May 2008

Ohio State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Annual CPE Reminder

If your license number begins with 03-2, have you submitted your continuing pharmacy education (CPE) reporting form yet? If not, you only have until May 15 to send it to the Ohio State Board of Pharmacy office. Remember, the procedure has changed this year. You do not have to list your individual program numbers as in the past. Beginning this year, all you are asked to do is check a box, certifying that you have done the required CPE 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, 2005, if you submit the report 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 submit your reporting form to the Board office.

For this year and all future reporting years, 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 some type of Board action. In addition, you should be aware that the Board will be randomly auditing a higher percentage of pharmacists who report CPE than in the past. Previously, we audited about 10% of those reporting. With this new procedure, that figure will rise to 20% to 25%, so your chances of being audited will be greater. **Please make sure you have the certificates in hand before you send in the reporting form**.

Physician Assistant Prescribing

Physician assistant (PA) prescribing is here. Many of you have already seen prescriptions issued by PAs and have called the Board office to verify the validity of the prescriptions. The State Medical Board of Ohio rules on PA prescribing were effective on October 31, 2007, and the Medical Board began issuing certificates shortly thereafter. The formulary for PA prescribing (which may be further limited by the supervising physician) was not approved until February 28, 2008. Drug Enforcement Administration (DEA) would not issue DEA numbers to the PAs until the formulary was approved. The formulary may be found on the Medical Board'sWeb site at *http://med.ohio.gov/pdf/rules/Formulary_appendix_2-28-08.pdf*.

PAs must have a Certificate to Prescribe (CTP) before they may begin issuing prescriptions for patients. Just as with the advanced practice nurses, the PA's CTP number must be included on each prescription written. In addition, of course, the PA must include his or her DEA number on all controlled substance prescriptions issued. By the time this *Newsletter* is published, some of the PAs should have received their DEA number from the DEA.

The PA formulary is similar to the formulary for the advanced practice nurses. The PA and his or her supervising physician are responsible for knowing what drugs the PA may or may not prescribe. Pharmacists are not expected to review the formulary before filling each and every PA prescription received. However, pharmacists should be aware of a few basic facts:

1. PAs may **not** write for any Schedule II controlled substance.
2. PAs may **not** write for controlled substance anorexiants (eg, phentermine).
3. PAs may **not** write for most antineoplastic agents.
4. The supervising physician's name does **not** need to be on the prescription. The PA is the prescriber and the label of the dispensed prescription should bear the PA's name and title.
5. If there is ever a question about a PA's authority to write for a drug, please check the formulary, call the PA, call the supervising physician (if you know who that is), or call the Medical Board or the Board of Pharmacy office.

Just as you have done with the advanced practice nurses and all other limited practitioners (dentists, podiatrists, etc), pharmacists should continue to use good judgment when filling prescriptions written by PAs. The majority of them will be doing their best to practice within their scope and will not be intending to circumvent the laws and rules. If you happen to find a PA who does not feel that the prescribing rules were made for him or her and you are not successful at changing the PA's mind, please let us know.

Optometrist Prescribing Changes

The legislature recently revised the optometry laws (HB 149), and the law became effective on March 24, 2008. This bill changed, among other things, the prescribing privileges for optometrists in a number of ways. Most of the changes will be relatively transparent to pharmacists as the optometrists will not be prescribing too many different drugs than they have been. However, the formulary of approved drugs has been eliminated. Instead of a listing of individual drugs, the optometrists now have a listing of classes of drugs from which they may prescribe. The exact wording from the new law (§4725.01 ORC) about the classes of drugs that may be prescribed is as follows:

(C) "Therapeutic pharmaceutical agent" means a drug or dangerous drug that is used for examination, investigation, diagnosis, treatment, or prevention of any disease, injury, or other abnormal condition of the visual system in the practice of optometry by a licensed optometrist who holds a therapeutic pharmaceutical agents certificate, and is any of the following:

(1) An oral drug or dangerous drug in one of the following classifications:

(a) Anti-infectives, including antibiotics, antivirals, antimicrobials, and antifungals;

(b) Anti-allergy agents;

Continued on page 4

NABP Launches Pharmacy Curriculum Outcomes Assessment Program

NABP launches its Pharmacy Curriculum Outcomes Assessment™ (PCOA®) mechanism in April 2008 for use by schools and colleges of pharmacy in evaluating their curricula. NABP invited schools and colleges of pharmacy to participate in the 2008 administration of the PCOA, scheduled for April 7-18. There will be no fee for participation in this first year of administration.

