



U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Regulatory Update

15th National Conference on Drug & Chemical Diversion
June 6-8, 2006
Houston, TX

*Mark W. Caverly, Chief
Liaison and Policy Section
Office of Diversion Control*

Combat Methamphetamine Epidemic Act of 2005

- Drafting Implementation Regulations:
 - Retail provisions
 - Quota provisions
 - Import provisions
 - “Spot market” provisions

Electronic Prescriptions for Controlled Substances

- Notice of Proposed Rulemaking
- Would permit use of digital signature technology and public key infrastructure to sign controlled substance prescriptions
- Would be electronic equivalent of written manually signed prescription

Electronic Prescriptions for Controlled Substances

- Notice of Proposed Rulemaking submitted to Office of Management and Budget for review, September 29, 2004
- In late December, 2004, withdrawn from OMB consideration due to concerns expressed by Department of Health and Human Services

Electronic Prescriptions for Controlled Substances

- To permit DEA and HHS to hear, jointly, from all interested parties, DEA, in conjunction with HHS will hold public meeting
- Meeting will allow prescribers, pharmacies, software/hardware vendors, and other interested parties to address how electronic prescribing systems can meet DEA prescription requirements under the Controlled Substances Act, without unduly burdening the parties to the prescribing transaction
- July 11-12, 2006, Crystal City Marriott, Arlington, VA

Controlled Substances Ordering System (CSOS)

- Final Rule April 1, 2005 (70 FR 16901)
- Effective May 31, 2005
- Permits use of digital signature technology and public key infrastructure to sign controlled substances orders
- If Schedule I and II orders electronic, must use; optional for Schedule III-V
- CSOS optional, may still use DEA Form 222

Controlled Substances Ordering System

- Performance standards: Authentication, non-repudiation, record integrity
- DEA serves as Certification Authority (CA)
- Digital certificate serves as electronic equivalent to DEA Form 222
- Digital certificate contains all registrant information preprinted on DEA Form 222

Controlled Substances Ordering System

- Electronic orders have same legal status as orders on DEA Form 222
- Some State laws specify “DEA Form 222”
- Use of electronic orders satisfies requirement
- State laws/regulations specifically referencing “DEA Form 222” will need to be updated

Diversion Control Fee Account

- 1993 Appropriations Act directed DEA to set registration fees “at a level that ensures the recovery of the full costs of operating the various aspects of that [Diversion Control] program.”
 - Congress did not define the activities constituting the Diversion Control Program (DCP)
- Fees became the direct funding mechanism for DCP
 - DEA fee-funds all diversion control activities that historically had been part of the DCP since 1971, with the exception of chemical control activities

DCFA New Legislation

- Appropriations Act of 2005 (P.L. 108-477) clarifies definition of DCP to include “activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals.”
 - Requires that DEA fully fund all of these DCP activities through fees and that reimbursements from the DCFA be made without distinguishing between controlled substances expenses and chemical expenses

DCFA NPRM

- November 16, 2005 (70 FR 69474)
- Incorporated changes in 2005 Appropriations Act to clarify activities to be funded through DCFA to include all activities related to the registration and control of the manufacture, distribution, importation and exportation of listed chemicals and controlled substances
 - Identified DCP activities across DEA, removing focus on business decision unit following internal DEA re-organization to increase efficiencies
- Would fully fund DCP through registration fees paid by manufacturers, distributors, importers, exporters, and dispensers of controlled substances and List I chemicals

Reexportation of Controlled Substances

- Controlled Substances Export Reform Act of 2005 provides authority for Attorney General to authorize export of controlled substances from United States to another country for subsequent export to a second country for consumption
- Schedules I, II, narcotic controlled substances in Schedules III, IV
- DEA drafting regulations to implement
- Until regulations finalized, reexportation is not permitted

Reports by Registrants of Theft/Significant Loss of Controlled Substances

- Final Rule August 12, 2005 (70 FR 47094)
- Effective September 12, 2005
- Initial report must be filed, in writing, within one business day
- DEA Form 106, Report of Theft or Significant Loss filed once circumstances surrounding theft/significant loss clear
- Listed factors to be considered in determining whether loss is significant

Questions?