

# Legal Requirements and Policy for Controlled Substances

Prepared for

FDA Regulatory Processes and Standards  
for the Review and Approval of Opioid Analgesics Forum



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# Office of Diversion Control Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources



*while*

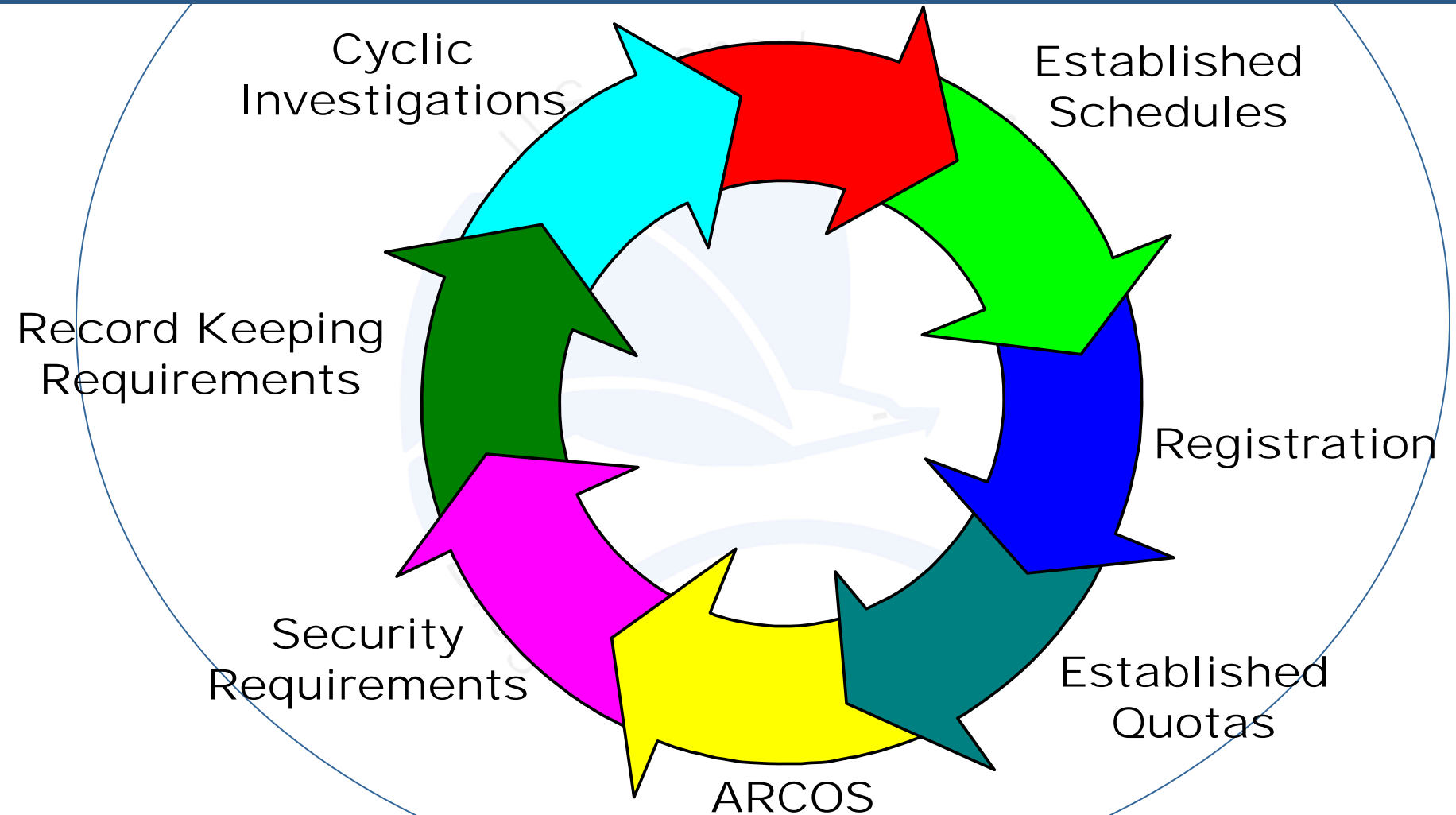


Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

# Controlled Substances Act of 1970

- System for U.S. compliance with international treaties.
- Legal foundation of the Federal government's authority over controlled substances and listed chemicals.
- Consolidated over 50 laws regulating the manufacture, distribution, import / export, and dispensing of controlled substances and listed chemicals.

