

May 2011

News



# Ohio State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Annual CPE Reminder

If your license number begins with 03-2, have you certified your compliance with the continuing education (CE) requirements to the Ohio State Board of Pharmacy yet? If not, you only have until May 15, to report it to the Ohio State Board of Pharmacy office. Remember, the procedure has really changed from years past. You do **not** have to list your individual program numbers as in the past. All you are asked to do is select a statement, certifying that you have done the required CE and **that you have the certificates in hand**. You will only have to produce the certificates if you are one of the pharmacists randomly chosen to be audited. Please be sure the certificates are dated on or after March 1, 2008, if you certify your CE on time. If you miss the May 15 deadline, you will be audited automatically. For those who fail to report by May 15, your certificates must be dated within the three years prior to the date you actually certify your CE to the Board office. In addition, the reporting is being done online, using a method similar to the one that you have used for license renewal recently. Those who are required to report this year should have received a letter with a user ID and password to use for the reporting. If your license begins with 03-2 and you have not received the instructions from the Board telling you how to report (other than pharmacists newly licensed after June 1, 2010), please contact the Board office immediately.

From now on, please make sure you have your certificates in hand before submitting the report form. If you are audited and cannot provide the certificates or if your certificates are dated **after the date you submit the form**, you will face Board action. In addition, you should be aware that the Board now randomly audits a higher percentage of pharmacists who report CE than in the past. Previously, the Board audited about 10% of those reporting. With this new procedure, that figure is about 25%, so your chances of being audited will be greater. **Please make sure you have the certificates in hand before you submit the reporting form**. In addition, please make sure the three hours of Board-approved jurisprudence are from a course listed on the Board's Web site. Do not assume that your courses on pharmacy law will count unless they are listed on the Board's Web page. If you have at least 60 hours worth of certificates in hand and you have verified that your jurisprudence credits are Board approved when you certify that you

have met the requirement, you should not have any difficulty with the audit, should you be lucky enough to be chosen.

If you are audited, please submit the original documents to the Board when requested. It would be a very good idea to make sure you have copies of them before you send the originals to the Board office. Every year, we have one or two people whose documents end up disappearing within the United States Postal Service system.

## 4729-5-24 Transfer (Copy) Rule Revised Again

On January 1, 2011, the Board changed its transfer rule to limit the number of transfers on every prescription to one transfer during the life of the prescription. However, due to some rather intense political pressure, the Board at its March 2011 meeting decided to reverse that decision and put the transfer rule back to its previous language. The revised rule showing the language as it existed before the January 1, 2011 change has been filed. The copy of the refiled rule is available on the Board's Web site under "What's New," as is the Notice of the Public Hearing. Assuming that there are no corrections or changes as a result of the public hearing, the Board will probably act to finalize the change at its June meeting. In the meantime, knowing that this change back to the previous language is being implemented, the Board would appreciate pharmacists using good judgment and taking care of the needs of the patients despite the fact that the one transfer rule is still on the books.

## Corresponding Responsibility Is Needed More Than Ever

In last year's May *Newsletter*, the Board mentioned that it is having a tremendous problem in Ohio with so-called pain clinics that are doing nothing but providing large amounts of controlled substances, particularly oxycodone and hydrocodone, to people who have no legitimate medical need for them. That problem has, if anything, increased over the last year. The temptation resulting from the large amounts of money that can be made by trafficking in "legal" drugs has been an enticement to doctors, pharmacists, and other criminally inclined individuals. Quite often, these operations are owned by non-health care

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## Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birth date (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at [www.nabp.net/pharmacists](http://www.nabp.net/pharmacists). Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at [www.nabp.net/technicians](http://www.nabp.net/technicians). Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) for more information.

## FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly

combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at [www.fda.gov/Drugs/DrugSafety/ucm239821.htm](http://www.fda.gov/Drugs/DrugSafety/ucm239821.htm).

## Looking for Risk

*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at [www.ismp.org](http://www.ismp.org). ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

## FMEA

The Failure Mode and Effects Analysis (FMEA) process is a “systematic method of identifying and preventing product and process problems before they occur.” FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.



FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

## AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

## Pharmacists' Role

Pharmacists are often assumed to be the “guardians” in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- ◆ Explain the important processes and sub-processes of medication use from prescription through administration.
- ◆ Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- ◆ Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- ◆ Identify effects, as well as their severity and probability, when a system failure occurs.
- ◆ Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit [www.ismp.org/Tools/pathways.asp](http://www.ismp.org/Tools/pathways.asp).

To learn more about assessing risk in community pharmacy visit [www.ismp.org/communityRx/aroc/](http://www.ismp.org/communityRx/aroc/).

