



# Promising Legal Responses to the Epidemic of Prescription Drug Overdoses in the United States

## *State Issued Prescription Forms*

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# Objectives

- Present overview of paper-based Prescription Drug Monitoring Programs (PDMPs)
- Describe 'prevalence' of paper-based PDMPs
- Examine benefits and pitfalls of paper-based PDMPs
- Review empiric evidence for effectiveness of paper-based PDMPs in:
  - Reducing abuse and diversion
  - Influencing appropriate and necessary medical care

# Objectives – Not!

- Describe electronic systems
- Compare paper-based PDMPs to electronic approaches
- Discuss the pros and cons of PDMPs generally

# What is a State-Issued Rx Form?

- Pre-printed w/ Rxer name, address, license #, DEA #
- Serially-numbered and/or numbered and 'logged'
- Tamper-resistant
- Originally printed in triplicate or duplicate
- Prescriber → Dispenser → State Agency
- New forms often have quantity check-off boxes

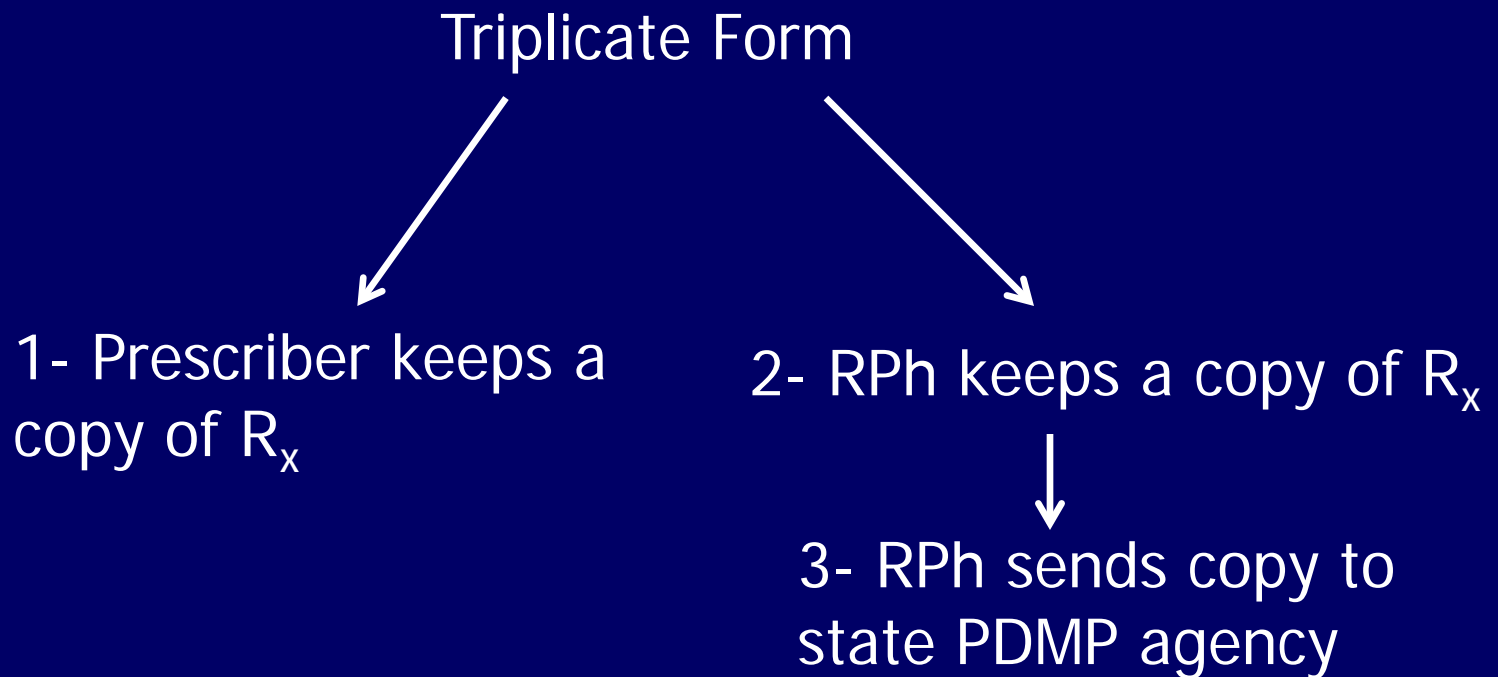
# What is a State-Issued Rx Form?