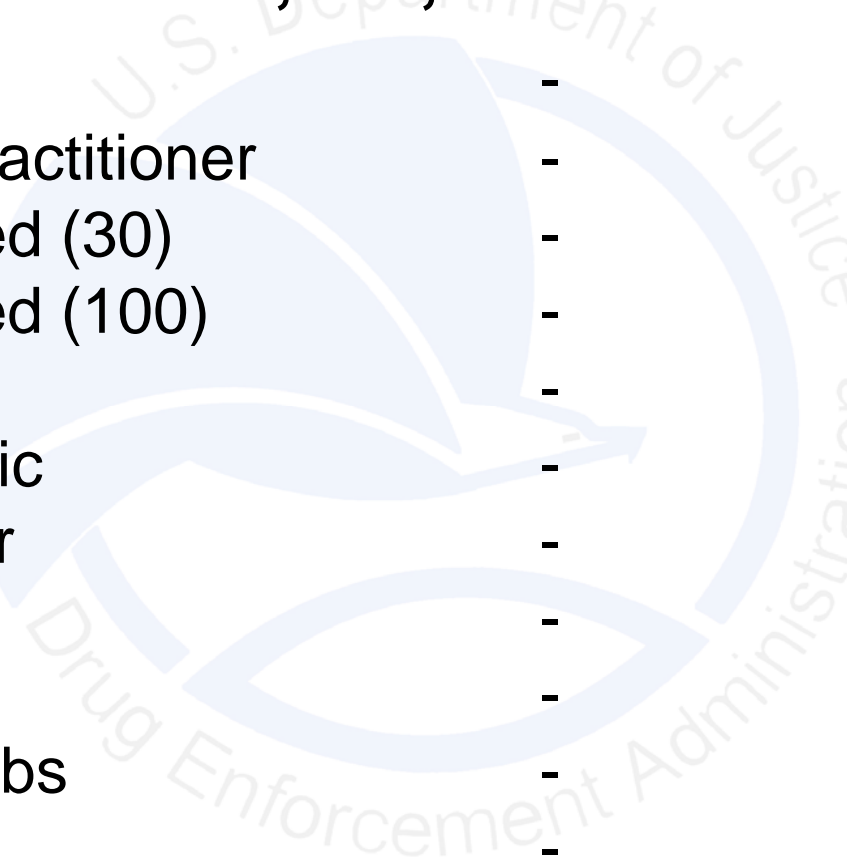
# The CSA's Closed System of Distribution



# CSA Registrant Population

as of 1/12/2009

## Total Population: 1,320,306



• Practitioner	-	1,063,806
• Mid-Level Practitioner	-	158,346
• DATA-Waived (30)	-	12,970
• DATA-Waived (100)	-	2,693
• Pharmacy	-	66,776
• Hospital/Clinic	-	16,343
• Manufacturer	-	507
• Distributor	-	830
• Researcher	-	6,261
• Analytical Labs	-	1,448
• NTP	-	1,254

# Prescription Requirements

In order to be legal, a prescription must:

- Be issued by a registered practitioner
- For a legitimate medical purpose
- In the usual course of professional practice



**21 CFR §1306.04(a)**

# Prescription Requirements

- DEA does not define or regulate medical practice standards.
- There are no federal laws or regulations that puts limits on the quantity of controlled substances that may be prescribed.
- Some states or insurance providers may limit the quantities of controlled substances prescribed or dispensed.

# CSA and CFR Citations

- Prescription must be for legitimate medical purpose by a practitioner acting in usual course of professional practice. 21 CFR § 1306.04 (a)
- Practitioners are not limited in their ability to prescribe, administer, or dispense narcotics to persons with intractable pain. 21 CFR §1306.07 (c)
- Corresponding responsibility rests with the pharmacist who fills the prescription. 21 CFR § 1306.04 (a)



# Pain Management DEA's Policy Statement

## Dispensing Controlled Substances for the Treatment of Pain

- Policy Statement published 09/06/2006.
- Reiterates DEA policy to prevent abuse and diversion without adversely impacting the legitimate need of patients to have full access to pain relief prescribed by their physician.

# Pain Management DEA's Policy Statement

## Dispensing Controlled Substances for the Treatment of Pain

- To reassure physicians that DEA does not apply a greater scrutiny to the prescribing of controlled substances to treat pain.
- Discussed the phrase “legitimate medical purpose”.
- Addressed requests for a guidance document on treating patients for pain.

