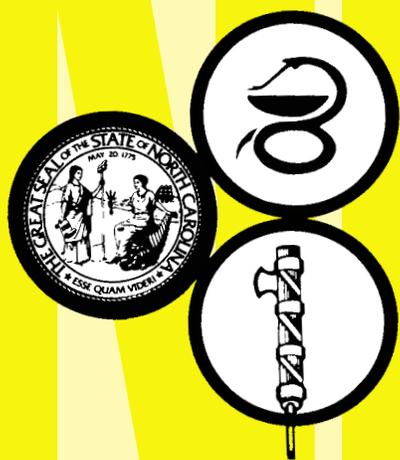


July 2005



North Carolina Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Item 2073 – Disciplinary Actions

March-April 2005

Full Hearings: None

Consent Order: 1

The Consent Order was issued in lieu of an administrative hearing for indulgence in the use of an intoxicating substance to an extent that rendered the pharmacist unfit to practice pharmacy. License of pharmacist suspended indefinitely, stayed with specific conditions.

Reinstatement Order: 1 with specific conditions to be met.

Prehearing Conference:

Letter of Concern: 3 [one pharmacist, two pharmacy permits]

Warning: 1 [pharmacist]

Reprimand: 4 [two pharmacists, two pharmacy permits]

Suspension with Stay order and specific conditions: 1 [pharmacist]

The Warning was issued for dispensing hyoscyamine drops with incorrect dosage instructions.

The Reprimands were issued for dispensing an excessive amount of Fioricet®, Ultram®, and Neurontin® to one patient; and dispensing an unknown medication on a prescription order for Zyrtec® 10 mg.

The Suspension with Stay was issued for dispensing Reglan™ 10 mg tablets on a prescription order for Reglan 1 mg Suspension.

The Cautions were issued for dispensing of a compounded prescription mouthwash to a patient who suffered unusual side effects from the product; and a non-pharmacist employee dispensing four compounded prescriptions to patients while no pharmacist was on duty.

Item 2074 – Hurricane Season

We are now in the middle of hurricane season and pharmacist-managers have a responsibility for a plan to protect the pharmaceuticals and records if a storm hits their community. See North Carolina Board of Pharmacy Rule 21NCAC 46.2502(j).

A University of North Carolina (UNC) pharmacy student, Tsz Yin (Jeremy), compiled a disaster plan in the fall of 2004. It can be found on the Board's Web site under "Catalyst for Colloquy."

Item 2075 – Board-certified Technicians

The members of the Board of Pharmacy have taken steps to increase responsibility of Board-certified pharmacy technicians. These are registered pharmacy technicians who have also passed the Pharmacy Technician Certification Board (PTCB) examination. Pharmacist-managers can increase the technician-to-pharmacist ratio above 2 to 1 if the additional technicians are Board certified by PTCB. Board-certified technicians can receive oral prescriptions and can transfer prescriptions to pharmacists or other Board-certified technicians.

Item 2076 – New Public Member

Parker Chesson, PhD, has been appointed by Governor Mike Easley effective May 1, 2005, to a five-year term as the public member on the Board of Pharmacy. See biographical information below.

Dr Parker Chesson had a 36-year career in the North Carolina Community College System and with other work force agencies. Since his retirement, he has worked as a consultant on various projects including the nationally acclaimed Rural Community College Initiative and trustee training for the North Carolina Association of Community College Trustees. He now does work through his consulting firm, JPC Associates, Inc. He has worked with various colleges and nonprofit organizations during the past two years on work force development topics, board retreats, and special projects.

One of three children, Dr Chesson grew up in his native county and graduated from Perquimans County High School in 1959. He attended East Carolina University in Greenville, where he graduated magna cum laude in biology in 1963 and received his master's degree in biology and education in 1964. He also completed a National Science Foundation Institute at the Duke University Marine Laboratory in the summer of 1964.

After graduation, Dr Chesson worked at College of The Albemarle in Elizabeth City, serving as an assistant professor of biology, chairman of the department of mathematics and natural sciences, director of college transfer education, and dean of instruction. While a faculty member, he directed two institutional self-studies, the first of which led to the college's first full accreditation by the Southern Association of Colleges and Schools.

Continued on page 4



New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.



Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

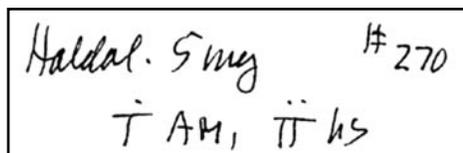
For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for



the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as “phenobarbital 32.400MG tablet.” The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily.



The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.

Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- ◆ Always include a leading zero for dosage strengths or concentrations less than one.
- ◆ Never follow a whole number with a decimal point and a zero (trailing zero).
- ◆ Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- ◆ Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- ◆ Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- ◆ Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- ◆ When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to “fax noise.” Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- ◆ Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- ◆ Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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He received his PhD in science education and zoology from North Carolina State University in 1974. He was selected as president of College of The Albemarle in 1975. During his 17-year tenure as president, he served as president of the North Carolina Association of Community College Presidents, a member of the Commission on the Future of the North Carolina Community College System, a member of the Task Force on Excellence in Secondary Education, and chairman of the North Carolina Coastal Resources Commission. He received the Governor's Award for Distinguished and Meritorious Service in 1984 and was named a Paul Harris Fellow by the Elizabeth City Rotary Club in 1992.

Dr Chesson accepted the position of executive vice president of the North Carolina Community College System in July 1992, where he served for four years. In 1995, he received the Distinguished Alumnus Award from North Carolina State University's Department of Education and Psychology.

In October 1996, he was appointed by Governor James B. Hunt as chairman of the Employment Security Commission of North Carolina. During his four years as head of this work force development agency, the National Employers Council named him "1997 Outstanding State Administrator," the International Association of Personnel in Employment Security named him "1998 Administrator of the Year," and the National Association of State Workforce Agencies presented him with its highest honor in 2000, the Eagle Award. His volunteer work includes serving on the Board of Directors of the Jim "Catfish" Hunter ALS Association.

He is married to Wynda Chesson, née Chappell, his high school sweetheart, who is a former elementary school teacher and a former member of the Elizabeth City-Pasquotank County Board of Education. He has two daughters, one a pharmacist and the other a physician. Both are graduates of College of The Albemarle and UNC-Chapel Hill.

Dr Chesson replaces Tim Rogers, executive vice president of the North Carolina Association for Home and Hospice Care in Raleigh. Mr Rogers was the first public member in the history of the Board to serve the maximum of two complete consecutive five-year terms.

Item 2077 – Generic Name on Prescription Label

Effective January 1, 2006, all prescription labels will need to contain the generic name of the drug. This rule was adopted several years ago with a delayed effective date to give pharmacists ample time to reach compliance. It is the responsibility of the software vendor to have their products in compliance by January 1, 2006.

Item 2078 – Update on Death Reporting Rule

In the Spring of 2005, Meredith Smith, a UNC Pharmacy School student at the time, served a rotation through the Board office and updated results on the Board's death reporting rule. It can be found at www.ncbop.org at "Catalyst for Colloquy". A complete list of the drugs with categories of products follows this topic on the Web site.

Item 2079 – Board Member Election

Pursuant to the North Carolina Pharmacy Practice Act, G.S. 90-85.6 and 90-85.7, the Board conducted an election this spring for a five-year term on the Board to begin in May of 2006. Ballots were mailed out to all licensed pharmacists in the state in April and were counted on May 16 in the Board office in Chapel Hill. The results follow below.

District 5

Andy Bowman	187
Jim Boyd	401
Joey McLaughlin	922
Tim Giddens	844
Chris Peoples	373

Board rule provides for a run-off election and ballots were mailed out in June and will be counted at the July meeting of the Board on July 18. Counting will begin after the reciprocity session between 4 and 5 PM on that day.

Item 2080 – Canadian Storefronts

On May 9, 2005, Default Judgments were entered in Durham County Superior Court against Leon Edward Mitchell, individually and d/b/a Canada Drugs located in Asheboro; Robert and Judy Coon, individually and d/b/a Discount Drugs of Canada located in Gastonia; and Nicholas and Heather Green, individually and d/b/a Canada Meds of Asheville. An additional business, Canada Outlet, Inc (formerly Canada Drug Outlet, Inc) in Concord has signed a Consent Judgment, which, at the time of this writing, has been sent to Durham County Superior Court for entry. All of the Judgments referenced above permanently enjoin and prohibit the individuals and entities from receiving prescription orders and causing the importation of drugs into the United States from a foreign country in violation of state and federal laws.

