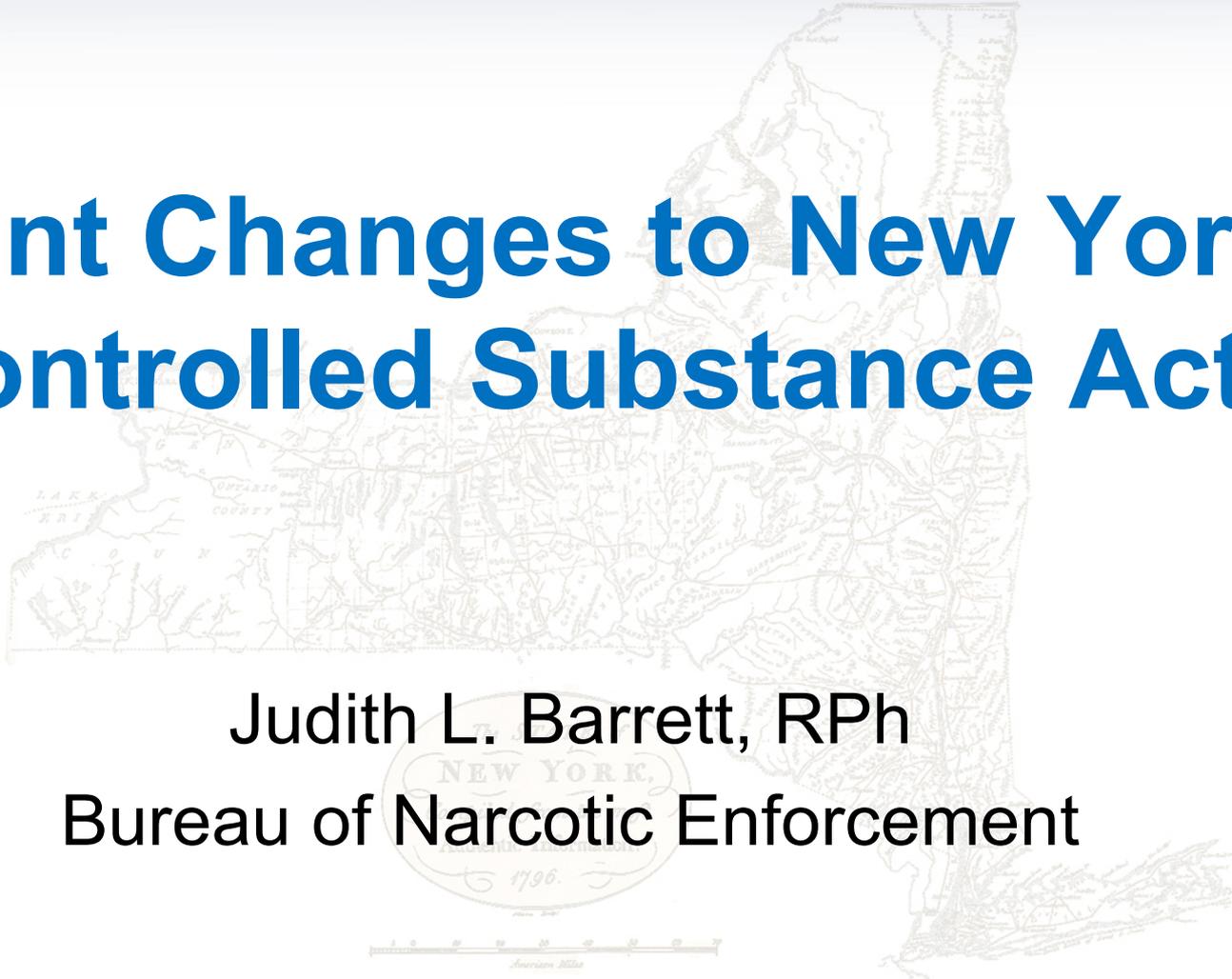
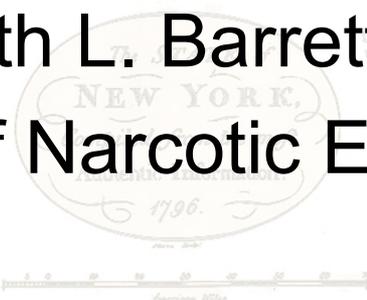


