



Alabama State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

10 Inverness Center, Suite 110 • Birmingham, AL 35242 • Tel: 205/981-2280
Fax: 205/981-2330

680-X-2-.39 Non-Hospital Pharmacy Off-Site Order Entry

- (1) The purpose of this Rule is to provide Alabama standards for remote or off-site order entry in any nonhospital pharmacy to which a permit has been issued by the Alabama State Board of Pharmacy (“the Board”).
- (2) Definitions
 - (a) “Off-site order entry pharmacy” means a non hospital pharmacy (“pharmacy”) which has a valid permit issued by the Board to process legend and controlled substance prescriptions that remotely accesses another pharmacy’s electronic data base from outside the pharmacy in order to process prescription drug orders, provided the pharmacy establishes controls to protect the privacy and security of confidential records.
 - (b) “Off-site order entry” does not include the dispensing of a prescription drug order but includes any of the following:
 1. Interpreting or clarifying prescription drug orders;
 2. Data entering and transferring of prescription drug order information;
 3. Performing drug regimen review;
 4. Obtaining refill and substitution authorizations;
 5. Performing therapeutic interventions; and
 6. Providing clinical drug information concerning a patient’s prescription.
 - (c) “Drug regimen review” means an evaluation of prescription drug orders and patient profile records for:
 1. Known allergies;
 2. Rational therapy-contraindications;
 3. Reasonable dose and route of administration;
 4. Reasonable directions for use;
 5. Duplication of therapy;
 6. Drug-drug interactions;
 7. Drug-food interactions;
 8. Proper utilization, including over-utilization or under-utilization.
- (3) The Board may approve a request for off-site order entry based on a presentation before the Board.

- (4) The supervising pharmacist or the permit holder of the pharmacy shall submit a written request for off-site order entry a minimum of 30 days prior to the Board meeting at which the pharmacy seeks Board approval.
 - (a) The request shall be accompanied by a policy and procedure manual for off-site order entry which shall be maintained at all pharmacies involved in off-site order entry and be available for inspection. Each pharmacy is required to maintain only those portions of the policy and procedure manual that relate to that pharmacy’s operations. The manual shall:
 1. Outline the responsibilities of each of the pharmacies;
 2. Include a list of the name, address, and telephone numbers of the pharmacies involved in off-site prescription order entry; and
 3. Include policies and procedures for:
 - (i) Patient confidentiality and full compliance with HIPAA requirements;
 - (ii) Maintenance of appropriate records to identify the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist or pharmacy technician who performed any processing and the store it was processed in;
 - (iii) Mechanism for tracking the prescription drug order during each step of the dispensing process;
 4. Specify that a pharmacist holding a current license in good standing or a pharmacy technician working under the direct supervision of a pharmacist shall enter prescription drug orders at a location that is a duly licensed pharmacy.
 5. Comply with federal and state laws and regulations; and
 6. Include procedures for annually reviewing the written policies and procedures for needed modification with documentation of such review.
- (5) General requirements.
 - (a) A Pharmacy may utilize the services of an off-site order entry pharmacy provided the pharmacies:
 1. Share a common electronic file or have appropriate technology to allow access to sufficient

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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.

information necessary or required to process a non-dispensing function; and have;

2. The same owner; or
 3. Entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.
- (6) All pharmacies involved in off-site order entry approved by the Board shall comply with all applicable provisions of the Alabama Pharmacy Practice Act and/or Board Rule. Nothing in this Rule shall expand allowable duties of pharmacy technicians as set forth in Board Rule 680-X-2.14.
- (7) Off-site order entry may only be performed by pharmacies to whom a permit has been issued by the Board and which permit is in good standing.
- (8) Notifications to patients.
- (a) A pharmacy that outsources off-site prescription order entry to another pharmacy shall prior to outsourcing their prescription:
 1. Notify patients that prescription processing may be outsourced to another pharmacy; and
 2. Give the name of that pharmacy; or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.
- (9) Records.
- (a) All pharmacies shall maintain appropriate records, which identify, by prescription drug order, the name(s), initials or identification code(s) of each pharmacist or pharmacy technician who performs a processing function for a prescription drug order. Any record generated in this process whether in a hard copy or electronic format shall be maintained for a minimum period of two years from the last date of entry. Such records may be maintained:
 1. Separately by each pharmacy and pharmacist; or
 2. In a common electronic file as long as the records are maintained in such a manner that the data processing system can produce a printout which

lists the functions performed by each pharmacy and pharmacist.

- (10) In the operation of the off-site order entry, patient confidentiality and full compliance with HIPAA requirements shall be observed at all times.
- (11) This rule does not apply to or allow any step of processing a prescription to be performed outside the physical premises of a pharmacy holding a permit with the Alabama State Board of Pharmacy. The following are expressly prohibited:
 - (a) Work from home, work from call centers, and work from portable or hand held computers operated outside a location holding a permit with the Alabama State Board of Pharmacy. The Board of Pharmacy may at any time audit the records of any pharmacy holding a permit to ensure compliance with this provision.
- (12) Each hard copy prescription must be readily retrievable. Neither the original hard copy prescription, nor a scanned image of the original prescription shall be assigned more than one prescription number. Prescription numbers shall be sequential and shall only be used for numbering prescriptions; specifically they may not be created or used for billing or accounting purposes absent the dispensing of a prescription drug.

Author: Herb Bobo, RPh, Secretary

Statutory Authority: §34-23-92, Code of Alabama 1975

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Do You Know a Pharmacist or Technician Who Needs Help?

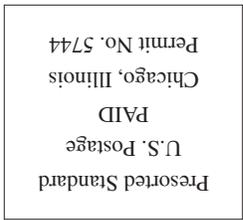
Call the Committee on Rehabilitating Impaired Pharmacists help line at the voicemail of Steve Moore at 205/975-8548. All calls are confidential.

The *Alabama State Board of Pharmacy News* is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Joyce C. Altsman, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Larissa Doucette - Communications Manager



NATIONAL ASSOCIATION OF BOARDS OF PHARMACY FOUNDATION, INC
 1600 FEEHANVILLE DRIVE
 MOUNT PROSPECT, ILLINOIS 60056
 ALABAMA STATE BOARD OF PHARMACY