

August 2013

News



# Ohio State Board of Pharmacy

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## ***New Paperless Notification Process! It Is Time to Renew Your Pharmacist License***

The pharmacist renewal notice that contained your “online user ID” and “online password,” which was traditionally mailed, is now going paperless! The notification reminder and explanation of this new process was done via e-mail, which you should have already received. Essentially, this e-mail directs you to access your renewal notice from the Ohio State Board of Pharmacy Web site at [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov). Starting on July 30, 2013, all pharmacists will be able to access their online user ID, online password, and instructions needed for renewal by clicking on the top banner indicating “Click Here for Pharmacist and Intern Renewal.” Here you will need to provide your pharmacist license number and National Association of Boards of Pharmacy® (NABP®) CPE Monitor® e-Profile ID number. As you recall, an e-Profile ID number is mandatory to renew your Ohio pharmacist license. If your license is not renewed by September 15, 2013, you may not continue to practice as a pharmacist in Ohio.

**Please note:** If you are unable to renew online, you must submit a written, e-mailed, or faxed request for a printed renewal application. You will not be able to utilize a credit card for payment if you renew with a printed renewal application. If you have problems or concerns, please e-mail the Board office utilizing the “Contact the Board” selection along the left side of the Web site. Be sure to select “General Licensing Information” as your subject line.

Interns will follow the same process, except along with your intern license number you will need to supply the last four digits of your Social Security number. The Board office only requests the last four digits to help protect your confidential information.

Since this is the first time pharmacists with license numbers beginning with 031 are “attesting” (reporting) their continuing education (CE) online during the pharmacist license renewal, let us review a few items. First, you **no**

**longer** report or enter the actual CE program numbers anywhere in this process. You will answer “Yes” or “No” to the appropriate CE reporting questions during the online renewal process. All CE certificates of completion must be dated between March 1, 2010 and May 15, 2013, unless this is the pharmacist’s first-ever CE reporting year, which means your start date is your licensure date through May 15, 2013. Please carefully read the online renewal question titles and questions as the Board must take into account all CE reporting situations. These questions are presented in a specific order to address each reporting situation.

**(Note:** All pharmacists who practice pharmacy in the state of Ohio, regardless of your address, **must** complete the required 6.0 continuing education units (CEUs) of CE experience, of which 0.3 CEUs must be Ohio Board-approved jurisprudence. Out-of-state pharmacists practicing in Ohio **cannot** use another state’s pharmacist license to satisfy Ohio’s CE requirements.)

Pharmacists whose license numbers begin with 033 or 032 will see the same online renewal process in use for the past few years, with the addition of your NABP e-Profile ID number. Pharmacy interns’ online renewal process is unchanged.

The only real problem that occurs during the renewal process is double-billing of credit cards. This is a result of hitting the “back” button after submitting final information. Every time you hit the back button, your credit card is charged. If you accidentally get charged more than once, the Board tries to catch it and credit your account. However, if a double billing appears on your statement, let the Board office know and the Board will try to get it fixed.

Again, you need to renew your license by September 15, 2013, if you plan to continue practicing pharmacy in Ohio after that date. If you do not wish to renew your license, please notify the Board office immediately. The Board truly appreciates all of the pharmacists and pharmacy interns who utilize the online renewal process.



## Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.


Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at [www.yourhealthathand.org/images/uploads/OTC\\_Trust\\_Survey\\_White\\_Paper.pdf](http://www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf).

## ISMP Study on Targeted Mandatory Patient Counseling

 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!<sup>®</sup> 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 an 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).

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- ◆ Opioid-containing analgesics
  - ◇ fentanyl patches
  - ◇ hydrocodone with acetaminophen
  - ◇ oxycodone with acetaminophen
- ◆ Anticoagulants
  - ◇ warfarin
  - ◇ enoxaparin
- ◆ Antidiabetic drugs (insulin analogs)
  - ◇ Humalog<sup>®</sup> (insulin lispro)
  - ◇ NovoLog<sup>®</sup> (insulin aspart)
  - ◇ Levemir<sup>®</sup> (insulin detemir)
  - ◇ Lantus<sup>®</sup> (insulin glargine)
  - ◇ Apidra<sup>®</sup> (insulin glulisine)
- ◆ Antineoplastic drug (non-oncologic use)
  - ◇ methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at [www.ismp.org/AHRQ/default.asp?link=ha](http://www.ismp.org/AHRQ/default.asp?link=ha).

## Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow,



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

encourage, or mandate pharmacists to substitute generics for brand-name drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book*, is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients**

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders; experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal; and the background to communicate relevant trends or issues to the patient.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancil-

lary supplies, and hazardous waste disposal assistance as well as access to nursing services.

3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders exactly as written within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements; be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system; and regularly review insurance payment information with patients, and provide unit cost information to help patients manage medication costs.

The full article regarding standards of care for hemophilia patients, including information on state implementation of such standards, will be available in the forthcoming June-July 2013 *NABP Newsletter*, which will be accessible in the Publications section of [www.nabp.net](http://www.nabp.net).

## **NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands**

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in NABPLAW® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. NABPLAW Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about NABPLAW Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at [www.nabp.net/programs/member-services/nabplaw/](http://www.nabp.net/programs/member-services/nabplaw/).



**Pharmacists & Technicians:**  
Don't Miss Out on Valuable CPE Credit.  
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit [www.MyCPEmonitor.net](http://www.MyCPEmonitor.net) to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.*

## Upcoming Changes to OARRS Reporting

Ohio Automated Rx Reporting System (OARRS) reporting will be changing to the American Society for Automation in Pharmacy (ASAP) 4.2 format. To facilitate this change, the Board will begin accepting files in ASAP 4.2 format beginning January 1, 2014. Although this format is not currently mandated by Ohio, the Board is aware that a number of states are beginning to require it. The Board will accept files in ASAP 4.1 or ASAP 4.2 until May 31, 2014, to allow vendors to make the necessary changes and also use the same format for multiple states. **Start speaking with your software vendors now about this upcoming change.**

Please note the following, which have not changed:

- ◆ Pharmacies must report all controlled substances (CS) (Schedules II through V) and all tramadol products.
- ◆ Pharmacies must report **at least** every week. Data uploads are accepted 24/7 and may be submitted more often, even daily. In the near future, the Board will require daily reporting. Pharmacies should look into options for their software vendor to automatically upload files. Many pharmacies are currently reporting daily, including the OARRS data upload as part of their nightly close-out routine.
- ◆ Pharmacy software **must** have a field to capture the Drug Enforcement Administration (DEA) suffix, which properly identifies prescribers utilizing a hospital's DEA number. Federal and Ohio law requires this information as part of the prescription record and it must be reported to the prescription monitoring program.
- ◆ If a prescriber or pharmacy does not have a DEA number, the pharmacy should report the prescriber's state United States Postal Service code and their state professional license number, eg, OH12345678, WV54321, MI24680, or KY99876.
- ◆ Pharmacies are required to report the patient telephone number, including area code.

## Legislative Updates

**Physician Assistants (PAs) Now Prescribing Schedule II:** Just as last year's advance practice nurse (APN) prescribing scope changed, the PA prescriptive authority legislatively changed as of May 22, upon the passage of House Bill 284. You have surely noticed Schedule II prescriptions coming into your pharmacies from PAs. Just as with APNs, this is now legal. However, there are parameters for each classification of drug, including opiates, sedatives/hypnotics, and stimulants. Also, as with the APN CS prescriptions, the PAs must have their certificate to prescribe and DEA numbers on the prescription. Please go to the State Medical Board of Ohio Web site for details at [www.med.ohio.gov](http://www.med.ohio.gov).

**Pseudoephedrine Tracking:** As a result of the passage of House Bill 334, all sales of products containing pseudoephedrine are now required to be electronically monitored and all pharmacies must comply with reporting requirements allowing for faster and more complete cross-referencing of such sales. This electronic tracking system (the National Precursor Log Exchange, known as NPLeX) will be run by the Ohio Attorney General's Office and will generate "stop-sale" alerts in the event that a sale exceeds the legal limits on pseudoephedrine purchases. Failure to submit information to NPLeX or a sale after receiving a "stop-sale" alert may result in criminal charges and/or fines. Questions regarding compliance with this new legal requirement should be directed to the Ohio Attorney General's Office at 1-800/282-0515.

## Compliance Update: Prescriptions

Prescriptions written on hospital prescription blanks often contain an illegible squiggle on the prescriber's signature line. Ohio Administrative Code (OAC) Rule 4729-5-30(B) (2), Manner of issuance of a prescription, specifically states that all prescriptions issued by a prescriber shall "contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber." Realizing that this does not always happen, it is the responsibility of the pharmacist to make a reasonable effort to identify the actual individual who wrote the prescription. OAC 4729-5-16(A)(3) requires the prescription label to contain the full name of the prescriber. "Dr Name of Hospital" is not acceptable. The Board knows this involves taking time and potentially adding another prescriber to your computer system; however, it is required by law and will prevent future problems.

