



Arizona State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

1700 W Washington St, Room 250 • Phoenix, AZ 85007 • Web site: www.azpharmacy.gov
E-mail: chunter@azpharmacy.gov

Hospital Pharmacies – Policies and Procedures

The Arizona State Board of Pharmacy has been receiving inquiries regarding hospital pharmacy policy and procedure (P&P) manuals from hospital medical staff. The most frequent questions are about whether the P&P manuals must be available for review by hospital personnel and how often the manuals must be reviewed and/or modified. These questions are answered in Arizona Administrative Code R4-23-653 Personnel: Professional or Technician, which states:

- A. Each hospital pharmacy shall be directed by a pharmacist who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy. The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge. The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall:
1. Be responsible for all the activities of the hospital pharmacy and for meeting the requirements of the Arizona Pharmacy Act and these rules;
 2. Ensure that the policies and procedures required by these rules are prepared, implemented, and complied with;
 3. **Review biennially** and, if necessary, revise the policies and procedures required under these rules;
 4. Document the review required under subsection (A)(3);
 5. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee; and

6. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its designee.

Readily Retrievable – Controlled Substances Invoices

Article contributed by Rich Cieslinski, RPh, Compliance Officer

During inspections, Board compliance officers routinely perform audits on randomly selected controlled substances as part of the inspection or when conducting investigations. On many occasions the audits result in the facility being determined to be “over” or “under” based on a lack of invoice availability or inaccurate or missing physical inventory counts. As a result, many times licensees will receive warning letters or violation letters for the discrepancies found. This is due to the lack of accurate information provided to the compliance officer at the time of the inspection. Compliance staff believes that these types of violation letters can be avoided if the pharmacist-in-charge (PIC) is aware of the following:

- ◆ Federal law requires that:
 1. Inventories and records of controlled substances listed in Schedule II shall be maintained separately from all of the records of the registrant.
 2. Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is “readily retrievable” from the ordinary business records of the registrant.
- ◆ State law {Arizona Revised Statute § 36-2523} requires that:

Registrants shall keep records and maintain inventories in conformance with the record keeping and inventory requirements of federal law and title 32, chapter 18, which is the current Arizona

Continued on page 4

NABPCelebrating
30 Years of
Pharmacy
News**30**

1980-2010



National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Compendium and can only be ascertained by examining the original article.)

JCPP 'Future Vision' Sets Course for Advancement of Pharmacy Practice

The Joint Commission of Pharmacy Practitioners (JCPP) brings together the chief executive and chief elected officers of national pharmacy associations, including NABP, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice. Established in 1977, the JCPP meets quarterly and forms workgroups that focus on priority projects. The JCPP has facilitated strategic planning efforts that have shaped positive change in the practice of pharmacy for more than 30 years, and will continue to influence pharmacy practice through its vision articulated in "Future Vision of Pharmacy Practice."

Past Impact

Recommendations resulting from JCPP conferences and quarterly meetings have been aimed to ensure public health and safety by optimizing the medication use process. Working collaboratively through the JCPP, leaders in the profession "acknowledged that the focus of pharmacy must move beyond the important but narrow aspect of 'right drug to the right patient' and encompass the responsibility for assuring that appropriate outcomes are achieved when medications are part of a patient's individual treatment plan." This perception of the function and responsibility of pharmacy practice helped to facilitate changes such as the shift to a universal doctoral level of education, and practice and legal changes that have helped pharmacists to increase their scope of services.

Also as a result of JCPP collaborations, coalitions among pharmacy organizations and other stakeholders have been formed, and have helped to shape new state and national legislation and regulations. For example, JCPP coalitions helped influence changes that resulted in Medicare's prescription drug benefit requirement for medication therapy management services as of 2006.

Future Impact

Through the "Future Vision of Pharmacy Practice," adopted by JCPP member organization executive officers in 2004, the JCPP will continue to influence positive change in the practice well into the next decade. The JCPP "Future Vision of Pharmacy Practice," endorsed by each JCPP member organization's board of directors, envisions what pharmacy practice should look like in 2015, as summarized in the document's opening statement: "Pharmacists will be the health care professionals responsible for providing patient care that ensures optimal medication therapy outcomes."

In his incoming speech at the NABP 105th Annual Meeting in May 2009, President Gary A. Schnabel, RN, RPh, endorsed the future vision outlined in the JCPP "Future Vision of Pharmacy Practice," stating, "As boards of pharmacy, I feel that it is also imperative for us to embrace this future vision, and through our statutes and regulations define and advance that vision in the context of patient care and protection of the public health. . . . If the boards of pharmacy can provide the regulatory environment that fosters the vision on behalf of the patient and the protection of the public health, then this collective vision of practitioners and regulators will serve as one of the pillars of a new foundation for the practice of pharmacy first proposed some 30 years ago and discussed ad nauseam every year since those words were first spoken and captured in the pharmacy journals."

