

July 2001

North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 1118 Disciplinary Actions

Full Hearing

January

Walter N. Coley (DOB June 1, 1934), Raeford. Dispensed Neo-Polymyxin Ear Solution on a prescription for Cortisone Ophthalmic Solution to a patient. Consent Order entered: License suspended one day, stayed two years with conditions: Violate no rules or regulations of the North Carolina Board of Pharmacy.

February

Angela I. Brown (DOB July 31, 1975), Gibsonville. Dispensed 100 mg Dilantin on the basis of a prescription written for 30 mg Dilantin resulting in the hospitalization of the patient after ingesting the incorrect dosage. Cautioned by the Board regarding her practice of pharmacy.

March

Jacquelynn A. Brown (DOB April 26, 1970), Charlotte; **Sanjay R. Patel** (DOB April 25, 1967), Huntersville; and **Eckerd Drugs**, 7611 Pineville Matthews Road, Charlotte. Failure to offer patient counseling for new prescriptions on two separate occasions for same patient. Both were warned regarding failure to comply with the Board's patient counseling rule.

David M. Young (DOB January 18, 1943), Kannapolis. Dispensed hydroxyzine HCL syrup with incorrect directions on an order for an infant patient. The error was discovered before the prescription was administered to the patient. Board Warning.

Mickey L. Buford (DOB January 22, 1950), Monroe. Dispensing Schedules II and III controlled substances to a patient without authorization and on a more frequent basis than should have been allowed. License suspended 30 days, stayed two years with conditions; active suspension of the license for 15 days; take and successfully pass the Board's jurisprudence examination; obtain approval from the Board's executive director prior to becoming pharmacist-manager of

any pharmacy during the stay period; notify the Board's office immediately of any change of address or employment involving the practice of pharmacy during the two-year stay; violate no rules or laws governing the practice of pharmacy or the distribution of drugs.

Prehearing Conferences

January

CVS Pharmacy, 960 W Main Street, Rockwell. Heard by Board member Haywood. Pharmacy operating without a pharmacist-manager from March 18, 2000 until September 6, 2000. Recommendation: Suspension of permit for two days, stayed five years with conditions: Submit a written Policy and Procedure to identify the protocol for actions to be taken any time there is a change in the pharmacist manager position at this location and submit this Policy and Procedures to the Board's director of inspections and investigations; develop and implement a Policy and Procedure for employees to follow in notifying the Board when transferring into or out of CVS pharmacy. Accepted by Barry Jasilli on behalf of CVS Pharmacy December 29, 2000; Board January 23, 2001.

William Krepps (DOB February 3, 1965), **Fuquay Varina**, and **Wal-Mart Pharmacy**, 7106 E US Highway 64, Knightdale. Heard by Board member Nelson. Dispensing 400 mg Amoxil on a prescription calling for and labeled as Augmentin 200 mg to a patient; dispensing Augmentin 200 mg on a prescription calling and labeled as Amoxil to a patient. Recommendation: Pharmacist: Board reprimand and pharmacist shall submit a signed statement attesting to the fact that he counsel all patients when dispensing a new prescription order and submit such statement to the Board Office of Investigations and Inspections; failure to comply with this order will be considered an aggravating factor in any future disciplinary action by this Board. Pharmacy: Board Reprimand and pharmacy shall submit to the Board Office of Investigations and Inspections a written plan for preventing medication errors; shall submit a statement attesting

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to the fact that all patients are counseled when being dispensed a new prescription order. Accepted by Krepps September 15, 2000; Elizabeth Mills on behalf of Wal-Mart Pharmacy November 20, 2000; Board January 23, 2001.

Elizabeth Perry (DOB March 18, 1951), **Oriental and CVS Pharmacy**, 11560 Unit 13, NC Hwy 55, Grantsboro. Heard by Board member Crocker. Dispensed amoxicillin suspension to a patient with incorrect directions for use on the bottle. Recommendation: Pharmacist and pharmacy warned to use greater care in the dispensing of prescription drugs in the future. Accepted by Elizabeth Perry December 20, 2000; Catherine J. Chitty on behalf of CVS Pharmacy December 13, 2000; Board February 23, 2001.

