It's Time to Renew Your Pharmacist License

Pharmacist renewal notices were mailed out in July to all pharmacists licensed with the Ohio State Board of Pharmacy who are eligible for renewal. If you have not received your renewal notice yet, you need to check with the Board office to find out what you need to do to renew your license. If your license is not renewed by September 15, 2011, you may not continue to practice as a pharmacist in Ohio until you do get it renewed.

The process for renewal is the same as it has been the last few years. The Board is providing an online renewal process and that is the method the Board expects the majority of pharmacists to continue to utilize. Instructions for renewing your identification card online were included with the renewal notices. Please follow the instructions carefully and you should have no problems. If you do run into problems or have concerns, please call the Board office. If you do not have Internet access or cannot renew online for some other reason, you will need to contact the Board office in writing (fax or e-mail are also accepted) and request a paper renewal form. Unless the Board hears from you, you will be expected to renew online.

As stated in last year's *Newsletter,* the only real problem the Board has had with its online renewal process so far is with those pharmacists who fail to exercise a little patience and, after submitting their final information, fail to wait a few seconds before getting impatient and hitting the back button on their computer screen. Please do not do that. Every time you hit the back button, your credit card is charged again and again and again. The current record for impatience is somewhere around eight repeat billings. Remember, there is no contest here, so there is no need to try to beat the record. If you do accidently get charged more than once, the Board will try to catch it and credit your account. Many times last year, the Board caught it and fixed it before it got to the credit card company. However, if a double billing does appear on your credit card bill, please let the Board office know and the Board will try to fix the problem.

Again, you need to renew your license by September 15, 2011, 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.

Prescription Data Accuracy and OARRS

(Note: This article is reprinted from last year's August Newsletter in the hopes that it will have a better effect the second time around. In other words, these problems are still continuing and they must be corrected.)

Problem: Inaccurate prescription data submitted to Ohio Automated Rx Reporting System (OARRS)

Areas of Greatest Concern:
♦ Wrong prescriber identified
♦ Wrong date of birth

In recent weeks, the Board office has received several complaints from prescribers about wrong prescription data appearing on the OARRS reports.

When the Board staff investigates these complaints, they find that the data in the pharmacy's computer system is not accurate, resulting in inaccurate data being submitted to OARRS.

Increasing use of the OARRS program is highlighting areas of inaccuracy in prescription records. While an occasional data entry error is understandable, the frequency with which certain errors are occurring is cause for concern.

1. One of the most common errors with individual OARRS reports results from the pharmacist assigning the prescription to the wrong prescriber. Pharmacies only transmit the Drug Enforcement Administration (DEA) number of the prescriber to OARRS. The OARRS system utilizes a database to convert that DEA number to the name that is shown on the report. Some of these errors can be attributed to the selection of a similar prescriber's name or a collaborating (or former collaborating) physician for a nurse practitioner from the pharmacy's database listing. In other cases, no relationship between the DEA numbers can be determined.

   If the prescriber is identified by an incorrect DEA number, the wrong prescriber name will appear on the report. The result is a patient who disavows a prescription(s) by stating "I never saw that doctor." However, further inquiry usually reveals that the patient actually received a prescription on that date for that drug from that pharmacy. An OARRS client may contact the pharmacy to verify the report and find that the pharmacy data or hard copy reveals a different prescriber for that particular prescription. Yet, the entire patient's OARRS record is tainted by the uncertainty of accuracy.

2. Another common error is wrong date of birth (DOB). Some common causes are:
   ♦ Entering date of dispensing instead of patient's DOB.
   ♦ Entering DOB of spouse instead of patient's DOB.
   ♦ Using the profile of a father or son with the same name that assigns the wrong DOB. Mother/daughter or husband/wife with similar names causes the same mix-ups.

Pharmacists Provide Feedback at APhA: 'It's About Time! What a Great Tool'

Since the March 2011 launch of the new CPE Monitor™ service, more than 10,000 pharmacists and technicians have created their National Association of Boards of Pharmacy® (NABP®) e-Profile and obtained their permanent identification number. In its effort to educate licensees, NABP answered questions about CPE Monitor during the American Pharmacists Association (APhA) Annual Meeting and Exposition on March 25-28, 2011, in Seattle, WA, in which pharmacists shared with NABP staff positive feedback about the new service. Visitors to the booth noted that they are looking forward to using the new tool to track their continuing pharmacy education (CPE).