## Technological Advances

- For 'modern' single-copy prescription forms:
  - Use of special paper and/or inks – watermarks, embedded microfilaments, invisible inks, thermo-chromic inks
  - Latent 'void' which appears when copied, scanned, or treated w/ chemicals

# How State-Issued Triplication Rx Forms Worked (in the old days)

Prescribers must use state issued triplicate for to write  $R_x$  for a controlled substance



# Benefits of Paper-based PDMPs

- Tangible reminder of rxing controlled substance
  - Reduced availability of abusable Rx drugs
    - Can examine rxing, dispensing and consumption patterns → fraudulent providers and diverting patients
    - Deterrent to “Dr. shopping” and “pharmacy hopping” because can view Rx drug history
- Improved timeliness of law enforcement and regulatory investigations
- May improve rxing practices

# Concerns of Paper-based PDMPs

- Tangible reminder of rxing controlled substance → “Chilling effect”
  - Multiple copy paper forms considered “heavy handed”
  - Aimed towards Schedule II drugs
    - Last few years, expanded to Schedules II- IV
      - Less ability for prescribers to substitute with lesser scheduled drugs
- Intrusive
  - Paper → Prescriber and pharmacist burden
  - ePDMP → Pharmacist burden

# Concerns of Paper-based PDMPs

- Costs
- Administrative hassle
- Patient and provider privacy and confidentiality – implications for HIPPA?

# History of Paper-Based PDMPs

- 1<sup>st</sup> PDMP: California 1940
  - Covered Schedule II opioid analgesics
  - Transitioned to single copy, serialized 2004
- By 1995, 18 states had a PDMP; all were paper “multiple copy” programs
- NY first state to cover less than CII
  - Added CIII sedative-hypnotics in 1973
  - Added CIV benzodiazepines in 1989
- In 1990, Oklahoma first state to go “electronic”



# PDMP Programs in 2008

- 38 states have enacted PDMP legislation
  - 32 operational programs
  - 6 in start-up phase
  - 11 additional states in process of proposing legislation
- Of these 38 states, 3 employ some form of state-issued, paper-based prescription forms

# Current Status of State-Issued Forms

State	First Implemented	TPP Phased Out	Single Copy, Serialized and/or numbered (w/ electronic system)
CA	1939	2004	January 1, 2004
TX	1982	September 1, 1999	March 1, 2002
NY	1973	1998	1998

1. [http://www.deadiversion.usdoj.gov/faq/rx\\_monitor.htm#1](http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#1).
2. [http://www.csahq.org/pdf/bulletin/issue\\_4/fishman041.pdf](http://www.csahq.org/pdf/bulletin/issue_4/fishman041.pdf).
3. [http://www.txdps.state.tx.us/criminal\\_law\\_enforcement/narcotics/Triplicate/](http://www.txdps.state.tx.us/criminal_law_enforcement/narcotics/Triplicate/)

# California

- Oldest 'trip-scrip' program in US
- In 1998 added electronic monitoring (CURES) to existing MCPP
- In 2004, replaced MCPP w/ single, numbered, secure Rx form
- Covers CII-IV

# Texas

- Paper PDMP implemented in 1982 for CII drugs
- In 1999, added electronic system and expanded to CII-CIV
- In March 2002, changed from MCPP to single, serialized Rx form (though can still use MCPP form)
  - Pantograph thermochromatic link
  - DPS seal
- In 2008, expanded to include through CV

# New York

- In 1973, expanded paper CII program to include CIII sedative-hypnotics
- In 1989, added CIV benzodiazepines
- In 1998, passed electronic legislation
- In April 2006, ALL Rxs (CII – CVI) must be issued on single, serialized official NYS Rx forms

# The Evidence: Do Paper-based PDMPs Work?

- Intended consequence: Reduce abuse and diversion of targeted prescription drugs
- Unintended consequence: Reduce legitimate and appropriate medical use of targeted prescription drugs

# The Evidence: Do Paper-based PDMPs Work?

- Two bodies of empiric literature:
  - Opioid Analgesics
  - Benzodiazepines
- All focus on multiple-copy prescription forms
- There are NO rigorous studies which evaluate the impact of single, serially-numbered or numbered prescription forms