## Disciplinary Actions: Lessons Learned

Below is a sample of recent disciplinary actions. For the privacy of all involved, all identifying information has been removed.

**Illegal Possession of Dangerous Drugs and CS by a Pharmacist:** An Ohio registered pharmacist illegally possessed numerous dangerous drugs given to him by a patient of the pharmacy in which he worked. He stored these medications in the trunk of his personal vehicle for approximately two weeks. The pharmacist stated that in the interest of good service to a well-known customer of his pharmacy, he agreed to take the medications in question to a free redistribution/disposal organization where he volunteers. He expressed regret at having forgotten about the drugs he had placed in his trunk and for not being more diligent about making sure he knew exactly what he was accepting from the customer. The Board concluded that the pharmacist is guilty of unprofessional conduct in the practice of pharmacy. The Board issued a formal reprimand, required the pharmacist to obtain six hours of CEUs in pharmacy law, and imposed a \$1,000 fine.

**Failure to Secure and Safeguard CS:** Over a one-and-one-half year period, the responsible pharmacist at an Ohio pharmacy failed to provide adequate safeguards to prevent the sale or other distribution of dangerous drugs by any person other than a pharmacist or licensed health professional authorized to prescribe drugs. Specifically, the responsible pharmacist confronted a pharmacy technician who had two stock bottles of hydrocodone products found in her purse. The responsible pharmacist admitted that any employee of the pharmacy could access and change the computer on-hand inventory, biennial inventories were conducted with a comparison of the computer on-hand inventory to physical stock, and no comparison of the computer on-hand inventory to the dispensing records and invoices were ever conducted. As a result, thousands of doses of CS were missing from the store. The Board concluded that the responsible pharmacist was guilty of unprofessional conduct in the practice of pharmacy and guilty of aiding and abetting the violation of Chapter 4729 of the Ohio Revised Code. The Board issued a formal reprimand, indefinitely suspended the responsible pharmacist's license to practice pharmacy for a period of at least one year, required that the pharmacist may never again serve as the responsible pharmacist at any pharmacy licensed by the Board, and required that he obtain 12 hours of CEUs in pharmacy law.

**Second-Time Offender/Addiction:** An Ohio pharmacist's license was summarily suspended by the Board in March 2013, as a result of his addiction and/or abuse of drugs that impaired him physically or mentally to such a degree as to render him unfit to practice pharmacy. Specifically, in 2008, he admitted his addiction to hydrocodone and his license was summarily suspended. Ultimately, his license was indefinitely suspended and he was required to enter a treatment monitoring program and reappear before the Board and prove his fitness to practice pharmacy. In December 2009, the Board reinstated his license with required continuation of a treatment contract with an approved treatment provider – including a requirement that he refrain from ingesting any dangerous drug that was not legitimately prescribed to him. On February 22, 2013, and dates subsequent, he admitted to the director of his treatment provider and to Board agents that on at least two separate occasions he ingested phentermine that had been prescribed to his wife that he found in his garage because he “needed energy.” This breach of his treatment contract and admission of his addiction and behavior led to his pharmacy license being suspended for a second time. Ultimately, the Board found him guilty of being addicted to or abusing liquor or drugs and/or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy and of willfully violating Chapter 4729 of the Ohio Revised Code. The Board revoked his license permanently.

**First-Time Offender/Addiction:** An Ohio pharmacist's license was summarily suspended by the Board in January 2013, when he was charged with being addicted to or abusing drugs or alcohol and/or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy. He was also charged with theft of CS from two pharmacies he worked in. Specifically, he admitted to and was observed stealing hydrocodone/APAP 10/325 mg tablets and hydrocodone/APAP 10/500 mg tablets. The Board found him guilty of all theft charges, gross immorality, dishonesty and unprofessional conduct in the practice of pharmacy, being addicted to or abusing liquor or drugs and/or impaired physically or mentally to such a degree as to render him unfit to practice pharmacy, and willfully violating Chapter 4729 of the Ohio Revised Code. The Board indefinitely suspended his license to practice pharmacy for a period of at least two years, required that he attempt to pay restitution to his employer, and other standard conditions for substance abuse treatment monitoring.

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 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)

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

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