



# North Carolina Board of Pharmacy

P.O. Box H, 602H Jones Ferry Road, Carrboro, NC 27510

Published to promote voluntary compliance of pharmacy and drug law.

## ITEM 473—CONTINUING EDUCATION INFORMATION

At its regular October meeting, the Board adopted a regulation which requires that pharmacists obtain continuing education as a condition of license renewal. The text of the regulation appears below:

### SECTION .2201—CONTINUING EDUCATION

.2201 Hours; Records; Providers and Correspondence Courses; Reciprocity;

(a) As a condition of license renewal, each practicing pharmacist holding an active license shall report on renewal forms the hours of continuing education obtained during the preceding year. Annual accumulation of ten (10) hours is considered satisfactory to meet the quantitative requirement of this section.

(b) All records, reports of accredited hours and certificates of credit shall be kept at the pharmacist's regular place of practice for verification by Inspectors during regular or other visits. The Board reserves the right to require submission of such documentation on a random basis. Pharmacists who do not practice regularly at one location shall produce such record within 24 hours of a request from Board authorized personnel. All records of hours and certificates of credit shall be preserved for at least three (3) years.

(c) All continuing education shall be obtained from a provider approved by the Board. Not more than 50% of the continuing education credits can be obtained through correspondence, self-study or other non-contact programs in any calendar year.

(d) Continuing education shall not serve as a barrier to reciprocity, however all licensees by reciprocity must observe continuing education standards specified in (a), (b) and (c) above within the first renewal period after licensure in this state.

History Note: Statutory Authority G.S. 90-85.17; 90-85.18; Eff. January 1, 1985

In other words the Board requires that all pharmacists in North Carolina who renew their licenses must also obtain at least ten hours of continuing education with no more than five hours in correspondence courses. The members obviously approve the concept of continuing education but not just for the activity itself. The members are concerned about continuing competency and adopted this as a step towards that goal.

There is substantial opinion among Board members that all continuing education credits should be obtained from providers approved by the American Council on Pharmaceutical Education (ACPE), the accreditation group in pharmacy. However, the members also recognized that other efforts can have education value and have decided to initially accept a variety of activities for credit.

The Board will accept continuing education offered by all pro-

viders approved by the ACPE. It is possible for local groups to obtain their programs with ACPE credit by working with pharmacists in the Area Health Education Centers located throughout the state. Either of the two alternatives above has the advantage to the pharmacist of knowing the credit hours which will be determined prior to the program. Other organizations, such as city, county or regional associations, can have programs approved by meeting similar standards through submission of information on content, method of delivery, attendance records and evaluation on a form to the Board office within 60 days of the program's occurrence. These programs will be reviewed by the Tripartite Committee consisting of representatives from the NCPHA, Board and School which will make recommendations to the Board on each program. Pharmacists participating in programs that have not received prior approval risk disallowance of credit. For these purposes 1 hour means 60 minutes of program such as 60 minutes of lecture or 45 minutes of lecture and 15 minutes of questions and answers. A meeting which consists of a 20 minute program and a 40 minute meal will not qualify. Providers must supply participants with certification papers.

Graduate or professional school courses are acceptable for credit in the same manner as continuing education in other fields providing there is some reasonable connection to pharmacy or medical care. For example, study towards a masters degree in Business Administration would be acceptable while course work on a Divinity degree would not. Teaching activities by a person whose primary occupation is not education is acceptable for credit equal to hours of instruction. Repeating the same subject activity will not count for additional hours. Excess hours in one year will not be carried over to the next year and credit can only be used once. Attendance at meetings of the Board of Pharmacy, subject to available space, will count up to 1 hour for one meeting. Acting as a preceptor for at least 400 hours of internship can satisfy up to 5 contact hours of CE, providing that the internship experience meets Board standards. Pharmacists should take note that they can satisfy the entire CE requirement through correspondence courses and serving as a preceptor, at least through this initial period. Receipt of a license by examination shall satisfy the continuing education requirement for the next following calendar year. Pharmacists in foreign countries may obtain all hours by correspondence. It will be the responsibility of each pharmacist to maintain his or her own records of attendance or completion of approved CE programs. Pharmacists should understand that this is not a permanent situation and the entire subject will be reviewed for effectiveness in one year. Pharmacists would be