Those schools and colleges of pharmacy that participate in the April 2008 administration will receive detailed score reports for their students that sit for the assessment, as well as national comparative data. NABP developed the PCOA at the request of schools and colleges of pharmacy and accreditation stakeholders that have expressed a need for a national assessment that is psychometrically validated to assist with measuring curriculum development and student performance.

Details are posted under Assessment Programs on the NABP Web site, *www.nabp.net,* or by contacting NABP Customer Service at custserv@nabp.net.

An e-Educated Consumer is Your Best Customer (Patient)

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and Food and Drug Administration (FDA) in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

According to the Pew Internet and American Life Project, Online Health Search 2006, 80% of American Internet users, or some 113 million adults, have searched for information on at least one of 17 health topics. Many Americans turn to the Internet before, or instead of, seeking information from their doctor or pharmacist. People want to make better decisions in their lives and therefore seek more in-depth research, research that is offered online.

Patients and caregivers have a vested interest to keep up-to-date on their own or their loved ones' medical conditions. The average doctor's appointment is just 10 minutes – hardly enough time to get into lengthy conversations about treatment options and medication side effects. Long lines, busy and distracted pharmacists, and lack of privacy and confidentiality deter patients from seeking more information from their community pharmacists. It is no wonder then, when patients do not understand medical terminology or want to explore the medication treatment options that are available, they do not call their doctor or pharmacist – they just log on. In the privacy of their home they can find practical information such as lists of foods they should or should not take with certain medical conditions or certain medications. Instead of bothering busy pharmacists who do not appear to have the time to answer questions, they can get peace of mind when dealing with chronic conditions. They surf the net for reassurance and answers to their questions.

But what about the quality of those online sources? Some are better than others; obviously, Medline offered by the National Institutes of Health is a reliable source, but what if the site is sponsored by a pharmaceutical company? How does the consumer know which information to trust? Research suggests that most health information seekers do not check the source and date of the information they find online. Most Internet users use a search engine and key words from their own limited medical knowledge and rely on the algorithms of the search engines to find them reliable Web sites and scientific articles.

How can you, the pharmacist, help your patients find a credible health care information site? Patients need an easy-to-use, comprehensive medical Web site where they can learn about health conditions and medications. Patients should look for Web sites that offer unbiased health information written by medical professionals.

Tell patients to always check sources and dates of the information provided. For example, information on hormone replacement therapy has changed significantly in the last few years. Articles offering advice and recommendations on drug therapy from 10 years ago could be detrimental to the reader.

The patient-doctor-pharmacist triad has changed. We now live in an era of the square – the patient, doctor, pharmacist, and Internet. Help patients understand what they are reading. Go to the sites yourself and confirm the information is reliable and timely. And of course, find time to answer their questions. Look for a soon to be released consumer Web site being developed by ISMP.

FDA Warns against Using OTC Cold Medicines in Babies

FDA issued a public health advisory on January 17, 2008, recommending that over-the-counter (OTC) cough and cold medicines should not be used to treat infants and children younger than 2 years of age, citing the risk of "serious and potentially life-threatening side effects." FDA held a public advisory committee meeting October 18-19, 2007, to discuss the issue, after which many pharmaceutical manufacturers voluntarily withdrew cough and cold medicines marketed for use in this age group.

FDA says the agency is in the process of evaluating the safety of OTC cough and cold medicines in children 2-11 years of age and will announce its recommendations "in the near future."

The public health advisory is available on the FDA Web site at *www.fda.gov/cder/drug/advisory/cough_cold_2008.htm.*

Bayer Diabetes Care Recalls Contour Test Strips

Bayer Diabetes Care recently recalled test strips (sensors) for use with the Contour TS Blood Glucose Meter. The company recalled the product because test strips from specific lots could result in blood glucose readings with a positive bias that could demonstrate 5% to 17% higher test results.