The 2015 future vision is detailed in the document in three sections: the foundations of pharmacy practice, how pharmacists will practice, and how pharmacy practice will benefit society. The first section outlines the foundations of pharmacy education that prepares pharmacists

"to provide patient-centered and population-based care that optimizes medication therapy." The second section explains that the pharmacist's scope is to include managing medication therapy, accounting for patients' therapeutic outcomes, and promoting patient wellness. The section also emphasizes that as they work with other health care professionals, pharmacists will be the most trusted source of medications and supplies, and the primary resource for advice regarding medication use. Finally, the last section stresses that, by realizing the expanded scope of their practice, pharmacists will achieve public recognition as practitioners who are essential to providing effective health care.

In January 2008, the JCPP released the final version of "An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice," which identifies three critical areas for initial focus as it works toward achieving the vision. JCPP anticipates more discussions to help align the action steps of the implementation plan and the policies of participating organizations. Thus, in keeping with the organization's mission, JCPP continues to implement its initiatives, including the "Future Vision of Pharmacy Practice," through the collaborative efforts it fosters.

The JCPP's "Future Vision of Pharmacy Practice" and "An Action Plan for Implementation of the JCPP Future Vision of Pharmacy Practice" can be downloaded from the National Alliance of State Pharmacy Associations' Web site at www.naspa.us/vision.html.

ISMP Stresses Need to Remove Non-Metric Measurements on Prescriptions and on Patient Labels to Prevent Error



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.

ISMP is calling upon prescribers, pharmacists, and other health care professionals, as well as pharmacy computer system and e-prescribing system vendors, to remove or prevent the use of "teaspoonful" and other non-metric measurements in prescription directions in order to better protect patients.

In the past, mix-ups involving confusion between measuring medications in milliliters or teaspoonfuls and other non-metric measurements have resulted in the serious injury of children and adults.

These mistakes continue to happen. ISMP has received more than 30 reports of milliliter-teaspoonful mix-ups, including cases where injuries required treatment or hospitalization. In one case, a child who recently had surgery was seen in an emergency department and later was admitted with respiratory distress following an unintentional overdose of acetaminophen and codeine liquid. The pharmacy-generated label on the child's medication bottle instructed the parents to give the child six



teaspoonfuls of liquid every four hours. The original prescriber stated the prescription was for 6 mL. The child received five doses before arriving at the emergency department.

In a second case, a child received an overdose of the antifungal medication Diflucan® (fluconazole) suspension. The physician phoned a prescription for Diflucan 25 mg/day to a community pharmacy for a three-month-old child with thrush. The pharmacist dispensed Diflucan 10 mg/mL. The directions read “Give 2.5 teaspoons daily.” The directions should have read “Give 2.5 mL daily.” Prior to the error, the child had been ill for the previous three weeks with an upper respiratory infection, nausea, vomiting, and diarrhea. It is suspected that the child’s subsequent hospitalization was related to this error.

ISMP Safe Practice Recommendations

The health care industry – including practitioners and computer vendors – needs to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. Steps, like the following ISMP recommendations, must be taken to prevent errors:

- ◆ Cease use of patient instructions that use “teaspoonful” and other non-metric measurements, including any listed in pharmacy computer systems. This should include mnemonics, speed codes, or any defaults used to generate prescriptions and labels.
- ◆ Express doses for oral liquids using only metric weight or volume (eg, mg or mL) – never household measures, which also measure volume inaccurately.
- ◆ Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- ◆ Coach patients on how to use and clean measuring devices; use the “teach back” approach, and ask patients or caregivers to demonstrate their understanding.

The *Model State Pharmacy Act* and *Model Rules of the National Association of Boards of Pharmacy’s (Model Act)* labeling provisions state that the directions of use language should be simplified, and when applicable, to use numeric instead of alphabetic characters such as 5 mL instead of five mL. The *Model Act* also provides for the pharmacist to personally initiate counseling for all new prescriptions, which can decrease patient injuries due to improper dosing.

Clarification on HIPAA Regulations and Claims Submission

NABP received questions about a statement that appeared in the article, “Concerns with Patients’ Use of More than One Pharmacy,” published in the 2009 fourth quarter *National Pharmacy Compliance News* which read, “Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient.”