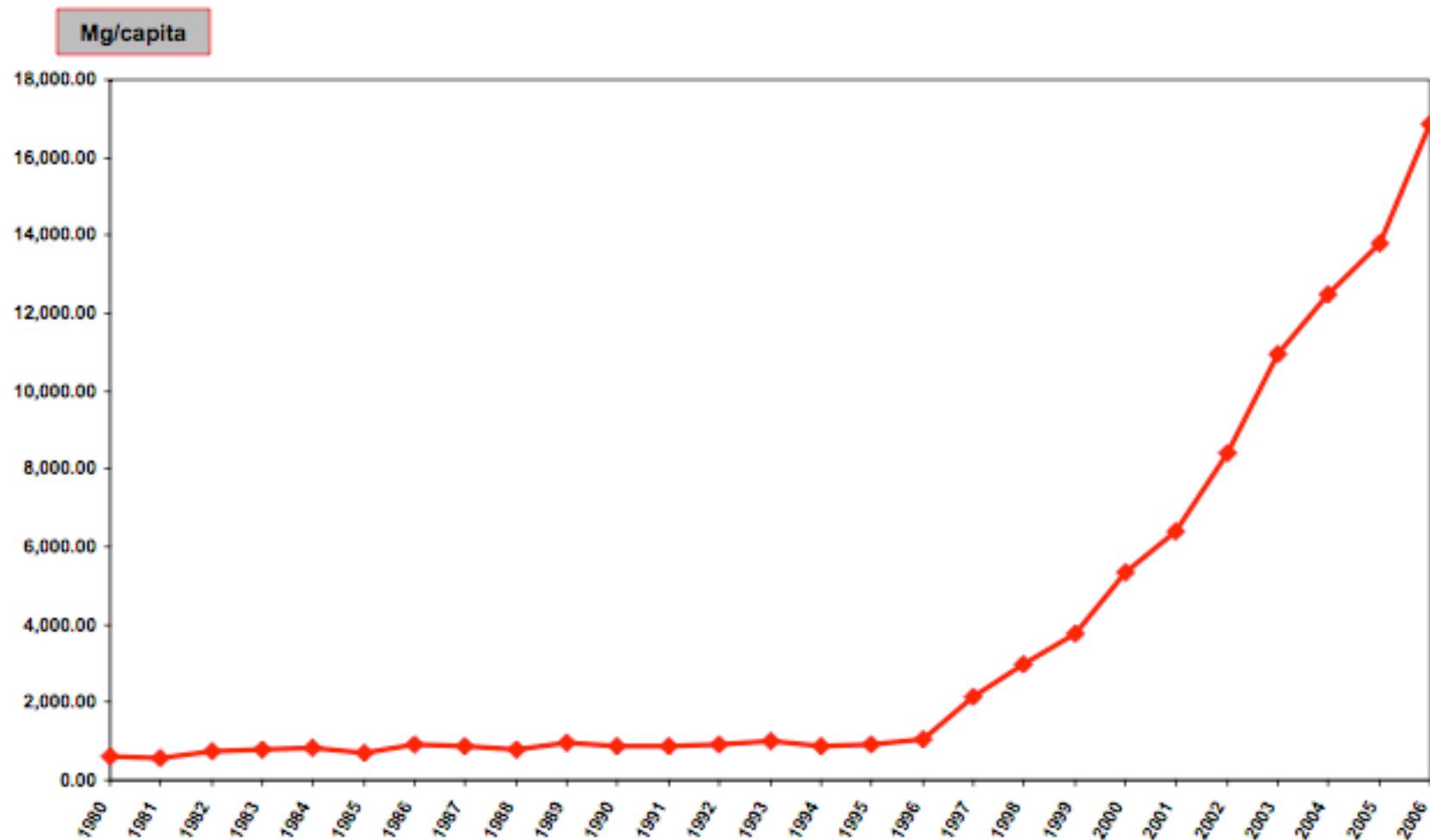
# Recent Changes to New York's Controlled Substance Act



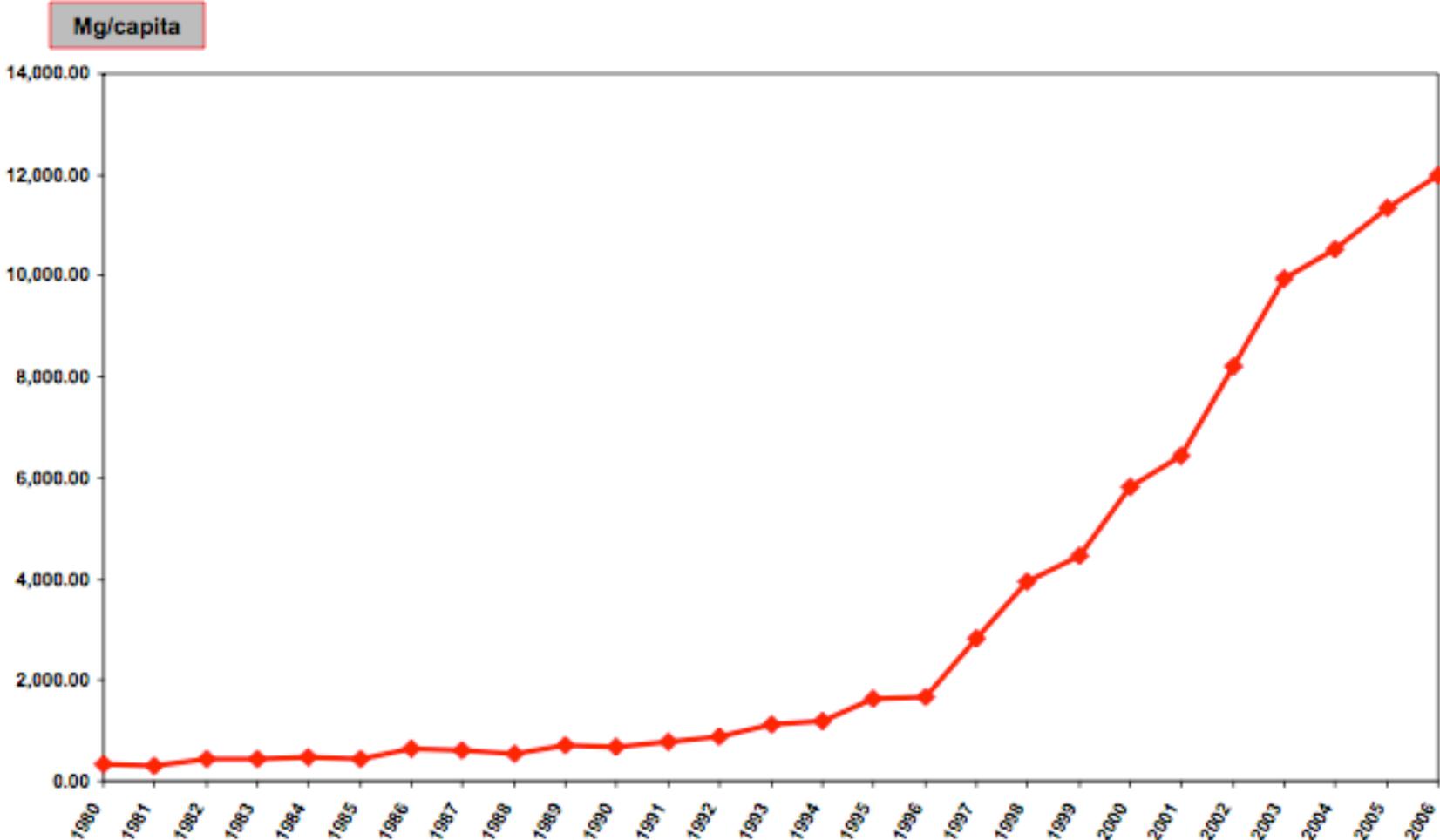
Judith L. Barrett, RPh  
Bureau of Narcotic Enforcement