*Continued on page 4*



# National Pharmacy

## REGISTRATION CHANGES BEING CONSIDERED BY DEA

The Drug Enforcement Administration is considering a change in the registration procedures that will affect most or all of the manufacturers, wholesalers, pharmacies and practitioners registered with DEA. DEA is studying the establishment of lifetime registration numbers that would enable them to better keep a complete history on each registrant. DEA is also considering moving toward a three year registration of pharmacies and others handling controlled substances. New pharmacy registration numbers will start with the letter "B" instead of the presently used letter "A". New distributor (wholesaler) registrations will start with an "R" rather than the currently used "P".

---

## PROBLEM OF COUNTERFEIT DRUGS SURFACES AGAIN

The Pharmaceutical Press from time to time carries articles regarding the growing problem of the counterfeiting of legend drug products and the problems associated with the entry into legitimate channels of distribution of these counterfeit products. Counterfeit drug products affect not only the manufacturer of the legitimate pharmaceuticals whose products are being counterfeited but also affect the health and safety of patients.

The latest instance of counterfeiting of legend drug products is perhaps more serious than most and involves the oral contraceptive product Ovulen 21 marketed by Searle Pharmaceuticals.

The counterfeit products being found in distribution have been analyzed by FDA and have been found to be sub-potent. The counterfeit products might not provide effective birth control.

To protect patients and avoid confusion, Searle is voluntarily withdrawing from distribution all Ovulen 21 packages with the lot number -441 or -489 following the expiration date on the right hand side of the foil blister pack containing the tablets. Pharmacists should note that these numbers are not found on the outside envelope containing the foil blister pack nor should they be confused with the number 401 that is imprinted on one side of each tablet. Searle officials have advised patients having these two Ovulen lots to contact their pharmacists who are being sent information from the company to enable them to determine whether the product is counterfeit.

Complaints about the counterfeit products were received from pharmacists in Kansas, Florida, Wisconsin and Illinois.

Pharmacists should be extremely suspicious of any buying opportunities offered them where the products involved are unusually low priced. Pharmacists must also be alert to unusual changes in numbering, shapes or colors on tablets. Any suspicious pharmaceutical products should be reported to FDA immediately.

---

## DRUG PRODUCT DEFECT REPORTING PROGRAM

Since the program began, the Drug Product Problem Reporting Program has received more than 60,000 reports from pharmacists and other health professionals reporting on questionable bio-availability and stability of drugs, inadequate package insert information, poor packaging enclosures, mislabeling, illegible labeling, broken tablets, and other defects in the drug products themselves.

All pharmacists are urged to continue reporting drug quality and packaging problems that come to their attention. Reports on defects observed by pharmacists can be submitted by mailing information to United States Pharmacopeia, 12601 Twin Brook Parkway, Rockville, MD 20852, Attn: Dr. Joseph V. Valentino, or by calling the toll free number 800-638-6725. Information required is the name, address and phone number of the pharmacist reporting the defect; the product name, strength, etc.; lot number and expiration date, if available; date purchased and source, if known; manufacturer's name and address; labeler's name and address, if different from manufacturer's; and a description of the problem noted.

---

## SURVEY OF PHARMACY LAW AVAILABLE

The National Association of Boards of Pharmacy has announced the availability of the 1984-85 *Survey of Pharmacy Law*. This is the thirty-fourth year that the Association has published this composite review of state pharmacy practice acts and regulations.

New information that has been added to this year's Survey include:

- A summary of continuing education requirements for the thirty-three state boards of pharmacy who currently require CE for relicensure.
- A new summary of the various drug product selection laws now existing in most states.
- A summary, by state, of the number of pharmacists practicing in each state and the total number licensed and where they practice.
- A summary of the number of pharmacies in the United States.
- A summary of states that register "drug dealers" who sell OTC drugs.

