

Prescription Drug Abuse and NASPER
19th National Conference on Pharmaceutical & Chemical Diversion
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Overview

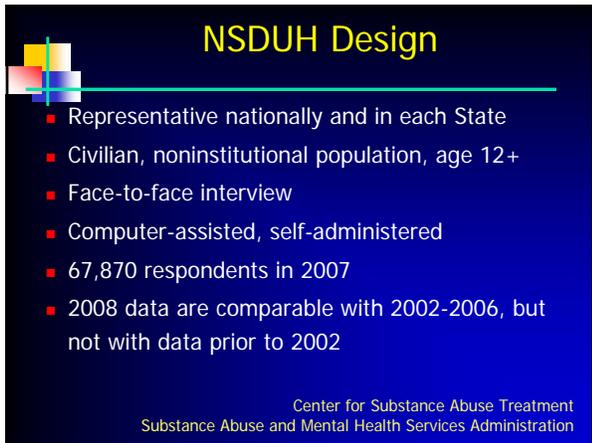
- National Survey Trends –Rx Drug Abuse
- Rx Drug Mortality
- Rx Drug Costs
- NASPER – Rx Monitoring Programs

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Is prescription drug abuse a problem?

- National Survey on Drug Use and Health – NSDUH, formerly national household survey.
- Drug Abuse Warning Network – DAWN
 - Emergency Department
 - Medical Examiner
- Monitoring the Future

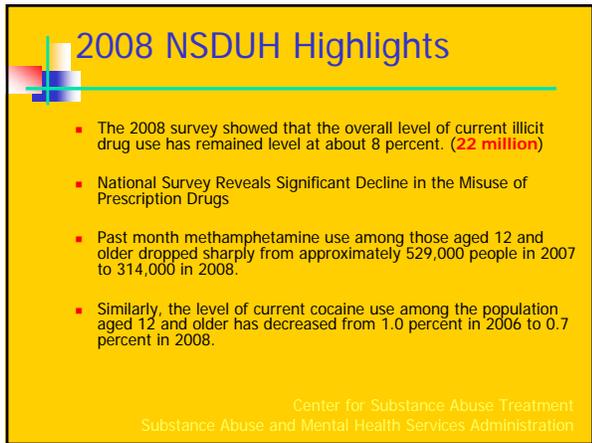
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NSDUH Design

- Representative nationally and in each State
- Civilian, noninstitutional population, age 12+
- Face-to-face interview
- Computer-assisted, self-administered
- 67,870 respondents in 2007
- 2008 data are comparable with 2002-2006, but not with data prior to 2002

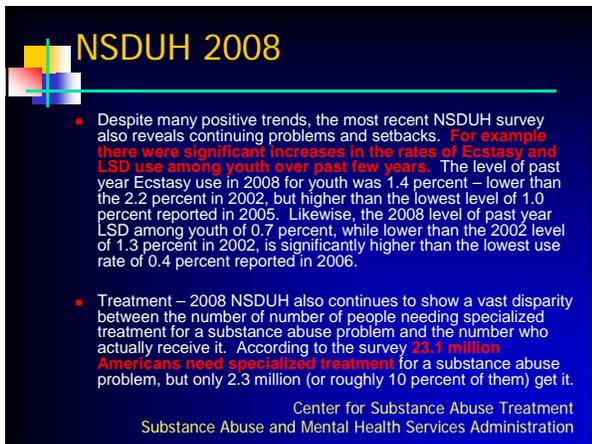
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2008 NSDUH Highlights

- The 2008 survey showed that the overall level of current illicit drug use has remained level at about 8 percent. **(22 million)**
- National Survey Reveals Significant Decline in the Misuse of Prescription Drugs
- Past month methamphetamine use among those aged 12 and older dropped sharply from approximately 529,000 people in 2007 to 314,000 in 2008.
- Similarly, the level of current cocaine use among the population aged 12 and older has decreased from 1.0 percent in 2006 to 0.7 percent in 2008.

