

Drug Enforcement Administration Policy Update

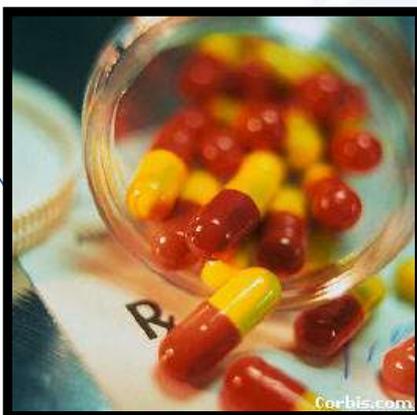
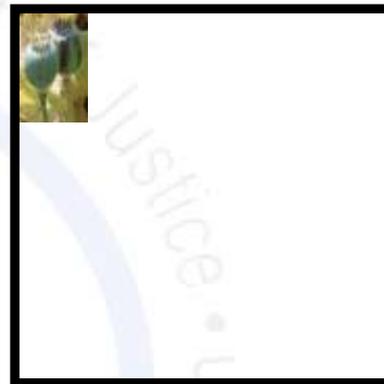
14th DEA Pharmaceutical Industry Conference
Portland, Oregon
October 14-15, 2009



*Cathy A. Gallagher, Associate Chief
Liaison and Policy Section*

DEA 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



DEA Registrant Population & Online Tool

CSA Registrant Population

**Current Number of
DEA Registrants**

1,320,889

09/12/2009

**Provisional registrations
in effect at the time CSA
was passed (relative to
the Harrison Narcotics
Act of 1914)**

480,000

1973

CSA Registrant Population as of 9/12/2009

Total Population: 1,320,889

• Practitioner	-	1,035,285
• Mid-Level Practitioner	-	162,839
• Pharmacy (all)	-	64,903
• Pharmacy (chain)	-	35,458
• Hospital/Clinic	-	15,521
• Manufacturer	-	446
• Distributor	-	792
• Reverse Distributor	-	48
• Researcher	-	5,830
• NTP	-	1,136
• DATA Waived Practitioner (30)	-	14,042
• DATA Waived Practitioner (100)-	-	3,036



U.S. DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

OFFICE OF DIVERSION CONTROL

HOME PRIVACY POLICY CONTACT US WHAT'S NEW HOT ITEMS SITEMAP SEARCH

DIVERSION PROGRAMS

- APPLICATIONS & ON-LINE FORMS
- ARCOS
- CHEMICALS
- CONTROLLED SUBSTANCE SCHEDULES
- CSOS
- IMPORT AND EXPORT
- NFLIS
- QUOTAS
- REGISTRATION SUPPORT
- REPORTS REQUIRED BY 21 CFR

RESOURCES

- CAREER OPPORTUNITIES
- DEA MAILING ADDRESSES
- DRUGS/CHEMICALS OF CONCERN
- e-COMMERCE INITIATIVES
- FEDERAL REGISTER NOTICES
- MEETINGS & EVENTS
- OFFICES & DIRECTORIES
- PROGRAM DESCRIPTION
- PUBLICATIONS
- QUESTIONS & ANSWERS
- REGULATIONS & CODIFIED CSA

Drug Registration > Registrant Population

Registrant Population

- **Registrant Population - Summary**
- Active Registrants by State
- Active Registrants by Business Activity
- Active Chemical Handler Registrants



[Drug Registration](#) > [Registrant Population](#) > [Summary Report](#)

Registrant Population - Summary

Total Registrants

You must select a cycle and click the "View" button to insure you are viewing accurate figures for the selected cycle.

SELECT CYCLE:

08 - 2009

Retail Level (RL) Registrants	1,309,031	*Chemical Handlers	1,267
Wholesale Level (WL) Registrants	12,821		
TOTAL	1,321,852		

* Chemical Handler Registrants are not included in Controlled Substance Act Registrant Totals
[View Active Chemical Handler Registrant Statistics](#)

RETAIL LEVEL		WHOLESALE LEVEL	
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RETAIL LEVEL		WHOLESALE LEVEL	
Retail Pharmacy	65,200	Manufacturer	511
Hospital/Clinic	15,594	Distributor	781
Practitioner	1,065,028	Researcher	8,346
Teaching Institute	375	Analytical Labs	1,480
Mid-Level Practitioner	162,834	Importer	191
		Exporter	234
		Reverse Distributor	47
		Narcotic Treatment Program	1,231

