

**New Federal Methamphetamine Law
to Further Change the Landscape
on Selling Cold Medicine in North Carolina**

On Thursday, **March 9, 2006**, President Bush signed into law legislation that reauthorizes the USA Patriot Act. While the large majority of the USA Patriot Act deals with concerns about security issues attributable to September 11th, also contained within this legislation are additional nationwide restrictions on the sale of cold medicine containing pseudoephedrine or ephedrine.

Because the USA Patriot Act legislation **does not preempt state law**, North Carolina retailers are left to **determine** whether the **federal laws** or North Carolina's restrictions are more stringent and then **implement the more stringent provision**. In other words, retailers must review both the North Carolina and the federal provisions. If a North Carolina provision addresses a subject-matter **not covered in the new federal law**, the North Carolina provision **still applies**. If a federal provision addresses a subject-matter not addressed in the North Carolina law, the federal provision is applicable. If a North Carolina provision and the federal provision address the same subject-matter, retailers must determine which provision is more stringent and apply the more stringent provision.

Therefore, some North Carolina specific provisions enacted in the North Carolina General Statutes in September, 2005 and subsequently amended in July, 2006 will remain in place and some other federal provisions will also apply to North Carolina stores. There are several instances in which North Carolina law is in direct conflict with the federal law which will cause much **confusion among retailers and customers alike**. Many of the provisions on this new federal law become effective September 30, 2006. However, **a few provisions** of this new **federal law became effective on April 8, 2006** – just thirty days after the federal law was enacted – leaving retailers **little time to come into compliance** with these provisions.

What follows is a careful review of each of both the state and federal legislation, so that your store operations will know what is required to continue to sell this product. This analysis exists nowhere else and we are pleased to offer this to your company as a **member benefit of the North Carolina Retail Merchants Association**. Please note that this information is intended as a guide but is in no way intended as legal advice.

The North Carolina law enacted in September, 2005 and subsequently amended in July, 2006 **essentially removed cold medicine** containing pseudoephedrine or ephedrine in **caplet or tablet** form from the shelves of most retailers and required that these products be **sold from behind a pharmacy counter**. The selling of tablet and caplet forms of these products by pharmacies triggered additional requirements for pharmacies such as training, **sales logs** and **sales limits** for these products. The North Carolina law essentially placed none of these additional duties for non-pharmacy retailers selling **gel capsules, liquids and pediatric products**. The new **federal law strips away the exemptions from the North Carolina restrictions for gel capsules, liquids and pediatric products** and classifies any retailer selling cold medicine containing pseudoephedrine or ephedrine as a “regulated seller” of this product.

Products Covered by News Federal Law (Effective April 8, 2006)

While the North Carolina General Assembly differentiated between cold medicine containing pseudoephedrine or ephedrine depending on the form of the product, the new federal law treats all cold medicine containing pseudoephedrine or ephedrine in the same manner. Under North Carolina law, cold medicine containing pseudoephedrine or ephedrine in caplet or tablet form could only be sold from behind the counter of a pharmacy while all retailers were still free to sell cold medicine containing pseudoephedrine or ephedrine in the form of a gel capsules, liquids or pediatrics.

The new **federal law** creates a new category for **all** cold medicine containing pseudoephedrine or ephedrine under the federal Controlled Substances Act entitled “**Scheduled Listed Chemical Products.**” In creating this new category, the new federal law dramatically **alters the exemptions for gel capsules, liquids and pediatric products.**

In North Carolina, the result is that effective **September 30, 2006**, cold medicine containing pseudoephedrine in tablet or caplet form will still be required to be sold from **behind the pharmacy counter** pursuant to the North Carolina law. As of **September 30, 2006**, all other products containing pseudoephedrine or ephedrine - **gel capsules, liquids and pediatric** products –can be **sold only** from **behind a counter or in a locked cabinet** to which consumers do not have direct access.

