in favor of the FDA, concluding that the agency did not use the CPG as a binding set of norms, but instead used it only as a guidance to industry.

FDA MODERNIZATION ACT

In 1997, the FDA Modernization Act (FDAMA) included a provision that formally excused compounding pharmacies from violations of the new drug approval requirement, from the misbranding provisions, and from the adulteration standards. To be excused from these requirements, the pharmacies could not engage in a set of activities that essentially mimicked the 1992 FDA CPG. It was a balanced approach intended to promote access to needed medications but restrict access under circumstances that would threaten public safety. **The FDAMA provisions guaranteed that most pharmacists who compounded prescriptions from a local physician and dispensed the resulting pharmaceutical product to a local patient, on a one-to-one basis, would not be subject to any interference by the FDA. On the other hand, FDAMA made it clear that pharmacies engaged in manufacturing under the guise of compounding were at significant risk of regulatory enforcement action.**

Many pharmacists continued to feel frustrated by the limitations placed on compounding. One of the most controversial provisions of the FDAMA legislation was the section of the statute that dealt with advertising. Congress specified that a pharmacist could not advertise or promote compounding for any drug, drug class, or drug type. The statute allowed pharmacists to advertise their general compounding service, without mention of any particular drug. This restriction made it difficult for compounding pharmacists to inform physicians and patients of the specific services they could provide. Most physicians and patients had little awareness of the drugs that could be compounded by pharmacists, so the advertising of general compounding services was necessary to make people aware of what they could legally have if they were to ask for it. In effect, compounding pharmacists felt that the law said to them, "you can legally do it, but you can't tell anybody that you can do it, so it is unlikely that you will ever really do much of it."

FDAMA LITIGATION

Feeling that the FDAMA provisions were vague, overly restrictive, and still unnecessarily risky for compounding pharmacists, a group of pharmacists filed a lawsuit that eventually was resolved by the Supreme Court of the United States in 2002. In the case of *Thompson v. Western States*, the Supreme Court acknowledged that governmental interests in protecting the drug approval process and in protecting access to compounded medications are substantial. But the court held that the FDAMA provisions were unconstitutional because the statute was not narrowly tailored to protect freedom of speech under the First Amendment. It has long been a firm principle of law that a government objective should be achieved in a way that least interferes with individual freedoms. Government should achieve its objective through the least intrusive of alternate means available for action. The court said, "we have made clear that if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."

The prohibition on advertising, a restriction on freedom of speech, doomed the FDAMA provisions. It invalidated FDAMA. The Supreme Court clearly sided with compounding pharmacists, noting an interest in protecting the practice of pharmacy compounding so that patients' unique pharmaceutical needs could be met. The court also made it clear that it would approve of limitations on compounding that did not restrict freedom of speech, and these could include bans on commercial-scale equipment, limitations on anticipatory compounding, prohibitions on wholesale distribution, and strict volume-based limits.

CURRENT GUIDELINES

Following the lead suggested by the Supreme Court, the FDA reissued its CPG, but this time without the restriction on advertising. It is this document from 2002 that is in effect today and expresses the best guidance the agency can offer to pharmacists who want to feel safe while compounding medications for their patients. Most of the provisions are the same as the original CPG from 1992. But the restrictions on speech are omitted. Pharmacists are free to exercise their First Amendment right of free speech, and they are allowed to promote their specific compounding activities through advertising and other means. A CPG is not the same as a statute. Without the protection of the safe harbor afforded to pharmacists by the FDAMA legislation, a risk continues to exist for pharmacists who conduct a compounding practice. The FDA frequently asserts that it has the authority to prosecute pharmacists who compound, but

the CPG provides guidance on when it will, and will not, assert that authority. The safe harbor of FDAMA is gone.