# NFLIS 2007 Data

- National Forensic Laboratory Information System
- Nation-wide partnership with state and local forensic laboratories
  - Database of drug intelligence
- For Calendar year there were 1,472,625 drug items analyzed

# NFLIS National Data - 2007

## Narcotic Analgesics

	Number	Percent
<b>Hydrocodone</b>	<b>30,504</b>	<b>39.66%</b>
<b>Oxycodone</b>	<b>24,029</b>	<b>31.24%</b>
<b>Methadone</b>	<b>7,496</b>	<b>9.75%</b>
<b>Morphine</b>	<b>4,202</b>	<b>5.46%</b>
<b>Codeine</b>	<b>2,674</b>	<b>3.48%</b>
<b>Buprenorphine</b>	<b>2,094</b>	<b>2.72%</b>
<b>Hydromorphone</b>	<b>1,559</b>	<b>2.03%</b>
<b>Propoxyphene</b>	<b>1,306</b>	<b>1.70%</b>
<b>Dihydrocodeine</b>	<b>957</b>	<b>1.24%</b>

# NFLIS National Data - 2007

## Benzodiazepines

	Number	Percent
<b>Alprazolam</b>	<b>29,187</b>	<b>65.86%</b>
<b>Clonazepam</b>	<b>7,015</b>	<b>15.83%</b>
<b>Diazepam</b>	<b>6,110</b>	<b>13.79%</b>
<b>Lorazepam</b>	<b>1,527</b>	<b>3.45%</b>
<b>Temazepam</b>	<b>307</b>	<b>0.69%</b>
<b>Chlordiazepoxide</b>	<b>88</b>	<b>0.20%</b>
<b>Triazolam</b>	<b>50</b>	<b>0.11%</b>
<b>Flunitrazepam</b>	<b>24</b>	<b>0.05%</b>
<b>Midazolam</b>	<b>9</b>	<b>0.02%</b>

# Electronic Prescriptions for Controlled Substances

- NPRM Published on June 27, 2008 in the Federal Register
- Proposal to provide DEA registered practitioners and pharmacies with the ability to electronically create, transmit, receive, and archive C II-V controlled substance prescriptions
- An addition to, not a replacement of, the current system of prescribing
- Comment period ended on September 25, 2008  
More than 230 comments received

# DEA Diversion Website

The screenshot shows the homepage of the DEA Office of Diversion Control. At the top, it features the U.S. Department of Justice Drug Enforcement Administration logo and the text "OFFICE OF DIVERSION CONTROL". Below this is a navigation bar with links for HOME, PRIVACY POLICY, CONTACT US, WHAT'S NEW, HOT ITEMS, SITEMAP, and SEARCH. The main content area is divided into three columns. The left column contains a "DIVERSION PROGRAMS" section with links to APPLICATIONS & ON-LINE FORMS, ARCOS, CHEMICALS, CONTROLLED SUBSTANCE SCHEDULES, IMPORT AND EXPORT, IFLIS, QUOTAS, REGISTRATION SUPPORT, and REPORTS REQUIRED BY 21 CFR. Below this is a "RESOURCES" section with links to CAREER OPPORTUNITIES, DRUGS/CHEMICALS OF CONCERN, e-COMMERCE INITIATIVES, FEDERAL REGISTER NOTICES, MEETINGS & EVENTS, OFFICES & DIRECTORIES, PROGRAM DESCRIPTION, PUBLICATIONS, QUESTIONS & ANSWERS, and REGULATIONS & CODIFIED CSA. The bottom of the left column has a "LINKS" section with links to FEDERAL AGENCIES & RELATED, INDUSTRY RELATED, and PUBLIC INTEREST. The middle column features a "WELCOME TO THE DIVERSION CONTROL PROGRAM" section with the registration number and toll-free number. Below this is a "REGISTRATION SUPPORT" section with a "SAVE TIME" graphic and text explaining the benefits of on-line registration. The right column contains several promotional boxes: "RENEWAL Apply On-Line REGISTRATION APPLICATIONS", "NEW APPLICATIONS FOR REGISTRATION New Registration Applications", "DEA FORM 106 ONLINE REPORT THEFT OR LOSS OF CONTROLLED SUBSTANCES", and "Sales of Ephedrine & Pseudoephedrine Products COMBAT METH ACT 2005 Combat Methamphetamine Epidemic Act 2005". A "WHAT'S NEW" section at the bottom of the middle column lists updates for registration matters and provides the toll-free number 1-800-882-9539.

For Additional Information

[www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov) or  
[www.dea.gov](http://www.dea.gov)

# Thank You