STATE	RETAIL LEVEL	WHOLESALE LEVEL
ALABAMA	15,176	120
ALASKA	3,650	28



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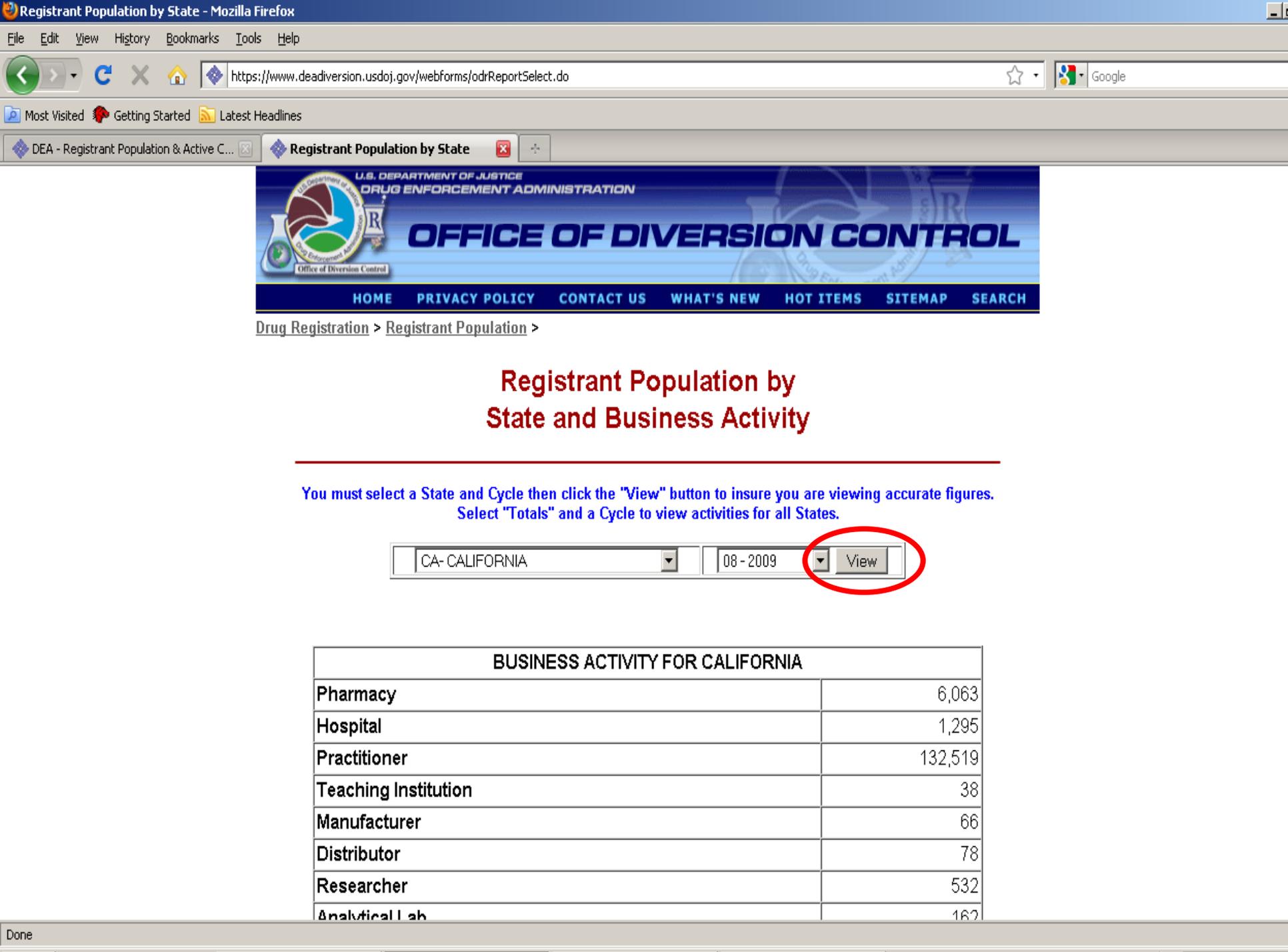
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Drug Registration > Registrant Population

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[Drug Registration](#) > [Registrant Population](#) >

Registrant Population by State and Business Activity

You must select a State and Cycle then click the "View" button to insure you are viewing accurate figures. Select "Totals" and a Cycle to view activities for all States.

CA-CALIFORNIA 08 - 2009 **View**

BUSINESS ACTIVITY FOR CALIFORNIA	
Pharmacy	6,063
Hospital	1,295
Practitioner	132,519
Teaching Institution	38
Manufacturer	66
Distributor	78
Researcher	532
Analytical Lab	162



U.S. DEPARTMENT OF JUSTICE
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[Drug Registration](#) > [Registrant Population](#)

Registrant Population by Business Activity

You must select a Business Activity and Cycle then click the "View" button to insure you are viewing accurate figures for the selected cycle.