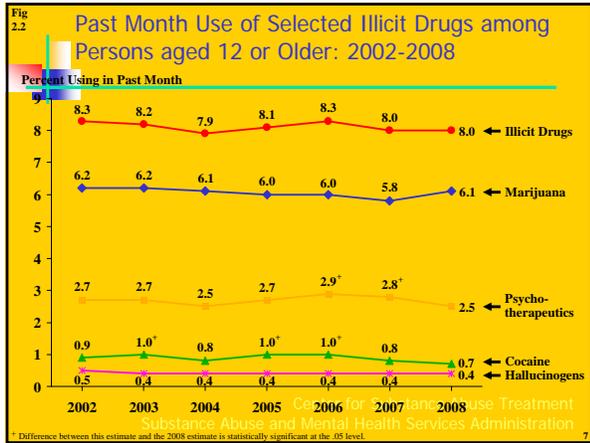
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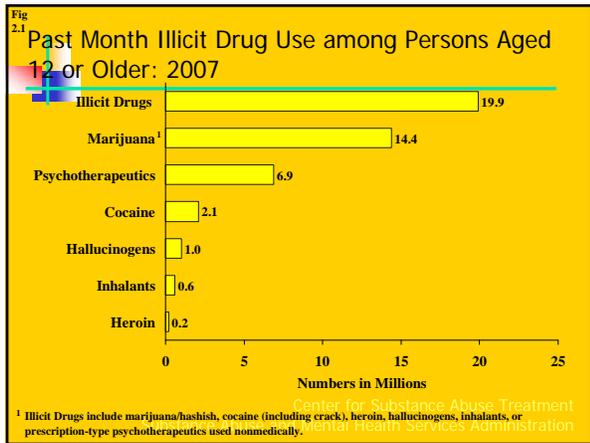


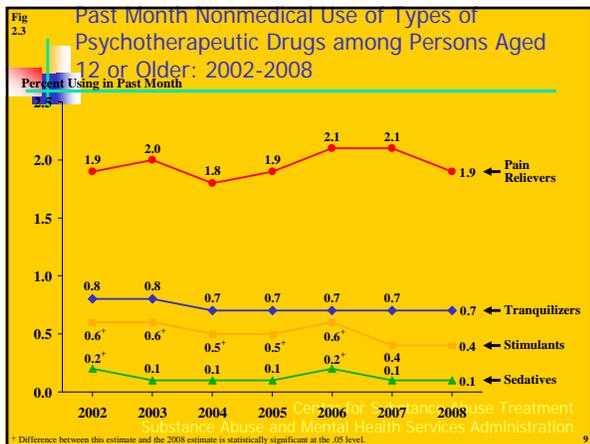
NSDUH 2008

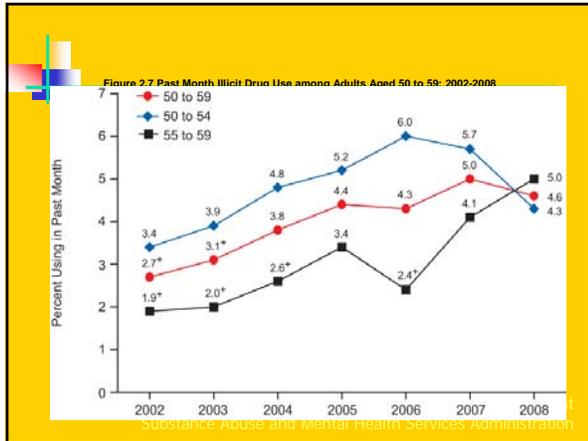
- Despite many positive trends, the most recent NSDUH survey also reveals continuing problems and setbacks. **For example there were significant increases in the rates of Ecstasy and LSD use among youth over past few years.** The level of past year Ecstasy use in 2008 for youth was 1.4 percent – lower than the 2.2 percent in 2002, but higher than the lowest level of 1.0 percent reported in 2005. Likewise, the 2008 level of past year LSD among youth of 0.7 percent, while lower than the 2002 level of 1.3 percent in 2002, is significantly higher than the lowest use rate of 0.4 percent reported in 2006.
- Treatment – 2008 NSDUH also continues to show a vast disparity between the number of number of people needing specialized treatment for a substance abuse problem and the number who actually receive it. According to the survey **23.1 million Americans need specialized treatment** for a substance abuse problem, but only 2.3 million (or roughly 10 percent of them) get it.