# New York Consumption of Oxycodone 1980 - 2006

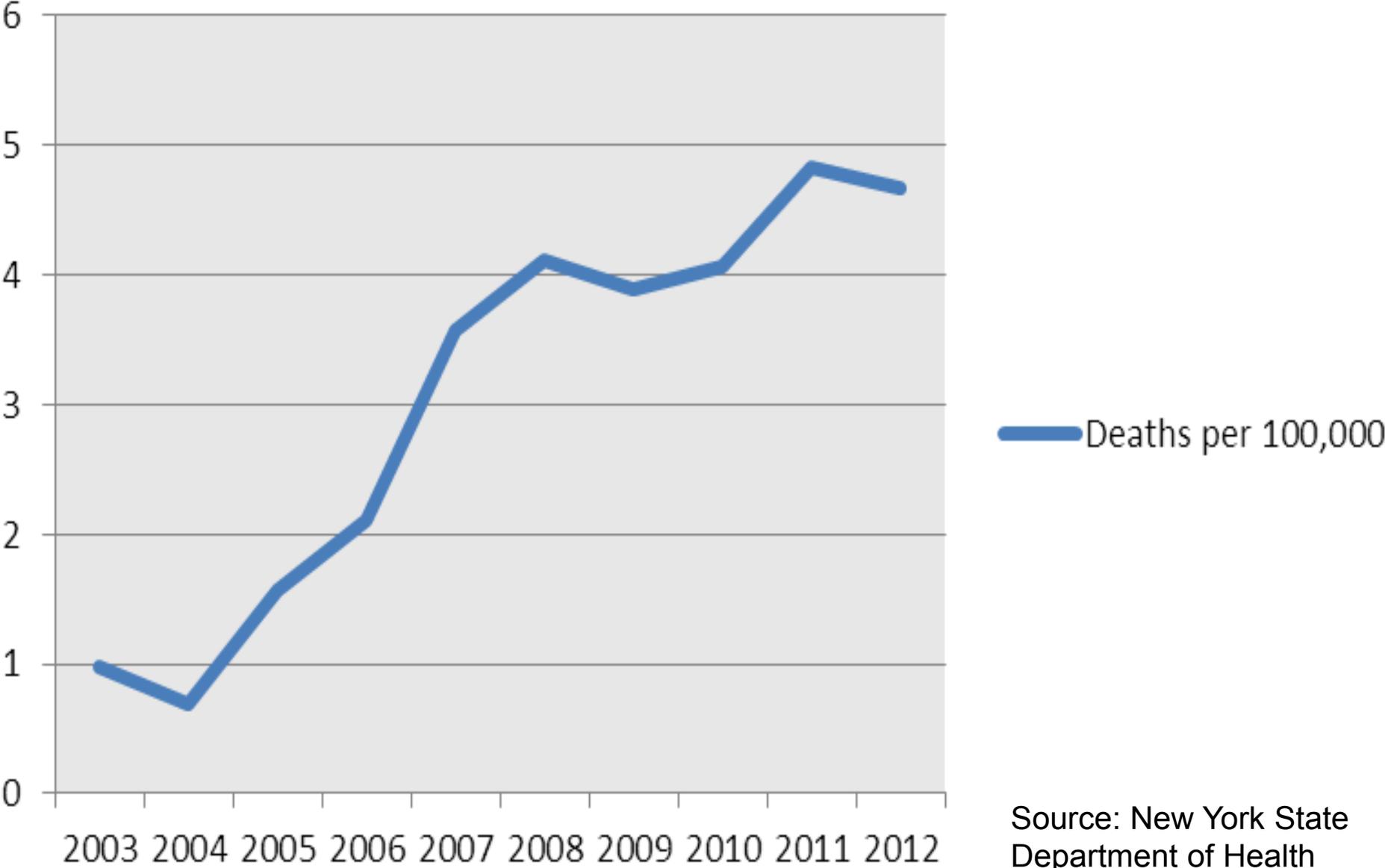


# New York Consumption of Hydrocodone 1980 - 2006



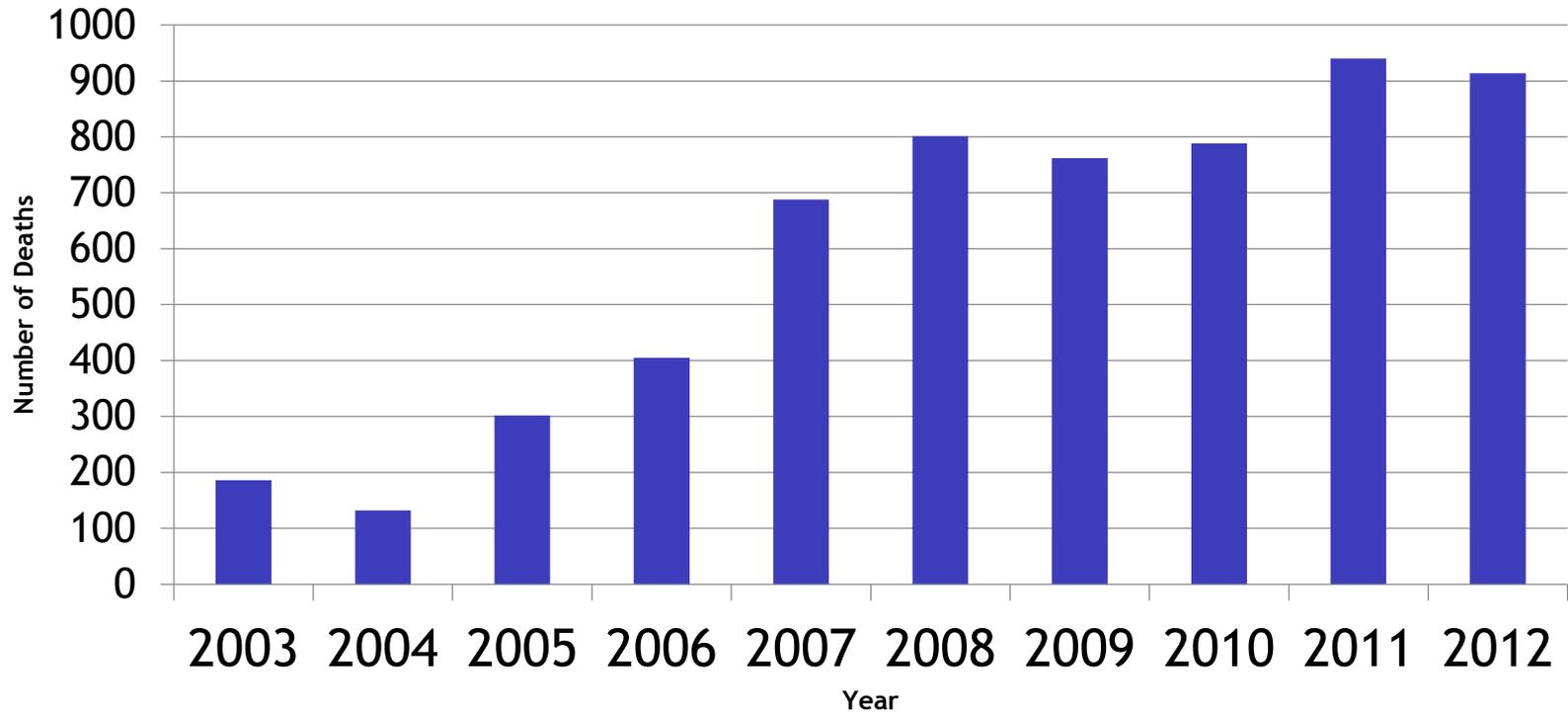
Sources: U.S. Dept of Justice, Drug Enforcement Administration, Office of Diversion Control

# Opioid Deaths in New York State



Source: New York State Department of Health

# Deaths Involving Opioid Analgesics in New York State 2003-2012



■ Poisonings Involving Opioid Analgesics

# New York's Prescription Drug Reform Act - Legislation

**“I-STOP” law took effect on 8/27/2013.**

- Part A: I-STOP (Internet System to Track Over-Prescribing)
- Part B: Electronic Prescribing
- Part C: Schedule Changes
- Part D: Work Group
- Part E: Safe Disposal Program

# Legislation

This law:

- Overhauled New York's Prescription Monitoring Program;
- *Required* practitioners consult the PMP before prescribing;
- Required dispensing data be reported in real time;
- Required electronic prescribing;
- Placed hydrocodone on C-II and tramadol on C-IV; and
- Created a workgroup to advise the Department of Health.

# Duty to Consult PMP Registry

- Practitioners *must* consider their patient's information presented in the PMP Registry prior to prescribing or dispensing any controlled substance listed in Schedule II, III, or IV.
- The data considered by the practitioner must be obtained from the PMP Registry no more than 24 hours before the prescription is issued.
- Prescribers may utilize a designee to obtain the information for them, but may not designate the actual review of data.

# Exceptions

- Practitioner administering a CS
- Prescribed for use within an institutional dispenser (does not include discharge, therapeutic leave, or other off-premise use)
- Prescribed within an ED attached to a general hospital (limited to 5 day supply)
- Hospice

# Exceptions

- Technological failure of PMP or practitioner's hardware;  
Practitioner must take reasonable steps to correct the technological failure or limitation
- If consulting the PMP Registry would result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient

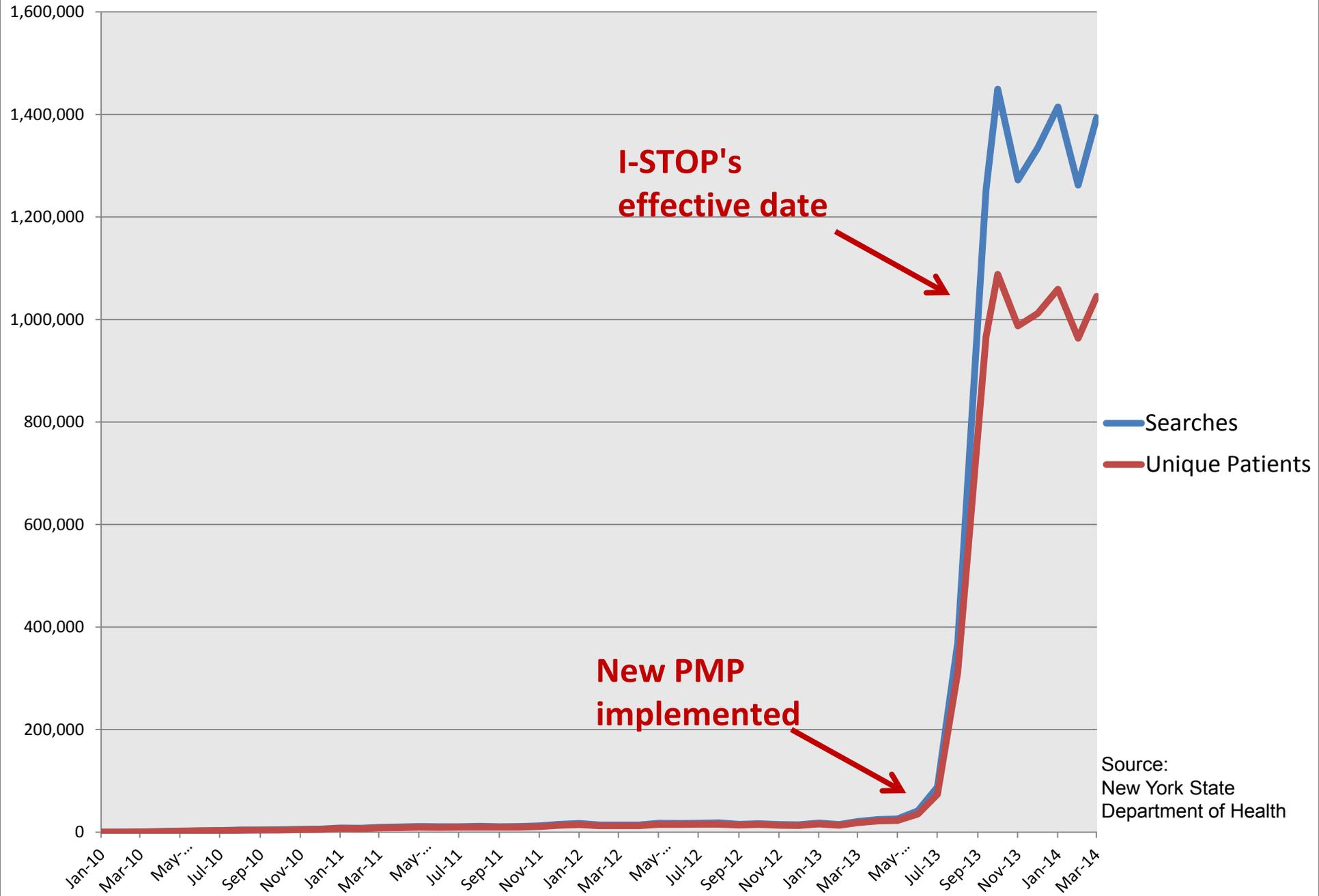
# Exceptions

- It is not reasonably possible to access the PMP, no other practitioner/designee may access for practitioner, AND the quantity prescribed is 5 days or less;

All three elements must be satisfied.

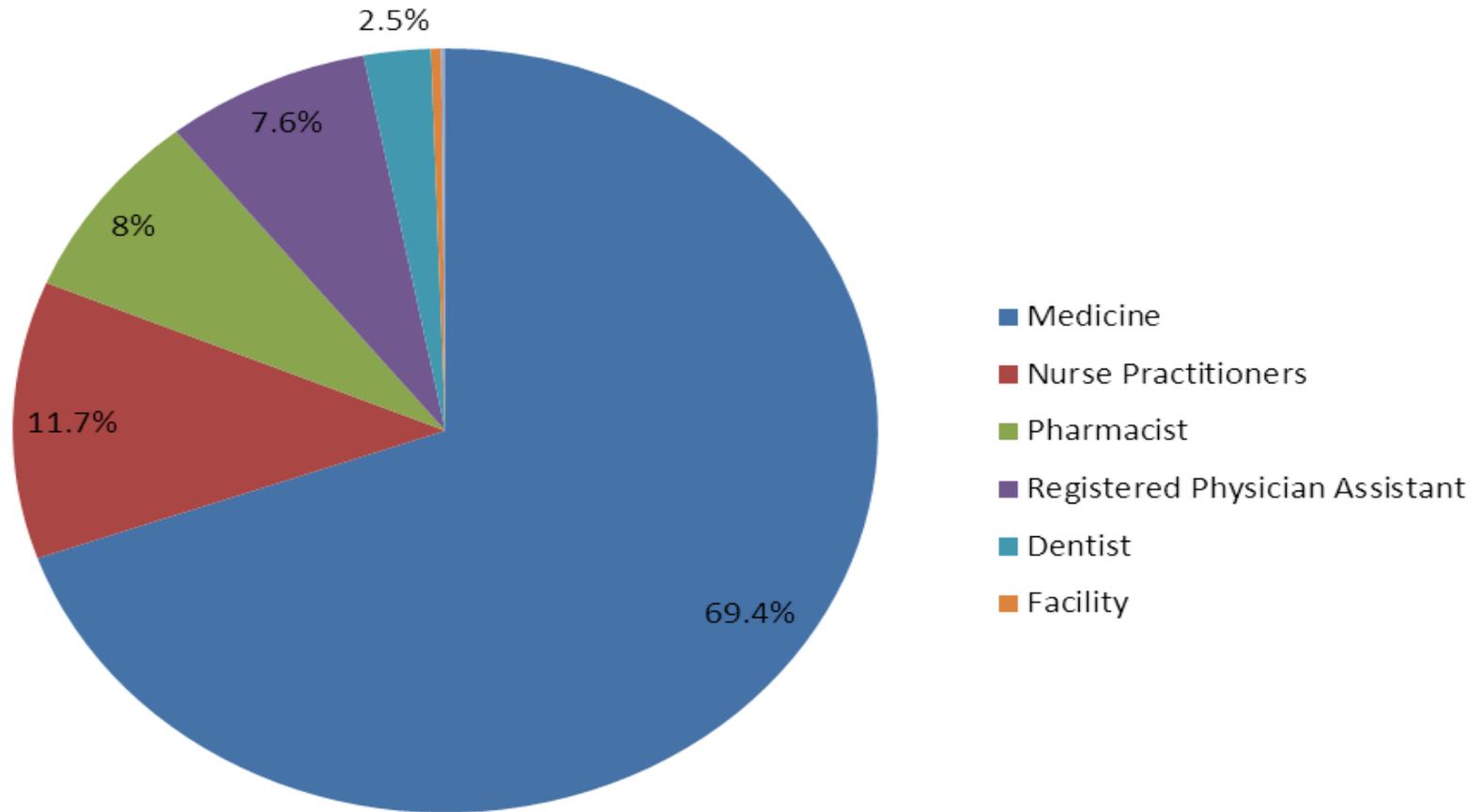
Merely writing a 5 day prescription does not relieve a practitioner from having to check the PMP