Beginning in the latter part of 2011, the CPE Monitor service will allow pharmacists and technicians to easily track their Accreditation Council for Pharmacy Education (ACPE)-accredited CPE credits. The service will also provide a streamlined reporting and compliance verification process for participating state boards of pharmacy, a capability scheduled for availability in 2012. In the latter part of 2011, the e-Profile ID and birth date (MMDD) will be required to receive credit for any CPE activities taken from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering for CPE or when submitting participation data to the provider.

Pharmacists whose names have changed since the last time they interacted with NABP will need to go through the name change process before beginning their CPE Monitor registration. Name changes can be made in the licensee's NABP e-Profile by submitting a photocopy of the document granting your name change and completing the correct NABP name change form. These downloadable forms are available on the NABP Web site at *www.nabp.net/programs/cpe-monitor/cpe-monitor-service* in the frequently asked questions section. One form pertains to those who have had their name change granted by a United States government agency, and the other form pertains to those who have had their name change granted by a foreign government agency. In addition to the form, licensees must submit a photocopy of the documentation noting the name change, which includes marriage license or certificate, divorce decree, or court ordered name change document.

Pharmacists and technicians may access additional information about CPE Monitor in the Programs section on the NABP Web site at *www.nabp.net/programs* or at *www.MyCPEmonitor.net.* CPE Monitor is a collaborative effort between NABP, ACPE, and ACPE providers.

Protecting Yourself from Identity Theft

Being asked for your Social Security number (SSN) when applying for a loan or credit card, or even when setting up an account with a business for a service, is now commonplace. With this increased use of SSNs comes the increased risk of identity theft, and reputable businesses have been diligent in taking measures to implement security protocols to protect their customers.

Although some may believe that non-governmental organizations are prohibited from obtaining SSNs, in fact there is no law banning private organizations, such as NABP, from collecting this information. In recent years, a federal government task force recognized the importance of SSN use by private entities and preservation of such use. In addition, many states' laws specifically permit private entities to collect and use individual SSNs for purposes of application and enrollment processes, to confirm SSN accuracy, or for internal verification or administrative purposes.

For many decades, NABP has supported the boards of pharmacy in their licensure processes and the Association adheres to state and federal laws when collecting SSNs for purposes of internal data verification and board of pharmacy licensure processes. In addition, NABP has high security protocols and utilizes required technologies and protections, including encryption technologies, to protect sensitive information.

Some pharmacists have asked about using the National Provider Identifier (NPI) number from the Centers for Medicare & Medicaid Services (CMS) as an alternative to providing their SSN. However, applying for an NPI number requires candidates to disclose their SSN to CMS, and may not address candidate concerns about providing their SSN to third parties. In addition, this excludes pharmacy technicians, who are not eligible for an NPI number.

A verification process using the SSN is the best way for organizations like NABP to help ensure the accuracy of data within its systems. NABP collects and reports data such as examination scores and continuing education records to the boards of pharmacy and having incorrect data could create serious adverse consequences for licensees. The use of the full nine-digit SSN, along with other demographic information such as license number(s), will help NABP internally verify that each profile created within its systems is unique, contains accurate information, and will match state board licensure records. The SSN is not used for any other purposes and is not shared with other entities except for the purposes of delivering requested services.

Reputable organizations use secure collection, storage, and disposal procedures, such as SSL encryption, access restriction and monitoring, firewalls, and shredding to protect customers information and thwart would-be hackers and identity thieves. Nevertheless, understanding how identity thieves steal your information will help you protect yourself from identity theft. According to the Social Security Administration thieves acquire your personal information by:

♦ Stealing wallets, purses, and your mail (bank and credit card statements, pre-approved credit offers, new checks, and tax information);
♦ Stealing personal information you provide to an unsecured site on the Internet, from business or personnel records at work, and personal information in your home;
♦ Rummaging through your trash, the trash of businesses, and public trash dumps for personal data;
♦ Posing by phone or e-mail as someone who legitimately needs information about you, such as employers or landlords; or
♦ Buying personal information from "inside" sources. For example, an identity thief may pay a store employee for information about you that appears on an application for goods, services, or credit.

