

Federal Limits on Pseudoephedrine-Containing Products

In March, Congress passed new requirements for the sale of all (single and multi-ingredient) pseudoephedrine and ephedrine-containing products. The new law (Public Law 109-177) places ephedrine, pseudoephedrine (PSE), and phenylpropanolamine in a new Controlled Substances Act (CSA) category of 'scheduled listed chemical products'. Drug products containing ephedrine, PSE, and phenylpropanolamine are subject to sales restrictions, storage requirements and record keeping requirements. Some of these requirements, which apply to all sellers of these products, go into effect by April 8th; others require compliance by September 30, 2006. If your state has more stringent requirements, the stronger requirements remain in place.

APhA has secured clarification from the DEA on two issues facing pharmacists as they work to implement the new law. First, DEA has clarified that the new law is intended to apply only to OTC sales of ephedrine, PSE, and phenylpropanolamine products and does not apply to prescriptions for such products.

Second, the law creates a daily sales limit (3.6 grams) and monthly purchase limit (9.0 grams) which go into effect April 8th. Additionally, the law establishes a requirement to maintain a logbook of sales, which must go into effect by September 30. The regulations needed to implement the logbook requirement have not yet been promulgated. These different effective dates create a challenge for pharmacists who might use the logbook in a good faith effort to hold purchasers to the 30-day limit.

The DEA understands and appreciates this challenge and suggests that pharmacists (and other sellers) make 'good faith efforts' to design and implement a system to track sales to enforce the 30-day purchase limit (9 grams at retail) until the logbook requirement (and accompanying regulations) are effective September 30.

Key 'Combat Meth Act' Implementation Dates

Effective April 8, 2006	
	3.6 gram daily sales limit
	9.0 gram 30-day purchase limit
	All non-liquid forms must be sold in blister packs or unit dose packets or pouches
	Mail-service pharmacy must verify patient's identification before shipping product
	Mail-service pharmacy 7.5 gram 30-day sales limit

[continued]

Effective by September 30, 2006	
	Products must be placed behind a counter or in a locked cabinet
	Seller must maintain a written or electronic logbook* which must identify: <ul style="list-style-type: none"> • the product name • the quantity sold • names and addresses of purchasers • dates and times of sales
	Purchasers must present a photo ID* and sign the logbook
	Sellers must self-certify to the U.S. Attorney General that their sales personnel have been trained as required by regulations (yet to be promulgated)
	7.5 gram 30-day sales limits for mobile sellers (such as kiosks in airports)
* Logbook and ID requirements do not apply to sales of 60 mg or less of pseudoephedrine.	

There are more changes on the horizon. Many of the requirements that go into effect by September 30th will require promulgation of regulations to address logbook and training requirements and ways to address privacy issues that could arise with the logbook. To keep up to date with these requirements, go to [APhA's Government Affairs website](#) and/or subscribe to APhA's Political Information Network (PIN) by sending an e-mail message to the APhA Government Affairs Department at gvtaff@APhAnet.org.