

# Regulatory Update

17<sup>th</sup> National Conference on Drug & Chemical Diversion

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# Combat Methamphetamine Epidemic Act of 2005

# Combat Methamphetamine Act Update - Enacted Provisions

- **Retail Provisions**
  - **Effective September 2006**
- **Spot Market**
  - **Effective June 2007**
- **Import and Production Quotas**
  - **Effective July 2007**
- **Elimination of Chemical Mixtures – Eph, Pse**
  - **Effective July 2007**
- **Assessment of Annual Need**
  - **Effective December 2007**

# Combat Methamphetamine Act Update - Pending Provisions

- **Self Certification Fee**
  - Proposed October 2007
- **Removal of Thresholds for PSE, PPA**
  - Proposed November 2007
- **Record Requirements for Chemical Dist.**
  - Proposed September 2007
- **Registration Requirements for Imp & Man of RX drugs containing Eph, Pse, & Ppa**
  - Proposed January 2008
- **Foreign Chain of Distribution**
  - Proposed May 2008

# Assessment of Annual Need 2008

Update as of 4/15/2008

<b>Chemical</b>	<b>2008 Assessment (kgs)</b>	<b># of Applicants</b>	<b>Amount Requested (kgs)</b>	<b>Amount Issued (kgs)</b>
<b>Eph (for sale)</b>	<b>11,500</b>	<b>11</b>	<b>18,111</b>	<b>1,167</b>
<b>Eph (for conversion)</b>	<b>128,760</b>	<b>2</b>	<b>142,557</b>	<b>69,069</b>
<b>Pse (for sale)</b>	<b>511,100</b>	<b>19</b>	<b>422,417</b>	<b>106,270</b>
<b>Ppa (for sale)</b>	<b>5,545</b>	<b>4</b>	<b>4,489</b>	<b>142</b>
<b>Ppa (for conversion)</b>	<b>85,470</b>	<b>4</b>	<b>52,539</b>	<b>14,577</b>



# Finalized Rules

# Iodine

- **Moved Iodine from a List II chemical to List I**
- **Increased controls for iodine and mixtures containing more than 2.2 percent iodine**
- **Reduced thresholds for regulated transactions to zero**
- **Added registration, import, export, and other regulatory controls**
- **Final Rule effective in August 2007**
- **Temporary registration exemption if apply before August 31, 2007**

# Multiple CII Prescription Rule

- **Permit practitioners to issue multiple prescriptions for C II substances to allow patients up to a 90-day supply.**
- **Provide greater control to physicians for prescribing schedule II controlled substances.**
- **Effective in December 2007**



# Authorized Sources of Narcotic Raw Materials

- **United States does not cultivate or produce NRM**
- **NRM can be imported only from seven countries**
  - **80 percent from traditional suppliers (India and Turkey)**
  - **20 percent from non-traditional suppliers (France, Poland, Hungary, Australia and Yugoslavia)**
- **Amends the list of non-traditional countries authorized to export NRM to the United States**
- **Removes Yugoslavia and adds Spain**
- **Effective March 2008**

# Changes to Patient Limits for OBT Practitioners

- **Conforms regulations to August 2005 amendment to CSA**
- **Changes the limit from 30 to 100 patients to prescribe for addiction treatment by a qualified practitioner**
- **To qualify to treat additional patients, a practitioner may start not sooner than one year after initial notification to HHS**
- **Effective on June 23, 2008**



# Pending Rules

# Single Sheet DEA Form 222

- **Permit practitioners to issue multiple prescriptions for C II substances to allow patients up to a 90-day supply.**
- **Provide greater control to physicians for prescribing Schedule II medications.**
- **Rule published as NPRM in November 2007. Currently being finalized.**
- **Four comments to rule:**
  - **1 positive, 2 negative, 1 question**

# Electronic Prescribing of Controlled Substances

- **Proposal to allow electronic prescribing of schedules II-V controlled substances**
- **NPRM accepted by the Office of Management and Budget on 2/13/2008.**
- **Currently under review at OMB**

A large, light blue watermark of the Drug Enforcement Administration (DEA) logo is centered in the background. The logo features a circular border with the text "U.S. Department of Justice" at the top and "Drug Enforcement Administration" at the bottom. In the center of the circle is a stylized eagle with its wings spread, perched on a banner.

***Questions?***