



National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Com and can only be ascertained by examining

Prescription Drug Marketing Act of 1987

Deadline for Licensure September 14, 1992

As the September 14, 1992 implementation date for the Prescription Drug Marketing Act of 1987 (PDMA) draws closer, pharmacists are trying to determine which entities need to be licensed. The PDMA stipulates that no person may engage in the wholesale distribution of human prescription drugs in interstate commerce in a state unless such person is licensed by the state and such license is in accordance with FDA Guidelines for Wholesale Distributors.

With regard to retail pharmacies that conduct wholesale distribution, FDA has taken the present position that the sale of minimal quantities of prescription drugs by such pharmacies to licensed practitioners for their office use is not wholesale distribution as contemplated by the PDMA. The statute requiring state licensure of wholesale distributors was intended by Congress to encompass only distribution of wholesale quantities of prescription drugs. In this context, the sales by a retail pharmacy to licensed practitioners of prescription drugs for office use will not be considered wholesale distribution requiring state licensure if the total annual dollar volume of prescription drugs sold to licensed practitioners does not exceed five percent of that retail pharmacy's total annual prescription drug sales.

Please note that the guideline proposed by the FDA does not preclude individual states from enacting more restrictive requirements. As always, it is best to consult with your state board of pharmacy in regard to the licensing requirements for wholesale distributors.

Retail Pharmacies and Buying Groups

Another question that has arisen concerning the PDMA is the definition of retail buying groups and whether these entities need to be licensed under the terms of the legislation. Retail buying groups, as defined by the FDA, usually exist for the purpose of obtaining lower prices for their members through the purchase of products at volume discount from manufacturers and distributors. These products are then distributed to members of the buying group.

The PDMA defines wholesale distribution as, "... the distribution of prescription drugs to other than the consumer or patient. . ." The purchase or other acquisition of prescription drugs from a group purchasing organization by member hospitals or other health care entities for their own use is excluded from this definition. Retail pharmacies are not considered health care entities as

defined by PDMA. Since retail buying groups (of any size) are not hospitals or other health care entities, the FDA believes that licensure is required if that pharmacy engages in the distribution of prescription drugs in interstate commerce to persons or firms other than the consumer or patient.

CPSC Stresses PPPA Compliance Responsibilities

The U.S. Consumer Product Safety Commission (CPSC), which has the responsibility for enforcing the Poison Prevention Packaging Act (PPPA), has noted what it regards as a misconception on the part of many pharmacists regarding their responsibility to comply with the special child resistant packaging (CRP) requirements of the PPPA.

Section 4(b) of the PPPA (15 USC 1473) provides an exemption for drugs subject to the special packaging standards which are dispensed pursuant to an order of a physician, dentist, or other licensed medical practitioner authorized to prescribe. Such prescription drugs may be dispensed in noncomplying (non-child resistant) packages "only when directed in such order or when requested by the purchaser" (*emphasis added*). Many pharmacies enter patient profiles, including package preference (CRP or non-CRP), in the store's computer or in a log book where the request may reside unchanged for an indefinite period (possibly as long as the individual remains a customer of the pharmacy).

In a recent letter to the National Association of Boards of Pharmacy (NABP), CPSC noted that **the procedures given above for maintaining a record of an individual patient's request for noncomplying packaging may not serve as the basis for dispensing a new prescription or prescription refill in noncomplying packaging.** There is no provision in the law or the regulations for a permanent exemption to the special packaging requirement.

The law requires that **each separate transaction for filling a prescription is a new order subject to the special packaging requirement at 16 CFR 1700.14(a)(10), even if the same drug is involved as in a previous transaction, as in a prescription refill order.** This means that it is the responsibility of the pharmacist, as the packager of the prescription drug subject to the standard, to ensure that it is dispensed in CRP, unless specifically requested otherwise - for the specific order - by the purchaser or the prescriber.

Compliance News



Compliance News to a particular state or jurisdiction should not be assumed to represent the law of such state or jurisdiction.)

A patient who previously requested non-child resistant packaging may change his or her mind about the use of CRP, **but the patient has no obligation to spontaneously inform the pharmacist of the change in CRP preference.**

It is the responsibility of the pharmacist who packaged the prescription drug to ensure that it is placed in CRP unless a specific request for non-CRP has been initiated by the purchaser or the prescriber. The request for non-CRP only applies to the instant transaction and cannot be applied to future prescription drug purchases. The pharmacist may record the consumer's preference for non-CRP in a computer or log book, but must verify that the preference continues for each transaction.

