



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

Electronic Prescriptions for Controlled Substances

Drug Enforcement Administration
Department of Health and Human Services
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Prescription Drug Abuse Top National Priority

National Survey on Drug Use and Health, 2004:

- Estimated 6.0 million Americans (2.5%) aged 12 or older engaged in non-medical use of prescription medications in the last month. Of these:
 - Pain Relievers: 4.4 million
 - Anti-Anxiety (tranquilizers): 1.6 million
 - Stimulants: 1.2 million
 - Sedatives: 0.3 million

Foundations of CSA

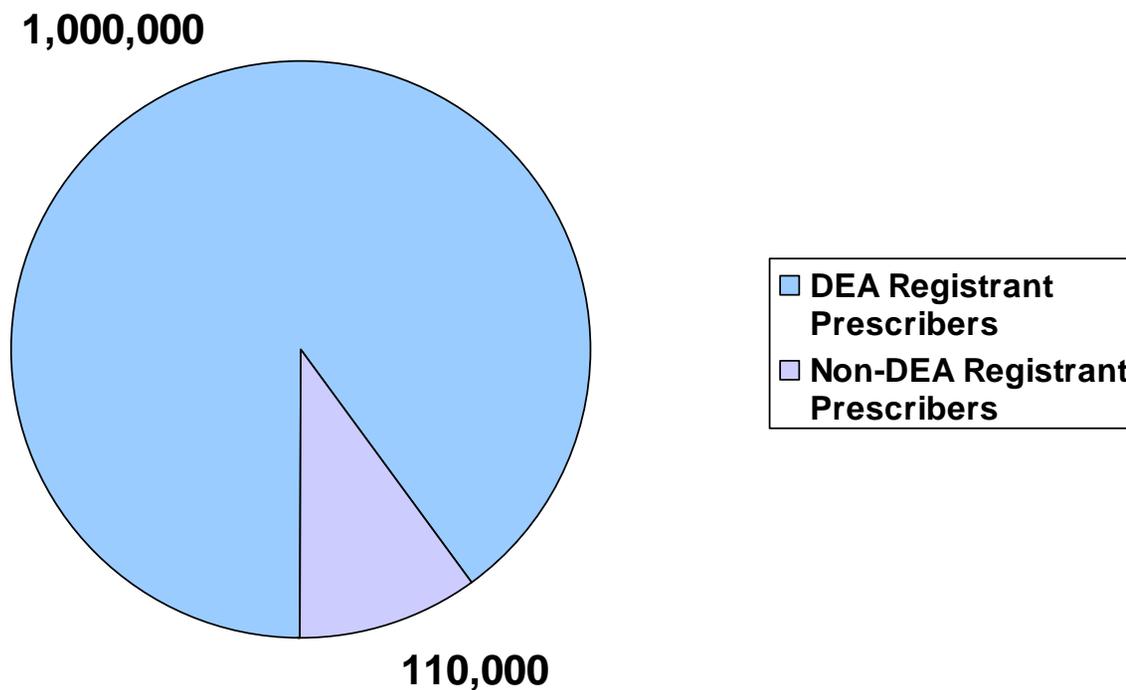
- CSA, Congress, clearly differentiated controlled substances from other “legend” drugs handled by the Federal Food, Drug and Cosmetic Act
- CSA mandates “cradle to grave” control:
 - Creates “closed system” of distribution
 - Registration: any person handling controlled substances must be registered with DEA
 - Dispensing: legitimate medical purpose in usual course of professional practice by prescription that, if written, must be manually signed

