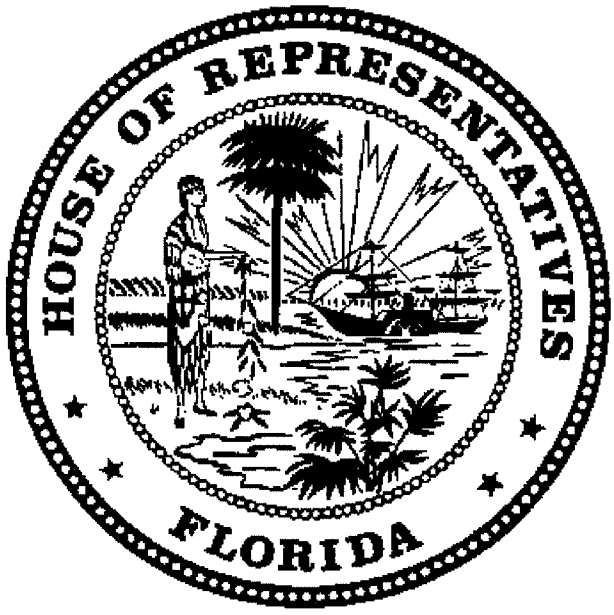


Health & Human Services Committee

Thursday, February 24, 2011
12:15 PM
Morris Hall (17 HOB)

Dean Cannon
Speaker

Robert C. "Rob" Schenck
Chair

The Florida House of Representatives

Health & Human Services Committee

Dean Cannon
Speaker

Robert C. "Rob" Schenck
Chair

AGENDA
February 24, 2011
12:15 p.m. – 2:45 p.m.
Morris Hall (17 HOB)

Workshop on the following:

The Prescription Drug Monitoring System and Regulation of Controlled Substances

Department of Health Presenters:

- Lucy Gee, Director, Division of Medical Quality Assurance
- Manufacturer and Distributor Regulation –
  - Gregg Jones, Acting Executive Director, Board of Pharmacy
- Pharmacy Regulation –
  - Gregg Jones, Acting Executive Director, Board of Pharmacy
- Dispensing Physician Regulation –
  - Gregg Jones, Acting Executive Director, Board of Pharmacy
- Pain Management Clinic Regulation and Enforcement –
  - Larry McPherson, Executive Director, Florida Board of Medicine
  - Kathryn Price, Chief Legal Counsel and Pain Management Coordinator
  - Susan Love, Chief, Bureau of Enforcement
- Prescription Drug Monitoring Program Update –
  - Becki Poston, Program Manager, PDMP

214 House Office Building, 402 South Monroe Street, Tallahassee, Florida 32399-1300
(850) 414-5600 Fax: (850) 488-9933

Most Commonly Abused Drugs

The most commonly abused drugs (highlighted below) are found in all four prescribable controlled substance Schedules.[1]

Substance	Other Names
Schedule II - high potential for abuse; severely restricted medical use	
1-Phenylcyclohexylamine	Precursor of PCP
1-Piperidinocyclohexanecarbonitrile	PCC, precursor of PCP
Alfentanil	Alfenta
Alphaprodine	Nisentil
Amobarbital	Amytal, Tuinal
Amphetamine	Dexedrine, Biphetamine
Anileridine	Leritine
Benzoylecgonine	Cocaine metabolite
Bezitramide	Burgodin
Carfentanil	Wildnil
Coca Leaves	
Cocaine	Methyl benzoylecgonine, Crack
Codeine	Morphine methyl ester, methyl morphine
Dextropropoxyphene, bulk (non-dosage forms)	Propoxyphene
Dihydrocodeine	Didrate, Parzone
Diphenoxylate	
Diprenorphine	M50-50
Ecgonine	Cocaine precursor, in Coca leaves
Ethylmorphine	Dionin
Etorphine HCl	M 99
Fentanyl	Innovar, Sublimaze, Duragesic
Glutethimide	Doriden, Dorimide
Hydrocodone	dihydrocodeinone
Hydromorphone	Dilaudid, dihydromorphinone
Isomethadone	Isoamidone
Levo-alphacetylmethadol	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	
Levorphanol	Levo-Dromoran
Meperidine	Demerol, Mepergan, pethidine
Meperidine intermediate-A	Meperidine precursor
Meperidine intermediate-B	Meperidine precursor
Meperidine intermediate-C	Meperidine precursor
Metazocine	
Methadone	Dolophine, Methadose, Amidone
Methadone intermediate	Methadone precursor

[1] National Institutes of Health, National Institute on Drug Abuse, *see*, http://www.drugabuse.gov/DrugPages/DrugsofAbuse.html (last viewed January 30, 2010); U.S. Drug Enforcement Administration, *see*, http://www.justice.gov/dea/pubs/scheduling.html (last viewed January 30, 2010). This is a very basic list which describes the parent chemicals, not the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

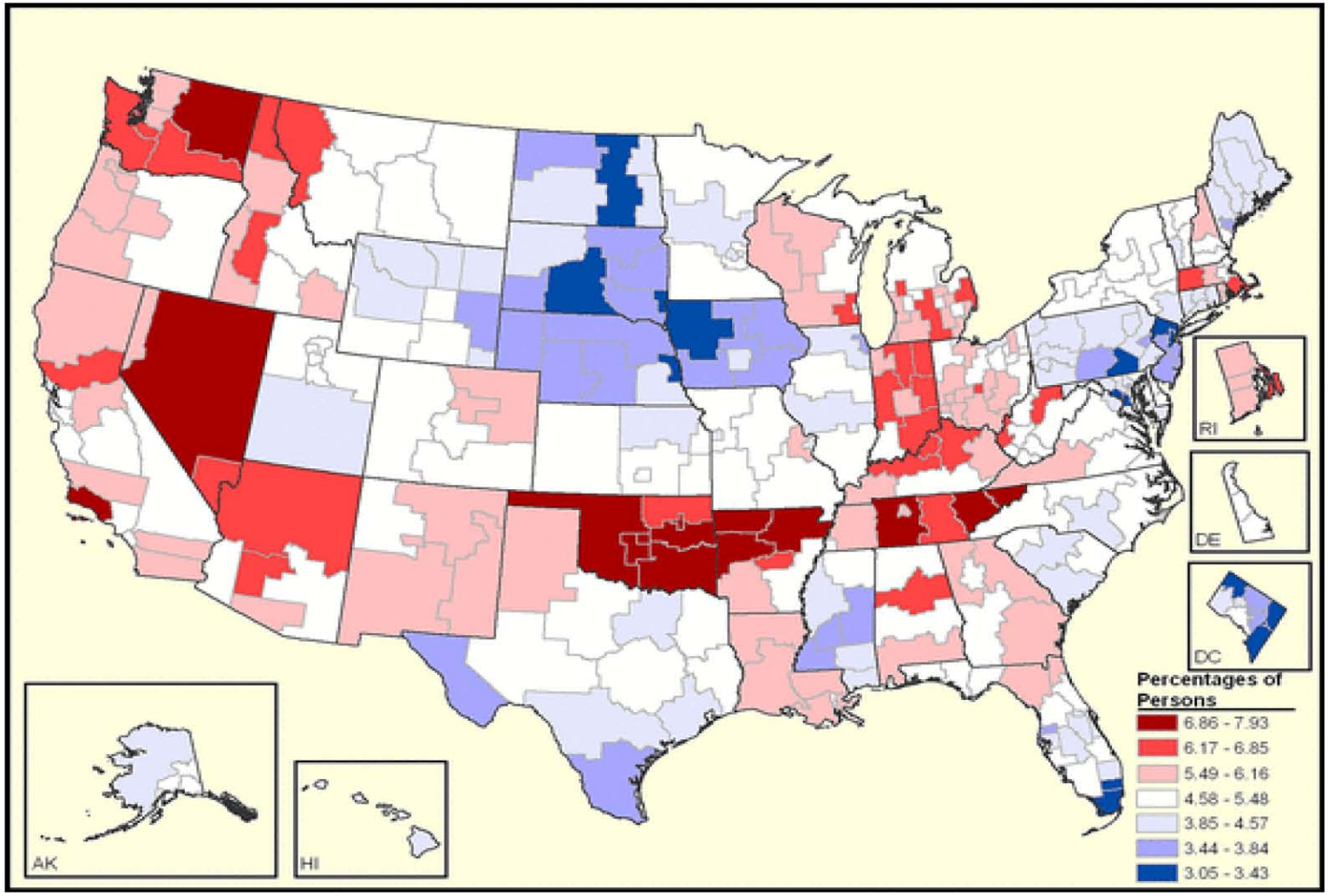
Methamphetamine	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	Ritalin
Metopon	
Moramide-intermediate	
Morphine	MS Contin, Roxanol, Duramorph, RMS, MSIR
Nabilone	Cesamet
Opium extracts	
Opium fluid extract	
Opium poppy	Papaver somniferum
Opium tincture	Laudanum
Opium, granulated	Granulated opium
Opium, powdered	Powdered Opium
Opium, raw	Raw opium, gum opium
Oxycodone	OxyContin, Percocet, Tylox, Roxicodone, Roxicet,
Oxymorphone	Numorphan
Pentobarbital	Nembutal
Phenazocine	Narphen, Prinadol
Phencyclidine	PCP, Sernylan
Phenmetrazine	Preludin
Phenylacetone	P2P, phenyl-2-propanone, benzyl methyl ketone
Piminodine	
Poppy Straw	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	Concentrate of Poppy Straw, CPS
Racemethorphan	
Racemorphan	Dromoran
Remifentanil	Ultiva
Secobarbital	Seconal, Tuinal
Sufentanil	Sufenta
Thebaine	Precursor of many narcotics
Schedule III - (less potential for abuse than Schedules I or II substances; some accepted medical use)	
Amobarbital & noncontrolled active ingred.	Amobarbital/ephedrine capsules
Amobarbital suppository dosage form	
Anabolic steroids	"Body Building" drugs
Aprobarbital	Alurate
Barbituric acid derivative	Barbiturates not specifically listed
Benzphetamine	Didrex, Inapetyl
Boldenone	Equipoise, Parenabol, Vebonol, dehydrotestosterone
Buprenorphine	Buprenex, Temgesic
Butabarbital	Butisol, Butibel
Butalbital	Fiorinal, Butalbital with aspirin
Chlorhexadol	Mechloral, Mecoral, Medodorm, Chloralodol
Chlorotestosterone (same as clostebol)	if 4-chlorotestosterone then clostebol
Chlorphentermine	Pre-Sate, Lucofen, Apsedon, Desopimon
Clortermine	Voranil
Clostebol	Alfa-Trofodermin, Clostene, 4-chlorotestosterone
Codeine & isoquinoline alkaloid 90 mg/du	Codeine with papaverine or noscapine

