

REVISIONS TO COMPLIANCE BULLETIN 2006-001

When the Board published Compliance Bulletin 2006-001 in April, we did so with the thought that most people would prefer to know the “bottom line” so they could set up one system and not be required to rearrange shelving and policies twice. Since that time, several people have questioned that approach, but felt that they were mandated to follow the exact wording of the Compliance Bulletin to avoid problems with the Board. Obviously, the Board does not make law and cannot mandate that all of the laws relating to PEP (pseudoephedrine, ephedrine, and phenylpropanolamine) products be implemented at once if a retailer does not wish to do so.

As a result of these concerns, some modifications have been made to the wording in the Compliance Bulletin to clarify the exact dates by which the requirements in the individual laws must be implemented. The revised Compliance Bulletin appears below:

COMPLIANCE BULLETIN 2006-001

April 10, 2006

As Revised May 10, 2006

Both the Ohio Legislature and Congress have recently enacted legislation to decrease the availability of products needed to illegally manufacture methamphetamine. Both laws place additional requirements on the sale of pseudoephedrine, while the federal law also addresses products containing ephedrine and phenylpropanolamine. Senate Bill 53 (SB53) was passed in Ohio and will become effective on May 17, 2006. House of Representatives Bill 3199 (HR3199) was passed federally and some portions of the bill become effective on April 8, 2006, and others on September 30, 2006. It is recommended that you review the complete language of both SB53 and HR3199¹. As you know, you must follow whichever portion of the state or federal law that is most restrictive.

In Ohio, most ephedrine-containing products are classified as schedule V controlled substances. Since the requirements in the newly enacted federal law are less restrictive than those for Schedule V substances, the new law does not change the way that these products are handled in Ohio. However, for those excepted ephedrine-containing products (listed in §3719.44(K) ORC and in Rule 4729-12-09 OAC), the restrictions listed below for pseudoephedrine now apply to these products as well.

A few years ago, the FDA asked manufacturers to voluntarily withdraw phenylpropanolamine products from the market. Since there are currently no phenylpropanolamine-containing OTC products available, the new federal law does not impose any additional requirements that pharmacists in Ohio need to follow at this time.

The following information should assist you to comply with both laws by outlining what we feel to be the most restrictive requirements from each of the laws:

- The OTC sales restrictions apply to ALL products containing pseudoephedrine, ephedrine, and phenylpropanolamine (**PEP products**). This includes combination products and liquid products. All non-liquid forms (including gel caps) must be packaged in blister packs and each blister pack must not contain more than two

dosage units. If the use of blister packs is technically infeasible, the product may be packaged in unit dose packages or pouches. [Effective 4-8-2006/HR3199]

- A retailer (includes a pharmacy or any other retail establishment) that sells these products must restrict direct access by customers (i.e. the products must be behind the counter or locked up, although the counter does not have to be the pharmacy counter). No member of the public may procure or purchase such products without the assistance of the retailer. [Effective 5-17-2006/SB53 for single entity pseudoephedrine (SEP) products; Effective 9-30-2006 for ALL PEP products]
- A person shall not purchase more than 9 grams of a PEP product base within a 30 day period. A retailer shall not sell more than 9 grams of SEP products to an individual within a 30 day time period. (The Board would expect that a retailer would not want to aid and abet the violation of this purchase restriction by knowingly selling more than 9 grams of a PEP product to an individual in a 30 day period.) [SEP products: Effective 5-17-2006/SB53; Other PEP products: Effective 4-8-2006]/HR3199].
- A retailer must not sell more than 3.6 grams of a PEP product base per day to any purchaser. [Effective 4-8-2006/HR3199]
- The purchaser of SEP products must be at least 18 years of age or have permission from a parent or guardian. [Effective 5-17-2006/SB53]
- The retailer must maintain a logbook documenting the date and time of each sale, and the name and quantity of the product sold. [Effective 5-17-2006/SB53 for SEP products; Effective 9-30-2006 for ALL PEP products]
- The purchaser must put the purchaser's signature, printed name, and valid address in the logbook and then must provide the retailer with a government-issued photo ID for proof of age and identity. [Effective 5-17-2006/SB53 for SEP products; Effective 9-30-2006 for ALL PEP products]
- Either by a sign posted in a conspicuous location or by printing on the cover of the logbook and on every page therein, the retailer must make the following statement available to all purchasers [Effective 5-17-2006/SB53]:

"Ohio law prohibits the over-the-counter purchase within any period of thirty consecutive days of more than nine grams of any consumer product in which pseudoephedrine is the only active ingredient. If you purchase a consumer product in which pseudoephedrine is the only active ingredient, you are required to sign a log book that may be accessible to law enforcement officers and to provide a government-issued identification card to verify your identity. Except in limited circumstances, the purchase within any period of thirty consecutive days of more than nine grams of any consumer product in which pseudoephedrine is the only active ingredient, and the purchase by any individual under eighteen years of age of any consumer product in which pseudoephedrine is the only active ingredient, are subject to criminal prosecution or delinquency proceedings in accordance with Ohio law. Also, the provision of false information concerning an individual's name, age, or other identification for the purpose of acquiring any consumer product in which pseudoephedrine is the only active ingredient is subject to criminal prosecution or delinquency proceedings in accordance with Ohio law."

- Information in the logbook must be maintained for two years from the date of the last purchase. [Effective 9-30-2006/HR3199]

- For privacy reasons, access to the logbook is restricted to a court order or subpoena or to a law enforcement official for law enforcement purposes.
- Self certification of each place of business where these products are sold, including documentation of the training of all persons involved in the sale of these products must be done after the U.S. Attorney General promulgates regulations to that effect. [Effective Date to be determined/HR3199]
- There are further restrictions on pseudoephedrine products sold by mail. Anyone planning to sell these products by mail is encouraged to review the law for details.
- The U.S. Attorney General may promulgate regulations that exempt products from compliance with the federal law. [HR3199]
- None of the above restrictions apply to a PEP product dispensed pursuant to a legitimate prescription.

If you have any questions, please call the Board office and we will try to assist.

1. The full text of SB53 can be found at: http://www.legislature.state.oh.us/bills.cfm?ID=126_SB_53.

2. The full text of H.R.3199 may be found by going to <http://thomas.loc.gov>. In the "Search Bill Text" box, enter H.R.3199 and click on "Search". Scroll down the page and select [H.R.3199.ENR] for the full text. For the specific section for PEP products, scroll down the page to "Title VII—Combat Methamphetamine Epidemic Act of 2005".

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