

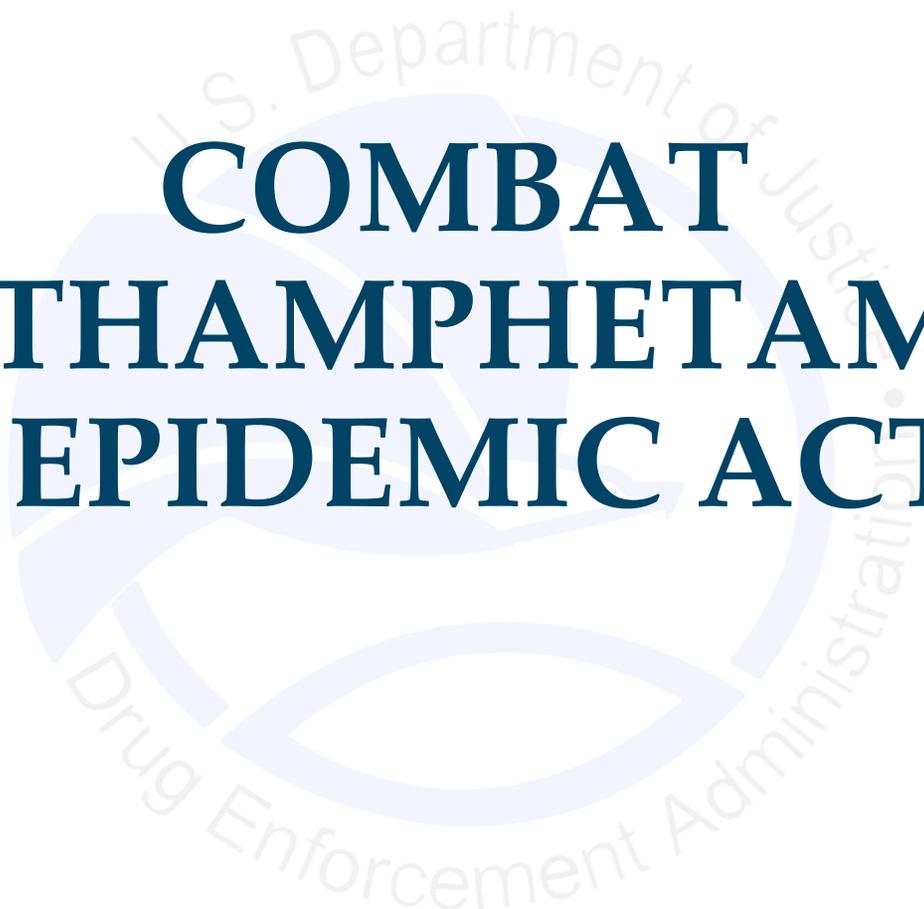
# COMBAT METHAMPHETAMINE EPIDEMIC ACT of 2005

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# **COMBAT METHAMPHETAMINE EPIDEMIC ACT**

# Combat Methamphetamine Epidemic Act

- **Title VII of USA Patriot Improvement and Reauthorization Act of 2005, March 2006 (Public Law 109-177)**
- **Purpose:**
  - To provide greater controls of OTC products containing ephedrine, pseudoephedrine, and phenylpropanolamine.
- **Retail Provisions became fully effective on September 30, 2006**

# CMEA: Key Definitions

## ● Scheduled Listed Chemical Product –

- Non-prescription drug containing ephedrine, pseudoephedrine, or phenylpropanolamine.

## ● Regulated Seller –

- Retail distributor (including pharmacy, or mobile retail vendor)
  - Does **not** include employee or agent.

## ● Mobile Retail Vendor –

- A person who makes retail sales from a temporary stand (kiosk) / cart –
  - Located in a shopping center / mall, **or**
  - Can be moved to different locations (i.e., an unimproved lot, or a field during an outdoor event).

# CMEA: Retail Provisions

## ● Who May Sell “Scheduled Listed Chemical Products”:

- Regulated Sellers
- Mobile Retail Vendors
- Mail Order Sellers

# Requirements for Regulated Sellers

- **Self-Certification**
- **Employee Training**
- **Maintain Records of Training**
- **Product Packaging (blister-packs)**
- **Product Placement**
- **Logbook (Manual or Electronic option)**
  - Logbook information disclosed only as permitted
- **Daily and 30-Day Sales/Purchase Limits**

# Self-Certification: Regulated Sellers

- **Must self-certify.**
  - May **not** sell any Scheduled Listed Chemical Product at retail unless their self-certification has been submitted to DEA.
- **Self-certification is location specific, not employee specific.**
- **Individual application is available online only on DEA Diversion website at [www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov)**

# Availability of Self-Certification Information

- **CMEA database containing self-certification records is available to state and local law enforcement agencies.**
- **This database is currently available only through FBI's Law Enforcement Online (LEO).**

# Employee Training

- **Regulated sellers must train employees who:**
  - Deliver scheduled listed chemical product to custody of purchasers, or
  - Who obtain payment for scheduled listed chemical product purchases.
- **Record of training must be maintained by the regulated seller.**
  - Record not required to be sent to Attorney General.