This interpretation runs counter to previous CPSC interpretations of the PPPA. NABP and its member state boards of pharmacy will continue working with the CPSC to clarify this latest interpretation.

For further information regarding this issue, or any other issues relating to the PPPA, please call Michael T. Bogumill, Compliance Officer, at 301/504-0400, or write to the U.S. Consumer Product Safety Commission, Washington, DC 20207-0001.

VHA Issues New Prescription Forms

Effective May 1992, the Veterans Health Administration (VHA) replaced its prescription form, VA Form 10-2577D, with VA Form 10-2577F. Designed to provide greater security and accountability in the medication ordering process, VHA's new prescription form is printed on security paper, sequentially numbered, and bears the phrase "To be filled in VA Pharmacies Only." VA medical center directors have been ordered to destroy all Form 10-2577D prescription forms dated 1978 or earlier.

The new form, which will be used primarily for controlled and acute medication orders, was developed in response to a June 1991 hearing conducted by the Subcommittee on Oversight and Investigations of the House Veterans Affairs Committee. Testimony presented during that hearing indicated that VA prescription forms were easily obtainable for unauthorized use and were the prescription form of choice for forgery rings because of their generic form and their ready acceptance in most states for Schedule III, IV, and V controlled substances.

The Department of Veteran Affairs emphasizes that while there is no federal law prohibiting the filling of VA prescriptions for non-controlled substances by community pharmacists, this practice may be subject to state interpretation. It would seem, therefore, that if a prescrip-

tion (controlled or non-controlled) is presented at a community pharmacy, there is a high probability that it is a forgery. In such a situation, individual pharmacies are encouraged to contact their local VA medical center.

Questions about the new VA prescription form or the policies concerning its use may be directed to Dr. Jeff Ramirez or Mr. Andrew Muniz at 202/535-7302.

State Newsletter Adds C.E. Component

Beginning with this issue of the *Newsletter*, pharmacists holding current licensure in this state will have the opportunity to earn continuing education (C.E.) credit via a series of articles, included with the newsletter, which will examine federal drug law compliance issues.

The National Association of Boards of Pharmacy Foundation (NABPF), through a grant from Glaxo, Inc., and in cooperation with U.S. Pharmacist, convened an editorial review board that included representatives from the state Drug Utilization Review (DUR) Boards, the Food and Drug Administration (FDA), the Health Care Financing Administration (HCFA), and Senator David Pryor's staff to develop the initial four-part series, which examines the patient counseling and DUR mandates of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90).

The first article, included with this newsletter, is entitled "OBRA '90: What it Means to Your Practice." Written by Professor David B. Brushwood, JD, RPh, University of Florida College of Pharmacy, NABPF Executive Director Carmen A. Gatzzone, MS, RPh, and John M. Coster, PhD, RPh, professional staff member for the Senate Special Committee on Aging, the article summarizes this landmark legislation and its affect on the pharmacist's delivery of pharmaceutical care to Medicaid patients. It also provides an overview of OBRA 90's DUR provisions, both prospective and retrospective, the patient counseling standards, and the implementation guidelines, while discussing the role of the state boards of pharmacy in establishing and enforcing the regulations. Subsequent articles will address the role of the pharmacist in patient counseling, OBRA 90's DUR component, and enforcement.

Each article is accredited for two continuing education hours (or 0.2 CEUs), and a \$6 administrative fee will be charged for each self-examination form that is submitted for scoring. Program Management Services of New York will score and process the examinations, and C.E. certificates will be issued through Glaxo, Inc.

Continued from page 1

These drugs do, however, need to be taken out of circulation. It is our recommendation that a pharmacist or nurse, while acting as a witness, urge the family to destroy such drugs by flushing them into the sewer system. This way the drugs can be kept out of the hands of individuals who might abuse them or send them to the same fate as the decedent.

Item 723 – Members and Employees of the Board

While many pharmacists may not readily perceive the distinction, there is a large difference between a Board member and a Board employee. Board members are elected and/or appointed by the Governor to decide policy issues, adopt rules, and preside over disciplinary cases. Current members of the Board are Mr. Harold Day, President, Spruce Pine; Mr. Wm. Whitaker Moose, Vice President, Mount Pleasant; Mr. William H. Randall, Jr., Lillington; Mr. William T. Biggers (public member), Asheville; Mr. Al Lockamy, Raleigh; and Mr. Jack Watts, Burlington. The Board staff, which is headed by Mr. David Work, consists of Board Inspectors Belvin, Hudson, Mayo, and Wilkins, as well as the office staff in Carrboro.

