



Ohio State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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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, 2010, you may not continue to practice as a pharmacist in Ohio until your license is renewed.

The process for renewal is the same as last year. The Board is providing an online renewal process and that is the method the Board will expect the majority of pharmacists 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.

The only real problem the Board has had with its online renewal process over the last two years 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. There is no contest here, so there is no need to try to beat the record. If you do accidentally 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 contact the Board office and the Board will try to get it fixed.

Again, you need to renew your license by September 15, 2010, 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 immediately.

Prescription Data Accuracy and OARRS

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 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 the wrong date of birth (DOB). Some common causes are as follows:
 - ◆ 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, which assigns the wrong DOB. Mother/daughter or husband/wife with similar names causes the same mix-ups.
 - ◆ "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 or 1954 is entered as 1984 or 1924.

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FDA Updates 'Medicines in My Home' Patient Education Resources

Food and Drug Administration (FDA) has updated the Medicines in My Home (MIMH) section of the agency's Web site with new resources and materials for patients. MIMH resources teach patients from adolescence through adulthood how to choose over-the-counter (OTC) medicines and how to use them safely. An interactive video teaches users how to understand the drug facts label and make sound medicine decisions. Downloadable documents provide information on caffeine use, choosing appropriate OTC medications, and other related topics. The MIMH Web page can be accessed at www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm092139.htm.

DEA Releases e-Prescription for Controlled Substances Interim Final Rule

The Drug Enforcement Administration (DEA) Interim Final Rule on electronic prescriptions for controlled substances was published in the *Federal Register* on March 31, 2010, and was scheduled to go into effect June 1, 2010, subject to Congressional review. The regulations would allow prescribers the option to write prescriptions for controlled substances electronically, and allow pharmacies to receive, dispense, and archive these electronic prescriptions. The regulations are an addition to existing rules, and include stipulations to ensure that a closed system of controls on controlled substances dispensing is maintained. The regulations have the potential to reduce prescription forgery and reduce the number of prescription errors, and should also reduce paperwork and help integrate prescription records into other medical records.

Confirmation Bias



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. 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. ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Although pharmaceutical companies and regulatory agencies have been working on design changes to improve the situation, ISMP still associates many medication errors with confusion over "look-alike" or "sound-alike" product names. Since patients receive the wrong drug, these sometimes result in serious harm. A common cause of name mix-ups is what human factors experts call "confirmation bias." Confirmation bias refers to a type of selective thinking whereby individuals select what is familiar to them or what they expect to see, rather than what is actually there.

Many errors often occur when pharmacists or technicians, due to familiarity with certain products, see the name of the product they think it is rather than what it actually is. For instance, if a pharmacist reads a poorly written drug name, he or she is most likely to see a name that is most familiar to him or her, overlooking any disconfirming evidence. Another example of this is if a pharmacy technician chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the shape, size, or color of the container, or the location of the item on a shelf.

Although various compilations of look-alike name pairs are available for posting (see www.ismp.org/Tools/confuseddrugnames.pdf for ISMP's List of Confused Drug names, which has recently been updated), these lists have only limited usefulness since it is impossible for practitioners to memorize them in order to know when to check on questionable prescriptions. Also, when confirmation bias occurs, there is never a reason for the practitioner to question the order to begin with.

In many cases, hospital or pharmacy computer systems can be used to reduce the risk of confirmation bias and resulting name mix-ups. Many systems have a "formulary note" field that can be easily adapted to display important information prominently on the computer screen. Similar to a road sign warning about a dangerous intersection ahead, this feature can be used to alert the person inputting the medication when a look-alike or sound-alike danger is present. For example, when *Norvase*® is entered into the computer, a formulary note screen appears, alerting the pharmacist that *Norvasc* often looks like *Navane*® when handwritten. The pharmacist will then take the necessary steps to confirm the prescription if necessary.

In addition, physically separating drugs with look-alike labels and packaging helps to reduce this confirmation bias as does implementing bar-coding technology for the verification process of drug selection. Employing a simple system that compares computer-generated National Drug Codes (NDC) on prescription labels and NDC codes on manufacturers' containers to verify that the appropriate drug has been selected and dispensed also helps reduce confirmation bias.

It is human nature for people to associate items by certain characteristics. It is very important for the health care community and regulators to recognize the role that confirmation bias may play in medication errors and to work together to address associated problems.