Codeine combination product 90 mg/du	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Dehydrochlormethyltestosterone	Oral-Turinabol
Dihydrocodeine combination product 90 mg/du	Synalgos-DC, Compal
Dihydrotestosterone (same as stanolone)	see stanolone
Dronabinol in sesame oil in soft gelatin capsule	Marinol, synthetic THC in sesame oil/soft gelatin
Drostanolone	Drolban, Masterid, Permastril
Ethylestrenol	Maxibolin, Orabolin, Durabolin-O, Duraboral
Ethylmorphine combination product 15 mg/du	
Fluoxymesterone	Anadroid-F, Halotestin, Ora-Testryl
Formebolone (incorrect spelling in law)	Esiclene, Hubernol
Hydrocodone & isoquinoline alkaloid 15 mg/du	Dihydrocodeinone+papaverine or noscapine
Hydrocodone combination product 15 mg/du	Tussionex, Tussend, Lortab, Vicodin, Hycodan, Anexsia ++
Ketamine	Ketaset, Ketalar, Special K, K
Lysergic acid	LSD precursor
Lysergic acid amide	LSD precursor
Mesterolone	Proviron
Methandienone (see Methandrostenolone)	
Methandranone	
Methandriol	Sinesex, Stenediol, Troformone
Methandrostenolone	Dianabol, Metabolina, Nerobol, Perbolin
Methenolone	Primobolan, Primobolan Depot, Primobolan S
Methyltestosterone	Android, Oreton, Testred, Virilon
Methyprylon	Noludar
Mibolerone	Cheque
Morphine combination product/50 mg/100 ml or gm	
Nalorphine	Nalline
Nandrolone	Deca-Durabolin, Durabolin, Durabolin-50
Norethandrolone	Nilevar, Solevar
Opium combination product 25 mg/du	Paregoric, other combination products
Oxandrolone	Anavar, Lonavar, Provitar, Vasorome
Oxymesterone	Anamidol, Balnimax, Oranabol, Oranabol 10
Oxymetholone	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Pentobarbital & noncontrolled active ingred.	FP-3
Pentobarbital suppository dosage form	WANS
Phendimetrazine	Plegine, Prelu-2, Bontril, Melfiat, Statobex
Secobarbital & noncontrolled active ingred	various
Secobarbital suppository dosage form	various
Stanolone	Anabolex, Andractim, Pesomax, dihydrotestosterone
Stanozolol	Winstrol, Winstrol-V
Stimulant compounds previously excepted	Mediatric
Sulfondiethylmethane	
Sulfonethylmethane	
Sulfonmethane	
Talbutal	Lotusate
Testolactone	Teslac
Testosterone	Android-T, Androlan, Depotest, Delatestryl
Thiamylal	Surital

Thiopental	Pentothal
Tiletamine & Zolazepam Combination Product	Telazol
Trenbolone	Finaplix-S, Finajet, Parabolan
Vinbarbital	Delvinal, vinbarbitone
Schedule IV - (less potential for abuse than Schedules I, II, or III substances; some accepted medical use)	
Alprazolam	Xanax
Barbital	Veronal, Plexonal, barbitone
Bromazepam	Lexotan, Lexatin, Lexotanil
Butorphanol	Stadol, Stadol NS, Torbugesic, Torbutrol
Camazepam	Albego, Limpidon, Paxor
Cathine	Constituent of "Khat" plant
Chloral betaine	Beta Chlor
Chloral hydrate	Noctec
Chlordiazepoxide	Librium, Libritabs, Limbitrol, SK-Lygen
Clobazam	Urbadan, Urbanyl
Clonazepam	Klonopin, Clonopin
Clorazepate	Tranxene
Clotiazepam	Trecalmo, Rize
Cloxazolam	Enadel, Sepazon, Tolestan
Delorazepam	
Dexfenfluramine	Redux
Dextropropoxyphene dosage forms	Darvon, propoxyphene, Darvocet, Dolene, Propacet
Diazepam	Valium, Valrelease
Dichloralphenazone	Midrin, dichloralantipyrine
Diethylpropion	Tenuate, Tepanil
Difenoxin 1 mg/25 ug AtSO4/du	Motofen
Estazolam	ProSom, Domnamid, Eurodin, Nuctalon
Ethchlorvynol	Placidyl
Ethinamate	Valmid, Valamin
Ethyl loflazepate	
Fencamfamin	Reactivan
Fenfluramine	Pondimin, Ponderal
Fenproporex	Gacilin, Solvolip
Fludiazepam	
Flunitrazepam	Rohypnol, Narcozep, Darkene, Roipnol
Flurazepam	Dalmane
Halazepam	Paxipam
Haloxazolam	
Ketazolam	Anxon, Loftran, Solatran, Contamex
Loprazolam	
Lorazepam	Ativan
Lormetazepam	Noctamid
Mazindol	Sanorex, Mazanor
Mebutamate	Capla
Medazepam	Nobrium
Mefenorex	Anorexic, Amexate, Doracil, Pondinil
Meprobamate	Miltown, Equanil, Deprol, Equagesic, Meprospan
Methohexital	Brevital

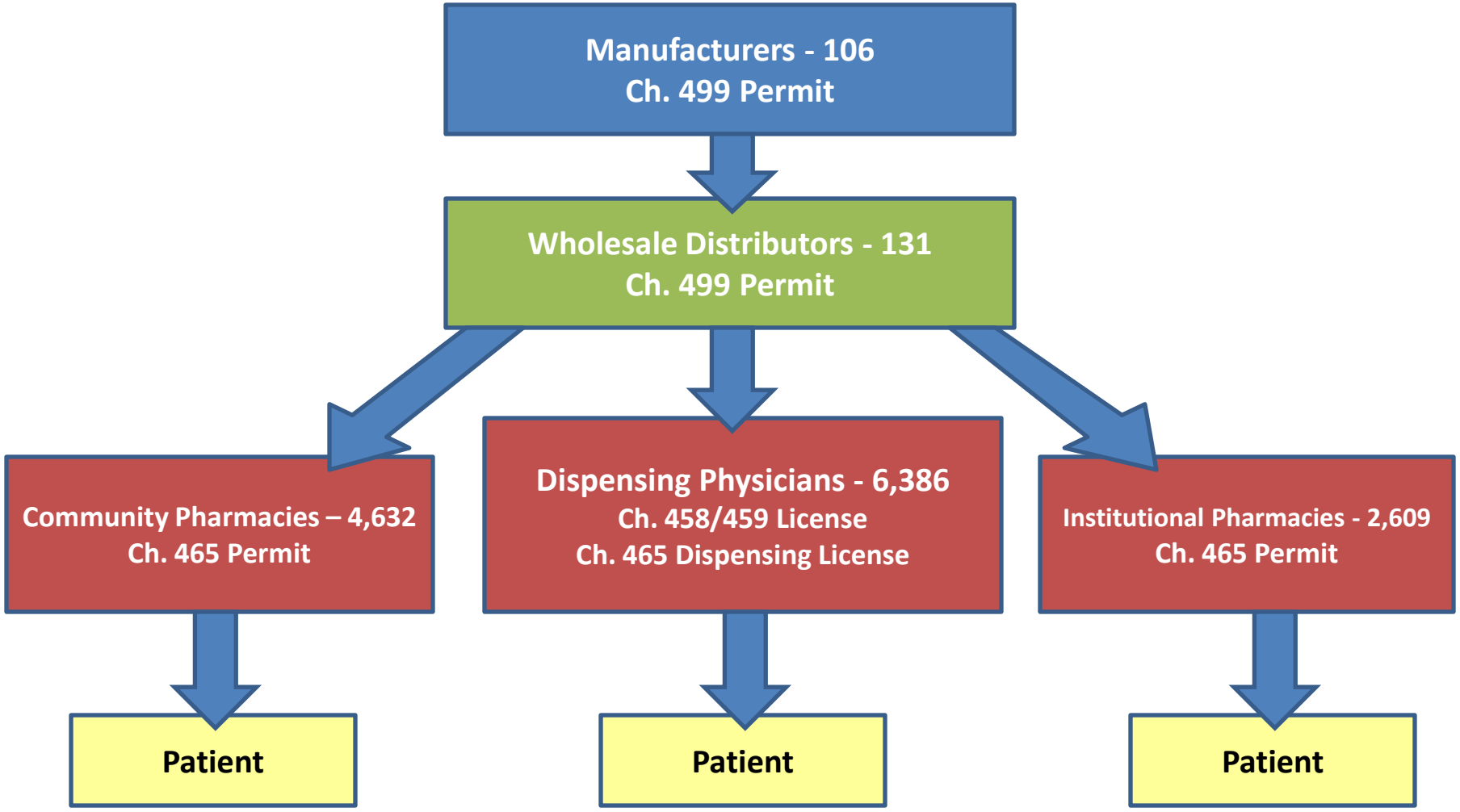
Methylphenobarbital (mephobarbital)	Mebaral, mephobarbital
Midazolam	Versed
Modafinil	Provigil
Nimetazepam	Erimin
Nitrazepam	Mogadon
Nordiazepam	Nordazepam, Demadar, Madar
Oxazepam	Serax, Serenid-D
Oxazolam	Serenal, Convertal
Paraldehyde	Paral
Pemoline	Cylert
Pentazocine	Talwin, Talwin NX, Talacen, Talwin Compound
Petrichloral	Pentaerythritol chloral, Periclor
Phenobarbital	Luminal, Donnatal, Bellergal-S
Phentermine	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Pinazepam	Domar
Pipradrol	Detaril, Stimolag Fortis
Prazepam	Centrax
Quazepam	Doral, Dormalin
Sibutramine	Meridia
SPA	1-dimethylamino-1,2-diphenylethane, Lefetamine
Temazepam	Restoril
Tetrazepam	
Triazolam	Halcion
Zaleplon	Sonata
Zolpidem	Ambien, Stilnoct,Ivadal
Schedule V - (low potential for abuse compared to Schedule IV substances; some accepted medical use)	
Codeine preparations - 200 mg/100 ml or 100 gm	Cosanyl, Robitussin A-C, Cheracol, Cerose, Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du	Motofen
Dihydrocodeine preparations 10 mg/100 ml or 100 gm	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4	Lomotil, Logen
Ethylmorphine preparations 100 mg/100 ml or 100 gm	
Opium preparations - 100 mg/100 ml or gm	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pyrovalerone	Centroton, Thymergix