# Product Packaging and Placement

- **Non-liquid Scheduled Listed Chemical Products must be packaged in blister packs, each blister containing not more than 2 dosage units**
- **All Scheduled Listed Chemical Products (liquid, non-liquid, pediatric, gel caps, etc.) must be stored behind the counter, or in a locked cabinet.**

# Logbook Information

- Contains a written or electronic list of sales of Scheduled Listed Chemical Products.
- Seller **must** write, or enter in the logbook the name of the drug product and the quantity sold.
- Purchaser **must** write, or enter in the logbook their name and address, and the date and time of the sale.
- Purchaser **must** sign the logbook.
- Seller **must** maintain logbook two years from date of sale.

# Identification and Verification

- Purchasers **must** provide regulated seller photo identification issued by a State or the Federal government.
- If this identification not available, alternate forms of identification are permissible.
- Regulated sellers **must** verify that the purchaser's name on the ID corresponds to the name s/he wrote in logbook.
- Regulated sellers **must** verify that date and time of the sale that the purchaser entered in logbook are correct.

# Display of Warning Notice

- The “logbook” **must** contain a notice to purchasers that false statements or misrepresentations in the logbook is a criminal offense.
  - If not feasible to display notice within the logbook, the “notice” must be prominently displayed where purchasers will see it when purchasing Scheduled Listed Chemical Products.
    - Prominently displayed sign on the counter or wall, near the logbook.

# Warning Notice Text

- **WARNING:** Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than \$250,000 if an individual or \$500,000 if an organization, imprisoned not more than five years, or both.

# Exemption for 60-mg PSE Products

- Individual sales transactions in which purchaser purchases a single package containing not more than 60 mgs of pseudoephedrine\* (i.e., 1 x 60 mg tablet, or 2 x 30 mg tablets) are exempt from:
  - Logbook requirements.
  - Verification of identification.
    - **NOTE:** This does not apply to either ephedrine, or phenylpropanolamine drug products.

# Disclosure of Logbook Information

- **Logbook information shall be provided as appropriate to Attorney General and to State and local law enforcement.**
- **Law prohibits accessing, using or sharing information for any purpose other than to ensure compliance with Title 21, U.S. Code, or to facilitate product recall to protect public health and safety.**

# Daily Sales Limit

- Regulated sellers **cannot** sell more than 3.6 grams per day to each purchaser of Scheduled Listed Chemical Products, regardless of number of transactions.
- Daily sales limit per chemical.
- Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 grams.

# CMEA: Point-of-Sale Requirements

## ● Effective April 8, 2006:

- Daily sales limit 3.6 grams per day per customer.
- Non-liquids packaged in blister pack only – 2 dosage units / blister pack.

Ingredient	# of Tablets (base)
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77
120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.

# CMEA: Point-of-Sale Requirements

## ● Effective April 8, 2006:

- Daily sales limit 3.6 grams per day per customer.
- Liquid quantities.

Ingredient	# of Milliliters (base)
6.25 mg / 5 ml Ephedrine HCl	3,515
15 mg / 1.6 ml Pseudoephedrine HCl	468
7.5 mg / 5 ml Pseudoephedrine HCl	2,929
15 mg / 5 ml Pseudoephedrine HCl	1,464
15 mg / 2.5 ml Pseudoephedrine HCl	732
30 mg / 5 ml Pseudoephedrine HCl	732
30 mg / 2.5 ml Pseudoephedrine HCl	366
60 mg / 5 ml Pseudoephedrine HCl	366
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.

# Mail Order Distributors

## ● Requirements:

- Verify identification prior to shipping product,
- Monthly mail order reports,
- Daily sales limit of 3.6 grams, and
- 30-day sales limit of 7.5 grams.

## ● Not Required:

- Self-certification,
- Employee training, and
- Maintain a logbook.

# Verification of Identities

- Mail order distributors **must** verify identity of purchasers and recipients (*if different than purchaser*), prior to shipping product.
- Identity verified by purchaser providing copy of ID to mail order distributor prior to shipment of product.
  - Law / regulations do not stipulate how ID must be provided. Some examples, include:
    - Mailing,
    - Faxing, and
    - Scanning and e-mailing.

# Monthly Mail Order Report

- **Mail order distributors must file monthly mail order reports regarding their sales of Scheduled Listed Chemical Products.**
  - Reporting requirement same as before, **except** must now specify method used to verify identity of purchaser and, where applicable, recipient.