OTHER LITIGATION

Following the *Western States* case there have been other judicial decisions that have eroded the scope of FDA jurisdiction regarding compounding. In 2006, a federal court in Texas ruled that although the advertising provisions of the FDAMA legislation were struck down by the Supreme Court, the other provisions were not. The effect of this ruling, if it were followed in other jurisdictions, would be to give new life to the protections of FDAMA for compounding, and remove the decision about the legality of compounding from the discretion of the FDA. This is a ruling that is of precedential value only in Texas and nearby states.

In 2011, a federal judge in Florida issued a decision that drastically restricts FDA authority over compounding of veterinary drugs, and has the potential to limit FDA authority over all compounding by pharmacists. The FDA brought an injunction action against a Florida pharmacy, to stop the pharmacy's practice of compounding medications from bulk ingredients for non-food-producing animals (primarily race horses). The FDA's position was that compounding animal drugs from bulk violates the federal Food, Drug & Cosmetic Act (FDCA). The pharmacy admitted that it engaged in this activity, but contended that it does not violate the FDCA.

The court reviewed the regulatory history of extemporaneous compounding, noting that it was a widespread practice in 1938 when the FDCA was enacted, but that the Congress did not grant the FDA explicit authority to regulate it. State boards of pharmacy have traditionally regulated compounding by pharmacists, although the FDA began to assert its authority over compounding in the early 1990s, to prevent large national manufacturing companies from masquerading as pharmacies.

The court described the series of interwoven FDA compliance policies and federal court rulings over the previous two decades, none of which has unambiguously established the scope of FDA authority over compounding by state licensed pharmacists. Against this background, the judge evaluated the FDA's claim that, under the plain language of the FDCA, the agency has enforcement authority to prevent pharmacists from bulk compounding medications for non-food-producing animals. The court noted that the FDA did not rely on its assertions that the pharmacy maintained a "large" and "interstate" operation, nor did it contend that the compounded medications were unsafe or ineffective. Because the agency concluded that the compounded medications were "new animal drugs," the agency contended that it enjoyed what the judge referred to as "unfettered enforcement discretion." The judge disagreed with the FDA, and the injunction was denied.

The judge first applied the "elephants-in-mouseholes" doctrine, which recognizes that Congress does not delegate decisions of economic and political significance to an agency in a vague or cryptic fashion, thus it does not hide elephants in mouseholes. For example, the Supreme Court of the United States has previously held that the federal Controlled Substances Act does not prohibit physicians from prescribing drugs for physician-assisted suicide in states where that procedure is permitted. The Florida judge in the present case said, "The elephant in mouseholes doctrine is equally applicable here: it is not at all clear that Congress meant to hide the elephant of the FDA's regulation of traditional pharmacy compounding in the mousehole of the FDCA's new drug approval process."

The judge then applied the "plain statement rule," which requires that Congress speak in clear terms when displacing traditional state regulation of a particular practice. Examining the statutory structure of the FDCA, the history of the law, and the purpose of the law, the judge concluded that the FDA new drug approval process is an "especially poor fit" for the regulation of traditional pharmacy compounding. The court concluded that although the "new animal drug" definition affords the agency license to enforce the FDCA against pharmacists who manufacture in the guise of compounding, Congress did not give the FDA the authority to enjoin traditional pharmacy compounding of animal drugs, a practice never before regulated by a federal agency and never mentioned in the FDCA.

The judge noted that "the FDA seeks to expand its statutory authority by enjoining an individual pharmacy which is engaged in traditional pharmacy compounding of animal drugs in compliance with state law. In so doing, the FDA overreaches."

The judge concluded "The FDA is certainly statutorily authorized to draw clear distinctions between manufacturing and compounding generally. However, what the FDA seeks to do here is reinterpret the FDCA to allow it to *eradicate* the line between manufacturing and traditional compounding of animal medications. Its wholesale assertion of authority over traditional pharmacy compounding in the context of a pharmacist-veterinarian-patient relationship is contrary to congressional intent. Thus, the Court concludes that the FDA lacks the statutory authority it seeks to exercise here." While this ruling could dramatically reduce FDA authority over compounding, the case was dropped when the pharmacy was sold, so a final resolution of the agency's appeal will not be issued and the full impact of the case is difficult to predict.