Examples of Controlled Substances

<u>Schedule</u>	<u>Examples</u>
Schedule I	Heroin, marijuana, methylenedioxymethamphetamine (MDMA; Ecstasy)
Schedule II	Amphetamine, codeine, fentanyl (Duragesic®), Hydromorphone (Dilaudid®), meperidine (Demerol®),methadone (Dolophine®), Methylphenidate (Ritalin®, Metadate ER®, Concerta®), morphine, Oxycodone (Percodan®, Tylox®, OxyContin®)
Schedule III	Anabolic steroids (Anadrol®, Depo-Testosterone®, Dianabol®), phendimetrazine (Prelu-2®), acetaminophen with codeine, hydrocodone/acetaminophen (Lorcet®, Vicodin®)
Schedule IV	Alprazolam (Xanax®), diazepam (Valium®), lorazepam (Ativan®), phentermine (Fastin®, Ionamin®, Adipex-P®)
Schedule V	Some cough preparations that contain a limited amount of codeine

Persons prescribing

- Controlled substances account for approximately 11% of all prescriptions



Content of Prescriptions

- Must be dated as of, and signed on, day issued
- Name, address, registration number of practitioner
- Full name and address of patient
- Drug name
- Strength
- Dosage form
- Quantity prescribed
- Directions for use

Requirements for Prescriptions

- Issued by individual practitioner authorized to prescribe and registered with DEA
- Issued for legitimate medical purpose by individual practitioner acting in usual course of professional practice

Requirements for Prescriptions

- **Schedule II prescriptions:**
 - Written, manually signed
 - Fax of written, manually signed, permitted in limited circumstances
- **Schedule III-V prescriptions:**
 - Written, manually signed
 - Fax of written, manually signed
 - Oral, pharmacist immediately reduces to writing

Responsibilities Regarding Prescriptions

- Responsibility for proper prescribing rests with prescribing practitioner
- Corresponding responsibility rests with pharmacist filling prescription to ensure prescription meets DEA requirements
- Practitioner writes prescription, pharmacy dispenses prescription and maintains record
- Prescription records must be retained by pharmacy for two years from date of dispensing

Enforcement of CSA

- CSA stipulates permissible acts; if not explicitly permitted, then prohibited
- Violations can be administrative, civil, criminal

Illegal Acts

- Unlawful for any person knowingly or intentionally to:
 - Manufacture, distribute, or dispense controlled substance except as authorized by CSA
 - Possess controlled substance unless obtained pursuant to valid prescription issued for legitimate medical purpose from practitioner acting in usual course of professional practice
 - Obtain controlled substance by fraud, forgery, deception, subterfuge

Illegal Acts

- Unlawful for any person knowingly or intentionally to:
 - Use DEA registration that is fictitious, revoked, suspended, expired, issued to another person in course of dispensing or acquiring controlled substance
- Unlawful to refuse or negligently fail to make, keep, or furnish records
- Unlawful to furnish false or fraudulent material information, or omit information from, records

Methods of Diversion

- Prescription pads stolen
- Legitimate prescriptions altered, copied
- Legitimate prescriber information altered
- Prescription forgery
- Prescriptions written for other than legitimate medical purpose
- Controlled substances stolen by employees; legitimately dispensed prescriptions may be altered to cover theft

Law Enforcement Needs

- Prescriptions and prescription information used in investigations/prosecutions
- Federal enforcement of Controlled Substances Act
- State and local enforcement of state laws and regulations
- Medicare, Medicaid, private insurance fraud

Electronic Prescriptions for Controlled Substances – Performance Standards

- Authentication: positively identify signer
- Non-repudiation: signer cannot deny signing specific document
- Record integrity: determine if record has been altered after signature

Need for These Performance Standards

- Authentication of practitioner-required by CSA and regulations
- Record integrity, non-repudiation
- Accountability
- Legal sufficiency: litigation strength for prosecution – prove beyond a reasonable doubt
- Electronic prescription must be substantially similar to written, manually signed paper prescription

Purpose of Meeting

- DEA needs appropriate law enforcement tools to enforce CSA
- Must meet performance standards substantially similar to the authentication, non-repudiation, record integrity present in written, manually signed prescriptions
- DEA invites input on how to meet law enforcement needs without undue burden