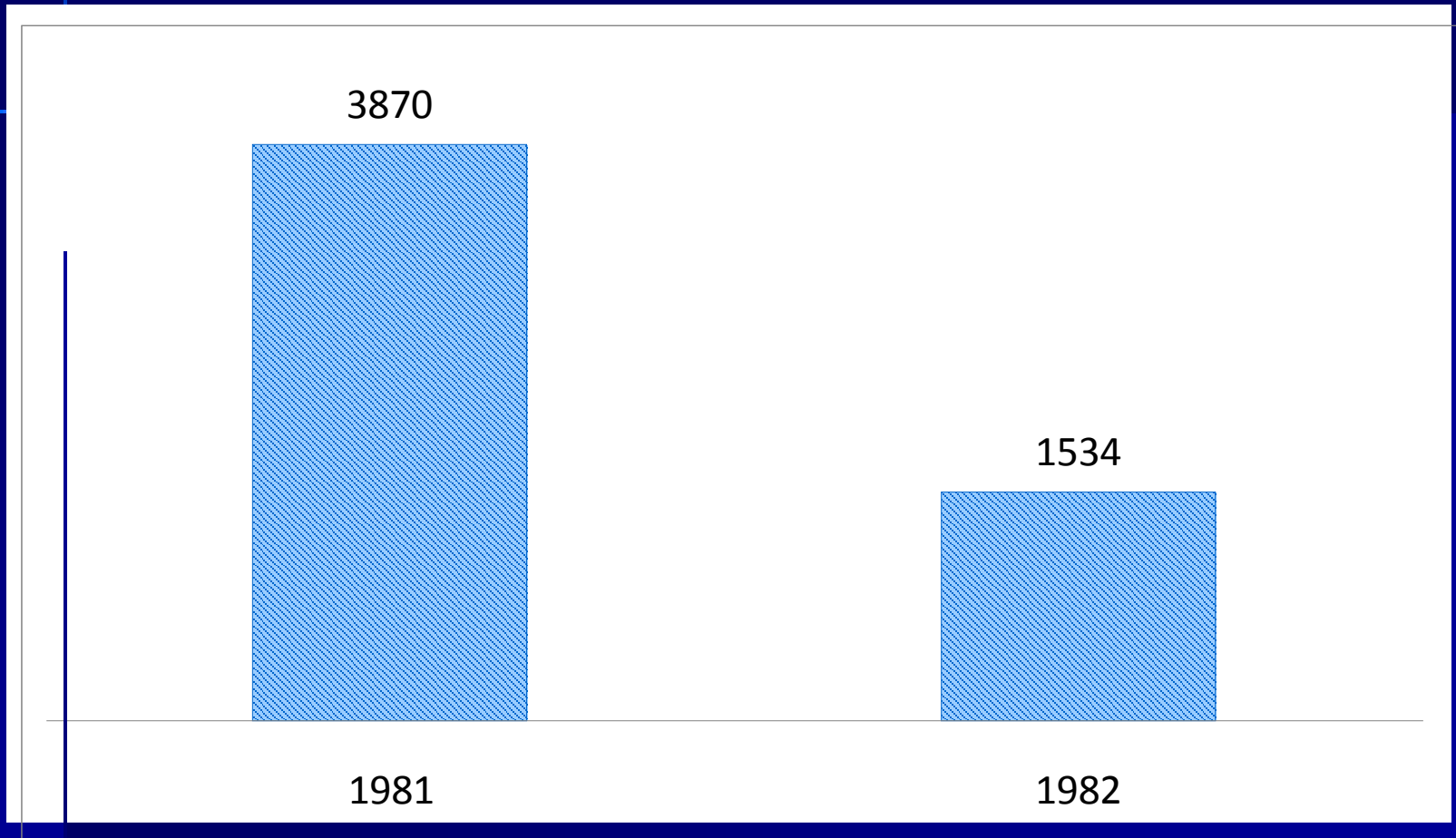
# PDMPs and the Opioid Analgesics

- Two primary empiric studies
  - Sigler et al: Texas CII; used hospital data
  - Wastila et al: Nationally-representative study using cross-sectional data

# Effect of PDMP on Schedule II Prescriptions

- Objective: To examine Schedule II drug prescriptions dispensed before and after PDMP implementation in TX
- Data: 1200-bed teaching hospital in TX in 1981 and 1982