# PMP Registry Activity by Month



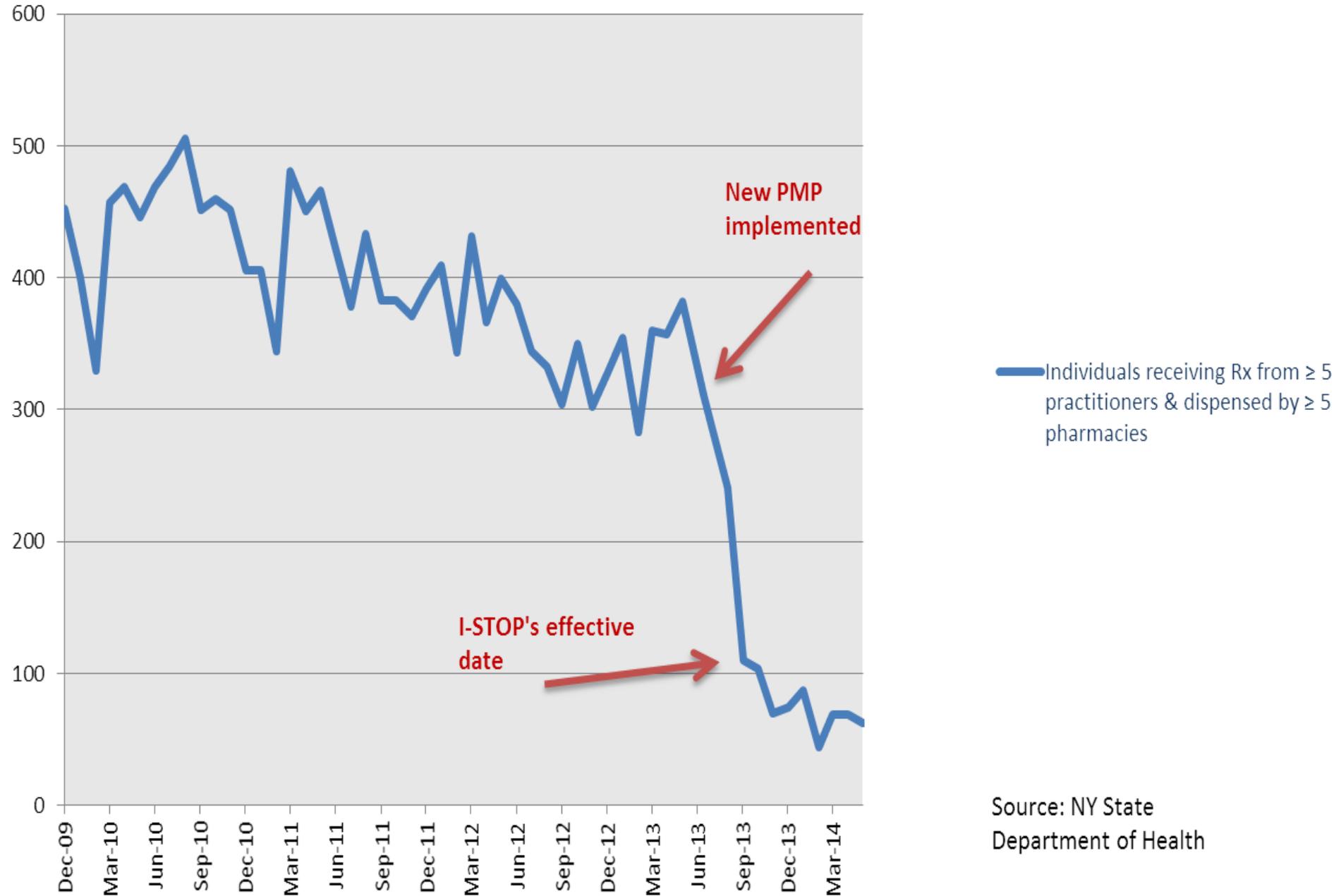
Source:  
New York State  
Department of Health