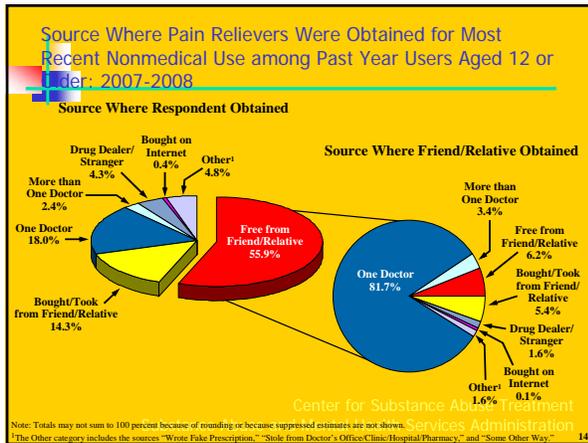
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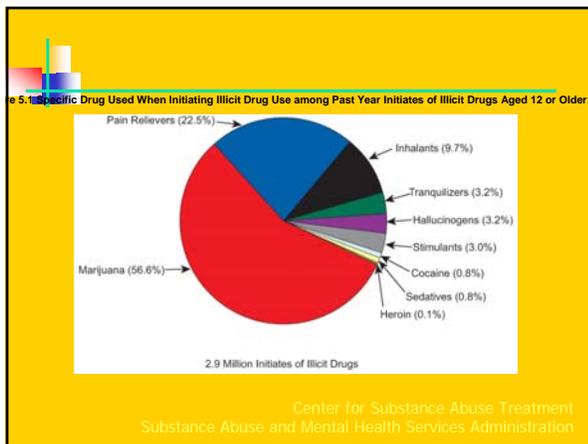