This issue is unrelated to the Contour TS meter itself and pertains only to certain test strips used with the meter. Strips used with other Bayer meters are unaffected.

Health care professionals are advised to check the lot number of the Contour test strips in their inventory and contact Bayer Diabetes Care for information on the return and replacement of strips.

More information is available in the manufacturer's press release at *www.fda.gov/medwatch/safety/2007/contourTS_recall.htm.*

Compliance News

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FDA Takes Action against Compounded BHRT Drugs

FDA sent letters warning seven pharmacy operations that the claims they make about the safety and effectiveness of their so-called bio-identical hormone replacement therapy, or BHRT, products are unsupported by medical evidence, and are considered false and misleading by the agency. FDA has expressed concern that unfounded claims like these mislead women and health care professionals.

The pharmacy operations receiving warning letters use the terms "bio-identical hormone replacement therapy" and "BHRT" to imply that their drugs are natural or identical to the hormones made by the body. FDA regards this use of "bio-identical" as a marketing term implying a benefit for the drug, for which there is no medical or scientific basis.

The FDA news release is available at *www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html.*

Manufacturers to Restrict Distribution of Methadone

As of January 1, 2008, manufacturers of methadone hydrochloride tablets 40 mg (dispersible) have voluntarily agreed to restrict distribution of this formulation to only those facilities authorized for detoxification and maintenance treatment of opioid addiction, and hospitals. Manufacturers will discontinue supplying this formulation to any facility not meeting these criteria.

The 5 mg and 10 mg formulations indicated for the treatment of pain will continue to be available to all authorized registrants, including retail pharmacies. The 40 mg methadone formulation is indicated for the treatment of opioid addiction; it is not FDA-approved for use in the management of pain. This measure comes in response to the reported increase in methadone-related adverse events.

For more information, see "Studies Show Increased Methadone-Associated Mortality Related to Pain Management" in the January issue of the *NABP Newsletter,* available on the NABP Web site at *www.nabp.net.*

New Compounding Standards Effective June 1; USP Offers Webinars

New standards for sterile compounding will become effective on June 1, 2008. United States Pharmacopeia (USP) published the revised General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations" on its Web site in December 2007 to give the compounding community time to implement changes before the effective date.

These revisions tighten standards and conditions for sterile compounding over the previous version of Chapter 797 to help improve patient safety. (See "Sterile Compounding 'Checklist' Revised to Better Protect Patient Health" in the February 2008 issue of the *NABP Newsletter.)* The revisions are included in USP 32–NF 27 and in the second edition of the *Pharmacists' Pharmacopeia,* published in March 2008.

USP is offering a series of educational Webinars and workshops to help compounding professionals appropriately interpret and implement the newly revised standard. The Webinars will provide direct dialogue with two compounding experts and ample time to address questions related to the standard. The workshops will provide added interaction plus hands-on demonstrations related to environmental monitoring, contamination control, and aseptic testing.

Full details on these programs are available on the USP Web site at *www.usp.org/hottopics/generalChapter797.html?hlc.*

CMS Names MSAs, Products for Round Two of DMEPOS Bidding

Centers for Medicare and Medicaid Services (CMS) recently announced the metropolitan statistical areas (MSAs) and product categories for the second round of the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding program.

All suppliers must meet quality standards and be accredited by a CMS-recognized accreditation organization, such as NABP, to obtain a contract under the Medicare DMEPOS competitive bidding program. The final deadline for all suppliers to obtain accreditation is September 30, 2009. However, CMS encourages suppliers to seek accreditation as soon as possible to avoid any potential difficulties that would affect their ability to bid.