<p style="text-align: center;">Select Business Activity:</p> <div style="border: 1px solid black; padding: 2px;">Pharmacy (A) ▼</div>	<p style="text-align: center;">Select Cycle:</p> <div style="border: 1px solid black; padding: 2px;">08 - 2009 ▼ View</div>
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BUSINESS ACTIVITY	
Pharmacy (A)	
ALABAMA	1,320
ALASKA	101
AMERICA SAMOA	0
ARIZONA	1,080
ARKANSAS	758
CALIFORNIA	2,888

Electronic Prescriptions for Controlled Substances



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.

Electronic Prescriptions for Controlled Substances

- Comment period ended 9/25/08. More than 230 comments received.
- Processes and procedures proposed include:
 - Initial identity verification
 - Two-factor authentication
 - Use of HHS transmission standards
 - No alteration of prescription during transmission

Electronic Prescriptions for Controlled Substances

- Final Rule has been drafted with HHS.
- Informal interagency review completed.
 - HHS, GSA, VA, NIST
- Next steps – DOJ review, submission to OMB.
- OMB has 90 days to review prior to publication in the Federal Register.

Disposal of Controlled Substances



CSA Definitions

- An “ultimate user” is a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or by a member of his household.
- To distribute means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical.

21 U.S.C. 802

Registration Requirement

- Ultimate users are not permitted to distribute controlled substances without being separately registered.
- Because of registration requirement, it is unlawful for ultimate users to give their controlled substances to pharmacies, reverse distributors, etc. for destruction.

Controlled Substance Waste

Proper Disposal

- DEA does not specify the manner of destruction.
- “Waste” not defined in CSA.
- No distinction between expired, contaminated controlled substances and saleable product.
- Accountability required of all controlled substances.

ANPRM Ultimate User Disposal

- ANPRM published on January 21, 2009 in the Federal Register.
- Entitled *Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration*.
- Seeks options for the safe and responsible disposal of patient owned controlled substances consistent with CSA.
- Comment period ended March 23, 2009.

ANPRM Ultimate User Disposal

- Solicited information on the disposal of cs dispensed to ultimate user from:
 - ✓ ultimate users
 - ✓ law enforcement
 - ✓ interest groups
 - ✓ long-term care facilities
 - ✓ hospices and in-home care groups
 - ✓ pharmacies
 - ✓ reverse distributors
 - ✓ state regulatory agencies
 - ✓ other interested parties

158 Comments Received

ONDCP Guidelines

- ONDCP guidelines for the disposal of ultimate user medications, including dispensed controlled substances (Feb. 20, 2007).
- Advise public to flush medications only if the prescription label or accompanying patient information specifically states to do so.
- ONDCP recommends a minimal deactivation procedure, and disposal in common household trash.

Law Enforcement Involvement

- Law enforcement officers, acting to enforce laws regarding controlled substances, may receive controlled substances from ultimate users.
- Must safeguard the controlled substances and ensure that they are destroyed properly.
- Law enforcement must be present during the destruction of the controlled substances.

Safe Disposal Act of 2009

- House Resolution 1191
 - Introduced on 2/25/2009 by Rep Inslee (WA)
 - Amend the CSA to allow states to operate disposal programs
 - Direct the Attorney General to create 5 models for implementation
- Companion Senate Bill 1336
 - Introduced on 6/24/2009 by Sen Murray (WA)

Secure and Responsible Drug Disposal Act of 2009

- House Resolution 1359
 - Introduced on 3/5/2009 by Rep. Stupak (MI)
 - Amend the CSA to permit ultimate user to deliver drugs for destruction
 - Grants the Attorney General discretion to promulgate regulations
- Companion Senate Bill 1292
 - Introduced on 6/18/2009 by Sen Klobuchar (MN) and Sen Grassley (IA)

Bring your OLD PILLS to
any INGLES for
Free Disposal!



OPERATION PILL



FOR INFO contact
Sheriff Holland
(829) 319-2152

Saturday April 18, 2009 10 a.m. till 2 p.m.