A current review of how a student pharmacist acquires a license and continues to maintain that license is provided through the Survey.

Pharmacists who are contemplating reciprocating to other states and pharmacy students who are interested in learning of the licensure requirements in various states will find the *Survey of Pharmacy Law* an invaluable tool.

Orders are now being received for the 1984-85 *Survey of Pharmacy Law* through the NABP Publications Desk. The price of the Survey is \$20.00. A check for that amount should accompany your

---

# Compliance News



order. The NABP is housed at One East Wacker Drive, Suite 2210, Chicago, IL 60601.

---

## CONTROLLED SUBSTANCE INVENTORY DATE FAST APPROACHING

The general rule under the Federal Controlled Substances Act is that all pharmacies must complete an accurate inventory of all stocks of controlled substances on hand every two years. The biennial inventory date for most pharmacies is May 1 of each odd numbered year. May 1 of 1985 is fast approaching. The biennial inventory date of May 1 may be changed by the registrant to fit his regular general physical inventory date, if any, so long as the date is not more than six months from the biennial date that would otherwise apply. A registrant desiring to change the date of his biennial inventory must notify the regional director of DEA in advance.

Pharmacies that have first opened for business since 1971 generally will take their controlled substances inventory on the two year anniversaries of their original opening.

The inventory record must:

- (1) List the name, address and DEA registration number of the registrant.
- (2) Indicate the date and the time the inventory is taken, i.e., at the opening of business or after the close of business for the day.
- (3) Be signed by the person or persons responsible for taking the inventory.
- (4) Be maintained at the location appearing on the registration certificate for at least two years.

When taking the inventory of Schedule II controlled substances, an exact count or measure must be made. When taking the inventory of Schedule III, IV and V controlled substances, an estimated count may be made unless the container holds more than 1,000 dosage units in which case an exact count must be made if the container has been opened.

---

## IMPORTANCE OF CHILD RESISTANT PACKAGING

Statistics gathered by the Consumer Product Safety Commission have shown that since the imposition of the CPSC requirement that all prescriptions be dispensed in child resistant packaging, the number of accidental ingestions of legend drugs and resultant poisonings has dropped rather dramatically. While many pharmacists and some consumers complain about the difficulty of manipulating the child resistant caps, facts show that the use of child resistant packaging has saved many lives throughout the country.

In one instance where child resistant packaging was not used and a life was lost, the pharmacist learned the hard way of his responsibilities under the Act. Earlier this year an article was run by

---

the Associated Press reporting on an Iowa lawsuit in which parents of a child who died allegedly as a result of a pharmacist's failure to comply with the Child Resistant Packaging standards of the Poison Prevention Packaging Act sued an Iowa pharmacist for one million dollars in damages. The Associated Press article stated:

"A Palo Alto county couple have been awarded one hundred and sixty thousand dollars in a lawsuit claiming a pharmacist was responsible for the death of their eleven month old daughter because he failed to put a child proof lid on a bottle of medicine.

The suit was brought by Julie J. and Ricky D. Baas in the U.S. District Court in Cedar Rapids in connection with the death of their daughter Jessica. She died in 1981 after taking some of her father's asthma medicine, Tedral. The parents sued Donald Hoyer, owner of Hoyer Super Rexall Drug in Estherville, and Robert H. Young, the Pharmacist who filled the prescription. They had sought one million dollars in damages.

The defendants contended they were under no obligation to use a child proof lid and that the child's parents contributed to her death by leaving the medicine within her reach. The defendants also claimed that if they were found liable they should be reimbursed by James L. Coffey, M.D. and Patricia Nystrom, Family Nurse Practitioner. The Nurse Practitioner allegedly failed to give proper instructions when Julie Baas called Coffey's Clinic to report the child had taken some of the father's pills. The seven person jury returned the verdict after deliberating about six hours. They found Hoyer and Young negligent, but not the doctor or the nurse."

