**Review of Changes to Physician Assistant Statutes and Rules**

The Arizona State Board of Pharmacy office is still getting a large number of inquiries regarding the relatively recent changes to physician assistants’ (PAs) prescribing authority and documentation of compliance with the new requirements. Here is the Board’s best effort of summarizing the changes again; the Board’s October 2012 Newsletter, which addresses this topic as well, is available at [www.nabp.net/publications/assets/AZ102012.pdf](http://www.nabp.net/publications/assets/AZ102012.pdf).

The first and perhaps most discussed requirement is that the name of the PA’s supervising physician must still appear on all of the prescriptions issued by a PA. According to the Arizona Regulatory Board of Physician Assistants and pursuant to statute A.R.S. §32-2532(B), “all prescription orders issued by a physician assistant shall contain the name, address and telephone number of the supervising physician . . .” This includes handwritten and electronic prescriptions.

Second, a “supervising physician” is no longer required to submit Prescribing Authority Forms to the Arizona Medical Board. The Arizona Administrative Code (A.A.C.) includes rule A.A.C. R4-17-203.D, which states:

> When the [Arizona Regulatory Board of Physician Assistants] issues a regular license to an applicant, the Board is also approving the applicant to issue prescriptions or dispense or issue schedule II or schedule III controlled substances.

A PA may prescribe up to 30 days of Schedule II and III controlled substances (CS) if:

1. The Board approves,* and the Delegation Agreement on file at the practice site includes delegation by the PA’s supervising physician(s) to prescribe Schedule II and III CS, and
2. The PA has a current Drug Enforcement Administration registration with matching authority (A.R.S. 32-2532(A)(1)).

*Under current law, the Board will approve all PAs for 30-day prescription privileges if they are certified by a national commission that provides certification of PAs at the time of licensure (A.R.S. §32-2504(A)(11)).

It is important to note that meeting the certification requirement is almost never the limiting step in approval for 30-day prescription privileges because A.R.S. §32-2521(A)(2) already requires all initial PA applicants to pass the certifying examination of the National Commission on the Certification of Physician Assistants before a license is granted.

**PAs Who Are Authorized Less than 30 Days Delegation**

If a supervising physician chooses to delegate less than the new standard of 30 days of prescribing authority, the supervising physician may choose to specify this limitation on the prescription pad by stamping or pre-printing. Although not a requirement of statute or rule, this practice would enable pharmacists to quickly verify the PA’s delegated authority. Even if the limitation is specified on the prescription pad, however, **the supervising physician and the PA are responsible to their licensing boards for ensuring compliance with the terms of the delegation agreement on file at the practice site(s).**

Finally, readers may ask how a pharmacist can verify that a PA has been delegated the authority by his or her supervising physician to prescribe Schedule II and III CS, and whether or not he or she is delegated to prescribe up to a 30-day supply.

Any (all) modifications to the 30-day prescribing authority that are reflected in the individual PA’s Delegation Agreement must be on file with the Arizona Regulatory Board of Physician Assistants, not with the Arizona Medical Board as previously was the case. This information may be found at [www.azpa.gov](http://www.azpa.gov) under “PA Center,” while the form itself can be obtained at [www.azpa.gov/PDFs/Prescribing%20Modification%20Form.pdf](http://www.azpa.gov/PDFs/Prescribing%20Modification%20Form.pdf).

**License and Permit Renewal Time Again**

Renewal of permits and licenses that expire on October 30, 2013, will start on September 1, 2013. Do not wait to change your mailing address and finish up on those continuing education classes.

**New Board Member and Not So New Compliance Officer**

The Board staff is pleased to report that Governor Jan Brewer has appointed Darren Kennedy, a pharmacist employed at Walgreens Healthcare Plus, to the Board, replacing Dan Milovich.
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.


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! 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/FALL-SAFE (1-800/326-8233) 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.

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
- Antineoplastic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (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.

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,
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.

**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.

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

**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/.

**Pharmacists & Technicians: Don’t Miss Out on Valuable CPE Credit.**
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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 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.
whose five-year term expired. Mr Kennedy graduated from the University of Kansas School of Pharmacy in 1997 with a bachelor of science degree in pharmacy. He began his career as a staff pharmacist for Walgreens in the Phoenix, AZ, area and has held positions as a retail pharmacy manager and district pharmacy supervisor. Mr Kennedy is currently the operations manager at Walgreens Central Pharmacy Operations in Tempe, AZ, where he is responsible for Walgreens mail order and regional retail centralization. Mr Kennedy is also an adjunct faculty member at Midwestern College of Pharmacy and the University of Wyoming. He is a member of both the National Association of Drug Diversion Investigators and Strategic National Stockpile team for Maricopa County.

Mr Kennedy resides in Gilbert, AZ, with his wife Jennifer and their two children Gavin and Sydney. Welcome Darren and many thanks to Mr Milovich for his five years of service. The Board members and staff wish him well in his new home amid the cool pines of Happy Jack, AZ.

Board staff is also pleased to announce the re-hiring of Dennis Waggoner as the Board’s fifth compliance officer. Some readers will remember that he previously served in the same capacity from 2000 to 2003. Dennis returns to the Board after a 10-year hiatus, eight years of which were spent in drug manufacturing, an area in which he has an extensive background. His knowledge and skills in this area were recognized when he was appointed to the Board’s Compounding Task Force, which reviews the Board’s existing compounding statutes and rules in order to update and revise them. One goal is to ensure that Arizona remains a modern and progressive state that allows the proud tradition of pharmacy compounding to flourish while maintaining its history of protecting the citizens in this state and of states where products from this state are shipped. Coincidentally, the staff is finally back to 18 full-time employees, which was the number of employees before the budget crunch and hiring freeze that began in 2009.

**Disciplines – Licensees**

**Pharmacists**

Castaneda, Thomas (S006020) – Probation terminated. Effective May 9, 2013.

Harris, David (S015757) – $250 fine and eight continuing education units (CEUs) within 90 days. Effective May 10, 2013.

Jade, Amanda (S018421) – $250 fine and eight CEUs within 90 days. Effective May 10, 2013.

Liberato, Justine (S019419) – $250 fine and eight CEUs within 90 days. Effective May 10, 2013.

Massey, Douglas (S016067) – $250 fine and eight CEUs within 90 days. Effective May 9, 2013.

Nguyen, Khang (S013435) – $500 fine and eight CEUs within 90 days. Effective May 10, 2013.

Peterson, James (S009155) – Probation terminated. Effective May 9, 2013.

Underhill, Stephanie (S015729) – Probation terminated. Effective March 20, 2013.


**Disciplines/Prescribing Modifications – Other Health Care Boards**

**Arizona Board of Medicine (MDs)**

Standage, Gregg (MD 22289) – Non-disciplinary – Consent Agreement for Practice Limitation – Physician’s practice is limited in that he shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment including prescription medications until physician applies to the Board and receives permission to do so. Effective March 27, 2013.


**Arizona Regulatory Board of Physician Assistants (PAs)**

Hankins, Tammy (PA 2228) – Letter of Reprimand, Probation, and Practice Restriction – Letter of reprimand issued and respondent placed on one-year probation with set terms and conditions. Respondent is prohibited from prescribing, administering, or dispensing any CS until completion of required continuing medical education courses. Effective April 4, 2013.

Sullivan, Timothy (PA 3803) – Consent Agreement for Decree of Censure and Probation – Decree of censure issued and respondent’s license suspended for a period of two years, effective September 1, 2011. Respondent placed on probation with set terms and conditions. Respondent shall not prescribe any CS during the term of probation. Effective February 28, 2013.