# Reduction in Schedule II Drug Rxs



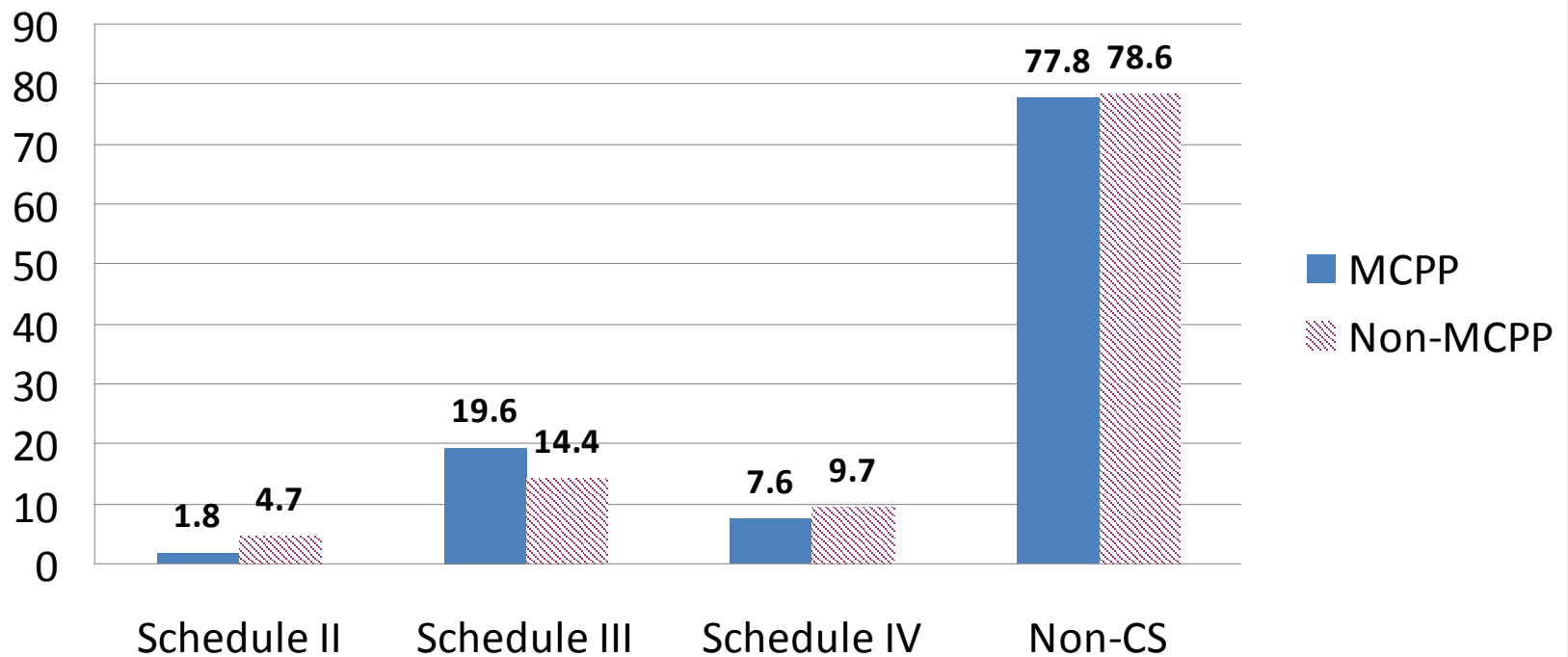
60.4% decrease in Schedule II prescriptions

# Influence of Multiple Copy Prescription Programs (MCPs)

- National Ambulatory Medical Care Survey (NAMCS), 1989
  - Cross-sectional, nationally-representative sample of office visits
  - Used two-stage multinomial logistic regression analyses
- Objective: Examine impact of MCPs on opioid and non-opioid analgesic use (by schedule)
  - i.e., examine the issue of therapeutic substitution

# Prevalence of Analgesic Prescriptions, by Schedule

Analgesics Prescribed, Weighted %



# MCPP's Impact on Analgesic Use

- MCPP exerts strong *negative* influence on CII analgesic use ( $\log pCII/NonCSA = -1.11$ )
- MCPP has strong *positive* influence on CIII analgesic use ( $\log pCIII/NonCSA = 0.59$ ), controlling for patient characteristics, insurance, diagnostic information, physician characteristics)

# MCPP's Impact on Analgesic Use

- In 2<sup>nd</sup> stage analysis, found MCPP has negative influence on likelihood of any analgesic use (*coefficient = -0.16*) and inclusive value is positive, suggesting substitutability of all four analgesic schedules
- Conclusion: MCPPs exert inhibitory effect on the probability of receiving any analgesic, with greatest effects on reducing CII rxing and increasing CIII rxing

# PDMPs and the Benzodiazepines

- Five primary empiric studies
  - Weintraub et al, 1991
  - Ross-Degnan et al, 2004
    - Simoni-Wastila et al, 2004
    - Pearson et al, 2006
    - Wagner et al, 2003 (BZD use post-hospitalization)

# Consequences of the 1989 NY TPP Regulations BZD Prescriptions

- Objective: Compare of psychoactive medication prescribing and Medicaid expenditures before (1987 through 1988) and after (1989 through 1990) the NY benzodiazepine MCPP
  - Looking for substitution and costs of substitution
- 3 data sources: National Prescription Audit (IMS America, Plymouth Meeting, Pa), New York State Medicaid, and Blue Cross/Blue Shield of the Rochester (NY) Area.