STATES' REGULATORY ROLE

As FDA authority over compounding began to erode due to court rulings, states started to undertake an expanded role in the regulation of compounding. There is no question that state boards of pharmacy have the authority to establish standards for compounding, inspection of pharmacies, and issuing administrative discipline of those pharmacies that violate the standards. State boards of pharmacy soon discovered that the challenge to effectively regulate compounding would be difficult to meet. One of the most challenging activities for states was the development of standards for the compounding of sterile dosage forms. Fortunately, the states discovered that the **United States Pharmacopeia** had already adopted *USP Chapter 797, Pharmaceutical Compounding: Sterile Preparations*. Many states either incorporated the **USP** standard directly into their state laws, or they used the principles of the **USP** standard by drafting a law that imposed fundamentally the same requirements. Unfortunately, many pharmacies soon learned that these standards are very complicated, burdensome, and expensive to comply with.

REACTION TO USP 797

As small compounding pharmacies became daunted by the high bar of **USP Chapter 797**, many of them, including hospital pharmacies, decided not to attempt compliance but to instead outsource to independent specialty pharmacies the function of compounding sterile preparations. This move makes sense because the high cost of the infrastructure, including personnel and instrumentation, necessary to meet the standards, can be afforded by only a few pharmacies within a geographic area. Centralizing the function of sterile product compounding in a few pharmacies, rather than having every compounding pharmacy

perform this function, could provide the economy of scale necessary to produce a reasonable return on the investment necessary for capitalization of a compliant pharmacy. It is an efficient way to use resources. On the other hand, focusing the sterile compounding activity at only a very few pharmacies caused these pharmacies to grow enormously and become the high volume businesses that had been the very reason for the initiation of FDA regulatory activity toward compounding pharmacies twenty years earlier. The potential problem is particularly acute when economic efficiencies lead to the outsourcing of sterile product compounding to pharmacies located hundreds or thousands of miles away. The process of regulation eventually led to the problem it had initially sought to avoid.

OUTCOME

The predictable result was an outbreak of fungal meningitis in many states, attributed to contamination of three lots of medication used for epidural steroid injections. The pharmacy that compounded, packaged, and distributed this product was the New England Compounding Center in Framingham, Massachusetts. Over half the 50 states reported patients who suffered, many died, as a result of this contaminated product.

Responding to this meningitis outbreak, many legislators called for stricter regulation of compounding pharmacies by the FDA. Perhaps these legislators were unaware of the long history during which the FDA had attempted to assert greater regulatory authority over compounding, only to be thwarted by the courts. Gradually, the national media, along with state and federal legislators, began to consider the possibility that granting expanded authority and resources to state boards of pharmacy might be the best approach. The FDA has sufficient challenges with oversight of the manufacturers it currently regulates. So the most recent tactic has been to suggest that states require every pharmacy engaged in high-risk compounding to obtain a special license and agree to more frequent inspections by reviewers who are highly trained in methods to assure regulatory compliance.

The regulation of extemporaneous compounding by pharmacies is a classic example of the "Goldilocks Effect" in regulation. Laws should not be too soft, and they should not be too hard; they must be just right. Patients who have unique needs for medications that are commercially unavailable should be able to get them from compounding pharmacies. At the same time, the public should be protected from harm that can be caused by huge multistate pharmaceutical manufacturers that are not regulated by the FDA because they masquerade as compounding pharmacies. This is a major challenge for pharmaceutical regulators, and the responsibility now seems to be primarily with the state boards of pharmacy.

Fill in the information below, answer questions and return **Quiz Only** for certification of participation to: CE PRN®, 400 Lake Cook Road, Suite 207, Deerfield, IL 60015.