***Nonmedical Use of Pain Relievers in Past Year* among Persons Aged 12 or Older, by Substate Region: Percentages, Annual Averages Based on 2006, 2007, and 2008 NSDUHs**



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies (August 2010), National Survey on Drug Use and Health, 2006-2008.

Prescribed Controlled Substance Distribution Path



House of Representatives Health and Human Services Committee
Workshop on the PDMP and Regulation of Controlled Substances, February 24, 2011

Licensee/ Permitee/ Registrant	Regulated By	Fee	Licensure/ Permit/ Requirements	Renewal	Initial Inspection	Inspection Requirements	Inspection Frequency
Manufacturer:							
Prescription Drug Manufacturer	Department of Health (Ch. 499, F.S.)	$1,650	• Completed application, which is signed and notarized • Type of ownership • List of owners, % of ownership, date of birth • FEID number • DBA and corporate name • Hours of operation • Disclosure of disciplinary information • Type of products handled • Type of customers • Type of sales (domestic or export) • Location of records • DEA # (controlled substances) if state license issued • FDA number • If no FDA #, a copy of application submitted to FDA • Must qualify as manufacturer based on Florida definition of manufacturer • Name of shipper of Rx drugs if do not ship own products • Type of drugs manufactured • If out of state, copy of resident state license with verification • If foreign applicant, must verify FDA approval to import products Who is excluded: • Applicants who are not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification • Applicants who have not met the requirements for the permit or certification. • Applicants who are not eligible for a permit or certification for any of the reasons enumerated in s. 499.012, F.S. • Applicants who are certified under s. 499.012(16), F.S., and demonstrates any of the conditions enumerated in s. 499.012, F.S. • Applicants who are certified under s. 499.012(16), F.S. and has committed any violation of ss. 499.005-499.0054, F.S. The department may deny, suspend, or revoke a permit: • if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of Chapters 499, 465, 501, or 893, F.S., any rules adopted under this part or those chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld. • if the assignment, sale, transfer, or lease of an establishment permitted under this part will avoid an administrative penalty, civil action, or criminal prosecution.	Biennial	Yes	• No unlicensed activity • Storage compliance • Security compliance • Written policies and procedures • Location can not be a residence	Annual
Prescription Drug Repackager		$1,650		Biennial	Yes		Annual
Non-Resident Prescription Drug Maufacturer		$1,000		Biennial	No		As needed

Licensee/ Permitee/ Registrant	Regulated By	Fee	Licensure/ Permit/ Requirements	Renewal	Initial Inspection	Inspection Requirements	Inspection Frequency
Wholesale Distributor:							
Prescription Drug Wholesale Distributor	Department of Health (Ch. 499, F.S.)	$950	• Completed application, which is signed and notarized • Personal information statement, fingerprint card and $47.00 fee for key personnel • $100,000 security • Certified Designated Representative • Ownership information • Top five corporate officers and five largest shareholders of corporation • Affiliated group members • Copy of lease or deed • Disclosure of disciplinary information • Open minimum 20 hours /wk Mon-Fri 8 – 5 • Rx drug activity • DEA # if already hold state license • Category of customers served (pharmacists, practitioners, wholesaler, etc.) • Other licenses for purchase & possession of Rx drugs • Group purchasing organization information • Suppliers list • Notification of where records stored • Amount of sales/purchases of Rx drugs • Provide tax year • 12 sales invoices (if renewing) • Key personnel, shareholder owning at least 5%, affiliate parties • Primary wholesaler form (if applicable) • Name/address of financial institution, account numbers, signatories for establishment • Source of funds for establishment • Copies of promissory notes/loans for borrowed funds • If out of state, resident state license with verification • Cannot be at same address of pharmacy or health care entity • Disclose felony information on key personnel; provide photograph taken within last 30 days Who is excluded: • Applicants who are not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification • Applicants who have not met the requirements for the permit or certification. • Applicants who are not eligible for a permit or certification for any of the reasons enumerated in s. 499.012, F.S. • Applicants who are certified under s. 499.012(16), F.S., and demonstrates any of the conditions enumerated in s. 499.012, F.S. • Applicants who are certified under s. 499.012(16), F.S. and has committed any violation of ss. 499.005-499.0054, F.S. The department may deny, suspend, or revoke a permit: • if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of Chapters 499, 465, 501, or 893, F.S., any rules adopted under this part or those chapters, or any federal or state drug law, regardless of whether the person	Annual	Yes	• No unlicensed activity • Storage compliance • Security compliance • Written policies and procedures • Location can not be a residence	Annual
Prescription Drug Wholesale Distributor - Broker		$950		Annual	Yes		Annual
Out of State Prescription Drug Wholesale Distributor		$800		Annual	No		As needed

Licensee/ Permitee/ Registrant	Regulated By	Fee	Licensure/ Permit/ Requirements	Renewal	Initial Inspection	Inspection Requirements	Inspection Frequency
			has been pardoned, had her or his civil rights restored, or had adjudication withheld. • if the assignment, sale, transfer, or lease of an establishment permitted under this part will avoid an administrative penalty, civil action, or criminal prosecution.				
Retail Pharmacy Wholesaler	Department of Health (Ch. 499, F.S.)	$100	• Completed application, which is signed and notarized • Identify type of ownership • Provide FEID number • List DBA name and corporate name • Provide hours of operation • List of owners, % of ownership, date of birth • Disclosure of disciplinary information • List of type of products being handled • Identify type of customers • Identify type of sales/ domestic or export • List of where records stored • Provide DEA # (controlled substance) if state license issued • Must hold a community pharmacy permit • Provide a copy of community pharmacy permit • Cannot hold any other pharmacy permits • Identify buying groups in which wholesaler is member • Must provide prescription services to the general public • Must have adequate inventory on hand to service Rx need of general public	Biennial	No	• No unlicensed activity • Storage compliance • Security compliance • Written policies and procedures • Location can not be a residence	Annual