Ronnie L. Chandler (DOB October 6, 1942), Roxboro. Heard by Board member Crocker. Dispensed glyburide on a prescription for Topamax. The incorrect product was administered to the patient three days before the error was recognized. Recommendation: Reprimand and submit a written Policy and Procedure to the Board office on how to accurately and efficiently loan and receive prescription drugs between other pharmacists and the pharmacy where he is employed. Accepted by Chandler December 11, 2000; Board January 23, 2001.

Anjali Shroff (DOB January 4, 1974), Cary. Heard by Board member Crocker. Dispensed Levsin 0.125 mg (hyoscyamine) on a prescription calling for Levotab 0.125 mg to a patient who ingested the incorrect product for 74 days before the error was detected. Recommendation: Reprimand. Accepted by Shroff December 4, 2000; Board January 23, 2001.

Charles A. Wrinkle (DOB May 24, 1940), Hickory. Heard by Executive Director Work. Failure to obtain the required hours of continuing education (CE) to renew license for 2000. Discovered through annual random CE audit in the Board office. Recommendation: Obtain additional 10 hours of continuing education during calendar year 2001 to be included on the renewal application for year 2002 for a total of 20 hours with at least 10 hours being contact. Accepted by Wrinkle January 14, 2001; Board January 23, 2001.

February

David Hix (DOB July 7, 1931), Gibsonville. Heard by Board member Overman. Dispensed tamoxifen on a prescription for Cytoxan in which 384 dosage units of tamoxifen were ingested by the patient before the error was identified. Recommendation: Warning and in addition prior to renewal of license to practice pharmacy for 2002, complete an additional five contact hours of continuing education in pharmacology. Accepted by Hix January 24, 2001; Board February 19, 2001.

Randy Ball (DOB July 15, 1958), Wake Forest. Heard by Board member Nelson. Dispensed both prednisone 5 mg and 10 mg in the same vial on an order for prednisone 5 mg for a patient; dispensed amitriptyline on an order for methotrexate, which was ingested by the patient for three weeks before discovery of the error. Recommendation: Cautioned to comply with patient counseling rule and statutes and regulations governing practice of pharmacy and distribution of

drugs. In the matter of commission of errors in the dispensing of prescription drugs: Suspension of license for three days, stayed two years with conditions; report all errors committed by Ball that reaches the patient to the Board office; not fill a greater number of prescriptions per shift than he can accomplish without jeopardizing the health and safety of patients; violate no laws or rules of the Board. Accepted by Ball September 11, 2000; Board February 19, 2001.

Charles A. Wrinkle (DOB May 24, 1940), Hickory. Heard by Executive Director Work. Used drugs to such an extent that it rendered him unfit to practice pharmacy. Recommendation: Suspension of license for two years, stayed five years with conditions: abstain from consumption of mood altering substances except as prescribed by duly licensed practitioner and such use must be reported to the Board within 48 hours of initiation; successfully complete Pharmacists Recovery Network (PRN) Contract; unannounced drug screens; may not serve as pharmacist-manager of any pharmacy during stay period; obtain prior approval from the Board's executive director of any future employment as a pharmacist in this state; shall not be employed as a pharmacist in any position where he is required to work more than an average of 42 hours per week. Accepted by Wrinkle January 17, 2001; Board February 19, 2001.

Daryl Waldrop (DOB June 2, 1966), Pisgah Forest. Heard by Board member Overman. Dispensed Premarin on a prescription for Prempro, which was ingested by the patient for 73 dosage units before the error was discovered. Recommendation: Reprimand and prior to renewal of license to practice pharmacy for 2002 shall complete an additional five contact hours of continuing education. Accepted by: Waldrop January 26, 2001; Board February 19, 2001.

Kenneth P. Hardin (DOB September 14, 1941), Forest City. Heard by Board member Overman. Dispensed propranolol LA 60 mg on a prescription for propranolol LA 80 mg. Recommendation: Suspension of license for three days, stayed two years with conditions: violate no laws or rules of the Board; within 30 days evaluate the operations of pharmacy where employed and submit a written plan to prevent errors from occurring in the future. Accepted by Hardin January 29, 2001; Board February 19, 2001.

Broughton Sellars (DOB May 11, 1943), Elon College. Heard by Board member Crocker. Dispensed albuterol on an order for penicillin, which was administered to the patient three days before the error was discovered. Recommendation: Reprimand and violate no rules of the Board or laws governing the practice of pharmacy. Accepted by: Sellars December 6, 2000; Board February 19, 2001.