Item 2081 – Tax Issues

1. Sales Tax on Drugs

a. Drugs sold pursuant to a prescription

Drugs sold pursuant to a prescription are exempt from the North Carolina Sales and Use Tax. N.C. Gen. Stat. §105-164.13(13). In addition to those drugs that may be dispensed only by prescription under federal law, this exemption also includes over-the-counter [OTC] drugs sold on prescription. Id. In addition, any packaging materials, instructions, and information about these drugs included in their packaging are also exempt from sales tax. Id. However, the constituent elements and ingredients used to produce the drugs are not exempt, as a result of a 2003 amendment to the statute. 2003 N.C. Sess. Laws 384 §45.5. *Note: this represents a change in the law since the topic was last reported in our April 2000 Newsletter under Item 1069.*

b. [OTC] drugs sold without a prescription

All [OTC] drugs sold without a prescription are subject to sales tax, with the exception of insulin. N.C. Gen. Stat. § 105-164.13(13). **Insulin (including any packaging materials, instructions, and information included in its packaging) is exempt from sales tax whether or not it is sold on prescription. Id.**

2. Sales Tax on Medical Supplies and Equipment

a. Medical Supplies and Equipment

All medical supplies and equipment are subject to sales tax, with the exception of four categories: (1) "prosthetic

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devices” (whether or not they are sold on prescription); (2) “mobility enhancing equipment” sold on prescription; (3) “durable medical supplies” sold on prescription; and (4) “durable medical equipment” sold on prescription. N.C. Gen. Stat. §105-164.13(12). This represents a change from the pre-1999 version of the statute, which only allowed an exemption for prosthetic devices if they were sold to patients on prescription. See 1999 N.C. Sess. Laws 438 §6 (setting forth pre-1999 language of statute). *Note: this represents a change in the law since the topic was last reported in our January 1998 Newsletter under Item 961.*

Repair and replacement parts are also exempt for prosthetic devices and durable medical equipment, but not for mobility enhancing equipment and durable medical supplies. N.C. Gen. Stat. §105-164.3.

The term “prosthetic device” is defined by statute as a replacement, corrective, or supporting device worn on or in the body that: (1) artificially replaces a missing portion of the body; (2) prevents or corrects a physical deformity or malfunction; or (3) supports a weak or deformed portion of the body. N.C. Gen. Stat. §105-164.3(30)(a).

The term “mobility enhancing equipment” is defined as equipment that is: (1) primarily and customarily used to provide or increase the ability of an individual to move from one place to another; (2) appropriate for use either in a home or motor vehicle; (3) not generally used by a person with normal mobility; and (4) not normally provided on a motor vehicle by a motor vehicle manufacturer. N.C. Gen. Stat. §105-164.3(21)(a).

The term “durable medical equipment” is defined as equipment that: (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) is generally not useful to a person in the absence of an illness or injury; and (4) is not worn in or on the body. N.C. Gen. Stat. §105-164.3(8)(b).

The term “durable medical supplies” is defined as those supplies related to use with durable medical equipment that are eligible to be covered under the Medicare or Medicaid program. N.C. Gen. Stat. §105-164.3(8)(c).

To further assist the public in determining whether a particular item falls within one of these four categories, the North Carolina Department of Revenue has provided a list of taxable items in a regulation, 17 N.C.A.C. 7B.1404. Although the Department expressly states in the rule that the list is not exhaustive, it lists the following items as subject to sales and use tax:

- (1) Adhesive tape;
- (2) Alcohol;
- (3) Bandages;
- (4) Battery chargers;
- (5) Bed pans;
- (6) Betadine solution;
- (7) Blood glucose monitors;
- (8) Blood glucose test/reagent strips;
- (9) Blood or urine control strips;
- (10) Breathing circuits;
- (11) CO₂ saturation monitors and accessories;