Licensee/ Permitee/ Registrant	Regulated By	Fee	Licensure/ Permit/ Requirements	Renewal	Initial Inspection	Inspection Requirements	Inspection Frequency
			• Cannot be issued to a health care entity • Purchases of prescription drugs must be made at fair market value for retail pharmacies • Company must identify if they can purchase prescription drugs under special contracts, arrangements, or discounts for health care entity Who is excluded: • Applicants who are not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification • Applicants who have not met the requirements for the permit or certification. • Applicants who are not eligible for a permit or certification for any of the reasons enumerated in s. 499.012, F.S. • Applicants who are certified under s. 499.012(16), F.S., and demonstrates any of the conditions enumerated in s. 499.012, F.S. • Applicants who are certified under s. 499.012(16), F.S. and has committed any violation of ss. 499.005-499.0054, F.S. The department may deny, suspend, or revoke a permit: • if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of Chapters 499, 465, 501, or 893, F.S., any rules adopted under this part or those chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld. • if the assignment, sale, transfer, or lease of an establishment permitted under this part will avoid an administrative penalty, civil action, or criminal prosecution.				
Community Pharmacies	Board of Pharmacy (Ch. 465, F.S.)	$255 $47 per fingerprint card	• Completed application, which is signed • Pharmacy manager or consultant listed with signature • Certificate of Status for the corporation from the Secretary of State • Fingerprint cards and $47.00 fee for each set of fingerprints for owner/officers who have 5% or greater and any person who directly or indirectly manages, oversees, or controls the operation of the applicant including members and board of directors. If the corporation has more than $100 million in business taxable assets you only have to send the prints of the corporate representative and the prescription department manager.	Biennial	Yes	• Storage/ equipment compliance • Proper medication labeling • Patient profile records available • Pedigree records available • Controlled substance records properly maintained	Annual

Licensee/ Permitee/ Registrant	Regulated By	Fee	Licensure/ Permit/ Requirements	Renewal	Initial Inspection	Inspection Requirements	Inspection Frequency
Dispensing Practitioners Who Can Dispense Controlled Substances	Board of Medicine (Ch. 458, F.S.) Board of Osteopathic Medicine (Ch. 459, F.S.) Board of Podiatry (Ch. 461, F.S.) Board of Dentistry (Ch. 466, F.S.) Board of Pharmacy (Ch. 465, F.S.)	$100 fee for dispensing practitioner registration	• Must have valid medical doctor, osteopathic physician, dentist, or podiatrist license • Must have valid Drug Enforcement Administration registration	Biennial	No	• Storage/ equipment compliance • Proper medication labeling • Practitioner personally checking prescription • Pedigree records available • Controlled substance records properly maintained	Annual
Pain Clinics	Department of Health (Ch. 456, F.S.) Board of Medicine (Ch. 458, F.S.) Board of Osteopathic Medicine (Ch. 459, F.S.)	$150	Privately owned pain management clinics, facility or office, which: • Advertise in any medium for any type of pain management services, or • Employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications • Must be wholly owned by a physician licensed under Chapters 458 or 459, F.S., or by a group of physicians, each of whom is licensed under Chapters 458 or 459, F.S., or have a Health Care Clinic license under Chapter 400, Part X, F.S. • Must designate a physician/osteopathic physician with a full, active, unencumbered license who will be responsible for complying with all requirements related to registration and operation of the clinic • Must fully complete, sign and submit registration application Who is **exempt** from licensure: • Clinics that are licensed as a facility pursuant to Chapter 395, F.S.; • Clinics in which the majority of the physicians who provide services in the clinic primarily provide surgical services; • Clinics that are owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million; • Clinics that are affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows; • Clinics that do not prescribe or dispense controlled substances for the treatment of pain; or • Clinics owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3). Who is **excluded** from licensure: • Clinics in which a principal or agent or affiliated person of applicant has been convicted or entered a plea of guilty or nolo contendere to a felony under Chapters 817, 893, F.S.; 21 USC 801-970 or 42 USC 1395-1396 • Clinics in which a principal or agent or affiliated person of applicant has been terminated for cause from Florida Medicaid program pursuant to s. 409.913, F. S.	One time registration	No	• Clinic is registered • Dept notified of Designated Physician • Physical exam performed by physician same day • Documented reason for prescribing or dispensing more than a 72 hr dose • Physician maintains control of Rx blanks • Designated physician practices at the clinic location	Annual, $1500 inspection fee

Licensee/ Permitee/ Registrant	Regulated By	Fee	Licensure/ Permit/ Requirements	Renewal	Initial Inspection	Inspection Requirements	Inspection Frequency
			• Clinics in which a principal or agent or affiliated person of applicant has ever been terminated for cause pursuant to appeal procedures established by the state or Federal Government or from any other state or Medicaid program or the federal Medicaid program • Clinics in which the applicant is not in good standing with State Medicaid program or the federal Medicaid program for the most recent five years • Clinics in which either the applicant or any physician with a contractual or employment relationship to the applicant has had his/her DEA number revoked • Clinics in which either the applicant or any physician with a contractual or employment relationship to the applicant has had his/her license to prescribe, dispense, or administer a controlled substance denied by any jurisdiction • Clinics in which either the applicant or any physician with a contractual or employment relationship to the applicant has been convicted of or plead nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in schedule I, II, III, IV or V of s. 893.03, F.S., in this state, any other state, or in the United States.				

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Permit Types Under Ch. 499, F.S.	# of Licenses/Permits /Registration	# of Complaints
Prescription Drug Manufacturer	106	15
Non-resident Prescription Drug Manufacturer	800	20
Prescription Drug Repackager	29	6
Prescription Drug Wholesale Distributor	131	31
Out-of-State Prescription Drug Wholesale Distributor	254	28
Retail Pharmacy Drug Wholesale Distributor	73	15
Prescription Drug Wholesale Distributor - Broker Only	4	1

Total # of complaints received from July 1, 2009 to date: 116

Dispensing of Controlled Substances by Location					
Locations	# of Licenses/Permits/ Registrations	# of Complaints	# with Probable Cause	Discipline	# Appeals July 1, 2009 to Date
Dispensing Practitioners***	6335	**188***	**40***	**29***	**1***
Community Pharmacies	4632	460	61	56	0
Pain Clinics	860	173	11	2**	0

* Complaints Related to Prescribing/Dispensing Allegations – July 2009 to date.
** During this period, January 1, 2010 to date, one pain clinic relinquished its license and one pain clinic was fined. Additionally, 54 clinics were administratively revoked.
***The dispensing practitioners reported above include only those who are authorized to dispense controlled substances identified below.

Dispensing Practitioners	Total
Podiatric Physician	132
Dentist	199
Medical Doctor	5116
Osteopathic Physician	888
Total	**6335**

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Status of Pain Clinics Considered for Revocation	Total
Pain clinics closed through Notice of Intent to Administratively Revoke (ITAR)	54
Pain clinics pending action after ITAR	72
Pain clinics in compliance after ITAR	110
Total ITARs	**236**

The ITARs were directed to registered pain management clinics that did not meet ownership requirements of s. 458.3265 or s. 459.0137, F.S., which became effective October 1, 2010.

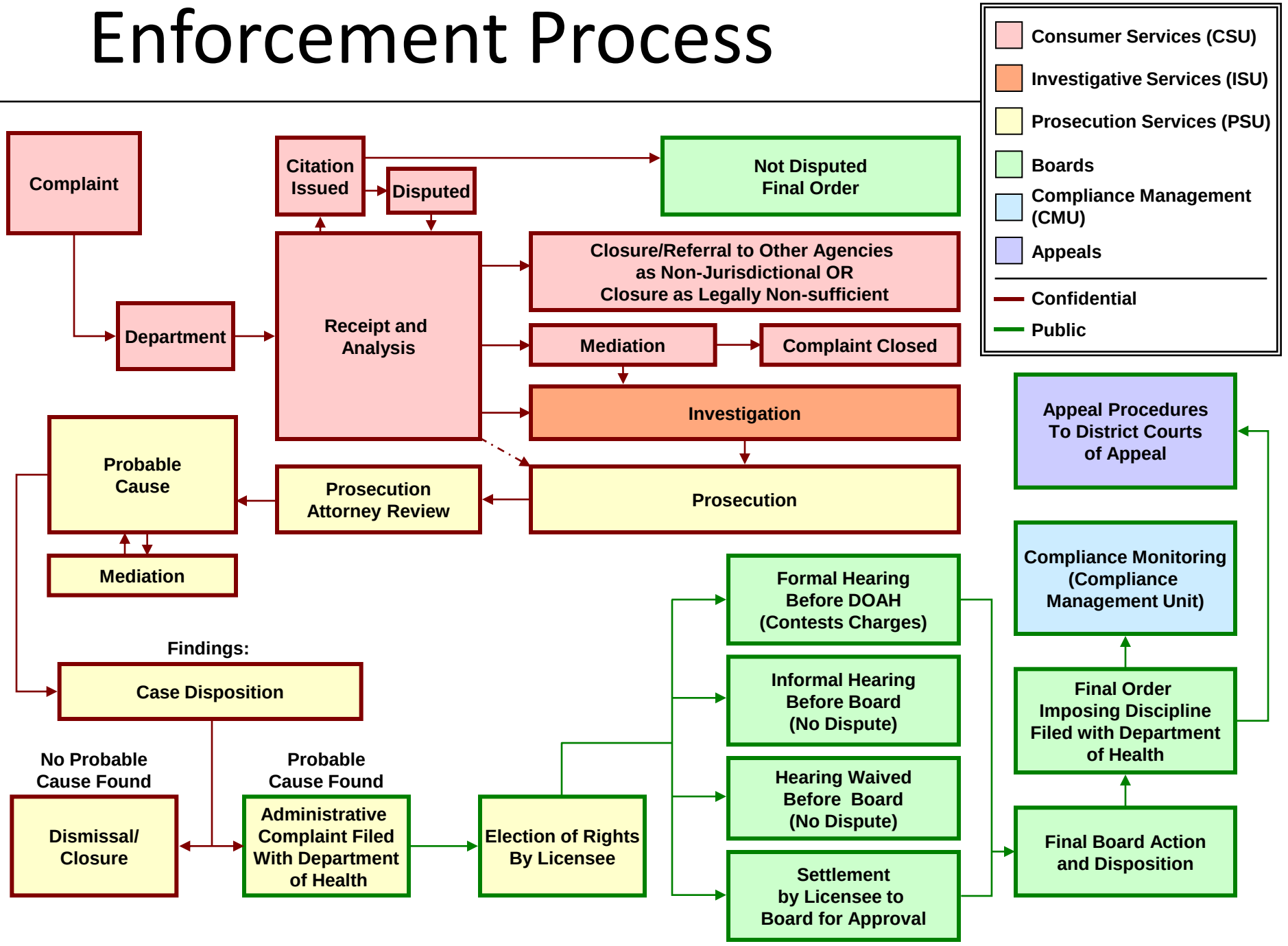
1) How many complaints have been filed against pain clinics for practicing without a license?