## NABP Launches New and Improved NAPLEX/MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

The profiles of candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 25 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

## New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

professionals, many of whom have a criminal record. They then hire temporary physicians to write the prescriptions. Since most of the pharmacists in Ohio have taken their corresponding responsibility requirements seriously, the “patients” of these operations are having more and more problems finding a place to get the prescriptions filled. The Board has had calls from pharmacies as far away as Virginia and South Carolina asking about the legitimacy of these prescriptions! Because of the problem with getting the prescriptions filled at a legitimate pharmacy, many of these operations have begun to directly dispense the drugs to their “patients.” Sometimes the doctor hands out the drugs, sometimes non-professionals are given that task, and occasionally they have even found pharmacists to set up a pharmacy specifically for that purpose, either within the clinic or separately. The Board of Pharmacy, working with other local, state, and federal agencies, has been able to close down or limit the activities of several of these operations. However, more are springing up around Ohio and pharmacists need to be vigilant as patients they may not know present them with prescriptions from doctors they may not know.

The legislature has taken note of the problem and has begun to address it. Shortly after this *Newsletter* is published, it is expected that HB 93 will pass, be signed by Governor John Kasich, and, due to an emergency clause, become effective almost immediately. This bill will do several things that should help in addressing the problem. First of all, it will require each pain clinic (as defined by the law) to license with the Board of Pharmacy as a Terminal Distributor of Dangerous Drugs, whether or not they possess drugs in the office or are otherwise exempt from licensure. This bill will also require that the pain clinic be owned by one or more physicians to eliminate those that are being run by convicted felons. It requires criminal background checks on the owners and requires the owners to run criminal background checks on their employees. It also limits the amount of controlled substances that a prescriber may personally furnish a patient to a 72-hour supply and it requires those prescribers who do personally furnish these drugs to patients to report those transactions to the Ohio Automated Rx Reporting System (OARRS) program. HB 93 will also require the use of OARRS by prescribers and pharmacists under certain conditions that are to be defined by the individual boards by rule. This does mean that every pharmacy will be required to have Internet access for the pharmacists so they will be able to run the required OARRS reports.

The law will also make some changes to the OARRS program. It will allow the Board to register unlicensed personnel as delegates for prescribers in order to improve efficiency. It adds criminal penalties for the improper use of OARRS reports – penalties that are needed in order for the Board to continue to get federal grants. Again, it will require the use of OARRS by both prescribers and pharmacists under certain conditions.

As stated above, HB 93 should help address the problem of illegitimate pain clinics throughout Ohio. However, just as the Board said in last year’s May *Newsletter*, please be aware that there are both legitimate and illegitimate pain treatment providers working in Ohio. In addition, there are both legitimate pain patients and people who are trying to obtain these drugs for illegitimate use. The pharmacist is often the last person who has the opportunity to make an independent judgment as to the legitimacy of the prescription and the pa-

tient. Both Ohio laws and rules and federal laws and regulations place a corresponding responsibility on the pharmacist to make that judgment and hold the pharmacist accountable for that judgment. Please note that the pharmacist is the one held accountable for making that independent judgment, not the employer, supervisor, or a fellow employee. The fact that the pharmacist called the prescriber and was assured that the prescription was legitimate may not be enough. The pharmacist needs to look at the prescribing habits of the prescriber, the patient and his or her condition, and the dose of the drug or drugs being prescribed. In addition, the pharmacist should take into consideration the distance that separates the patient, prescriber, and pharmacy. Just as in the Florida examples, is it reasonable for a patient to travel long distances, passing by numerous doctors and pharmacies, in order to obtain prescription medications? Sometimes it may be if they are visiting a well known specialist, but usually that long distance traveling is indicative of a problem.

Having said that, please remember that there are legitimate pain specialists and legitimate pain patients out there. Legitimate patients should have their prescriptions filled in a timely fashion and without harassment. People who travel long distances and prescribers whose pain therapy appears to come from a cookbook should receive a little extra review before medications are dispensed. The reports available from the OARRS program will frequently be able to provide assistance in making those judgments.

### **Disciplinary Actions**

Anyone having a question regarding the license status of a particular practitioner, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The professional licensing agency Web sites listed below may include disciplinary actions for their respective licensees.

**State Dental Board** – 614/466-2580, [www.dental.ohio.gov](http://www.dental.ohio.gov)

**State Medical Board** – 614/466-3934, [www.med.ohio.gov](http://www.med.ohio.gov)

**State Nursing Board** – 614/466-3947, [www.nursing.ohio.gov](http://www.nursing.ohio.gov)

**State Optometry Board** – 614/466-5115,  
[www.optometry.ohio.gov](http://www.optometry.ohio.gov)

**State Pharmacy Board** – 614/466-4143,  
[www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)

**State Veterinary Medical Board** – 614/644-5281,  
[www.ovmlb.ohio.gov](http://www.ovmlb.ohio.gov)

**Drug Enforcement Administration** – 800/882-9539,  
[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)