Sales and Purchase Transaction Limits

The new federal law implemented new **sales and purchase transaction limits** effective **April 8, 2006, on all products** containing pseudoephedrine or ephedrine. Even though the new federal sales and purchase log is not required until September 30, 2006, it would appear to be operationally impossible for a retailer to ensure compliance with the sales and purchase limits without also **implementing a sales and purchase log on April 8, 2006.**

a) Daily Sales Transaction Limit (April 8, 2006 Effective Date)

Effective July 20, 2006, both North Carolina and federal law prohibit retailers - both pharmacies and non-pharmacies – from selling in excess of **3.6 grams** of all cold medicine containing **pseudoephedrine or ephedrine in any one day regardless of the form** of the cold medicine. **We cannot emphasize enough that this daily sales limit applies to all forms of pseudoephedrine and ephedrine – tablets, caplets, gel capsules, liquids and pediatrics.**

In addition, North Carolina’s two-package purchase limit per day remains in effect for cold medicine containing pseudoephedrine or ephedrine in the form of tablets or caplets.

b) 30-Day Purchase Limit (April 8, 2006 Effective Date)

The North Carolina law enacted in September, 2005, prohibited customers from purchasing in excess of three packages or nine grams of tablets or caplets containing pseudoephedrine or ephedrine in a 30-day period. The **federal law** prohibits a customer from purchasing in excess of nine grams of **any** cold medicine containing pseudoephedrine or ephedrine in a 30-day period.

While the 30-day purchase limits in the federal law and the North Carolina law are very similar, the federal law dramatically affects the products that are subject to the 30-day purchase limits. The North Carolina law enacted in September, 2005, only applied 30-day purchase limits to cold medicine containing pseudoephedrine and ephedrine in tablet and caplet form. However, the new federal law goes a step further and applies the purchase limit to **all** products containing pseudoephedrine or ephedrine – caplets, tablets, gel capsules, liquids and pediatrics. The application of purchase limits to these additional products became effective on April 8, 2006. **North Carolina’s three package limit per 30-days on cold medicine containing pseudoephedrine or ephedrine in the form of a tablet or caplet remains in effect.**

Sales/Purchase Log Requirements (September 30, 2006)

North Carolina law requires a **sales/purchase log** be completed for the sale of cold medicine containing pseudoephedrine or ephedrine in the form of caplets and tablets. The North Carolina log for these products will remain the law of the land in North Carolina.

Because the federal law applies to **all** cold medicine containing pseudoephedrine or ephedrine – caplets, tablets, gel capsules, liquids and pediatrics - effective September 30, 2006, a sales/purchase log must be completed for the sale of these products. When purchasing cold medicine containing pseudoephedrine or ephedrine, a consumer will be required to complete and sign a **written or electronic log** stating their name, address, and date and time of sale. The retailer must enter the name and quantity of the product purchased. The retailer will be required to **maintain the log for a period of two years** and the United State Attorney General is charged with developing restriction on how the information contained in the sales/purchase log is protected for the purpose of protecting the privacy of consumers. Purchasers of cold medicine containing pseudoephedrine or ephedrine are also required to provide **state or federal issued identification** for the retailer to positively identify the purchaser’s information on the log.

The federal sales/purchase log requirement does not apply for sales of cold medicine containing pseudoephedrine and ephedrine if the sale is for 60 mg or less of pseudoephedrine or ephedrine. However, the North Carolina log requirements would still be applicable for these small purchases if the product being purchased is in the form of a caplet or tablet.

Retailers must provide **certification to the United States Attorney General** for each location that the retailer is in compliance with the federal law’s requirements including the maintenance of the sales and purchase logs.

Blister Packaging Requirement (April 8, 2006 Effective Date)

Effective April 8, 2006, all non-liquid forms of cold medicine containing pseudoephedrine or ephedrine must be sold in the form of **blister packaging** or in unit dose packaging. In other words, these products cannot be sold loose in bottles or packages.

Training (September 30, 2006)

Because North Carolina law only placed restrictions on cold medicine containing pseudoephedrine or ephedrine in tablet or caplet form and restricted the sale of these items to pharmacies, pharmacies were the only retailers that were required to train their employees under the North Carolina law.