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (45 CFR 164.501) establishes a foundation of federal protection for personal health information with which health care practitioners must comply. To avoid interfering with a patient’s access to, or the efficient payment of quality health care, the privacy rule permits a covered entity, such as a pharmacy, to use and disclose protected health information, with certain limits and protections, for treatment, payment, and health care operations activities. The rule includes the determination of eligibility or coverage and utilization review activities as examples of common payment activities, therefore allowing a pharmacist to submit cash claims. Additional information may be found at www.hhs.gov/ocr/

[privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html](http://www.nabp.net/privacy/hipaa/understanding/coveredentities/usesanddisclosuresfortpo.html).

Pharmacists should, however, verify with their state boards of pharmacy as to whether there are existing state laws that prohibit this practice.

State Newsletter Program Celebrates 30 Years of News on Pharmacy Regulation

This year, the NABP State Newsletter Program celebrates its 30th anniversary of partnering with the boards of pharmacy to provide pharmacists with vital information about their state’s pharmacy laws and regulations.

The State Newsletter Program, which is part of the NABP Foundation, was developed to support the Association’s educational programs and research and development projects. Published on a quarterly basis, the program serves the state boards of pharmacy by communicating board information to pharmacists, pharmacy technicians, pharmacies, and others throughout the pharmacy profession.

The goal of the State Newsletter Program was, to improve communications with practitioners regarding federal and state law, this allowing them to comply with the law on a voluntary basis, demonstrating that an informed and responsible professional is one of the most effective means of protecting the public health.

In addition to the news provided by the boards of pharmacy, a copy of the *National Pharmacy Compliance News* is included in each issue. Published quarterly by NABP, *National Pharmacy Compliance News* provides important news and alerts from the federal Food and Drug Administration, Drug Enforcement Administration, the Centers for Medicare and Medicaid Services, Consumer Product Safety Commission, and ISMP, as well as current national developments affecting pharmacy practice.

Using *National Pharmacy Compliance News*, merged with locally developed state news, a total of 16 states joined the program in its original summer 1979 publication, including 13 states that still participate today: Arizona, Arkansas, Delaware, Idaho, Kansas, Kentucky, Montana, Minnesota, North Carolina, Ohio, Oregon, South Carolina, and Washington.

Today, 31 states participate in the program. Of these, 18 state boards of pharmacy publish electronic newsletters rather than printed newsletters. The e-newsletter option was implemented in 2004, and has allowed boards with limited resources the opportunity to communicate important board information in a timely and cost-effective manner. State e-newsletters are posted on the NABP Web site rather than published by a printer; the board may also post the Newsletter to their Web site.

In 2006, the e-newsletter portion of the program was enhanced and NABP began offering the boards an e-mail alert service. The e-newsletter e-mail alert service, which consists of an e-mail notification that is sent through a state-specific e-mail database, is provided free of charge to participating state boards of pharmacy. Each alert notifies recipients that the e-newsletter is now available to download and provides a link to access the board’s newsletter. The Arizona State Board of Pharmacy was the first state to utilize this free service, and now the number of participating boards has grown to 12 states.

All NABP Foundation State Newsletters, including a copy of the *National Pharmacy Compliance News*, are available on the NABP Web site at www.nabp.net. Please note, years prior to 2000 are only available in hard copy form, and therefore, cannot be downloaded online. For more information about the NABP State Newsletter Program, contact custserv@nabp.net.

Pharmacy Act, and with any additional rules the Board issues.

- ◆ While there is no definition of “readily retrievable” in the Arizona Administrative Code, R4-23-110 (s) defines a red C stamp as:

[A] device used with red ink to imprint an invoice with a red letter C at least one inch high, (used) to make an invoice of a Schedule III through IV controlled substance, as defined in A.R.S. § 36-2501, readily retrievable as required by state and federal rules.

If a pharmacy’s Schedule III, IV, and V controlled substance invoices are not filed separately (**not recommended**) or if they are filed haphazardly, the routine use of the red C stamp to mark the controlled substance invoices **may** assist the compliance officer or pharmacy personnel in identifying and retrieving all the necessary invoices needed to perform an accurate controlled substance audit. Invoices **not** retrieved by or supplied to the compliance officer can of course **not** be counted and these “missing” invoices will adversely affect the audit results so that a warning letter will be issued needlessly. This is a waste of time for all involved.

Board Compliance Officer – Recruitment for Vacant Tucson Position

A vacancy exists in the Tucson area for a Board compliance officer. Arizona pharmacists with a current, unrestricted Arizona pharmacist license are invited to mail a cover letter with current resume to Ms C. Hunter, secretary to the Board executive staff. The applicant must have been licensed as a pharmacist in Arizona for at least five years. A valid, unrestricted Arizona drivers license is also required. Work schedule is Monday through Friday only.