Complaint Source	# Complaints Jan 2010 to Date
Consumer	2
Other Registrant	3
Other State Agency	2
Internally Generated	119
Anonymous	3
TOTAL	**129**

2) The number of complaints related to Dispensing Practitioner violations by year where the allegation was either a prescribing/dispensing related issue or interference with an inspection.
3) Number of final orders filed related to Dispensing Practitioner violations by year where the allegation was either a prescribing/dispensing related issue or interference with an inspection.
4) Number of citations issued. Citations are not issued for serious violations. As such, the citations listed below are for minor violations.
5a.) Number of complaints based on a violation of s. 465.016(1)(s), F.S., for complaints alleging selling or dispensing a medicinal drug without a valid prescription.
5b.) Number of final agency actions based on a violation of s. 465.016(1)(s), F.S., for complaints alleging selling or dispensing a medicinal drug without a valid prescription.

Dispensing Practitioners	2006-07	2007-08	2008-09	2009-10	2010-11 To Date	Avg / Yr
2.) Complaints Received	59	37	59	117	71	68.6
3.) Disciplinary Actions by Board	5	12	2	9	20	9.6
4.) Citations Issued for Minor Violations	65	57	85	33	33	54.6
5a.) Complaints, s. 465.016(1)(s), F.S.	100	34	24	33	16	41.4
5b.) Disciplinary Action Taken, s. 465.016(1)(s), F.S.	22	11	5	5	2	9

Enforcement Process



House of Representatives Health & Human Services Committee
Workshop on PDMP and Regulation of Controlled Substances, February 24, 2011

PDMP Funding and Expenditures

Federal Grants	Funding	Expenditures per Funding Source FY09/10	Expenditures per Funding Source FY10/11	Total Funds Remaining as of 1/31/11
Harold Rogers Implementation Grant	$400,000	($3,628)	($36,854)	$359,518
Harold Rogers Enhancement Grant	$400,000			$400,000
Federal Grants Sub-Total	**$800,000**	**($3,628)**	**($36,854)**	**$759,518**
Private Grants				
National Association of States Controlled Substance Authorities (NASCSA)Grant 1	$20,000	($2,595)	($9,369)	$8,036
NASCSA Grant 2	$6,271		($945)	$5,326
NASCSA Grant 3	$19,681			$19,681
Private Grants Sub-Total	**$45,952**	**($2,595)**	**($10,314)**	**$33,043**
Direct Support Organization				
Florida PDMP Foundation, Inc.	$240,660	($193)	($86,979)	$153,488
DSO Sub-Total	**$240,660**	**($193)**	**($86,979)**	**$153,488**
FUNDING TOTAL	**$1,086,612**	**($6,416)**	**($134,147)**	**$946,049**

Pain Medicine

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Prescription Drug Monitoring Programs and Death Rates from Drug Overdose

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The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

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Abstract

Objective. Drug overdoses resulting from the abuse of prescription opioid analgesics and other controlled substances have increased in number as the volume of such drugs prescribed in the United States has grown. State prescription drug monitoring programs (PDMPs) are designed to prevent the abuse of such drugs. This study quantifies the relation of PDMPs to rates of death from drug overdose and quantities of opioid drugs distributed at the state level.

Design. Observational study of the United States during 1999–2005.

Outcome Measures. Rates of drug overdose mortality, opioid overdose mortality, and opioid consumption by state.

Results. PDMPs were not significantly associated with lower rates of drug overdose or opioid overdose mortality or lower rates of consumption of opioid drugs. PDMP states consumed significantly greater amounts of hydrocodone (Schedule III) and nonsignificantly lower amounts of Schedule II opioids. The increases in overdose mortality rates and use of prescription opioid drugs during 1999–2005 were significantly lower in three PDMP states (California, New York, and Texas) that required use of special prescription forms.

Conclusions. While PDMPs are potentially an important tool to prevent the nonmedical use of prescribed controlled substances, their impact is not reflected in drug overdose mortality rates. Their effect on overall consumption of opioids appears to be minimal. PDMP managers need to develop and test ways to improve the use of their data to affect the problem of prescription drug overdoses.

Key Words. Opioid; Analgesic; Overdose; Prescriptions; Abuse; Regulation

Introduction

Increases in prescription drug overdoses have driven a steep rise in the rate of drug overdose mortality in the United States in the past decade with much of the increase attributable to prescription opioid analgesics [1–4]. Nonsuicidal prescription opioid overdose deaths increased by 142% during the period 1999–2004, while heroin deaths declined [2]. The increasing numbers of opioid-related deaths were associated with parallel increases in both the prescribing of opioids [4] and the self-reported nonmedical use of these drugs [5]. Persons dying of prescription drug overdoses generally have a history of abusing or misusing the drugs and frequently obtaining them without prescriptions [6,7].

Prompted in part by the diversion of prescription opioids and other pharmaceuticals to nonmedical use, Congress asked the U.S. General Accounting Office (GAO) to study state prescription drug monitoring programs (PDMPs). The GAO concluded in 2002 that PDMPs were useful in reducing drug diversion [8]. State PDMPs have since proliferated in the United States, operating in 16 states in 2000 [9] and in 32 states by 2008 [10]. The Department of Justice instituted the Harold Rogers Prescription Drug Monitoring Program to help fund PDMPs in fiscal year 2003 [11], and the Department of Health and Human Services began to fund PDMPs through the National

All Schedules Prescription Electronic Reporting Act (NASPER) in 2009 [12].

Although program specifics vary substantially from state to state, PDMPs typically require retail pharmacists to enter data from prescriptions for controlled substances into a centralized electronic database. These data identify the prescriber, dispenser, and patient, as well as the drug, dose, and amount dispensed. In a few states with special prescription forms, the pharmacists also capture a unique serial number that can be tracked to identify duplicates and stolen forms. PDMP information potentially allows state personnel to identify individuals who might be prescribing, dispensing, or using prescribed controlled substances inappropriately. Depending on the legally sanctioned uses of the data obtained, PDMPs can then employ various interventions designed to reduce the abuse and/or diversion of controlled substances and associated negative social and health consequences, such as drug addiction and drug overdoses [8].

Despite the increasing state and federal funding being made available to PDMPs and the program activity already underway, few empirical studies have addressed the effect of PDMPs on the prescribing or abusing of opioid analgesics [13]. Researchers have evaluated PDMPs' effect on substance abuse treatment rates from 1997 to 2003 [14] and on the prescribing of Schedule II opioid analgesics [14,15]. No known recent study has systematically evaluated the association of PDMPs with what is arguably one of the most severe consequences of opioid abuse, inadvertent lethal overdose. Accordingly, we evaluated the association of PDMPs with drug overdose mortality rates and consumption of prescription opioid medications in the United States during 1999–2005.

Methods

U.S. mortality data by state and by year for 1999–2005 were obtained from multiple cause of death mortality files produced by the National Center for Health Statistics (NCHS) at the Centers for Disease Control and Prevention (CDC). We examined drug overdose deaths that were unintentional or of undetermined intent (International Classification of Disease, 10th revision [ICD-10] codes X40–X44, Y10–Y14) and the subset of those deaths where an opioid analgesic was listed as a contributing cause of death ("opioid-related mortality"). Opioid analgesic poisoning was identified by the presence of the ICD-10 codes T40.2, T40.3, or T40.4. Overdose deaths of undetermined intent were included because some state medical examiners frequently use the undetermined intent category, and undetermined overdose deaths resemble unintentional overdoses more than suicidal overdoses [16,17].

Bridged-race census and intercensal year-specific population estimates of the 50 states and the District of Columbia (DC), developed jointly by the U.S. Census Bureau and NCHS in 2006, were obtained from the CDC Wide-ranging OnLine Data for Epidemiologic Research (WONDER) system for use in rate calculations [18]. From the Census Bureau, the authors obtained to test as covariates the median age of the population and the percentages that were Hispanic, white, black, Asian or Pacific Islander, and American Indian or Alaska Native. The Census Bureau also provided the median household income [19] and the percentages of high school and college graduates by state and year [20]. As an additional possible covariate, the authors obtained the proportions of state populations living in counties assigned by NCHS to each of four levels of urbanization [21] (of the six urbanization levels used by NCHS, the three most rural levels were combined into one to avoid small cell sizes).