# Mail Order Sales Limits

## ● Daily Limit:

- 3.6 gram per purchaser regardless of the number of transactions.

## ● 30-Day Limit:

- 7.5 grams per purchaser regardless of the number of transactions.
- 30-day sales limit per chemical product.

- **Refer to the charts on the next two slides for the amount of tablets or liquids that equals 3.6 and 7.5 grams.**

# CMEA: Mail-Order Sales (*tablets*)

- Daily sales limit 3.6 grams per day per customer.
- 30-day sales limit 7.5 grams per customer.
- Confirm identity of purchaser prior to shipping.

Ingredient	Tablets (3.6 gm)(base)	Tablets (7.5 gm)(base)
25 mg Ephedrine HCl	175	366
25 mg Ephedrine Sulfate	186	389
30 mg Pseudoephedrine HCl	146	305
60 mg Pseudoephedrine HCl	73	152
120 mg Pseudoephedrine HCl	36	76
30 mg Pseudoephedrine Sulfate	155	324
60 mg Pseudoephedrine Sulfate	77	162
120 mg Pseudoephedrine Sulfate	38	81
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

# CMEA: Mail-Order Sales (*liquid*)

- Daily sales limit 3.6 grams per day per customer.
- 30-day sales limit 7.5 grams per customer.
- Confirm identity of purchaser prior to shipping.

Ingredient	# of Milliliters (3.6 gm)(base)	# of Milliliters (7.5 gm)(base)
6.25 mg / 5 ml Ephedrine HCl	3,515	7,323
15 mg / 1.6 ml Pseudoephedrine HCl	468	976
7.5 mg / 5 ml Pseudoephedrine HCl	2,929	6,103
15 mg / 5 ml Pseudoephedrine HCl	1,464	3,051
15 mg / 2.5 ml Pseudoephedrine HCl	732	1,525
30 mg / 5 ml Pseudoephedrine HCl	732	1,525
30 mg / 2.5 ml Pseudoephedrine HCl	366	762
60 mg / 5 ml Pseudoephedrine HCl	366	762
Phenylpropanolamine	FDA issued a voluntary recall on this ingredient. Veterinary use is by Rx only.	

# Penalties for Sellers

- First time offense subject to imprisonment **not more than one year**, a fine under Title 18, or both.
- Repeat violation (one or more prior convictions), subject to imprisonment **not more than two years**, a fine under Title 18, or both.
- A person who sells a scheduled listed chemical product at retail without being self-certified is subject to civil penalties **up to \$10,000 per count**.
- Prohibition of sales of product.

# Penalties for Purchasers

- Offenders are subject to imprisonment **not more than one year** and fines in accordance with Title 18.

# Additional CMEA Rules

- **Assessment of Annual Need**

- First time assessment of eph, pseudo, and ppa needed for legitimate use
  - IMS hired to conduct study
- Initial publication in Federal Register on 10/19/06, comment period ended 12/04/06

- **Proposed quotas (kgs)**

➤ Ephedrine (for sale)	7,100 kg
➤ Ephedrine (for conversion)	128,760 kg
➤ Pseudoephedrine (for sale)	511,100 kg
➤ Phenylpropanolamine (for sale)	5,545 kg
➤ Phenylpropanolamine (for conversion)	6,240 kg

- **Final Rule circulating for review and signature**

# Additional CMEA Rules

- **Import and Production Quotas for Certain List I Chemicals**
  - Requires that eph, pseudo, and ppa be subject to production quota provisions for schedules I and II controlled substances
  - Establishes new requirements for import quotas for these three list I chemicals
  - Published and effective 7/10/07
  - Currently accepting quota applications for 2008
    - **Must be registered with DEA to apply for quota**

# Additional CMEA Rules

- **Record Requirements for Chemical Distributors**
  - Proposes to require that manufacturers, Importers, and distributors who distribute scheduled listed chemical products to regulated sellers maintain, as part of their records, the self-certification number of the regulated seller.
  - **Current Status: Cleared to publish, 8/10/2007. Circulating within DEA for signature.**

# Additional CMEA Rules

- **Notice of Transfer following Importation or Exportation**
  - Implements the “spot market” provisions of CMEA.
  - Importers, exporters, required to provide DEA with information on “down stream” customer and the amount to be transferred
  - Return declaration required once the importation, exportation, or international transaction has occurred.
  - Published on 4/9/2007. Rule became effective on 6/9/2007.

# Additional CMEA Rules

- **Self-Certification Fee for Regulated Sellers**
  - This rulemaking proposes to impose a fee for self-certification of regulated sellers of scheduled listed chemical products, based on DEA's costs for operation of this aspect of the Diversion Control Program.
  - **Current Status: Cleared to publish on 8/7/2007. Circulating within DEA for signature**



*Questions?*