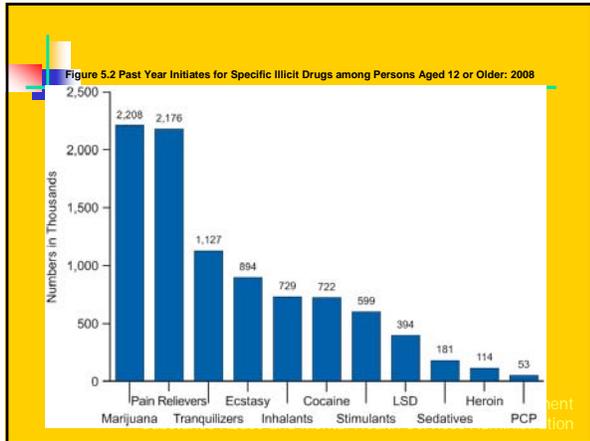


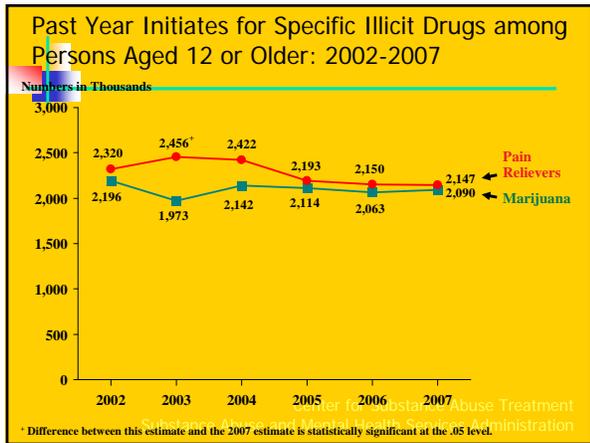












Drug Abuse Warning Network

■ Trends – 2004-2008

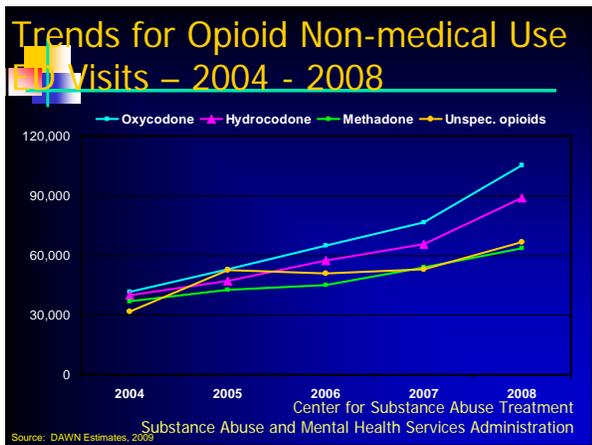
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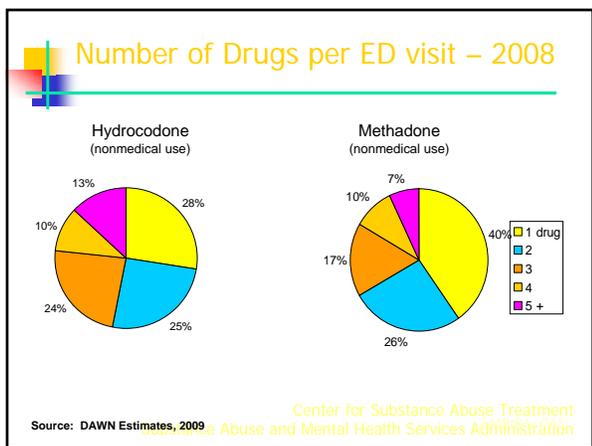
Trends in Nonmedical Use ED Visits – 2004 compared to 2008 -DAWN

- ED visits due to opioid pain medications increased 112% between 2004 and 2008
 - Benzodiazepines increased 89%
 - Antipsychotics increased 56%
- Most visits involved more than one drug
- Interactions between drugs can have a cumulative effect
- CNS depressants can reduce respiration, leading to unconsciousness and death

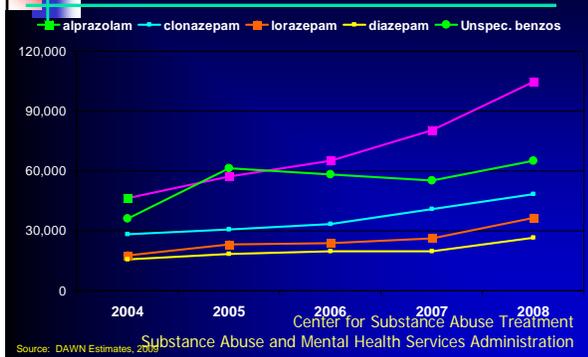
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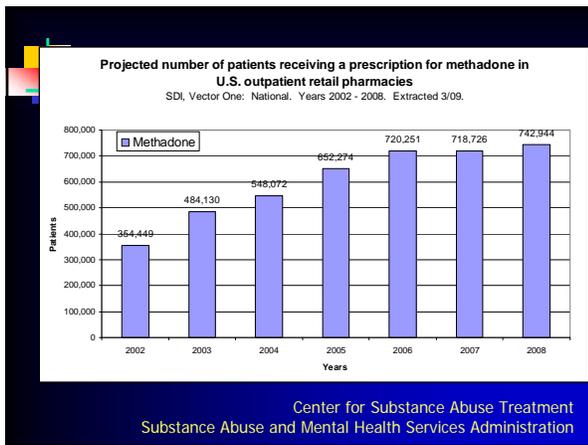
Source: SAMHSA / OAS