# Trends in BZD Prescriptions

Year	Number of Rxs			
	IMS	NY State Medicaid	BC/BS	
1988	5.3 M	4% decline 1987-88		
1989	2.96 M	1.5 M		
1990	603,000 (1 <sup>st</sup> quarter)	600,000	60%	30%

- Between 1988 and 1990
  - IMS: 33% BZD Rx reduction
  - Medicaid: 60% reduction
  - BCBS: 30% reduction

# BZD Substitution

- From IMS data (NY/US):
  - Meprobamate +125% / -9%
  - Methyprylon +84% / -15%
  - Ethchlorvynol +29% / -18%
  - Chloral hydrate +136% / -0.4%
  - Butabarbital +31% / -15%
- Total BZD Medicaid spending decreased 52% (\$21.7M to \$10.4M)
  - Total alternative sedative Medicaid spending increased 115% (\$3.9M to \$8.4M)

# Effect of Physician Surveillance on Problematic and Non-Problematic BZD Use

- Evaluation of BZD in New York (Study) and New Jersey (Control) for 12 months before and 24 months after TPP
  - Study participants were community dwelling  $\geq 18$  years old and Medicaid recipients; continuously enrolled from January 1988 to December 1990
- Objective: To examine differential impacts of MCPP on problematic and non-problematic BZD use, and substitution of alternative medicines

# Measures

- Alternative medicines: antidepressants; non-BZD anxiolytics; sedating antihistamines; barbiturate and non-barbiturate sedative-hypnotics; skeletal muscle relaxants; antipsychotics; opioids; NSAIDs; antipsychotics
- Potentially Problematic BZD Use:
  - Long-term use (>120 days)
  - Excessive dose (>20 DMEs/>10 DMEs)
  - Concurrent use of 2 or more LA or SA BZDs
  - Pharmacy hopping (2 or more pharmacies in 7 days)
  - Long  $\frac{1}{2}$  life BZDs in older adults (clorazepate, clordiazepoxide, diazepam, estazolam, flurazepam, halazepam, prazepam, quazepam)
- Non-problematic use: None of the above

# Analysis

- Segmented time series regression to estimate changes in levels (discontinuities) and trends (slope) in the use of BZDs and substitution medications, controlling for possible pre-existing trends and autocorrelation

# Findings

- During baseline year pre-MCPP, NY = NJ in BZD Rxing prevalence
- After the MCPP, BZD use in NY decreased by 54.8% with no change in NJ
  - This reduction sustained for entire study period
- Greater reductions experienced by: young women; persons residing in zip codes that were urban, predominantly Black, and/or with higher density of households in poverty
- New use in NY post-MCPP also markedly lower than in NJ

# Findings

- Baseline indicators of problematic and non-problematic BZD use similar in NY and NJ pre-MCPP
  - Exception: Pharmacy hopping, which was 2x more prevalent in NY
  - Differences here disappeared post-MCPP implementation
- Post-TPP reductions in BZD use were similar for both problematic and non-problematic use
  - However, since 60% of all BZD rxing met non-problematic criteria, more individuals who used BZDs appropriately were affected by the legislation
- Offsetting increases in use of substitute medications were modest Mostly driven by increased buspirone use)