Marguerite K. Gay (DOB August 18, 1970), Rocky Mount; **Leamon Mitchell, Jr** (DOB February 9, 1967), Greensboro; **Ozie Faison, Jr** (DOB August 28, 1944), New Bern and **Tara N. Pudelski** (DOB August 19, 1975), **Glen Allen**, Virginia. Failure to obtain required hours of continuing education to renew the license for 2000. Recommendation: An additional 10 hours of continuing education during the calendar year 2001 to be included on the renewal application year for 2002. Accepted by Gay January 24, 2001;

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Mitchell January 20, 2001; Faison January 19, 2001; Pudelski February 3, 2001; Board February 19, 2001.

March

Sandy Bergeron (DOB August 16, 1972), Concord. Heard by Board member Overman. Dispensed Zantac to a patient on a prescription calling for Zyrtec, which was ingested by the patient for three months before the error was identified. Recommendation: Reprimand and prior to renewal of license to practice pharmacy for 2002 shall complete an additional five contact hours of continuing education. Accepted by Bergeron February 14, 2001; Board March 20, 2001.

Christopher M. Draus (DOB April 13, 1971), Greensboro. Heard by Board member Watts. Dispensed cephalexin 250 mg/5 ml suspension, to be administered one teaspoonful four times a day. The vial was labeled with the directions to take two teaspoonfuls four times a day, which was ingested by the patient five days before discovery of the error. Recommendation: Draus should be aware of Board's concern over this matter and should evaluate and change whatever conditions are present in his practice setting, which may have led to the error; prior to renewal of license to practice pharmacy for 2002, complete an additional five contact hours of continuing education. Accepted by Draus February 14, 2001; Board March 20, 2001.

Joseph A. Saunders (DOB July 25, 1957), Fayetteville. Heard by Board member Watts. Dispensed 20 ml of Zithromax 200 mg/15 ml on a prescription order that called for the dispensing of 15 ml of Zithromax. Recommendation: Formal notice of Board's concern over actions in this matter; evaluate and change whatever habits or conditions which may have led to this error. Accepted by Saunders February 28, 2001; Board March 20, 2001.

Kathryn A. Yancey (DOB November 6, 1965), Charlotte. Heard by Board member Overman. Dispensed Cipro HC Otic suspension on an order for Ciloxan Ophthalmic Solution where two doses of incorrect product were administered before the error was discovered. Recommendation: Reprimand and complete an additional five contact hours of continuing education for the renewal year 2002. Accepted by Yancey February 21, 2001; Board March 20, 2001.

Steven J. Jones (DOB December 27, 1953), Lugoff. Heard by Board member Watts. Dispensed hydrocodone prescription to a patient with incorrect directions for administration; the patient ingested 20 teaspoonfuls based on erroneous directions. Recommendation: Reprimand and complete an additional five contact hours of continuing education for the renewal year 2002. Accepted by Jones February 16, 2001; Board March 19, 2001.

Joel P. James (DOB June 7, 1943), Chapel Hill. Heard by Board member Crocker. Dispensed Retrovir on an order for Rotonavir with patient ingesting the wrong product from April 4, 2000 to July 6, 2000 when the error was discovered. Recommendation: Reprimand and placed on notice that it is his responsibility to not put himself in an environment conducive to the occurrence of violations of the Phar-

macy Practice Act, where the likelihood of prescription dispensing errors occur. Accepted by James March 6, 2001; Board March 20, 2001.

Michael Lowman (DOB August 11, 1963), Connelly Springs. Dispensed Ambien and Zanaflex; however, the Ambien label was affixed to the Zanaflex product and the Zanaflex label was affixed to the Ambien product. None of the products was ingested by the patient before the error was discovered. Recommendation: Reprimand with condition that no laws governing the practice of pharmacy or the distribution of drugs and no rules of the Board are violated. Accepted by Lowman March 6, 2001; Board March 20, 2001.