As has been stated several times, the new federal law expands the number of restricted products to include all products containing pseudoephedrine or ephedrine including gel capsules, liquids and pediatric products. This expansion of restricted products has resulted in an expansion of employees that must be trained. The new federal law requires retailers to train employees on the sales restrictions imposed by both the state and federal law if the employee deals directly with customers. North Carolina **pharmacies must continue to train employees** involved in the sale of pseudoephedrine or ephedrine in tablet or caplet form as required under both the North Carolina and federal law. Additionally, North Carolina pharmacies are required to **train employees** on the new federal restrictions that are applicable to the sale of **all other forms of cold medicine containing pseudoephedrine** and ephedrine. Non-pharmacy retailers will also be required to implement a training program to train employees who deal directly with the public on the new federal restrictions on cold medicine containing pseudoephedrine or ephedrine that is not in tablet or caplet form. In other words, retailers must train employees to the applicable law for the products that they are permitted to and choose to sell.

The retailer must certify to the United States Attorney General that the required training has occurred.

Penalties (Effective Date Depends on the Provision Violated)

Violations of the new federal law summarized above come with pretty stiff penalties which may result in retailers deciding to seriously question the **cost-benefit analysis of selling cold medicine containing pseudoephedrine or ephedrine**. For violating one of the provisions stated above, a retailer would be subject to a civil penalty of up to **\$25,000**. If the retailer knowingly violates the law, the retailer would be subject to **one year of imprisonment**. A second conviction for violations of this law could result in imprisonment of up to **two years**.

A retailer – including a licensed pharmacy – may be prohibited from selling cold medicine containing pseudoephedrine and ephedrine for violating a provision of the federal law except for a violation of the retailer refusing to provide sales log information to law enforcement authorities.

Additional North Carolina Provisions That Remain in Place

There are several subject-matters addressed in North Carolina provision that are not addressed in the new federal law resulting in these North Carolina provisions remaining in place. Among the North Carolina laws that will remain applicable are the following North Carolina specific provisions:

- 1) The **North Carolina-specific signage is still required.**
- 2) The North Carolina-specific language contained in the **sales/purchase log** statement is still required.
- 3) **Flea markets** are still prohibited from selling over-the-counter drugs including all cold medicine containing pseudoephedrine or ephedrine.
- 4) The North Carolina specific training of employees on North Carolina law is still required.
- 5) Submission of reports by **wholesale distributors** of pseudoephedrine and ephedrine in tablet or caplet form to the State Bureau of Investigation is still applicable.
- 6) **Criminal and civil penalties** for violating North Carolina specific provisions remains in place for pharmacies. As a reminder the **penalties** for violating the North Carolina laws are **very strong**. Retailers can be subject to both North Carolina and federal penalties for violations of each law.

A pharmacy who knowingly and willfully violates the North Carolina law is guilty of a **Class A1 misdemeanor** for the first offense and a **Class I felony** for a second or subsequent offense. A pharmacy convicted of a **third offense** occurring on the premises of a single pharmacy can no longer offer the restricted for sale at that pharmacy. Additionally, a pharmacy who **fails to train or adequately supervise employees** in sales transactions involving restricted products, or reasonably discipline employees for violations of this Article shall be fined up to five hundred dollars (**\$500.00**) for the first violation, up to seven hundred fifty dollars (**\$750.00**) for the second violation, and up to one thousand dollars (**\$1,000**) for a third or subsequent violation of this section.

Pharmacy employees and customers are also subject to criminal penalties for violating the North Carolina. Any customer or pharmacy employee who **willfully and knowingly violates the log and sales transaction restrictions** is guilty of a **Class 1 misdemeanor** for the first offense, a **Class A1 misdemeanor** for a second offense, and a **Class I felony** for a third or subsequent offense. However, if a customer is deemed to be a bona fide innocent purchaser, the person is not guilty of these violations.