# PMP Registry Searches by License



Source: New York State  
Department of Health

# "Doctor Shopping" Activity in New York

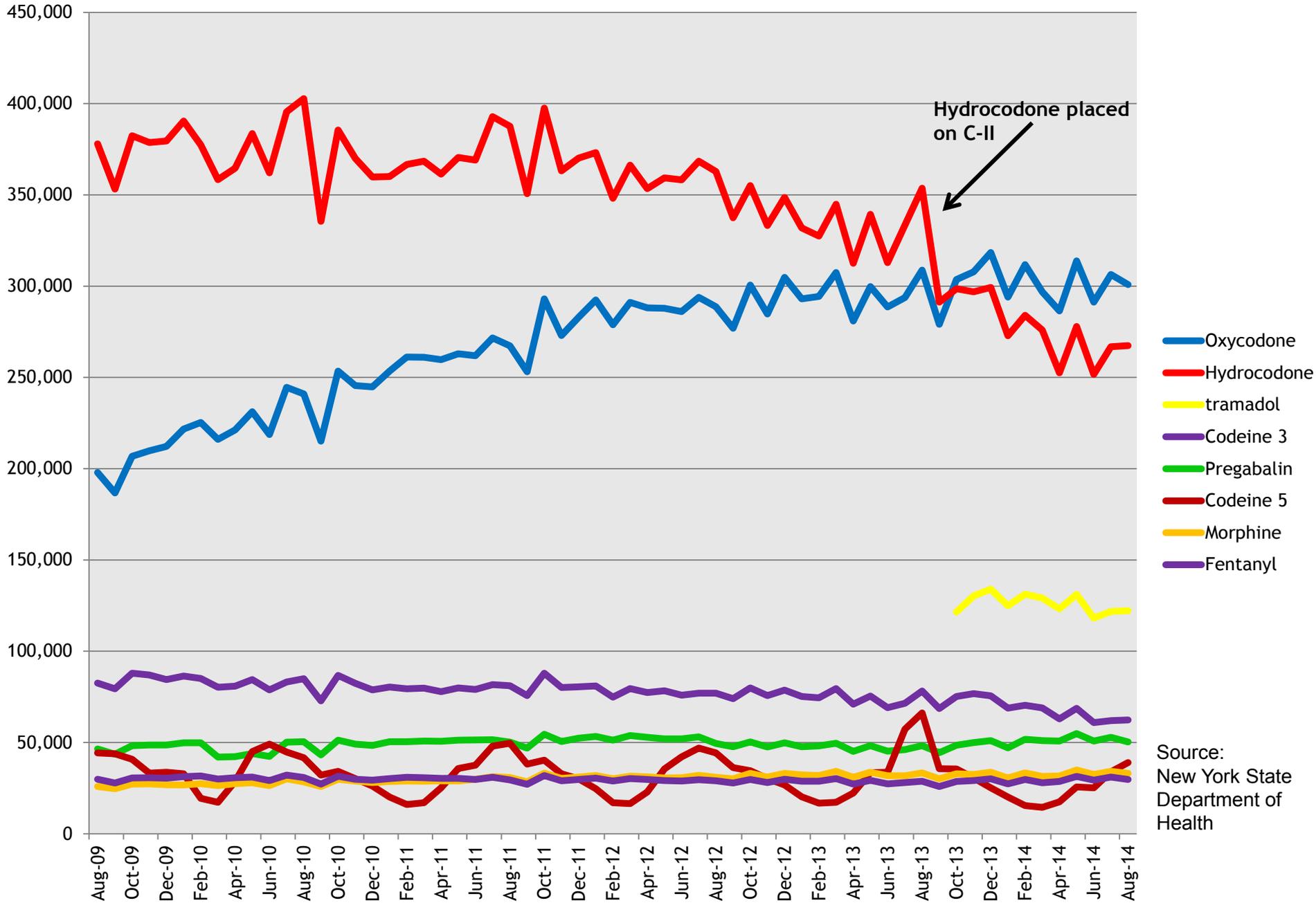


# Changes to Schedules - NY

**Effective February 23, 2013**

- All products containing **hydrocodone** were placed on Schedule II
- **Tramadol** was placed on Schedule IV

# Rxs for Opioids and Selected Drugs



# Change in Prescribing Behavior

Comparison of opioid prescribing during the year prior to mandated PMP use and year post implementation:

- 8.72% decrease in total prescriptions;
- 10.4% decrease in patients w/ a prescription;
- 10.3% decrease in total quantity dispensed;
- Largest decreases in prescriptions were codeine 5 (-24%), hydrocodone (-17.7%) and codeine 3 (-14.3%);
- Increases in prescriptions for fentanyl (3.5%), morphine (2.2%) and oxycodone (0.2%).

# Change in Prescribing Behavior

## Hydrocodone

- 17.7% decrease in prescriptions;
- 16.3% decrease in patients with a prescription;
- 16.44% decrease in total doses dispensed.

## Oxycodone

- 0.2% increase in prescriptions;
- 1.6% increase in patients with a prescription;
- 2.98% decrease in total doses dispensed.

# Change in Prescribing Behavior

## Buprenorphine prescribing:

- 11.3% increase in buprenorphine prescriptions;
- 10.9% increase in patients receiving a buprenorphine prescription.

# PMP Data Submission

- Effective August 27, 2013, pharmacies are required to submit prescription data to BNE within 24 hours.
- The Department created a new data collection tool to accommodate increased reporting.
- The PMP Data Collection Tool allows for unattended reporting in a secure fashion.
- Since August 13, 2013, a total of 33,495,803 records were submitted by pharmacies and other dispensers

# PMP Data Submission

After receiving these records, BNE;

- Screens all records for critical errors;
- Rejects any record containing a critical error and notifies the submitter so it can be corrected;
- De-duplicates any identical records;
- Matches new record to existing patient records;
- Presents new record in PMP Registry.

This process takes about 2 hours from when BNE receives the original record.

# PMP Data Submission – 1<sup>st</sup> year

- 31 million reported Rx (including errors, dups)
- Added 27 million valid unique Rx to the PMP Registry
- 25 million of these Rx are searchable via the PMP Registry
- 5 million Rx were submitted via unattended file upload
- Overall error rate of about 0.5 %

# Electronic Prescribing of Controlled Substances



# Official Prescription Program

- Bureau of Narcotic Enforcement issues forge-proof official prescription forms to all registered practitioners and facilities within the State
- Contain a number of security features
- Serial numbers are unique and can be tracked
- From 2006-2013 issued ~1.4 B prescription forms
- At a cost of \$78.7 M

**OFFICIAL NEW YORK STATE PRESCRIPTION**

INSTITUTION Q PUBLIC  
A PUBLIC INSTITUTION  
100 WEST MAIN STREET  
ANY TOWN, NY 00000  
(999) 999-9999  
Lic. 99999999

Imprinted Prescriber Name (Institutions Only) \_\_\_\_\_

Patient Name \_\_\_\_\_ Date \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_ Age \_\_\_\_\_ Sex  M  F