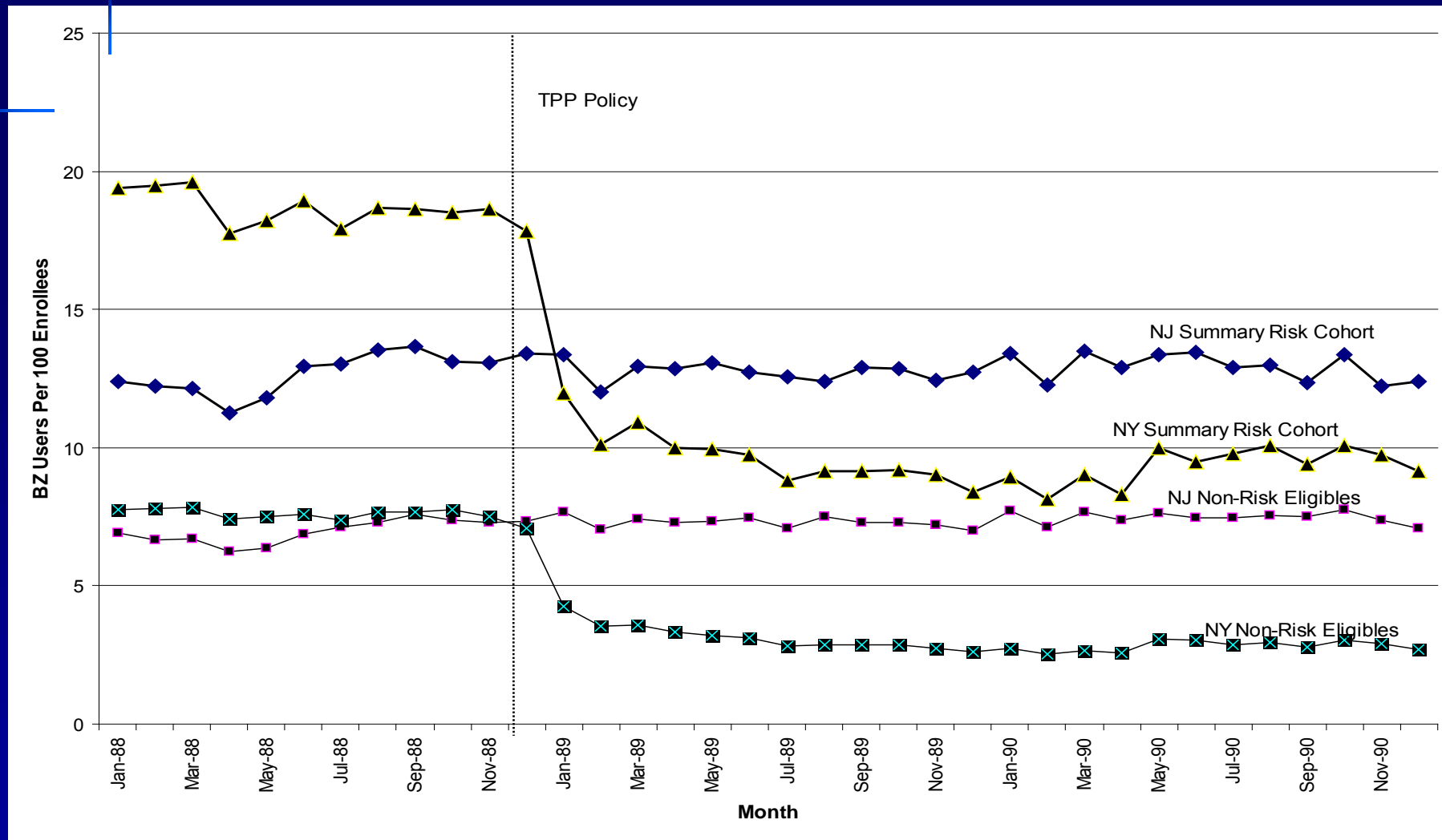
# Impact of PDMP on BZ Use in At-Risk Patients

- Three studies examining specific subpopulations:
  - clinically ill
  - racial/ethnic minorities
  - hospitalized

# Impact of PDMP on BZ Use in At-Risk Clinically Ill Patients

- Objective: Assess impact of TPP implemented in January 1989 on changes in prescribing of BZDs in clinically vulnerable Medicaid populations
  - Examine by diagnosis: schizophrenia and related disorders; bipolar disorder; seizure disorders; panic disorder; agoraphobia and other phobias
  - Two cohorts:
    - Individuals w/ 1 or more of these diagnoses
    - Individuals w/ 1 or more of these diagnoses AND at least 1 inpatient admission in baseline year

# Impact of PDMP on BZ Use in At-Risk Clinically Ill Patients



# Impact of PDMP on BZ Use in At-Risk Clinically III Patients

- At-Risk NY Cohort: -48.1% BZD reduction (no change in NJ)
  - Seizure disorder -59.9%
- At-Risk Inpatient Cohort: -31.8% BZD reduction (no change in NJ)
- These reductions were sustained 2 yrs post MCPP