State- and year-specific retail distributions of prescription opioids are tracked by the Automation of Reports and Consolidated Orders System (ARCOS) of the U.S. Drug Enforcement Administration (DEA). ARCOS monitors the flow of controlled substances from the point of manufacture through commercial distribution channels to the point of sale or distribution at the dispensing/retail level. State- and year-specific quantities of seven of the most commonly prescribed opioid drugs (fentanyl, hydrocodone, hydromorphone, meperidine, methadone, morphine, and oxycodone) were available for 1999 and 2001–2005 [6]. The DEA provided the lead author the quantities of these seven opioids for the year 2000 because they were not available on the ARCOS Website. DEA has assigned virtually all Food and Drug Administration (FDA)-approved formulations of six of these opioids to Schedule II of its Schedule of Controlled Substances, the most closely regulated of the four schedules to which prescription drugs are assigned (II–V). Hydrocodone has been sold almost entirely in combination products assigned to Schedule III, for which there are fewer restrictions on refills, documentation, and other aspects of drug dispensing [22].

To adjust for differences in opioid potency, the authors calculated morphine milligram equivalents (MME) as the product of the milligram weight of each drug and the following drug-specific multipliers: fentanyl, 75; hydrocodone, 1; hydromorphone, 4; meperidine, 0.1; methadone, 7.5; oxycodone, 1 [23]. The total MME per person and the MME per person for hydrocodone and the other six drugs were calculated separately for each state for each year.

For each of the seven study years and 51 jurisdictions (50 states and DC), a total of 357 state-years of observation, the authors determined the presence or absence of an operational PDMP. "Operational" was defined as "capable of collecting data and distributing data to one or more authorized users of the data" [24]. If a PDMP involved a major geographic subdivision but not the entire state (e.g., Virginia during 2003–2005), the authors considered it operational. If a PDMP was limited to specific prescribers who were being monitored, e.g., Washington State, it was not considered operational. Nineteen states had operational PDMPs at some time during 1999–2005: California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Maine, Massachusetts, Michigan, Nevada, New Mexico, New York,

Oklahoma, Pennsylvania, Texas, Utah, Virginia, West Virginia, and Wyoming.

"Proactive" PDMPs were defined as those generating reports for prescribers, dispensers, or law enforcement authorities without being solicited. PDMP reporting activity came from a 2006 survey by the Integrated Justice Information Systems Institute [25]. Thirteen of the operational PDMPs met the proactivity definition: California, Hawaii, Idaho, Maine, Massachusetts, Nevada, New Mexico, New York, Oklahoma, Pennsylvania, Texas, Utah, and Wyoming. The authors also used Integrated Justice Information Systems (IJIS) survey data to separately examine the state-years with more than 100 solicited or unsolicited reports per 10,000 population to doctors, dispensers, or other recipients. That high reporting rate was reached by four states: Kentucky, Nevada, Utah, and West Virginia [25].

The authors calculated and plotted crude mean mortality and MME rates and their standard errors for PDMP and non-PDMP states. To compare year-specific differences in means, Student's *t*-test was used.

The effects of PDMPs over time on 1) drug overdose mortality, 2) opioid overdose-related mortality, and 3) MME were modeled using regression models for multiple parallel time series, often referred to as "panel regression" [26]. These models included the following: structural variables (time, geography [state]), temporally lagged values of the dependent variable, and algebraically transformed (weighted), geographically lagged values of the dependent variable; the presence of a PDMP; and the potential covariates mentioned earlier added one at a time. When mortality was a dependent variable, the MME rate was tested as a potential covariate (confounder).

To prevent spatial autocorrelation (the tendency for one state to have values similar to neighboring states) from biasing estimation of the PDMP regression coefficient or its variance, we used geographically "lagged" values of the dependent variables, those related to the values of other states (weighted by proximity). Similar effects resulting from temporal autocorrelation were handled by using temporally lagged values, i.e., the values of previous years for a given rate. Because of the high level of temporal autocorrelation present in the mortality rates, these variables were also transformed by differencing. That is, instead of using the rates themselves as dependent variables, we used the year-to-year increase (or if negative, the decrease) in the rate's value. MME rates were similarly modeled as a function of the presence of a PDMP and the covariates (but not as a function of the mortality variables).

The fit of the final fixed effects panel regression model was evaluated by means of visual inspection of plots and tabulations of model residuals, and diagnostic testing of the model with Moran's I [27], Geary's C [28], and the extension of the Durbin–Watson statistic for panel data proposed by Bhargava et al. for temporal autocorrelation in multiple parallel time series [29]. In addition, techniques described by Arellano were used to mitigate the effects of heteroscedasticity (nonconstancy of the variance) in the data [30].

Substantial distortion caused by autocorrelation and indicated by regression diagnostics occurred only in the analysis of the differenced drug overdose mortality variable, the apparent result of extreme year-to-year variability in the values in drug overdose mortality rates reported by DC. Thus, indicator variables for the outlier years from DC were added to the model, resulting in satisfactory improvement in the regression diagnostics.

Where the Hausman m-statistic [26] indicated that modeling allowing for random effects was viable, we attempted such models, but no gain was noted over the fixed effects models, which permitted better diagnostic evaluation of regression modeling. Accordingly, we used fixed effects models as our final models throughout the analysis.

Results

For states with and without PDMPs, the mean drug overdose and opioid-related overdose mortality rates rose substantially and consistently during 1999–2005. The rates approximately doubled for drug overdose mortality and tripled for opioid-related overdose mortality (Figure 1). The differences between PDMP and non-PDMP states were not statistically significant for either mortality rate for any of the study years by Student's *t*-test. States with PDMPs had higher crude mortality rates during 1999–2005 (Table 1).

Proactive PDMP states did not have rates lower than other PDMP states regarding either drug overdose or opioid-related mortality nor did the states with PDMPs that sent out a high rate of reports differ from other states (Table 1). However, inspection of data for individual states revealed distinctly lower than average crude rates of drug and opioid overdose mortality on a year-by-year basis in the PDMP states of California, New York, and Texas (Table 1).

From 1999–2005, mean MME rates approximately tripled, increasing from about 175 MME/person to about 525 MME/person. PDMP and non-PDMP states had almost identical mean MME rates each year and over the entire time period (Table 1). Proactive states and states with high reporting rates did not have lower MME rates any year. As was true for mortality rates, mean MME rates in California, New York, and Texas did not increase as much as in other states. MME rates from hydrocodone were significantly higher by about 20 MME/person in PDMP states compared with non-PDMP states, whereas MME rates for the other opioids were consistently but not significantly lower by about 20 MME/person in PDMP states (Figure 2).

In the regression analysis, the presence of a PDMP was not a significant predictor of mortality or MME rates (Table 2). However, the negative regression coefficient for PDMP in the MME model indicated a nonstatistically

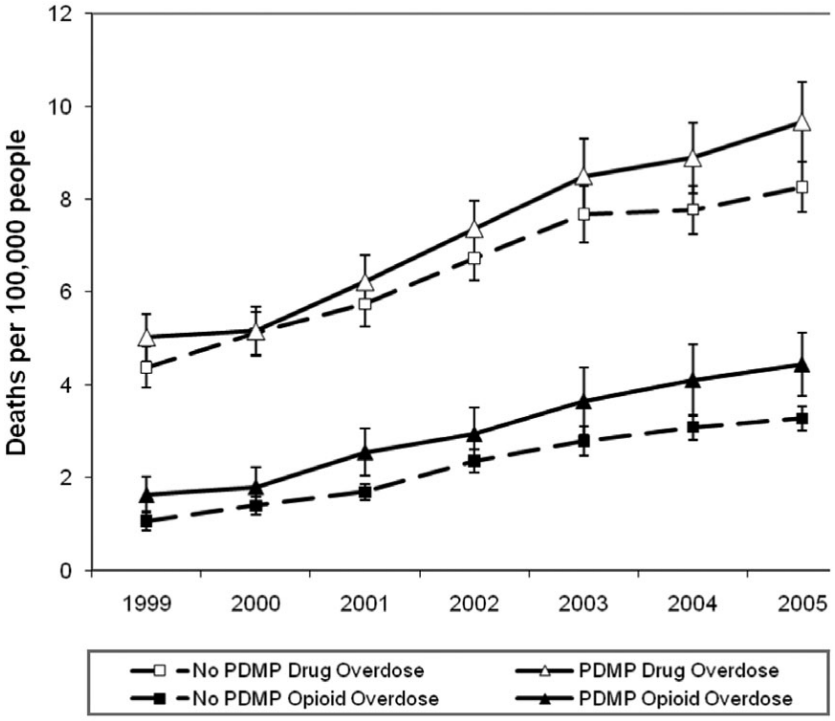

Figure 1 Mean drug overdose and opioid overdose mortality rates for PDMP and non-PDMP states by year, 1999–2005. Error bars indicate ±1 standard error of the mean.

significant trend toward *lower* rates of increase in MME rates in states and years in which a PDMP existed. Adding the racial, ethnic, median age, urbanization, education, income, and (for the mortality regression analyses) MME rate variables to each of the three final regression models did not significantly decrease any of the regression coefficients for the PDMP variable so none of these variables were included in the final analysis.