Contaminated TPN Spurs ISMP Call for Action

In response to the infections of 19 Alabama patients by contaminated total parenteral nutrition (TPN), the Institute for Safe Medication Practices (ISMP) called upon Food and Drug Administration (FDA) to take several actions, including collaborating with boards of pharmacy in enforcing compounding standards. An investigation led by Alabama Department of Public Health and Centers for Disease Control and Prevention (CDC) determined that a failure in a step of the sterilization process for the compounded TPN most likely led to its contamination with Serratia marcescens bacteria. Of the 19 cases of infection that resulted in Birmingham, AL, area hospitals, nine were fatal. An investigation revealed that TPN produced by Meds IV was the common source of the infections and that a container and stirrer, and a tap water spigot at Meds IV are likely the sources of the bacteria. The product was recalled by Meds IV on March 24, 2011.

ISMP has expressed support for the provision of additional resources to boards of pharmacy so that boards can survey compounding pharma-

cies to enforce compliance with United States Pharmacopeia Chapter 797 standards. ISMP also calls upon FDA to work with state boards of pharmacy to support enforcement efforts and to provide guidance documents for industry on relevant good pharmacy compounding practices. More information about ISMP's call for action is available in an April 7, 2011 article on the ISMP Web site at *www.ismp.org*.

ISMP Provides Strategies to Enhance Safety Procedures in Pharmacies

This column was prepared by 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. *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. *ISMP address: 200 Lakeside Dr; Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

When investigating errors, look for contributing factors and then apply prevention recommendations that make sense for your organization. Use a variety of the strategies listed below to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Fail-safes and constraints involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system is integrated with the cash register and requires the patient's date of birth be asked and entered at the point of sale.

Automation and computerization of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy and robotic dispensing devices with bar coding.

Standardization creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication.

Redundancies incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

Reminders and checklists help make important information readily available. For example, prescription blanks that include prompts for important information (eg, medication indication, allergies, patient birth date).

Rules and policies are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

Education and information are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

FDA Warning on Benzocaine Use

FDA has issued a warning to consumers and health care providers regarding the use of benzocaine and its association with a rare, but serious condition, methemoglobinemia. FDA also stresses that benzocaine products should not be used on children less than two (2) years of age, except under the advise of a health care provider. Methemoglobinemia results in the amount of oxygen carried through the bloodstream being greatly reduced, and in the most severe cases, can result in death. Benzocaine gels and liquids are sold over-the-counter under different brand names – such as Anbesol®, Hurricaine®, Orajel®, Baby Orajel, Orabase®, and store brands – and are used to relieve pain from a variety of conditions including teething, canker sores, and irritation of the mouth and gums. Benzocaine is also sold in other forms such as lozenges and spray solutions.

FDA notes that methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, including concentrations as low as 7.5%. Further, the cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. Symptoms include pale, gray, or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate and usually appear within minutes to hours of applying benzocaine. Symptoms may occur with the first application of benzocaine or after additional use. FDA advises that if consumers or their children experience any of these symptoms after taking benzocaine, they should seek medical attention immediately. The FDA safety warning is available at *www.fda.gov.*

FDA Reminder About Pradaxa Storage/Handling

FDA issued a safety alert regarding special handling instructions for Pradaxa® due to concerns that these requirements are not commonly known. FDA advises that Pradaxa, an anticoagulant medication known as a direct thrombin inhibitor, should only be dispensed and stored in the original bottle or blister package due to the potential for product breakdown from moisture and loss of potency.

Specifically, FDA advises pharmacists that Pradaxa should only be dispensed in the original manufacturer bottle with the original dessicant cap. Pradaxa should not be repackaged. Patients should be advised to store the medication in the original container and avoid using pill boxes or other containers for storage. Also, once a bottle is opened, the product must be used within 60 days to ensure potency. The Pradaxa label and medication guide contain more information about these storage and handling requirements. The FDA safety alert is available on the FDA Web site at *www.fda.gov.*

♦ "Fat fingers" that hit the adjacent key on a standard keyboard or the number above or below on a numeric keypad, eg, 1969 is entered as 1959 or 1979; 1954 is entered as 1984 or 1924.

♦ Putting the date of injury in the DOB field for a worker's compensation claim prescription.

Since the DOB field is one of the data elements used by the system to differentiate between individuals with similar names, putting the wrong date in the DOB field could mean that the prescription does not appear on the report at all or it may appear on the report but seem to indicate a father/son or mother/daughter situation rather than the fact that this is the same patient. Furthermore, errors in the DOB field often delay the arrival of an OARRS report due to the fact that it may now need to be reviewed by an OARRS pharmacist before it can be released. Finally, there are DOB errors that cannot be explained by any of the factors listed above – they are just plain incorrect.

