



# North Carolina Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Item 2341 – Proper Identification of Compounding Risk Levels and Notification to the Board**

Pharmacies that hold a permit from the North Carolina Board of Pharmacy and that engage in any type of compounding are required to notify the Board. Such pharmacies must report (both on an initial permit application and as part of each annual renewal): (1) whether they compound; (2) a good-faith estimate of the percentage of the pharmacy's dispensing that involves compounded products; (3) whether the pharmacy engages in nonsterile compounding; (4) whether the pharmacy engages in sterile compounding; and (5) what risk level of sterile compounding, as defined by United States Pharmacopeia (USP) Chapter <797>, the pharmacy performs. Accurate reporting of this information is crucial for at least two reasons. First, failure to provide accurate information in connection with seeking or renewing a permit is grounds to revoke or void a pharmacy permit (N.C.G.S. §90-85.38). Second, the Board's risk-based inspection intervals are driven by the scope and type of service provided at a pharmacy, particularly compounding services.

Please note: The estimate of the percentage of the pharmacy's dispensing that involves compounded products does not affect a pharmacy's inspection interval. That interval is determined by the type of compounding services provided, not the volume of compounding services provided.

Board staff published a guidance document intended to reduce any confusion about this reporting requirement, which is available at [www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf](http://www.ncbop.org/PDF/CompoundingRiskLevelsandCategoriesMar2015.pdf).

Pharmacists are also reminded that Board Rule 21 NCAC 46.2801 requires any pharmacy that provides compounding services to maintain a reference library that includes current USP standards for compounding. Board Rule 21 NCAC 46.2801 also requires that the pharmacist-manager or pharmacist-manager's designated pharmacist be knowledgeable in all compounding functions, including USP categories of compounding.

## **Item 2342 – Board Proposes Amendments to the Rule Governing Continuing Education**

As pharmacists know, in September the Board published for notice and comment various proposed amendments to Rule 21 NCAC 46.2201, which governs continuing education (CE). The proposed amendments and detailed instructions on how to submit comments and/or attend the public hearing on the amendments are found at [www.ncbop.org/rulemakings.htm](http://www.ncbop.org/rulemakings.htm). In response to some general inquiries about the proposed amendments, Board staff offer the following.

Each year, Board staff receive a number of complaints from pharmacists unhappy that they must enter all of their CE courses into the Board system (even CE obtained through an Accreditation Council for Pharmacy Education (ACPE)-accredited provider and logged through CPE Monitor®) in order to renew their licenses. One effect of the proposed amendments would be to eliminate the need to do so. The categories of CE that would satisfy renewal requirements are streamlined in the proposed amendment. Providers of each category of approved CE in the amendment can (and must) maintain an electronic database of each pharmacist to whom they have granted CE. This will eliminate the need for pharmacists to maintain any paper CE certificates. Moreover, it will allow pharmacists to simply attest at renewal that they have obtained the required amount of CE (although pharmacists will have to specify the number of hours they obtained from ACPE-accredited or North Carolina Association of Pharmacists-accredited courses, or preceptorship from a North Carolina-based pharmacy school). Board staff would begin sampling a larger number of pharmacists for CE audit and would require the CE providers to review the CE claimed by pharmacists selected for audit and report to Board staff that records do (or do not) show that the pharmacist in fact acquired the claimed number of CE credits. The present paper-based CE audit process – necessary because of the large number of categories


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## FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at [www.ecfr.gov](http://www.ecfr.gov).

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at [www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf](http://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf). FDA provides more information online at [www.fda.gov/Drugs/DrugSafety/ucm524320.htm](http://www.fda.gov/Drugs/DrugSafety/ucm524320.htm).

## Selected Medication Risks to Manage in 2017

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

### Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.<sup>1</sup> Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.<sup>1,2</sup> This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.<sup>1,2</sup>

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.<sup>3,4</sup> Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.<sup>4</sup> Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.<sup>4</sup> Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.<sup>4</sup> Medication rooms should provide illumination at 100 fc.<sup>4</sup> Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy<sup>3</sup> and should be used on mobile medication carts (including those used with bar code medication verification systems)<sup>4</sup> and near ADCs.

### References:

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2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. [www.ismp.org/sc?id=1664](http://www.ismp.org/sc?id=1664).

### DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

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of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at [www.dea.gov/divisions/hq/2016/hq100416.shtml](http://www.dea.gov/divisions/hq/2016/hq100416.shtml) and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

### **New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose**

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at [www.cdc.gov/drugoverdose/pdf/pharmacists\\_brochure-a.pdf](http://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf).

### **FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines**

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm).

### **FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians**

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars

targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).