William Walker (DOB May 5, 1942), Eden; **Clayburn Hawkins** (DOB July 2, 1927), Madison; and **Leonard Matthews** (DOB January 6, 1941), Stoneville. Heard by Board member Crocker. Walker dispensed prescription to a patient for Cyclobenzaprine indicating 10 refills when no refills were authorized; Hawkins dispensed a prescription for lorazepam 1 mg with the wrong patient's name on the label; Matthews dispensed Humibid LA 600 mgs with the wrong patient's name on the label. Recommendation: Reprimand. Accepted by Walker March 6, 2001; Hawkins March 6, 2001; Matthews March 5, 2001; Board March 20, 2001.

Rodgers S. White (DOB November 6, 1934), Lenoir. Heard by Board member Crocker. Dispensed perphenazine tablets on an order for cyproheptadine hydrochloride tablets; dispensed atenolol 25 mg on an order for atenolol 50 mg with a change in directions without the prescriber's authorization; dispensed Triam/Eucerin 1:1 60 gm with only the product name, refill information, and the pharmacist's name on the label; dispensed Roxicet on an order for Percocet; dispensed Tylox caps on an order for Percocet; dispensed Roxilox 500/5 on an order for Percocet; dispensed controlled substances products on altered or otherwise fraudulent prescriptions. Recommendation: Suspension of license indefinitely with conditions: take and pass the Board's jurisprudence examination; report to the Board's executive director within 48 hours of discovery of any dispensing error committed; advise the Board of any change of address, practice status, or compliance with terms and conditions of the order; violate no rules or laws governing practice of pharmacy or the distribution of drugs. Accepted by White March 12, 2001; Board March 20, 2001.

Stephen R. Gathy (DOB December 29, 1958), Chapel Hill. Heard by Board member Rogers. Dispensed Prilosec on an order for Prozac. Recommendation: Letter of Warning and complete an additional five contact hours of continuing education for renewal year 2002. Accepted by Gathy March 14, 2001; Board March 20, 2001.

James Haney (DOB May 9, 1956), Durham; **Laura Tapp** (DOB November 11, 1971), Franklin, Tenn. Dispensed Cardizem to a patient on an order for Ceftin in which the patient ingested the wrong medication for approximately six days before the error was discovered and the patient was also not offered counseling which, if performed, would have identified the error. Recommendation: Haney must comply with the "Prescription Accuracy Monitoring and Community Service Plan" submitted on his behalf as part of this

action; Letter of Caution to Tapp. Accepted by Haney November 2, 2000; Tapp March 19, 2001; Board March 20, 2001.

Voluntary Surrender of License

Joseph E. Riley (DOB January 20, 1960), Gastonia. Admission that he dispensed Schedule II drugs upon oral prescription without reducing the same promptly to writing and without filing the same. Surrendered November 17, 2000; accepted by Board January 23, 2001.

Warner L. Smith (DOB July 28, 1938), Charlotte. Admission that he dispensed an order calling for Dilantin liquid 125/5 ml with the directions for administration being 2 cc three times a day; however, he incorrectly labeled the order with the directions of 10 cc three times a day. Surrendered January 30, 2001; accepted by Board February 19, 2001.

Item 1119 – Election Results

The results of the election for two positions on the Board of Pharmacy were tabulated in Board offices on May 15, 2001. The results of the election are printed below.

District 1

John Anderson – 191
Rebecca Chater – 1,282
Michael Overman – 1,212

District 2

Betty Dennis – 895
Janet Nester – 183
William “Bill” Post – 931
Lori Setzer – 564
T. Steve Wilson – 163

Ms Rebecca Chater was declared the winner for District 1, representing the western part of the state. Ms Betty Dennis called for a run-off in District 2, and the ballots will be counted on the evening of July 16 in the Board’s offices in Carrboro.

Item 1120 – Patient Counseling Issues

The members of the Board continue to be concerned about pharmacist observance of the patient counseling rule. Most violations are observed when there is no counseling offer of any kind. They requested that an item be included in this *Newsletter* providing a brief summary of the rule’s requirements.

The patient counseling rule requires that an offer to counsel patients be made on every new or transferred prescription. The word “judgment” is used three times in the rule so there is much flexibility in what a pharmacist can do. An offer to counsel is optional on refills. The offer needs to be made orally and in person whenever possible or appropriate and needs to be positive to encourage acceptance.

The phrase “Do you have any questions?” has been determined on many occasions to **not** be an offer to counsel by the Board. Suggested alternatives are:

- ◆ “Our pharmacist will talk to you about this if you’d like.”
- ◆ “Counseling is available from our pharmacist on this prescription.”