REMEMBER



Internet Legislation & Implementing Regulations

An Internet Pharmacy

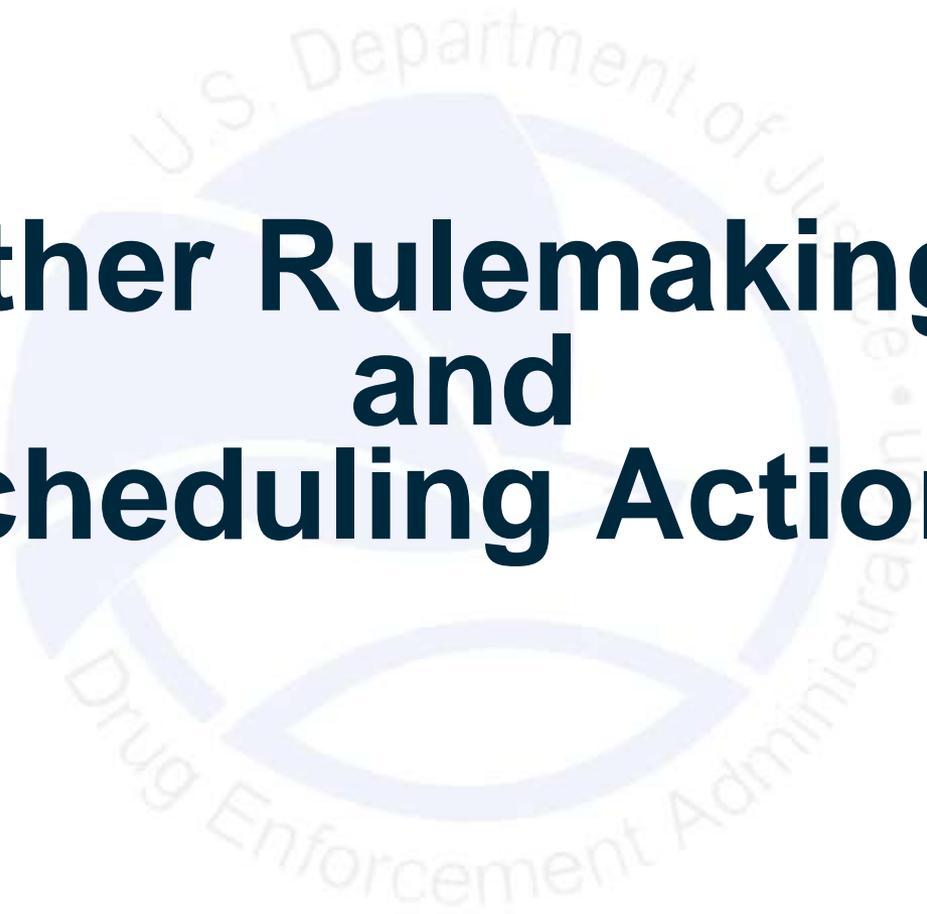


Ryan Haight Online Pharmacy Consumer Protection Act

- Amends the CSA adding new provisions to prevent the illegal distribution of controlled substances by Internet.
- Enacted on 10/15/08, effective on 4/13/09.
- As of 9/8/2009, only 6 pharmacies had requested modification to online pharmacy.

Ryan Haight Online Pharmacy Consumer Protection Act

- New DEA registration requirements for all Internet pharmacies
 - Modification of existing Retail Pharmacy registration
- Reporting requirements
 - Monthly basis
 - All controlled substances dispensed (total of each)
 - Thresholds
 - 100 or more cs prescriptions
 - 5,000 or more total dosage units
- Disclosure requirements on home page
 - Identify servicing pharmacies, pharmacist in charge, and physicians



Other Rulemakings and Scheduling Actions

DEA Registration Suffix

Identification of Institution-Based Practitioners

- Notice of Proposed Rulemaking published September 9, 2009.
- Seeks comments regarding standardizing suffix numbers issued to staff using the facility's DEA registration.
- Comment to E-prescribing NPRM.
- Comment period closes November 9, 2009.

Locum Tenens Practitioners Registration Requirements

Advanced Notice of Proposed Rulemaking

- CSA requires separate DEA registration for each principal place of business.
 - Limited exception provided for multiple locations within one state
- No CSA or CFR definition of locum tenens.
- Seeks industry input into current business practices.
- Cleared to publish.



Agent of a Practitioner in the Long Term Care Setting

Agent of a Practitioner LTCF Setting

- **CSA Definition:**

The term “agent” means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser . . . 21 USC 802 (3).

- **“Agent” is not defined in the CFR.**

Agent of a Practitioner LTCF Setting

- Federal Register Notice: April 25, 2001
“Preventing the Accumulation of Surplus Controlled Substances at Long Term Care Facilities.”

*However, a pharmacist may only fill an order issued by a physician and communicated by the physician or the physician’s agent. **Since no legal agency relationship exists between the LTCF nurse and the physician, this widely-used system is not in compliance with legal requirements.***

Agent of a Practitioner LTCF Setting

CII Prescriptions:

- Must be written except in emergency situations, [21 USC 829 (a)]
 - May be transmitted by fax for residents of a LTCF

CIII – V Prescriptions:

- May be written or oral [21 CFR 1306.21]

Comments / Questions?