Questions on the day-to-day operations of a pharmacy or law matters can usually be answered by Board staff. Inquiries should be made to P.O. Box 459, Carrboro, NC 27510-0459. You may also call 919/942-4454.

Board members, on the other hand, are involved with deciding disciplinary cases, considering new rules, and making policy decisions. They are not ordinarily involved in the day-to-day operation of the office.

Because Board members participate in disciplinary hearings, it is important that they are not subjected to information about such cases prior to the hearing. Board staff always withholds information about disciplinary hearings from Board members until the proceeding occurs. If members are contacted by individual pharmacists about a specific disciplinary case, they may, and often do, recuse themselves from that particular hearing.

Item 724 – Return Goods Policy

Last year, the Board adopted a rule that applies to all pharmaceutical manufacturers whose drugs are used in product selection. The rule states that, in order to have their products eligible for product selection, manufacturers must accept full or partial containers of their products up to six months after the labeled expiration date for full, prompt credit or replacement. Any report of manufacturers failing to follow this standard should be referred to the Board office, specifying dates, locations, and names of individuals who failed or refused to give credit, and the products involved.

Upon receipt of this information, our Board investigators will check into the matter. If the report is verified, a letter will be sent by certified mail to the manufacturer noting their failure or refusal to comply with Board rules. If necessary, a hearing will be held, at which time the Board could determine that the manufacturer is not in compliance with Board rules. This activity would occur under the North Carolina Administrative Procedures Act.

In a related matter, the Board took action to add another responsibility to the duties of pharmacist-managers. Pharmacist-managers must now separate all drug products from the dispensing stock that are more than six months out-of-date. This assures the public that all medications dispensed are within reasonable limits of their expiration date.

Item 725 – Staff Suggestions

Occasionally, the Board office receives complaints about the cost of pharmaceuticals, particularly when patients receive a new prescription containing a large quantity which they cannot consume. Board staff suggests that any prescription for a drug that a patient has not had in the past

be filled in very limited quantities. If the patients then discover they cannot take this drug or it is ineffective for their condition, a large amount of money is not at stake, which can produce ill feelings. Once the acceptability and effectiveness of the drug is established, it is easier to provide the remainder of the prescription at a better unit price.

Patient counseling will soon be an integral part of pharmacy practice, and the key to this whole procedure is communication. Pharmacists should ask questions that encourage open-ended answers instead of a "yes" or "no" response. An example of a poorly worded question is, "Are you doing okay on this new prescription?" The customer or patient can easily respond to this question with a yes or no answer. A more effective inquiry might be, "Tell me how you are doing on your new prescription." If the patient says "Okay," a follow-up question would be "In what way?" Pharmacists need to be giving these types of issues more thought as the January 1, 1993 deadline requiring patient counseling for all Medicaid beneficiaries draws near.

Item 726 – Technician Use

This item serves as a reminder that technicians cannot dispense drugs without the supervision of a pharmacist. This was underscored in a recent disciplinary case involving a hospital in this state. North Carolina statute and rule on the use of technicians is quite clear. Pharmacists must physically check the product and the order before it is dispensed.

Occasionally inquiries arise about the use of technicians to check another technician's work, especially in a hospital. Such a practice does **not** conform with state statute and rule, and its occurrence could be the subject of a Board disciplinary proceeding. It is also worthwhile to note that, as a public policy matter, insurance companies cannot insure against illegal acts. Therefore, any adverse effects that occur to a patient who receives a drug under the supervision of technicians, with no pharmacist involvement, may not be covered by malpractice insurance.

Item 727 – Caller I.D. Now Available

The State Utilities Commission has recently approved the implementation of the Caller I.D. Service for two companies, Southern Bell and Central Telephone Company. Caller I.D. is a system whereby a person receiving a telephone call can obtain the telephone number of the caller on automatic equipment. The two-year experimental program, which allows blocking of the caller's number on a per call or per line basis, may be offered by other telephone companies in the future, under the same terms as Southern Bell and Central Telephone.

Caller I.D. could be very useful for pharmacists to verify the source of telephone prescriptions and avoid forgeries by oral prescription. Pharmacies in areas which have experienced forgeries or attempted forgeries by telephone might wish to look into this service.

Note: Please Don't Forget to Furnish the Board with your Zip + Four Information (both Pharmacy and Pharmacist)

The *North Carolina Board of Pharmacy News* is published by the North Carolina Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc., to promote voluntary 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.

David R. Work, JD, RPH – State News Editor
Carmen A. Catizone, MS, RPH – National News Editor & Executive Editor
Janice Teplitz – Editorial Manager

This Newsletter printed at a cost of \$.10 per copy