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.

Effective April 8, 2006	
	3.6 gram daily sales limit
	9.0 gram 30-day sales limit
	All non-liquid forms must be sold in blister packs (with a few exceptions)
	Mail-service pharmacy must verify patient's identification before shipping product
	Mail-service pharmacy 7.5 gram 30-day sales limit
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: • 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. Additionally, APhA is working to get confirmation from the DEA that the regulations do not apply to prescribed products, including prescribed over-the-counter products. 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.