Discussion

PDMPs were not associated with lower drug overdose mortality rates for any of the study years or with decreases (or even with lesser increases) in the rates of death resulting from drug overdoses. The findings also indicate that PDMPs were not associated with lower rates of consumption of opioids during 1999–2005, although they were associated with lower rates of use of Schedule II drugs. Even when focused on proactive PDMPs or programs with relatively high rates of reporting, there were no associations of PDMPs with trends in overdose deaths or opioid use.

This study's findings differ from those of Simeone [14], who reported that PDMPs were associated with significantly lower rates of use of opioids. However, Simeone examined

Table 1 Crude rates for drug overdose mortality, opioid overdose mortality, and morphine milligram equivalents (MME), 1999–2005

State-years	N	Drug overdose mortality rate*	SE†	Opioid overdose mortality Rate*	SE†	MME per person‡	SE†
Without PDMPs	247	6.46	0.21	2.20	0.10	341.67	10.20
With PDMPs	110	7.45	0.31	3.13	0.25	362.43	15.99
With proactive PDMPs	72	7.64	0.38	3.30	0.29	365.67	20.47
With high-reporting PDMPs	12	11.41	0.82	6.57	0.70	540.75	45.54
California, New York, and Texas	21	5.36	0.31	1.65	0.17	251.19	18.38

* Rate per 100,000 person years.
† Standard errors are unadjusted for autocorrelation among observations and are therefore unsuitable for statistical tests of between-group differences.
‡ Morphine milligram equivalents per person per year.
PDMP = prescription drug monitoring program; SE = standard error.

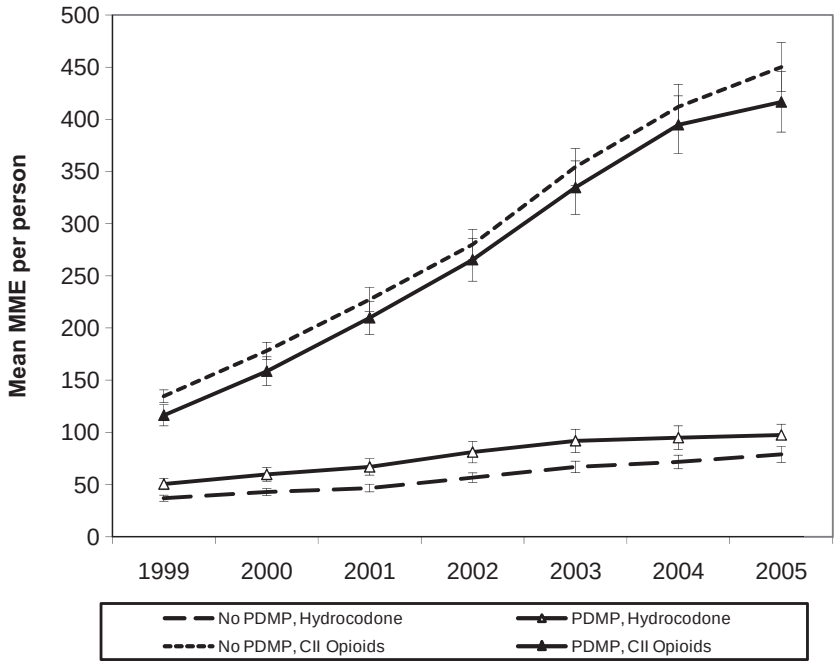

Figure 2 Mean morphine milligram equivalents (MME) per person for hydrocodone and Schedule II (CII) opioids in PDMP and non-PDMP states by year, 1999–2005. Error bars indicate ±1 standard error of the mean.

only Schedule II opioids, omitting hydrocodone, whose combination products fall into Schedule III. The current study also found lower usage of Schedule II opioids, but this difference was compensated for by increased use of hydrocodone, a substitution effect also noted in an earlier study [31]. The effect of PDMPs on opioid prescribing can not be fairly evaluated without including hydrocodone because it constitutes a sizeable fraction of total opioid dosage (18% of the MME totals for the United States during 1999–2005). Hydrocodone is, in fact, the most prescribed drug in the United States [32,33]. Patients and providers might choose hydrocodone over other opioids because Schedule III drugs such as hydrocodone combination products have fewer restrictions when prescribed and lesser criminal penalties when abused. A few state PDMPs do not track Schedule III drugs.

Table 2 Final models for drug overdose mortality, opioid overdose mortality, and morphine milligram equivalent rates (MME), 1999–2005

Variable	Drug overdose mortality rate*	Opioid overdose mortality rate*	MME per person year†
Name	Coefficient (*P*)	Coefficient (*P*)	Coefficient (*P*)
Intercept	0.58 (0.0001)	0.23 (0.0001)	3,828.99 (0.0001)
Year1	–0.12 (0.6265)	0.03 (0.8580)	1,219.08 (0.0299)
Year2	0.14 (0.5784)	0.16 (0.3389)	1,668.44 (0.0031)
Year3	0.56 (0.0277)	0.34 (0.0454)	2,693.59 (0.0001)
Year4	0.30 (0.2376)	0.27 (0.1125)	4,560.05 (0.0001)
Year5	–0.32 (0.2045)	0.12 (0.4666)	2,510.28 (0.0001)
DC00	4.42 (0.0001)		
DC02	–6.88 (0.0001)		
DC03	5.72 (0.0001)		
DC04	–3.08 (0.0001)		
Prescription drug monitoring program	0.10 (0.4953)	0.09 (0.3437)	–162.40 (0.5535)

* Rate per 100,000 person years.
† Morphine milligram equivalents per person per year.
DC00 through DC04 are indicator variables for the District of Columbia mortality rates.

Whether changes in the choice of drugs by physicians as a result of PDMPs adversely affect patients has been the subject of controversy [13]. For example, the addition of benzodiazepines to New York's PDMP in 1989 resulted in greater use of "less acceptable" sedating medications [34]. Some have argued that these substitution effects are transient or exaggerated [35]. Substitution of hydrocodone for other opioids is potentially problematic because of its combination with the potent hepatotoxin acetaminophen in many of its most popular formulations (e.g., Vicodin®). Narcotic–acetaminophen combination drugs now cause a large percentage of cases of liver failure resulting from acetaminophen poisoning [36]. Acetaminophen now causes more than half of the cases of acute liver failure in the United States, and the proportion is rising [36].

The observation that the three most populous states—California, New York, and Texas—have had lower rates of opioid prescribing and overdose mortality than other states with PDMPs in recent years has been made previously [3,15,37,38]. It has been suggested without explanation that these states' lower rates of opioid prescribing occurred because they had some of the oldest PDMPs in the country [15]. However, other states with long-established PDMPs, such as Massachusetts, Rhode Island, and Oklahoma, did not show similarly slower rates of increase in mortality or opioid use in this study. What might be different about California, New York, and Texas is their continued use of serialized tamper-resistant prescription forms, while other states have largely moved away from the use of special paper forms. In studies of the older, triplicate prescription forms, states consistently experienced decreased use of controlled substances following the introduction of such forms, with much of the decrease resulting from declines in inappropriate use [13].

Whether because of these special prescription forms or not, some aspect(s) of the programs in these three states might affect both overdose mortality and the rates at which opioids are prescribed. Given that these three states might be different in ways other than their continued use of special prescription forms (e.g., factors related to their large populations, their use of PDMP data, or the availability of heroin), firm conclusions can not be drawn about what is responsible for their lower mortality and opioid distribution rates. Moreover, the possible effectiveness of this specific aspect of the drug diversion control programs in these states was not among the *a priori* hypotheses of this study, another reason for cautious interpretation of lower mortality and drug distribution in these states.

The primary limitation of this study is its ecologic design. Ecologic studies can identify associations that are true at the state level but not at the individual level. This study attempted to rule out variables that may have confounded the analysis in this way by testing for the effect of several demographic variables on the definitive models. Adjustment for other factors that were more difficult to quantify, e.g., patterns of treatment, preventive measures such as changes in state regulations, or the availability of street drugs, was not possible. Therefore, this study can not rule out residual confounding that may have obscured a protective effect of PDMPs. For example, states with a predisposition toward drug abuse might have initially had higher drug overdose rates that made them more likely to establish a PDMP. Such a predisposition might, in fact, account for the higher crude drug overdose mortality rates seen in PDMP states in this study. As a result, we can not be certain that mortality rates in PDMP states would not have been even higher in the absence of a program. However, it can be said unequivocally that PDMP states did not do any better than non-PDMP states in controlling the rise in drug overdose mortality from 1999 to 2005.

Unfortunately, an alternative before–after design that would evaluate changes in state rates after the establishment of PDMPs to control for factors that may have led to PDMP legislation was not possible with available data. Information on opioid–analgesic-related mortality is only available after 1999. Drug distribution data are only available after 1997. Only a few states started PDMP data collection after 1999 and prior to 2005, thus allowing sufficient observation periods pre- and post-PDMP implementation. Such a study should be possible in a few years and would add to the evidence base on the effect of PDMPs on reductions in death rates due to opioid overdose.

Both the opioid distribution and mortality rates have sources of error. Errors in MME rates might have resulted when prescription drugs distributed to one state were sold to residents of neighboring states, as occurs when patients cross state lines or mail-order pharmacies distribute to multiple states. The extent to which such errors occur is not known. Overdose mortality rates might have been affected by state-to-state variation in the skill and thoroughness with which death investigations are conducted. Some overdoses might have been mistakenly attributed to natural causes, for example.