FDA-TRACK Provides Public Access to Agency's Performance Data

The new FDA-TRACK will provide access to updated information about FDA programs, projects, and core responsibilities. The system is part of the FDA transparency initiative and its objectives are represented in the TRACK name which stands for transparency, results, accountability, credibility, and knowledge-sharing. This agency-wide system will track performance measurement data reported from over 100 FDA program offices. Common measures, key center director measures, program measures, and key projects are the measurement areas currently in use, and more information about these areas is available in the FDA-TRACK announcement available at www.fda.gov/AboutFDA/WhatWeDo/track/default.htm. FDA-TRACK will continue to be updated and the latest information can be found on the following Web pages: Cross-Agency FDA-TRACK Program Areas available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm, Center FDA-TRACK Program Areas available at www.fda.gov/AboutFDA/WhatWeDo/track/ucm206441.htm.



AboutFDA/WhatWeDo/track/ucm195008.htm, and Dashboards available at *www.fda.gov/AboutFDA/WhatWeDo/track/ucm195011.htm*. Public feedback on FDA-Track and its measures can be submitted by e-mail to FDATRACK@fda.hhs.gov.

Survey Suggests Majority of Patients Seek Pharmacist Advice About OTC Medications

When selecting OTC medications, 82% of pharmacy customers base their decision on a pharmacist's recommendation, according to a survey of over 1,000 pharmacists conducted by the American Pharmacists Association (APhA). Survey results also indicate which products, among 76 categories presented to pharmacists, are most often recommended. The survey results are published in the Pharmacy Today Over-the-Counter Supplement available at *www.imirus.com/tmp/2536/2501/1001/pm2536.pdf*. An APhA news release, available at *www.pharmacist.com/AM/Template.cfm?Section=News_Releases2&Template=/CM/ContentDisplay.cfm&ContentID=23117*, indicates that 90% of patients seek help identifying the most appropriate product and 80% seek counsel regarding using an OTC product with their prescription medications.

California PMP Data Shows Frequency of Doctor Shopping

Early data collected from California's prescription monitoring program (PMP), the Controlled Substances Utilization Review and Evaluation System (CURES), correlates the frequency of patient "doctor shopping," or obtaining multiple prescriptions from various providers, with the number of prescriptions patients receive for additional controlled substances, as reported in *Medical News Today*. The research analysis, presented at the American Academy of Pain Medicine 26th Annual Meeting, showed that patients prescribed a single additional class of a controlled substance, such as benzodiazepines, had a two-fold likelihood of doctor shopping for multiple opioid prescriptions. A 13-fold increase in doctor shopping was seen when more than one additional drug class was involved. Researchers at the University of California, Davis, conducted the analysis using de-identified CURES data, and also found that patients involved in doctor shopping were involved in more than one episode about 50% of the time.

Highest Dose of Zocor Increases Risk of Muscle Injury, FDA Warns

FDA has informed health care practitioners that there is an increased risk of muscle injury in patients taking the highest approved dose of the cholesterol-lowering medication, Zocor[®] (simvastatin) 80 mg. This information is based on review of data from a large clinical trial and other sources, and FDA is currently reviewing additional data to better understand the relationship between high-dose simvastatin use and muscle injury. More information is included in an FDA Drug Safety Communication at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm204882.htm*.

New OxyContin Formulation to Help Prevent Abuse of the Drug

FDA has approved a new formulation of the controlled-release drug OxyContin[®] which is designed to decrease the likelihood that this medication will be misused or abused, and result in overdose. FDA explains that the new formulation adds in new tamper-resistant features aimed at

preserving the controlled release of the active ingredient, oxycodone. The old formulation allowed tampering with the tablet, via cutting, chewing, breaking, or dissolving, which resulted in dangerously high levels of oxycodone being released at once. In accordance with FDA requirements, Purdue Pharma L.P. will conduct a post-marketing study to determine the impact of the new formulation, and the manufacturers will follow a Risk Evaluation and Mitigation Strategy (REMS) for this product. The REMS will include the issuance of a Medication Guide to all patients who use the product. More information is provided on the FDA OxyContin Question and Answer Web page at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm207196.htm*.

Use of e-Prescribing Grows Dramatically

The number of electronic prescriptions increased 181% from 2008 to 2009, according to the 2009 National Progress Report on E-Prescribing, published by Surescripts, operator of the largest e-prescription network that connects prescribers' e-prescribing software to pharmacies. Over 190 million e-prescriptions were routed in 2009, compared with 68 million in 2008, and 29 million in 2007. Correlating with those increases, 156,000 prescribers were using e-prescriptions by the end of 2009 compared with 74,000 at the end of 2008, a 109% increase. The report also indicates that 85% of community pharmacies in the United States are connected and able to receive e-prescriptions from prescribers.