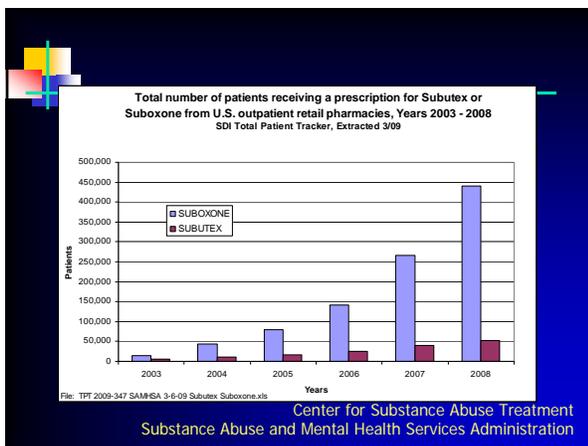


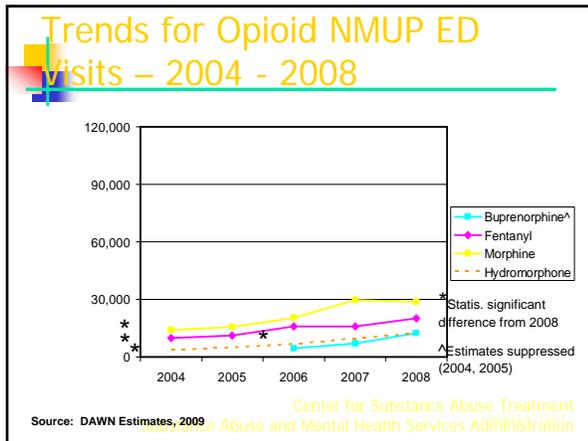


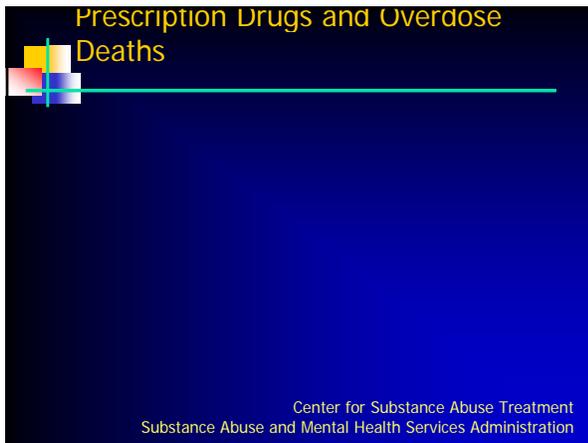
Trends for Benzodiazepine Non-medical Use ED Visits, - 2004 - 2008

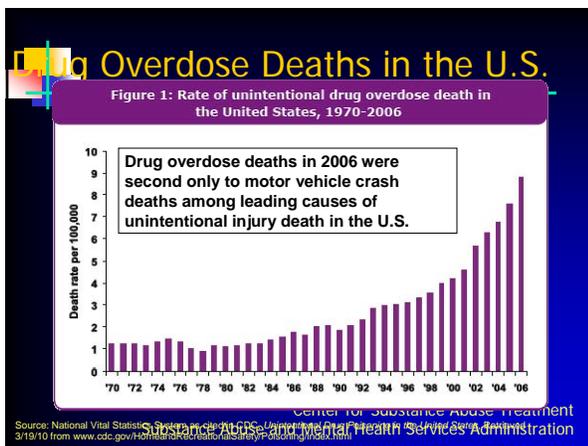




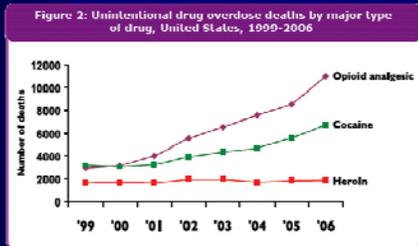








Drug Overdose Deaths in the U.S.



Source: National Vital Statistics System as cited in CDC, Unintentional Overdose Deaths in the United States, Retrieved 3/19/10 from www.cdc.gov/Heroin/overdose/deaths/overdose.htm
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Drug Overdose Deaths in the U.S.

States in the Appalachian region and the Southwest have the highest overall drug overdose death rates.