Pharmacists must constantly keep in mind the tragic consequences that can result from non-compliance with the Poison Prevention Packaging Act. A little inconvenience at the time of dispensing is certainly a small price to pay if the life of a small child can be saved.

---

## TRANSMITTAL OF ORAL AUTHORIZATIONS FOR RENEWAL

A physician's nurse or other member of his staff cannot authorize the renewal of a prescription order for a controlled substance that has been renewed five times or is six months old. The authority for prescribing controlled substances is vested only with the physician, and he cannot delegate this function to anyone else. However, nurses or staff members receiving calls from pharmacies regarding renewals, may act as the physician's agent and transmit the physician's order.

(Reprinted from *Pharmacist's Manual*, United States Department of Justice, Drug Enforcement Administration.)

---

well advised not to wait until the end of the year to obtain their hours of credit.

At the 1984 convention of the North Carolina Pharmaceutical Association, a Resolution was adopted placing that group on record as favoring continuing education for license renewal. The North Carolina Society of Hospital Pharmacists has passed resolutions affirming the same concept. The Board supported a study on continuing education across the United States which was performed by the Pharmacy Administration Division of the UNC School of Pharmacy. The results were presented to the Board on July 19, 1983 and were useful in their consideration of this subject. In November of 1983 the Tripartite Committee consisting of representatives of the North Carolina Pharmaceutical Association, the UNC School of Pharmacy and the Board recommended that continuing education be made a condition of license renewal and this was noted in the January, 1984 *Newsletter*.

A postcard, with postage paid, was included with the January *Newsletter* last year that asked pharmacists for their opinion on this subject. Slightly more than 50 percent of the pharmacists in the state returned postcards producing 55 percent favoring continuing education, 43 percent opposed and 2 percent had no opinion. This conveyed the clear feeling of interested pharmacists that they approved continuing education as a condition of license renewal. A public hearing on proposed regulations was held on September 18th at the Institute of Pharmacy in Chapel Hill and about a dozen pharmacists spoke on the subject. The regulation cited above is the result of this process.

According to statistics from the National Association of Boards of Pharmacy, 33 other states require continuing education for license renewal and North Carolina is the 34th. Most other states which require CE have a 15 hour standard. Pharmacists in this state have a useful asset in Area Health Education Centers which are not generally available in other states. During their last fiscal year, for example, AHEC pharmacy continuing education programs were held within an hour's drive of over 97 percent of the pharmacists in the state. For these purposes a distance of 40 miles was considered a one hour drive. For information on AHEC programs scheduled in your area, please contact your closest AHEC pharmacist and facility. They are listed below:

**Area L-AHEC:** Health Education Foundation of Eastern North Carolina, Inc., P.O. Box 1319, Tarboro, NC 27886, O. Barry Mangum, Pharm.D., 919/823-1353; **Charlotte-AHEC:** Charlotte Area Health Education Center, 1000 Blythe Blvd., P.O. Box 32861, Charlotte, NC 28232, William T. Sawyer, M.S., 704/331-3120; **Eastern-AHEC:** Eastern Area Health Education Center, ECU School of Medicine Department of Family Medicine, P.O. Box 1846, Greenville, NC 27834, David Hawkins, Pharm.D., Mark Ellison, Pharm.D., 919/757-4611; **Fayetteville-AHEC:** Fayetteville Area Health Education Center, 1601-B Owen Drive, Fayetteville, NC 28204, John S. Weiner, Pharm.D., 919/323-1152; **Greensboro-AHEC:** Greensboro Area Health Education Center, Moses H. Cone Memorial Hospital, 1200 North Elm Street, Greensboro, NC 27401, Peter Gal, Pharm.D., 919/379-4025; **Mountain-AHEC:** Mountain Area Health Education Center, 501 Biltmore Avenue, Asheville, NC 28801, C. Edwin Webb, Pharm.D., 704/258-0881; **Northwest-AHEC:** Northwest Area Health Education Center, Bowman Gray School of Medicine, Wake Forest University, Winston-Salem, NC 27103, Timothy Poe, Pharm.D., 919/748-2247 or Karen Oles, Pharm.D., 919/748-3649; **Wake-AHEC:** Wake Area Health Education Center, Wake County Medical Center, 300 New Bern Avenue, Raleigh, NC 27610, Joni I. Berry, M.S. and Pamela U. Joyner, M.S., 919/755-8018. \* See Wilmington below