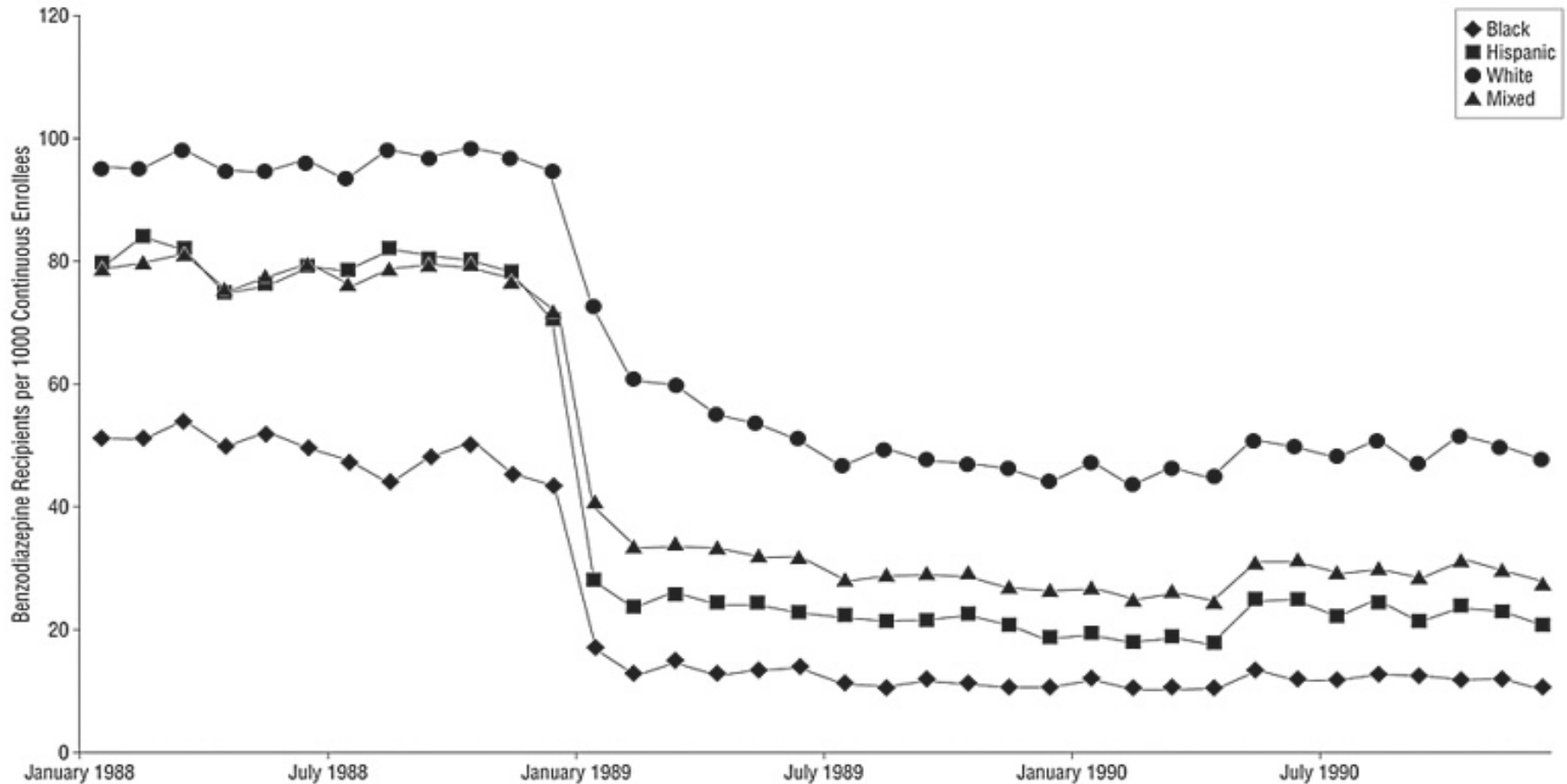
# Impact of PDMP on BZ Use in At-Risk Patients

- Use of non-BZD anxiolytics and sedative-hypnotics increased in 6 months post – MCPP
- Potentially problematic BZD rxing reduced from 7.1% in baseline to 2.4% post-MCPP (absolute change = 4.7%)
- Absolute change in non-problematic BZD use was -3.5%

# Racial Disparities in BZD Access in At-Risk Minority Patients

- Objective: Examine the impact of the BZD MCPP implementation on changes in prescribing of BZDs in racial and economically disadvantaged populations