### **FDA Approves Labeling Changes for All Prescription Testosterone Products**

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at [www.fda.gov/Drugs/DrugSafety/ucm526206.htm](http://www.fda.gov/Drugs/DrugSafety/ucm526206.htm).

### **Latest FDA Drug Info Rounds Training Videos Available**

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

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of CE presently allowed for renewal – is burdensome both for Board staff and for pharmacists selected for audit. The proposed amendments would allow a more robust audit, but one that is much less labor- and time-intensive for pharmacists and Board staff alike.

Based on feedback, Board staff believe that this simplified CE reporting and attestation system would be well-received by pharmacists. But, as in all things in life, achieving a simpler CE reporting and auditing system requires trade-offs. As already noted, the extremely wide variety of categories of CE previously accepted by the Board must be consolidated to a smaller population that can be readily tracked electronically by the CE provider and readily reviewed and reported upon to the Board during the CE audit process. For similar reasons, the five-hour carry-over is eliminated in the proposed amendments. Requiring CE providers to audit two years of CE data and then figure out which, if any, CE hours should “carry over” is not feasible.

Board staff and members welcome constructive feedback on the proposed amendments. Again, instructions for providing comments are found at [www.ncbop.org/rulemakings.htm](http://www.ncbop.org/rulemakings.htm).

### **Item 2343 – Board Proposes Rule Amendment to Align Board of Pharmacy Member Elections With the Annual Pharmacist License Renewal Period**

The Board has published proposed amendments to its rules governing Board member elections. The proposal would shift the member election period to coincide with the pharmacist license renewal period.

Pharmacist participation in Board member elections is poor. When the Board amended election rules in 2009 to allow for electronic voting, the number of pharmacist voters began to rise. Even so, the increase was not dramatic and peaked in the spring 2011 election when 3,347 pharmacists cast ballots (out of 10,321 eligible to vote, or 32.4%). The spring 2016 primary election saw just 1,941 ballots cast (out of 11,570 eligible to vote, or 16.8%).

Multiple factors likely contribute to poor pharmacist voter turnout in Board elections. That said, the Board believes (and is hopeful) that linking the voting period to the annual license renewal period will improve pharmacist voter participation. Every pharmacist in the state must log on to the Board’s website to complete his or her annual renewal of license. Providing pharmacists with a specific reminder of an ongoing Board member election – and a pop-up link to the electronic voting tool – as part of the electronic renewal would remove any possible convenience barrier to exercising the franchise.

The proposed amendments do not change the composition of the Board, the terms of Board members, eligibility for Board membership, or any other aspect of Board elections other than timing.

Board staff and members welcome constructive feedback on the proposed amendments. Instructions for providing comments are found at [www.ncbop.org/rulemakings.htm](http://www.ncbop.org/rulemakings.htm).

### **Item 2344 – Board Proposes Amendments to Rule Governing Licensure by Examination**

The Board has published for comment proposed amendments to Rule 21 NCAC 46.1505, which governs licensure by examination. The principal purpose of the proposed amendments is to codify a cap on the number of attempts that a licensure candidate may have to pass the North American Pharmacist Licensure Examination® and Multistate Pharmacy Jurisprudence Examination® at five attempts.

Five attempts is the default attempt limit established by the National Association of Boards of Pharmacy® (NABP®), and that limit has been determined to be one that is necessary to ensure test integrity and, relatedly, confidence that a passing score on the examinations actually reflects competency in the areas tested (and not just a capacity to memorize test items after multiple testing attempts).

Other amendments to Rule 46.1505 are not substantive in nature. Rather, they are intended to clarify existing testing requirements.

Board staff and members welcome constructive feedback on the proposed amendments. Instructions for providing comments are found at [www.ncbop.org/rulemakings.htm](http://www.ncbop.org/rulemakings.htm).

### **Item 2345 – Board Proposes New Rule to Require All Licensees, Permittees, and Registrants to Obtain an e-Profile ID and Report It to the Board**

The Board has published for comment a proposed new Rule 21 NCAC 46.1615, which would require all licensees, permittees, and registrants to obtain an NABP e-Profile ID and report it to the Board.

An e-Profile ID is a unique identifier that allows the Board to ensure accurate identification and collection of licensure, disciplinary, inspection, and other information in a secured electronic profile. Any licensee, permittee, or registrant may obtain an e-Profile ID at no cost by contacting NABP.

Most, if not all, pharmacists should already have an e-Profile ID, since it is necessary to obtain CE credit for a course administered by an ACPE-accredited provider. Many certified technicians likely have an e-Profile ID for the same reason.

Board staff and members welcome constructive feedback on the proposed amendments. Instructions for providing comments are found at [www.ncbop.org/rulemakings.htm](http://www.ncbop.org/rulemakings.htm).

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