Age-adjusted rate per 100,000 population
 11.2-10.1 8.5-11.2 11.2-10.1
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Costs tied to illicit Rx Drug

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GAO Study – Medicaid Fraud and Controlled Substances – Sept 2009

- 5 states – CA, IL, NY, NC, TX
- Findings – tens of thousands of beneficiaries involved in fraud purchases.
- Doctor shopping – 65,000 beneficiaries filled CS rx from 6 or more different prescribers.
- \$63 million
- Prescriptions filled for debarred prescribers, unregistered prescribers, dead beneficiaries.
- PMP's not used required, some cases available.
- Recommendations
- One relates to doctor shopping, - DUR identify and prevent doctor shopping.

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Prescription Drug Increases

- Since 1991.....
- Stimulant prescriptions increased 7 fold
(5-35 million)
- Opioid prescriptions increased 4 fold
(40 million, 180 million)

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How can PDMPs Reduce Opioid Overdose Risk?

– Dunn, et al, 2010, Annals of Internal Med

- 51 opioid-related overdoses were identified, including 6 deaths.
- Compared with patients receiving 1 to 20 mg/d of opioids (0.2% annual overdose rate),
- patients receiving 50 to 99 mg/d had a 3.7-fold increase in overdose risk (95% CI, 1.5 to 9.5) and a 0.7% annual overdose rate.
- Patients receiving 100 mg/d or more had an 8.9-fold increase in overdose risk (CI, 4.0 to 19.7) and a 1.8% annual overdose rate.

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NASPER

- National
- All
- Schedules
- Prescription
- Electronic
- Reporting
 - Act of 2005

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NASPER - P.L. 109-191 – Intent

- 1. to foster the establishment or enhancement of State-administered controlled substance monitoring systems in order
- 2. to ensure that health care providers have access to accurate, timely prescription history information.
- 3. for assisting in the early identification of patients at risk for addiction. Early identification will lead to enhanced substance abuse treatment interventions.

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Alliance Goals for PMPs

- Education and information
- Public health initiatives
- **Early intervention and prevention**
- Investigations and enforcement
- Protection of confidentiality

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How – Formula grant, annual

Establishes the authority for a grant program with the Secretary, HHS, wherein a State may submit an application to

- 1. **implement a new** controlled substance prescription monitoring system, or
- 2. **to make improvements** upon an existing State controlled substance monitoring system.

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How Much??

Authorizations, Future appropriations - \$15 million, no appropriation until March 2009 (\$2 million) –Authorization for appropriation ends 2010.

- Minimum Amount – no less than 1% of the amount appropriated. (\$20,000)
- Additional Amounts = appropriated amount x **number of pharmacies in the state/total number of pharmacies in all approved states.**

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Who is Eligible-requirements

- Law in effect and penalties for unauthorized disclosures.
- D. To participate
- (1) The State shall require dispensers* to report to such State each dispensing in the State of a controlled substance to an ultimate user **not later than 1 week** after the date of such dispensing.
- (2) The **State may exclude** from the reporting requirement of this subsection—
 - Direct administration to body of ultimate user
 - Dispensing in quantity 48 hours or less
 - Any other exclusion identified by the Secretary

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Improve vs Establish/Implement

- Improve – assurance of compliance or statement why not feasible or contrary to best interest
- Establish/Implement – assurance of compliance only

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2009 Appropriation - Process

- Consult with States, other parties
- Propose minimum requirements solicit comments - 04/29/09
 - 9 comments received
 - 6 States
 - Alliance, NACDS, ASAP
- SAMHSA Request For Grant App – 7/27/09
- 13 applications received and approved
- Entire \$2 million awarded

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2009 Awards

State	Allotment
Alabama	\$115,396
California *	\$454,587
Connecticut	\$65,976
Illinois	\$188,843
Indiana	\$108,079
Kansas *	\$66,407
Kentucky	\$101,409
Maine	\$40,514
Michigan	\$193,362
Mississippi	\$79,246
Nevada	\$52,922
New York *	\$342,264
Ohio*	\$190,995