Overall drug mortality rates are a crude indicator of the prevalence of overdoses involving controlled substances monitored by PDMPs because overall rates include deaths from illicit drugs such as cocaine. However, by 2004, overdoses involving opioid analgesics easily outnumbered deaths involving heroin or cocaine in the United States. In addition, changes in overall drug mortality rates since 1999 likely reflect changes in prescription opioid-related mortality, which far exceeded changes in rates of heroin- and cocaine-related mortality in the United States during this time period [2]. Opioid-related overdose mortality rates as defined in this study are a more precise measure, but they likely suffer from variability among state medical examiners and coroners on the extent to which they specify drugs on the death certificates of overdose deaths. In addition, the data do not permit a distinction between overdoses among persons actually prescribed opioids and persons who obtained them without a prescription. PDMPs might have had more impact on persons who obtained their drugs by prescription.

Finally, this study could not evaluate the potential benefits other than prevention of overdose fatalities that might

have resulted from PDMPs. For example, PDMPs are reportedly useful in facilitating criminal investigations [8], and they may have had salutary effects on drug diversion that could not be captured by our methods. Nor could this study evaluate the impact of other specific features of PDMPs that had not been captured in previous surveys, such as a high level of unsolicited reporting to law enforcement agencies.

Conclusions

The continuing epidemic of opioid overdose mortality documented in this study underlines the need for careful ongoing evaluation of public health and law enforcement programs designed to address drug diversion. Injury prevention programs usually should not be endorsed or abandoned based on a single evaluation so additional evaluation of PDMPs is required [39]. Clearly, however, PDMPs should work continuously to improve their effectiveness. All PDMPs should have the authority to monitor more than Schedule II drugs so that persons wanting to avoid scrutiny can not simply shift to lower-schedule drugs. The data collected by the PDMPs themselves about patterns of prescription use would probably be a useful way to monitor the effect of any such improvements. For example, PDMPs could track and report changes in standardized outcome measures, such as the percentage of patients seeing five or more doctors for controlled substances within the past 6 months or the receipt of multiple overlapping prescriptions [40]. In theory, PDMPs have the potential to address the problem of prescription drug overdoses, but to do so, their use of the information they collect will need to be enhanced.

Acknowledgments

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Testimony – For the Record

Health and Human Services Committee
The Florida House of Representatives

Prescription Drug Monitoring System and Regulation of Controlled Substances

Statement of

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Testimony of Len Paulozzi, MD, MPH, Medical Epidemiologist in the Division of Unintentional Injury, a Division of the National Center for Injury Prevention and Control within the Centers for Disease Control and Prevention (CDC).

Drug overdose death rates in the United States have increased five-fold since 1990 and have never been higher. In 2007, more than 27,000 people died from unintentional drug overdoses—one every nineteen minutes. This unprecedented rise in overdose deaths parallels a ten-fold increase since 1995 in the prescribing of opioid analgesics, drugs used to treat pain. Opioid analgesics are now involved in more overdose deaths than cocaine and heroin combined.

Florida is particularly hard-hit by this epidemic. An average of six people die every day in Florida due to prescription drug overdose, and Florida has one of the highest drug overdose death rates in the nation. Florida also has a significant problem with rogue pain clinics or "pill mills." In 2008, 49 of the 50 top dispensers of oxycodone in the U.S. were located in Florida. Despite these numbers, Florida remains the largest state without an operational Prescription Drug Monitoring Program (PDMP).

In my testimony, I will summarize the most relevant studies of PDMP effectiveness, including a forthcoming study in which I participated, explain the differences between these different studies, and conclude by explaining some of the key benefits that PDMPs can provide to address the prescription drug abuse epidemic.

Summaries of the most relevant studies of PDMP effectiveness

First, I will summarize a forthcoming study that evaluates the effectiveness of PDMPs and will be published later this year.[1] This study sought to quantify the relation of PDMPs to rates of death from drug overdose, opioid-related overdose, and per capita quantities of schedule II–III opioid analgesics distributed at the state level. The study used vital records and DEA ARCOS[2] data from 1999–2005. We found that PDMPs were not significantly associated with lower state-level rates of drug overdose or opioid overdose mortality or lower rates of consumption of opioid drugs. We also found that PDMP states consumed a higher proportion of schedule III hydrocodone combinations, like Vicodin, perhaps because lower schedule drugs are subject to less regulation. Three states with PDMPs, New York, Pennsylvania, and Texas, stood out for their markedly lower consumption of opioids and lower mortality rates. These three states made use of serialized, single-copy, tamper-resistant prescription forms, were proactive in their use of PDMP reports, and are authorized to report to law enforcement agencies.

Another recent study[3] analyzed how PDMPs affected rates of abuse treatment admission and quantities of schedule II opioids distributed at the state level.[4] This study found that PDMPs were

[1] Paulozzi et al., 2011 (in press).
[2] ARCOS is the Automation of Reports and Consolidated Orders System, an automated, comprehensive drug reporting system that monitors the flow of DEA controlled substances from their point of manufacture to the point of sale or distribution at the dispensing/retail level.
[3] Simeone R, Holland L. An Evaluation of Prescription Drug Monitoring Programs. 2006. Available from URL: www.simeoneassociates.com/simeone3.pdf.

significantly associated with lower rates of consumption of schedule II opioids and stimulants, and although treatment admission rates still increased over time, these increases were lower with PDMPs. States with proactive PDMPs—that is, PDMPs that generate unsolicited reports whenever suspicious behavior is detected—showed stronger effects.

A third study[5] used poison control center contacts and abuse/misuse exposures in states with and without PDMPs to evaluate how PDMPs affected abuse/misuse rates for long-acting opioids versus immediate release opioids. The study found that PDMPs were associated with slower rates of increase in abuse/misuse over time. It further concluded that PDMP effects did not vary by type of opioid.

The final relevant study[6] analyzed how PDMP data influenced the clinical management of 179 emergency department (ED) patients presenting with pain. Clinicians from a single Ohio ED were provided with patient PDMP records before deciding how to treat pain. The study concluded that PDMP data changed clinical management in 41% of cases. Of these, 61% were prescribed fewer or no opioids, while 39% were prescribed more.

Differences among the cited studies

There are a variety of factors that help explain the differences between these four different studies. First, each study covered a different time period during a decade when many states were starting or enhancing their PDMPs with new federal funding. Therefore, the full effects of new PDMPs might not have been apparent, and PDMP effectiveness might have improved over time.

Second, the studies examined different health outcomes—mortality, substance abuse treatment, and poison control center contact rates—and measured different aspects of the problem of prescription drug abuse. These rates might not correlate well with one another. For example, a state with high treatment rates might have lower mortality rates as a result. Further, factors other than PDMP impact, such as changes in the availability of treatment services, might have affected the observed associations.

Third, examination of only schedule II opioids, as done by Simeone et al., does not allow assessment of the impact of PDMPs on use of schedule III hydrocodone, the most prescribed opioid in the United States by a large margin.

Conclusions to draw from these studies

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[4] Simeone et al. was an observational study of the United States based on 1997–2003 prescription painkiller abuse admission data from Treatment Episode Data Set (TEDS) maintained by the Substance Abuse and Mental Health Administration and DEA ARCOS data.

[5] Reifler L, Droz D, Bartelson BB, Bailey E, Schnoll S, Dart RC. RADARS® system poison center opioid abuse and misuse rates over time in states with and without active prescription monitoring programs. Poster presented at: American Public Health Association Conference; 2010 Nov 6–10, Denver, CO.

[6] Baehren DF, Marco CA, Droz DE, Sinha S, Callan EM, Akpunonu P. A Statewide Prescription Monitoring Program Affects ED Prescribing Behaviors. Annals of Emergency Medicine 2010;56(1):19–23.

PDMPs are a promising mechanism for addressing the epidemic of prescription drug abuse. Sophisticated PDMPs can recognize patterns of diversion, help practitioners identify patients who are abusing opioids, and evaluate the effectiveness of policy interventions.

The contributors to this epidemic are as varied as the outcomes that PDMPs may affect. The studies discussed above demonstrate the breadth of these potential outcomes, ranging from overdose deaths and treatment admission rates to the consumption of controlled substances and the behavior of ED doctors. Although our forthcoming study does not show that PDMPs have yet impacted overdose death rates, the other studies mentioned above indicate the broad range of health outcomes PDMPs have affected, like changes in physician behavior and abuse admission rates. Affecting these types of outcomes are important first steps in addressing this epidemic.

These early studies provide only an early picture of what PDMPs can accomplish. On an individual level, a PDMP can assist a physician make an informed decision about how to treat a patient presenting with pain. On a broader scale, PDMPs can give policymakers information on how these powerful drugs are prescribed, arming them with data that they can use to implement sound, evidence-based prevention strategies. While PDMPs are not a silver bullet for ending the prescription drug epidemic, they are a critical tool to address this complex and worsening public health crisis.

In closing, unintentional drug poisonings are a significant and worsening public health problem. CDC continues to respond to this problem through state surveillance activities, epidemiologic research and evaluation of potential interventions. I would like to take this opportunity to thank the Health and Human Services Committee and the Florida House of Representatives for the opportunity to discuss this important public health issue. I would be happy to answer any further questions that you may have for the record.