NAME _____ **CE PRN I.D.#**(1st line on label) _____

ADDRESS _____ **CITY** _____ **STATE** _____ **ZIP** _____

CPE Monitor ID _____ **Birthdate (MM/DD)** _____

ARE YOU LICENSED IN FLORIDA? IF YES, FL LIC # _____

EMAIL Address (we need this) _____

LESSON EVALUATION

Please fill out this section as a means of evaluating this lesson. The information will aid us in improving future efforts. Either circle the appropriate evaluation answer, or rate the item from 1 to 7 (1 is the lowest rating; 7 is the highest).

1. Does the program meet the learning objectives?

Describe the historical evolution of compounding YES NO

Discuss the compounding authority that the FDA has over licensed pharmacists YES NO

List factors considered by the FDA to differentiate compounding & manufacturing YES NO

Describe how USP 797 may have led to centralization of compounding YES NO

2. Was the program independent & non-commercial YES NO

	Poor	Average	Excellent
3. Relevance of topic	1	2 3 4	5 6 7

4. What did you like most about this lesson? _____

5. What did you like least about this lesson? _____

Please Mark the Correct Answer(s)

- How many years ago was proof found regarding compounding?**
 - 40 years
 - 400 years
 - 1,000 years
 - 4,000 years
- Reconstitution of a powered pharmaceutical with a suitable diluent, pursuant to directions in the manufacturer's labeling, is considered compounding.**
 - True
 - False
- Extemporaneous compounding by pharmacists is risky, while commercial products & FDA-approved products are virtually risk free.**
 - True
 - False
- Thompson v. Western States struck down:**
 - Forbidding advertising
 - Compounding limited to independent pharmacies
 - Expanding patent protection to controlled substances
 - Allowing hospitals to compound IV admixtures
- Compounded drugs are necessarily classified in what way?**
 - Unapproved new drugs
 - Over the counter drugs
 - Controlled substances
 - Unacceptably high risk drugs
- What were nine factors established in 1990?**
 - Standards of Practice
 - Best Practices Advisory
 - Compliance Policy Guide
 - State Pharmacy Practice Act
- Which act excused compounding pharmacies from violations of the new drug approval requirement?**
 - FDA Modernization Act
 - Patient Protection & Affordable Care Act
 - OBRA-90
 - FDA Amendments Act
- For which of these drugs are there significant risks if using compounded products?**
 - Sterile formulations
 - Pediatric or geriatric products
 - Long acting products
 - All of these
- Court rulings placed greater compounding authority with:**
 - The DEA
 - The Supreme Court
 - The Department of Justice
 - The states
- What chapter of the USP deals with pharmaceutical compounding of sterile preps?**
 - 707
 - 727
 - 777
 - 797

Contributing Author

David D. Brushwood, RPh, JD
Professor, Healthcare Administration
University of Florida College of Pharmacy
Gainesville, FL

Executive Editor

William J. Feinberg,
BS Pharm, MBA

Program ID #707-000-13-002-H03-P.

CE Provider Registered # with CE Broker.com is 50-3170.



W-F Professional Associates, Inc. is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmaceutical education. Providers who are accredited by ACPE are recognized by **All States** for fulfilling CE requirements. Pharmacists completing this course by February 29, 2016 may receive full credit. This lesson furnishes 3.0 hours (0.3 CEUs) of credit.

NOTICE

CPE MONITOR IS HERE.

Since May 1, 2012, we have been electronically transmitting your CE credits to ***CPE MONITOR.***

So, if you have not signed up with ***CPE MONITOR,*** do it now.

We must have your ***CPE MONITOR*** ID# & your birthdate (day & month only).

Always, continue to send quiz answers to us like in the past.

YOUR CE CREDIT IS STILL BASED ON YOUR SENDING IN THE QUIZ ANSWERS TO US.

ONLY download your Credit Statements from the CPE MONITOR site.

NO PRINTED CREDIT STATEMENTS FROM CE PROVIDERS.