2010 Proposed Minimum Stds

- April 14, 2010 Federal Register
- 1. Existing PMPs must adopt the 2007 version of the ASAP standard for electronic prescription formatting by September 30, 2011.
 - Version 4.1, with commitment to change if legislation is required
- 2. Authentication requirements were proposed to bring PMPs into compliance with National Institute of Standards and Technology (NIST) 800-63.
 - (a) A practitioner or dispenser (pharmacist) must submit a hard copy written, signed, and notarized request every three years to the designated State agency, which in turn, verifies the information before providing a username and password to the practitioner. The request must include the practitioner's name and date of birth, a corresponding DEA registration number, and State medical license number.
 - Postpone for one year.
- 3. Sub Accounts - Proposed the authorization of one PMP sub-account per prescriber, if permitted by State law. The dispenser would not be permitted to obtain sub accounts.
 - Allow states to establish sub accounts, no limits, prescriber monitors

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Unsolicited Disclosure Proposal

- GAO Report
- "For PDMPs to be useful, health care providers and pharmacies must use the data. Officials from the five selected states said that physician participation in the PDMP is not widespread and not required. In fact, one state did not have a Web-based PDMP; a health care provider has to put in a manual request to the agency to have a controlled substance report generated."

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Unsolicited Disc, Continued

- Any individual that has filled six or more controlled substance prescriptions from six different prescribers, or six different dispensers in the State, within a six month period shall be the subject of a report from the prescription drug monitoring program to each prescriber.
- Reports must be sent to at least ten percent of the registered prescribers in the State in one calendar year.

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Unsolicited Reports, Cont

- Privacy – content of report not specified, does not need to include PHI (Michigan, Louisiana)
- Threshold – 6/6/1 month, or
- State applies alternate notification system that reaches at least 5% of registered prescribers.

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OTP Disclosure To PMP (1)

- 1200 Opioid Treatment Programs in the U.S.
- 270,000 patients in Tx
- Most OTPs dispense Schedule II methadone or Schedule III buprenorphine beyond 48 hour supply.
- Do State PMP laws require OTP reporting to PMPs?

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OTP Disclosure To PMP (2)

- 42 CFR Part 2 prohibits federally assisted alcohol and drug treatment programs from disclosing "patient health information"
- Information that would directly or indirectly reveal a person's status as a patient or formal patient.
- OTPs provide SA treatment and they are Federally assisted (licensure, OBOTs)

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OTP Disclosure To PMP (3)

- Disclosure only permitted if it falls under an "exception"
- A. "Audit and Evaluation"
 - Exception only for licensing/regulating entities – PMPs do not regulate OTPs
 - Only for audit/evaluation purposes – not identify "doctor shoppers"

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OTP Disclosure To PMP (4)

- Evaluation/Audit – no further disclosure, only back to program.
- OTP disclosure with patient consent?
 - Not permitted if there is any possibility that the information would be used to prosecute patient.
 - If there is no possibility to use information to prosecute,
 - Consent would need to name all parties
 - All parties would need to agree to disclose no further.

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OTP Disclosure To PMP (5) Central Registries

- Can States require "Central Registries" to report to PMPs?
 - Provision in 42 CFR Part 2 permits disclosure to registry "to prevent multiple enrollments" in OTPs.
 - Regulations limit only for preventing multiple enrollments
 - Not the type of information PMPs contain (no amounts distributed)

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Can OTPS request information from PMPs?

- Physician (sub account) with account queries PMP about OTP patient.
 - Encouraged by SAMHSA/CSAT
 - Required by some States (WV)
 - Becomes part of patient record.
- Indirectly reveal a person's status as a drug treatment program patient?

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PMP's Part of Solution

- Expanded/enhanced PMP use
- Doctor Shopping Laws? Tennessee
- Pain Clinic Regulation at State Level

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Rx Drug Abuse – Manufacturer Responsibilities

- FDA – Risk Evaluation Mitigation Strategy
- Schedule II sustained release opioids (includes methadone)
- Stakeholders/public meetings, open comments – 2009
- Physician, Consumer Education,

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Summary

- NSDUH –
 - overall illicit use same (8%, 19 million)
 - decreases in current Rx drug abuse
 - 7 million, 2.5% population
- Medication Assisted Treatment – Expanding
- NASPER
 - commitment to encourage uniform stds, treatment
- Practitioner, consumer education cont.

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