Pharmacists should review the pharmacy's own prescription data when an OARRS report is requested. Be certain that all the data from your pharmacy appears on the report and be certain that the data matches your own records. If the prescriber is incorrect, OARRS staff may be able to assist you in identifying the problem. Sometimes, modifications to your software may be necessary.

To increase the accuracy of prescription records, train and **retrain** your pharmacy staff that perform data entry. Accuracy matters!

Use terms like Sr, Jr, II, III, IV, Dad, Son, Mom, Wife, Pet, K9, Cat, Fluffy, etc, in addition to the name of the patient (or the owner of the animal). Such terms alert pharmacy staff to multiple or confusing profiles and will help ensure that the prescription is recorded accurately.

Other OARRS data fields with frequent errors are "Payment Type" and "New or Refill." These errors tend to be the result of software programming so you may need to work with your software vendor to correct the problem.

If you need to correct data that has already been submitted to OARRS, see Rule 4729-37-11 OAC (page F-172 of your *Drug Laws of Ohio* book).

All state prescription monitoring programs such as OARRS are receiving a lot of attention due to the prescription drug abuse problem. Legislators and others are beginning to ask for new requirements to ensure prescription data accuracy. This is one area where pharmacists can prevent new requirements and new audits by ensuring that prescription data is as accurate as possible.

Return to Stock Issues

The Board frequently is asked about returning medications to the stock shelves when a filled prescription is not picked up. How to handle these products has always been a problem for pharmacies, but it appears to have worsened now that many pharmacies have instituted an "Automatic Refill" process whereby prescriptions are refilled at the assumed time they should be needed rather than when the patient calls and requests a refill. Based on calls to the Board office and conversations with pharmacists at meetings, it appears that the number of "returns" has risen drastically as a result. Please note that the term "returns" in this case refers to drugs not picked up by the patient which means that they have never left the control of the pharmacy. This article is not addressing returns by patients, which would not be allowed (Rule 4729-9-04 OAC).

Inasmuch as these prescription products that have not been picked up do not bear a label stating the lot number and expiration date of the drug, they could be considered to be misbranded under both federal and state law when they are returned to the stock shelves. In addition, the plastic vials with the child-resistant lids usually used for solid oral dosage forms do not match the manufacturer's containers for moisture resistance, so the actual expiration date for the drug may not be the same in the vial as it was in the unopened manufacturer's container. The one-year expiration date that many pharmacy computer systems apply to the prescription container label is meaningless as it

is not determined by drug and container specific research and may, in addition, be later than the actual manufacturer's date when the pharmacist fails to check it. In other words, returning these products to the shelf could be considered a violation of federal and state law.

However, the Board realizes that many of these drugs are very expensive and, if used within a short period of time, are probably well within the original United States Pharmacopeia content standards, thereby making them safe to use. For that reason, the Board wants to affirm that it will not be overly concerned on an inspection about a **few** items that have not been picked up by patients and have been returned to the stock shelves for reuse, providing that the following conditions are met:

1. The products returned to the shelf remain in the container in which they were dispensed and they retain their prescription label so there is identification of the product's contents and the date originally dispensed.

2. There is, in the pharmacist's professional judgment, a reasonable period of time left before the original manufacturer's expiration date.

3. There are a limited number of returned products on the stock shelves at any one time.

4. The products are dispensed within a reasonable period of time and, if not, are removed from the stock shelves and properly destroyed.

5. **Under no circumstances are the contents of a prescription vial to be returned to the manufacturer's stock bottle.** Pharmacists have been cited and have had Board hearings when patients received the wrong drug because a drug product was returned to the wrong stock bottle and the next pharmacist did not notice the difference in the dosage forms being dispensed.

6. When dispensing these products to another patient, a new container should be used rather than placing the new label over the old one on the original container.

7. In the case of recalls, any prescription vial returned to stock containing the drug affected by the recall should be removed from the shelves immediately, assuming the lot number can no longer be determined.

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 agency Web sites listed below may include disciplinary actions for their respective licensees.

State Dental Board – 614/466-2580, *www.dental.ohio.gov*

State Medical Board – 614/466-3934, *www.med.ohio.gov*

State Nursing Board – 614/466-3947, *www.nursing.ohio.gov*

State Optometry Board – 614/466-5115, *www.optometry.ohio.gov*

State Pharmacy Board – 614/466-4143, *www.pharmacy.ohio.gov*

State Veterinary Medical Board – 614/644-5281, *www.ovmlb.ohio.gov*

Drug Enforcement Administration – 800/882-9539, *www.deadiversion.usdoj.gov*