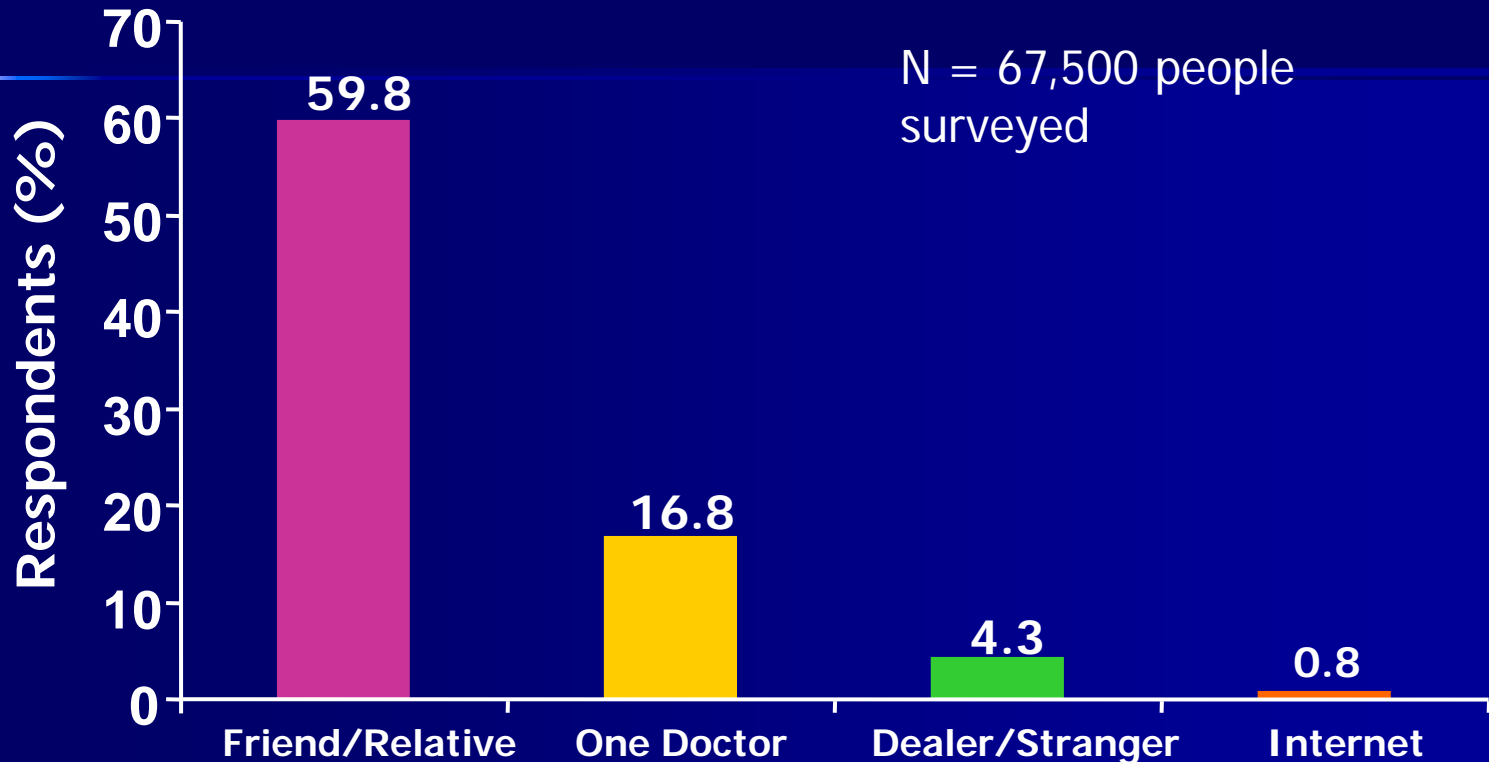
# Impact of PDMP on BZD Use in Patients in Living in Areas of Different Racial Compositions



# Conclusions

- Paper-based Multi-copy State-issued forms reduce use of targeted medications
  - Both problematic use (ie, abuse and diversion) and appropriate use
  - Evidence of therapeutic substitution (strongest with analgesic class)
- Caveat: Previous studies evaluated outcomes associated with multiple-copy PDMPS
  - No recent studies evaluate impact of ePDMPS
  - No studies evaluate single-copy forms (alone or with ePDMPS overlay)

# Sources of Analgesics for Nonmedical Use as Reported by Users



**Will PDMPs be effective if the primary source for Rx drugs with addiction potential come from friends and relatives?**

# Future Directions

- Measures of 'modern' PDMP effectiveness have relied on anecdotal and/or unpublished reports
  - No explicit studies of actual effectiveness
- Development of outcomes measures
  - What are appropriate measures of abuse/diversion?
  - What are appropriate measures of medical use?
  - Systematic approach needed to evaluate effectiveness of the current PDMP models in reducing diversion
    - MUST consider unintended consequences
    - NO studies have examined non-drug consequences (eg, hospitalization, ED use, LTC admission, etc – and attendant costs)

# The 64K Question

- Do paper-based PDMPs reduce diversion without reducing appropriate medical use?

# The 64K Question

– Answer: We really don't know...