- (12) Cotton;
- (13) Crutch and cane holders;
- (14) Cylinder tank carriers;
- (15) Dial-a-dose insulin delivery devices;
- (16) Dressings;
- (17) Exam gloves;
- (18) Gauze;
- (19) Knives;
- (20) [Intravenous] I.V. hangers;
- (21) I.V. poles;
- (22) Lancets;
- (23) Microscopes;
- (24) Mouthpieces
- (25) Needles;
- (26) Peak flow meters;
- (27) Percussors;
- (28) Pulse oximeters;
- (29) Rollabout chairs;
- (30) Scissors;
- (31) Sterile water;
- (32) Surgical gloves;
- (33) Syringes;
- (34) Tracheal suction catheters;
- (35) Tracheostomy care kits;
- (36) Tracheostomy cleaning brushes;
- (37) Tracheostomy masks and collars;
- (38) Tubing, sold by the linear foot or otherwise;
- (39) Urinals;
- (40) Urine test or reagent strips or tablets; and
- (41) X-ray machine

Note: This regulation was adopted after N.C. Gen. Stat. §105-16.13(12) was amended in 1999, and therefore represents a change since the topic was discussed in our January 1998 Newsletter under Item 961. It should be noted also that items not found in this list are still presumptively taxable unless they fall directly within one of the four categories of exemptions mentioned above. N.C. Gen. Stat. §105-164.26.

3. Sales Tax on Purchases by Physicians

a. Prescription and Nonprescription Drugs

Purchases of prescription drugs from a pharmacy by physicians (including their office, clinic, or other similiar entity) are exempt from sales tax. N.C. Gen. State §105-164.13(13). Before 1999, the exemption for prescription drugs was limited to purchases made by patients pursuant to a prescription, and did not include purchases made by physicians. See 1999 N.C. Sess. Laws 438 §6 (setting forth pre-1999 language of statute). In 1999, however, the legislature amended the statute to allow for this exemption. *Id.* *Note: this amendment was previously discussed in our April 2000 Newsletter under Item 1069.* Purchases of nonprescription drugs are still subject to sales tax when purchased by physicians, with the exception of nonprescription insulin. N.C. Gen Stat. §105-164.13(13).

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b. Medical Supplies and Medical Equipment

The exemption for medical supplies and medical equipment only applies where the supplies or equipment are sold on prescription to a patient. N.C. Gen. Stat. §105-164.13(12). As a result, purchases of medical supplies or medical equipment from a pharmacy by physicians are subject to sales tax. Id. An exception exists for purchases of prosthetic devices, however, which are exempt from sales tax whether purchased by a physician or by a patient pursuant to a prescription. Id. This represents a change from the pre-1999 form of the statute, which only allowed such an exemption for purchases by a patient pursuant to a prescription. See 1999 N.C. Sess. Laws 438 §6 (setting forth pre-1999 language of statute). *Note: this represents a change in the law since the topic was last reported in our January 1998 Newsletter under Item 961.*

4. Sales Tax on Donated Drugs

Drugs donated by pharmacies to non-profit organizations and governmental entities are exempt from sales and use tax. This exemption in N.C. Gen. Stat. §105-164.13(42) includes sales of the following:

[t]angible personal property that is purchased by a retailer for resale or is manufactured or purchased by a wholesale merchant for resale and then withdrawn from inventory and donated by the retailer or wholesaler merchant to either a governmental entity or a nonprofit organization, contributions to which are deductible as charitable contributions for federal income tax purposes.

This provision was adopted in 1996 and the previous version, N.C. Gen. Stat. §105-164.13(13a), reported in our October 1992 Newsletter under Item 737, was repealed. This does not, however, represent a substantive change in the law as donated drugs have been exempt from sales tax since 1992.

Item 2082 – Medicaid Change

Submitted by Amy Williams Phelps, PharmD, RPh, North Carolina Medicaid – Pharmacy Review, Program Integrity

Effective January 1, 2006, some of your patients who currently receive their prescription drug coverage through North Carolina Medicaid will begin receiving their prescription drug coverage through a Medicare Prescription Drug Plan. North Carolina Medicaid hopes that this will be a seamless transition for our recipients and providers. We would like to remind our providers and recipients that for recipients who receive their drug coverage through North Carolina Medicaid, North Carolina Medicaid does cover a 90-day supply of non-controlled, generic, maintenance medications provided the prescriber has written the prescription to authorize a 90-day supply to be dispensed at one time and provided that North Carolina Medicaid has covered the medication at least once in the past six months. This benefit may help to ensure a smoother transition for recipients and providers in January.

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