Study Shows e-Prescribing Reduces Prescriber Errors

Prescribers using e-prescribing were seven times less likely to make errors than those writing their prescriptions by hand, according to a new study published in the *Journal of General Internal Medicine*. The study, conducted by researchers at Weill Cornell Medical College, focused on 12 community practices and compared the prescriptions of 15 providers using e-prescribing and 15 providers writing prescriptions by hand. The researchers found that two in five handwritten prescriptions contained errors such as incomplete directions, prescribing a medication but omitting the quantity, and prescribing incorrect dosages. Further, comparing handwritten prescriptions and e-prescriptions one year from the start of the study, researchers found that errors dropped from 42.5% to 6.6% for the providers using e-prescriptions. Errors associated with the handwritten prescriptions in the study increased from 37.3% to 38.4% a Weill Cornell Medical College press release providing more information about the study is available at http://weill.cornell.edu/news/releases/wcmc/wcmc_2010/02_26_10.shtml.

Counterfeit Drug Investigation Leads to Two Arrests

Two individuals have been arrested and face charges related to illegally importing counterfeit weight-loss medication. FDA issued a series of alerts, from 2008 to 2010, about tainted weight-loss pills and counterfeit drugs, and an undercover investigation identified one of the defendants as the alleged trafficker of these tainted and counterfeit drugs. This investigation was a joint effort by FDA Office of Criminal Investigations, US Immigration and Customs Enforcement, and US Postal Inspection Service. More information about the investigation and arrests is available in a US Attorney's Office Press Release at *www.fda.gov/ICECI/CriminalInvestigations/ucm206314.htm*.

- ◆ 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 such as 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 OAC 4729-37-11 (page F-172 of your lawbook).

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.

DEA'S New e-Rx Rules Now Effective, but . . .

On March 31, 2010, DEA published an interim final rule allowing prescribers and pharmacies who wish to engage in the electronic transmission of controlled substance prescriptions (including CII prescriptions) to do so, **but only after the prescribing and pharmacy systems can meet the requirements set forth in the rule.** The rule became effective 60 days later, on June 1, 2010. Theoretically, therefore, it should now be possible for controlled substance prescriptions to be transmitted electronically among prescribers and pharmacies. **However,** at the time of the writing of this *Newsletter*, there are no prescribing or pharmacy systems that have been able to meet the requirements of the interim final rule and, therefore, there should be no electronic transmission of any controlled substance prescriptions occurring.

The published rule and its accompanying documentation in the *Federal Register* was 84 pages long. Obviously, it will not be possible to cover all of that in this *Newsletter*. The following are just a few key points for prescribers and pharmacies to keep in mind:

1. Only computer-to-computer transmission of controlled substance prescriptions will be allowed. The DEA rule is very specific in that the transmission of a prescription from the prescriber's computer to the pharmacy's fax machine will not be allowed. Therefore, the pharmacy system must be capable of receiving the transmitted prescription directly into the computer system. However, instead of transmission electronically,

the prescribing system may instead print out a hard copy of the prescription for the manual signature of the prescriber and the prescription may then be given to the patient or physically faxed to the pharmacy. This is no different than the system in place today.

2. The prescribing system may not, however, print out a duplicate prescription (other than one clearly marked as a copy) after one has been electronically transmitted to the pharmacy. If transmission fails, then the prescription may be printed out, but the prescribing system must document on the prescription that the transmission to "Pharmacy" was attempted and failed on "Date & Time." Upon receiving one of these hard copy prescriptions, the pharmacist must first determine that the prescription has not already been filled by checking his or her pharmacy system or with the other pharmacy listed on the prescription.
3. The final (but probably the most important) note for this edition of the *Newsletter* about DEA's rules is that they make it clear that prescribers may not transmit and pharmacies may not receive electronic controlled substance prescriptions until the prescribing or dispensing system that they use has been audited and found to be in compliance with DEA's rule. This audit is to be done by an independent auditor in a manner similar to the financial audits done on a company's financial records. Pharmacists should not accept controlled substance prescriptions transmitted electronically until their system vendor provides proof that the pharmacy system has been audited and found to be compliant with DEA's requirements.

As always, please feel free to call the Board office if you have questions about these rules. Hopefully, there will be e-prescribing and pharmacy systems that will soon be able to meet DEA's requirements, so the electronic transmission of controlled substance prescriptions can begin.

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

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