- ◆ “Our pharmacist is available to talk to you about your prescription.”
- ◆ “Our pharmacist would like to talk to you about your medicines.”

Patient records must be kept according to the rule and must include all records of refusals to accept the offer to counsel. The part of the rule which contains the most liability, in the opinion of the editor, is that involving drug use review. Section .2504 (d) states “Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or registrant before each prescription is filled or delivered typically at the point of sale or point of distribution to screen for potential drug therapy problems due to:”

- (1) therapeutic duplication;
- (2) drug-disease contraindication;
- (3) drug-drug interactions, including serious interactions with prescription or over-the-counter drugs;
- (4) incorrect drug dosage or duration of drug treatment
- (5) drug-allergy interactions; and
- (6) clinical abuse or misuse.

While inpatients are exempt from the patient counseling part of the rule they are **not** exempt from the Drug Utilization Review part of the rule.

Item 1121 – Clinical Pharmacist Practitioner Rules

The rule providing for Clinical Pharmacist Practitioners is now in effect. The Board will consider applications immediately prior to reciprocity sessions, ordinarily on the third Monday of the odd-numbered month. You should check the calendar on the Board’s Web site for confirmation of the schedule.

In the ordinary course of events, applications will be considered on Monday afternoons for a recommendation to the full Board meeting the following day. After approval, the application will then be sent to the Medical Board for their review. Several applications were approved at the May 2001 Board Meeting and please note that papers need to be in the Pharmacy Board office one week prior to the meeting when they will be considered.

Item 1122 – Access to Records

The Pharmacy Practice Act does not have an exemption for law enforcement officers to remove prescription records from the pharmacy. There is a section in the State Controlled Substances Act that allows some law enforcement people, primarily agents from the State Bureau of Investigation, access only to controlled substance records.

Instances have recently occurred where local law enforcement officers, police, or sheriffs, have attempted to go on “fishing expeditions” through prescription records. This is not permitted under state statute.

Pharmacists are, of course, required to respond affirmatively to subpoenas or court orders but, absent such a document, private patient records should not be disclosed.

Item 1123 – Going on a Medical Missionary Trip?

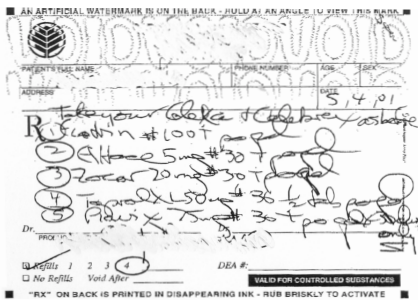
Q: Our local church group is planning to go on a medical mission to Central America. Can I take outdated drugs and samples on that trip?

A: Federal rules prohibit the use of outdated drugs in this way. Samples are also not intended for this purpose but may be used if complete treatments can be provided. Boxes of assorted samples of medications should not be left as donations.

A better solution to your problem is to contact MAP International (Medical Assistance Programs) This is a nonprofit, Christian, relief and development organization based in Brunswick, Ga. MAP can provide in-date and appropriate medicines for this purpose at a reasonable cost through their “Medicines for Missions” program. You can receive their guidelines and an application through their Web site at www.map.org or by calling Lisa Crosby at 1-800/225-8550.

Item 1124 – Bad Handwriting

The prescription reproduced below with identifiers deleted was offered to the Board as an example of challenges facing pharmacists.



Item 1125 – Prozac, Sarafem, and Prozac Weekly Issues

Eli Lilly and Company (Lilly) may lose market exclusivity for its daily formulation for Prozac® (fluoxetine hydrochloride) as early as August 3, 2001. Prozac is approved for the treatment of depression, obsessive compulsive disorder, and bulimia. Lilly markets newer forms of fluoxetine hydrochloride for two additional indications that will retain both patent protection and market exclusivity after August 2001. Sarafem (fluoxetine hydrochloride) is the only Food and Drug Administration (FDA)-approved medication for the treatment of Premenstrual Dysphoric Disorder (PMDD) and is packaged with a FDA-required patient package insert. Lilly has an exclusive license to a patent until 2007 that covers the use of fluoxetine hydrochloride for the treatment of PMDD. Prozac Weekly, a 90 mg, weekly formulation of fluoxetine hydrochloride with enteric coated pellets that delay the release of active drug for one-two hours, is approved for the long-term treatment of depression. Prozac Weekly is protected by a formulation patent that expires in 2017. Because Sarafem and Prozac Weekly will retain their patent protection for several years, the generic fluoxetine products, once approved by the FDA, will not be substitutes under North Carolina law when a prescription is written for the brand name and signed on the Dispense as Written line.