The competitive bidding program is designed to improve the effectiveness of Medicare's DMEPOS payments, reduce beneficiary out-of-pocket costs, and save the Medicare program money while ensuring beneficiary access to quality DMEPOS items and services. More information, including the lists of MSAs and product categories, is available on the CMS Web site at *www.cms.hhs.gov/CompetitiveAcqforDMEPOS.*

Adverse Event Reporting Requirements in Effect for OTC Products

FDA recently issued new adverse event reporting requirements for manufacturers, packers, and distributors of dietary supplements and over-the-counter (OTC) drug products marketed without an approved application. The new reporting requirements, as described in Public Law 109-462, became effective on December 22, 2007.

The act, as well as the FDA *Guidance for Industry: Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed without an Approved Application,* is available via the FDA MedWatch site at *www.fda.gov/medwatch/otc.htm.*

FDA Rule Calls for Toll-Free Number for Adverse Events on Drug Labels

FDA recently issued an interim final rule requiring certain medication labels to include a toll-free number for reporting adverse events. The interim final rule codifies provisions of the proposed rule "Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products" that became effective on January 1, 2008, under the FDA Amendments Act of 2007. The rule does not apply to over-the-counter medications approved as new drugs if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

To allow manufacturers, dispensers, and pharmacies time to update their labeling and systems to comply with the new requirements, FDA will delay enforcement actions regarding these regulations until January 1, 2009.

More information is available in the *Federal Register* (Docket No. 2003N-0342) at *www.fda.gov/OHRMS/DOCKETS/98fr/E7-25426.pdf.*

Continued from page 1

(c) Antiglaucoma agents;
(d) Analgesics, including only analgesic drugs that are available without a prescription, analgesic drugs or dangerous drugs that require a prescription but are not controlled substances, and schedule III controlled substances authorized by the state board of optometry in rules adopted under section 4725.091 of the Revised Code;
(e) Anti-inflammatories, excluding all drugs or dangerous drugs classified as oral steroids other than methylpredisolone, which may be used under a therapeutic pharmaceutical agents certificate only if all of the following conditions are met:
(i) The drug is prescribed for use in allergy cases;
(ii) The drug is prescribed for use by an individual who is eighteen years of age or older;
(iii) The drug is prescribed on the basis of an individual's particular episode of illness;
(iv) The drug is prescribed in an amount that does not exceed the amount packaged for a single course of therapy.

(2) Epinephrine administered by injection to individuals in emergency situations to counteract anaphylaxis or anaphylactic shock. Notwithstanding any provision of this section to the contrary, administration of epinephrine in this manner does not constitute performance of an invasive procedure.
(3) An oral drug or dangerous drug that is not included under division (C)(1) of this section, if the drug or dangerous drug is approved, exempt from approval, certified, or exempt from certification by the federal food and drug administration for ophthalmic purposes and the drug or dangerous drug is specified in rules adopted by the state board of optometry under section 4725.09 of the Revised Code.

Please note that the Ohio State Board of Optometry has to adopt rules specifying which Schedule III analgesics an optometrist may prescribe. At the time of the writing of this *Newsletter*, the Optometry Board was planning on submitting their rules after their April Board meeting. By the time the rules make it through the state's process, it should be June 2008, at the earliest before the rules are made final. After that, DEA will need to issue licenses to those optometrists who apply, so it should be late June or July at the earliest before you should see any Schedule III prescriptions from optometrists.

Please also note that optometrists' prescribing is limited to "examination, investigation, diagnosis, treatment, or prevention of any disease, injury, or other abnormal condition of the visual system in the practice of optometry" and, with the exception of epinephrine for emergencies, is limited to topical ocular and oral medications. Once again, pharmacists should use good judgment when deciding whether an optometrist's prescription should be dispensed. Optometrists are also limited practitioners and their scope of practice is limited to the visual system. The prescription must be to treat a condition that is affecting the visual system. Based on a review of the law, that can cover a wide array of drugs, including oral antihistamines, and antibiotics, that could also be used to treat another medical condition not involving the eye. Any optometrist's prescription issued for a purpose that does not involve the visual system is not valid and should not be filled. However, just as with the PAs, most of the optometrists will be doing their best to stay within their limitations. If you have any questions, talk to the optometrist first and call the Board office second, if needed.

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 – 800/230-6844, *www.deadiversion.usdoj.gov*

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