All resumes should be received by April 30, 2010, addressed to Ms Hunter at the Board offices located in the Executive Tower at 1700 W Washington St, Suite 250, Phoenix, AZ 85007.

Preference will be given to pharmacists with extensive experience in a variety of practice settings. Please do not call the Board office regarding the position. Qualified candidates will be contacted by Board staff after written materials have been received. It is the intention of Board staff to interview qualified candidates and fill the vacancy no later than June 30, 2010.

Disciplinary Actions

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (board).

Pharmacists

Afshari, Hossein [Tony] (S013911) – 60-day suspension followed by two years probation. \$1,000 fine. Must re-

take Multistate Pharmacy Jurisprudence Examination® (MPJE®) within 90 days. 200 hours community service. Cannot be preceptor or PIC while on probation. Effective January 14, 2010.

Castillo, Michael (S008588) – One-year suspension, followed by two years probation. \$1,000 fine within 60 days. Must retake MPJE within 90 days. 400 hours community service within three years. Effective January 13, 2010.

Dayton, Thomas (S011256) – Suspended not less than three months, followed by five years probation. 400 hours community service due within five years of consent’s effective date. Effective February 3, 2010.

Goebig, Thomas (S013463) – Suspended at least six months, effective October 19, 2009. Respondent must sign new Pharmacists Assisting Pharmacists of Arizona (PAPA) contract. Upon termination of his suspension, respondent will start a five-year probation period. Respondent cannot serve as preceptor or PIC while suspended or on probation. 400 hours community service. Effective January 13, 2010.

Lewis, Paul (S007190) – \$1,000 fine payable in 90 days and three continuing education (CE) hours on record keeping within six months. Effective January 14, 2010.

Martin [aka Beard], Steve (S011750) – Revoked. Effective January 13, 2010.

Wilson, Jr, Steve (S017740) – Probation until March 21, 2010. Effective December 29, 2009.

Interns

Amendt, Daniel (I008662) – Revoked. Effective January 19, 2010.

Technicians

Archibald, Timothy (T012277) – One-year probation, \$500 fine within six months, six CE hours within a year. Effective January 15, 2010.

Pitpitan, Consuelo (T000818) – Probation terminated. Effective January 13, 2010.

Robbins, Wanda (T000416) – One-year probation. \$500 fine within six months. Six CE hours within one year. Effective January 14, 2010.

Manufacturers

Apotheca, Inc. (M000027) – \$3,000 fine within 90 days. Effective January 13, 2010.

Board of Dental Examiners of the State of Arizona (DDS/DMD)

Chaffee, Jr, David L. (D 7789) – Respondent placed on probation for five years with set terms and conditions. Dr Chaffee’s prescribing privileges for Schedules II and III controlled substances are restricted. Effective February 9, 2010.

Arizona Medical Board (MD)

Cosmas, Thomas E. (MD 4685) – License surrendered to the Board. Effective February 11, 2010.

Diede, James H. (MD 18915) – Non-disciplinary – *Interim 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 December 15, 2009.

Fernandez, Octavio G. (MD 10957) – License surrendered to the Board. Effective February 11, 2010.

Fischer, Donald W. (MD 12741) – Non-disciplinary – 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 February 5, 2010.

Hayden, Joel A. (MD 23390) – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective October 7, 2009.

Kellermeyer, Tania S. (MD 26360) – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective February 23, 2010.

Klein, Timothy (MD 32213) – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective February 17, 2010.

Mouritsen, Mark R. (MD 28909) – Non-disciplinary – 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 February 12, 2010.

Paquin, James K. (MD12914) – Non-disciplinary – 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 January 12, 2010.

Pilson, Karl D. (MD R71802) – *Interim Consent Agreement for Practice Restriction* – Respondent shall not practice clinical medicine or any medicine involving direct patient care, and is prohibited from prescribing any form of treatment including prescription medications, until respondent applies to the Board and receives permission to do so. Effective December 11, 2009.

Strand, Frederick T. (MD 12506) – License surrendered to the Board. Effective February 11, 2010.

Taitague, Gerald J. (MD 26182) – License surrendered to the Board. Effective February 11, 2010.

Arizona State Board of Nursing (RN)

Cash, Mary Ann (RN 146825 and Advanced Practice Certificate AP 2769) – License summarily suspended. Effective March 5, 2010.

Arizona Board of Osteopathic Examiners (DO)

Arnold, Lloyd (DO 0641) – License surrendered to the Board. Effective February 27, 2010.

Arizona Regulatory Board of Physician Assistants (PA)

Ehlers, Gary (PA 1402) – License surrendered to the Board. Effective February 24, 2010.