#### ITEM 474—DISCIPLINARY ACTIONS OF THE BOARD

September: **Randolph E. Riddle**, Bakersville. Pleaded guilty in Superior Court of Mitchell County to charges of failure to keep records for controlled substances. License suspended 5 years and other conditions of probation.

**Marion B. McCurdy**, Greensboro. Making false entries in a hospital

**Bruce Canaday**, Pharm.D., 919/343-0161

pharmacy's records regarding the use of Demerol<sup>®</sup>. License suspended for 180 days and other conditions.

**William P. Powell and Community Medical Center Pharmacy**, Mars Hill. Pleaded guilty to Medicaid charges, also charged with dispensing generic drugs labeled as brand name, allowing unlicensed persons to dispense prescription drugs, failure to charge a lower price for generic drugs than brand name drugs as required by the Drug Product Selection Law and dispensing sample drugs and charging them to Medicaid. License suspended for 180 days, permit placed on probation for 5 years under conditions.

October: **Larry James Toth**, Raleigh. Found responsible as pharmacist-manager for shortages of Desoxyn<sup>®</sup>, Dexedrine<sup>®</sup>, cocaine, Demerol<sup>®</sup> and Dilaudid<sup>®</sup> and admission of personal use of controlled substances. License suspended 120 days beginning not later than December 15, 1984 under several conditions.

**Justin E. Benfield**, Concord. Admitted consumption of numerous prescription legend drugs and controlled substances without a prescription to such an extent that it could be indulgence in the use of drugs. Four years probation under several conditions.

**Larry Robert Godwin**, Fountain Inn, South Carolina. Admission of consumption of numerous prescription legend drugs and controlled substances without a prescription to such an extent that it could be indulgence in the use of drugs and a physical or mental disability. License suspended indefinitely.

**Daniel R. Paoloni**, Durham. License reinstatement after pleading guilty in Federal Court to distributing controlled substances outside the course of legitimate business. The Board revoked his license in September of 1983 for a period of 5 years under certain conditions, one of which was an active suspension of his license for the active period of incarceration plus 90 days. Mr. Paoloni completed and passed the examination in September and at the October meeting, the Board reinstated his license to practice pharmacy.

November: **Harry Clifton Greeson**, Sanford. Plea of guilty to Medicaid fraud, 3 years probation.

**Margo Jane Fotos**, Kitty Hawk. Charged with misappropriation of Schedule III and IV controlled substances. Case continued indefinitely under certain conditions involving treatment.

#### ITEM 475—APRIL BOARD MEETING

The members of the Board voted to change the April meeting of the Board to April 10 at the North Raleigh Hilton in Raleigh. You will note that this corresponds to the location and time of the Annual Convention for the North Carolina Pharmaceutical Association.

#### ITEM 476—BOARD MEMBER ELECTION

Pharmacist members of the Board are elected for 3 year terms and all licensed pharmacists residing in the state are eligible to vote.

Two terms will expire in the spring of 1986 and the elections are held one year in advance to give any newly-elected member some time to attend Board meetings as an observer. Candidates for these positions must be from either the Western part of the state which is now represented by **Harold Day** or the North Central part, now represented by **Evelyn Lloyd**. A committee will consider nominations in February, and anyone interested should submit a resume to the Board office prior to February 15.

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**, R.Ph., J.D.—State News Editor

**David E. Holmstrom**, J.D., R.Ph.—National News Editor

**B.J. Crawford**—Managing Editor

**Diane Griffin**—Production Assistant