Item 1126 – DME Update

The Devices in Medical Equipment Subcommittee met on May 23, 2001, in the Newton office. A Prehearing Conference was conducted concerning allegations of serious violations by a licensed provider. There was some discussion again about opening up dialogue with the new staff at the Division of Facility Services. The committee hopes to meet with the new administration in order to discuss dual licensure issues. Anticipating severe weather this fall (hurricanes), the subcommittee reminds everyone about the mandatory 24-hour, oxygen, back-up requirement. The next committee meeting is scheduled for September 19, 2001.

Item 1127 – Methadone

CITE: CFR 1306.07 – Administering or dispensing of narcotic drugs.

Methadone may be used for any legitimate medical purpose. An outpatient prescription for methadone may not be dispensed if the prescription will be used to treat or maintain addiction.

Methadone may be provided in a hospital to treat or maintain addiction or to detoxify an addict when used as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

In an emergency, a physician who is not specifically registered to conduct a narcotic treatment program may obtain a one-day supply of methadone or other C-II narcotic drugs via a Drug Enforcement Administration 222 form to administer (not dispense) to a person for the purpose of relieving acute withdrawal symptoms while making arrangements for treatment. Not more than one day's medication may be administered for the person's use at one time. This emergency treatment cannot be carried out for more than three days and may not be renewed or extended.

Item 1128 – Hurricane Season

Pharmacists should be alert to the possibility of tropical storms and hurricanes through the summer and fall of each year. It should be remembered that the purpose of your license to practice is to protect and serve the public, and citizens' needs should be met if at all possible.

Everyone is aware when a hurricane is coming our way, but many do not realize that most damage and deaths occur inland. Hurricane Floyd, for example, did far more damage between Rocky Mount and Kinston than on the coast.

Board Rule 21NCAC 46.1809 specifically provides for an emergency prescription refill for up to a 30-day supply of maintenance medication or other drugs where the interruption of therapy would produce undesirable health consequences. This applies to all drugs except Schedule II controlled substances. The rule does not specify where the original prescription needs to be on file, and the Board has historically taken hurricane conditions into account. The specific section of the rule can be found on our Web site at www.ncbop.org.

Printed copies of the Board's statute and rules can be obtained from the Board office by sending a check for \$10.60, and the laws will be mailed promptly.

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During the last major hurricane, the Board contacted pharmacies by fax, and we may need to use that method again. Please make sure the Board has your fax number. We will also notify all pharmacists through our Board Information Service (BIS) by e-mail. If you want to be on this list, please be sure that the Board office has your e-mail address.

The Board's rule on computer records specifies that, in the event of downtime, a manual system must be implemented. See Section .1814. Pharmacist-managers also have a responsibility under Section .2502(i) to have a plan to safeguard prescription records and pharmaceuticals in the event of a hurricane. The Board does not expect perfection in this regard, but some plan does need to be in place. Chain drug pharmacists or others in large organizations should contact their supervisors to determine company policy on this issue.

North Carolina statute provides that the governor may declare a disaster or state of emergency, and the Board **may** waive certain requirements of statutes and rules. Board communication with pharmacists and pharmacist-managers is critical in this regard.

Lastly, and we hope this does not occur, the Practice Act provides at G.S.90-85.25 that any disaster or emergency which may affect the strength, purity, or labeling of drugs or devices should be reported to the Board. If this does occur in your pharmacy, you should contact the Board office to obtain a form for such report.

Devices in Medical Equipment suppliers who provide oxygen need to be aware of the DME Subcommittee recommendation that all patients should have a 24-hour oxygen supply as a backup for emergencies.

Item 1129 – Red Cross Vouchers

During the Hurricane Floyd aftermath, many pharmacists became aware of Red Cross vouchers for the first time. These forms are used by disaster victims to pay for essential goods such as prescription drugs. More information can be obtained from the National Red Cross office at 202/737-8300, ext. 8544.

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