**Rx**

Prescriber Signature **X** \_\_\_\_\_

THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'dau' IN BOX BELOW

REFILLS  None  Refills: \_\_\_\_\_

PHARMACIST TEST AREA: \_\_\_\_\_

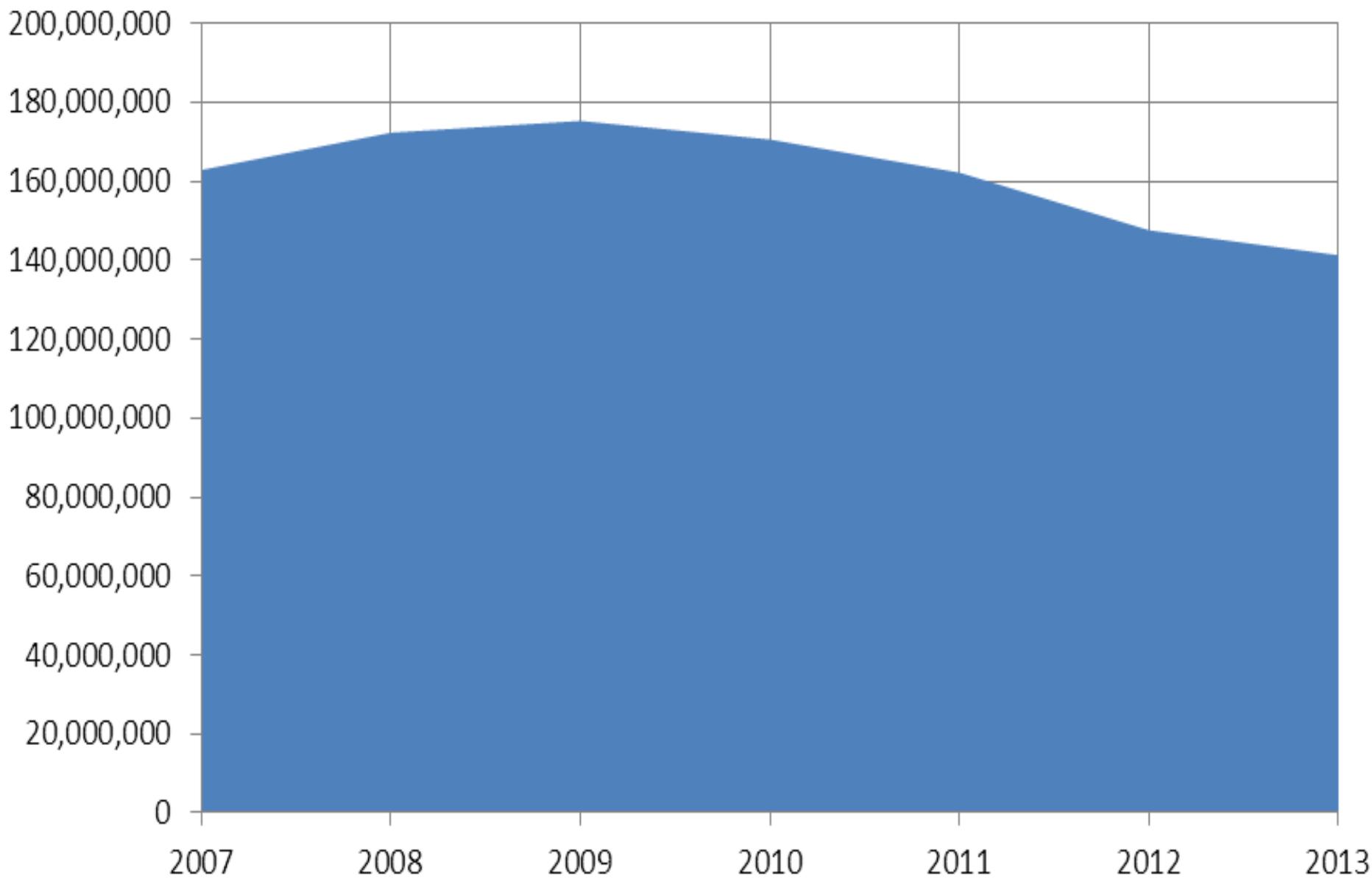
Dispense As Written

MAXIMUM DAILY DOSE (controlled substances only) \_\_\_\_\_

ZZZZZZ 00

Barcode

# Official Prescription Forms Shipped



# Electronic Prescribing

- Regulations allow for electronic prescribing of controlled substances (EPCS) in NY effective March 27, 2013.
- Electronic prescribing of controlled and non-controlled substances becomes mandatory for all practitioners in NY as of March 27, 2015.
- Prescribers must use an application that has satisfied the DEA's security requirements.

[http://www.deadiversion.usdoj.gov/fed\\_regs/rules/2010/fr0331.pdf](http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf)

# EPCS Exceptions

- Veterinarians;
- Technological or electrical failure;
- Use of EPCS would impact the patient's medical condition (up to 5 day supply);
- Issued by a practitioner to be dispensed outside of New York State;
- Practitioners who have received a waiver from the Department of Health.

# Waivers

- Practitioners may apply for a waiver from the requirement to electronically prescribe controlled substances.
- Waivers will be granted upon a proper showing of economic hardship, technological limitations outside of the practitioner's control or other exceptional circumstances.
- By statute, waivers are good for one year, after which a practitioner may apply for a renewal.

# Recent Legislation

In June 2014, Governor Andrew M. Cuomo signed into law a series of bills enacting further reforms. These laws:

- Allow for the expanded availability of naloxone;
- Require expanded coverage for addiction treatment services
- Create increased penalties for practitioners and pharmacists who illegally dispense controlled substances.

# What's Next in New York?

- Mandatory electronic prescribing - March 2015
- Interoperability
- PMP/EHR integration
- Expanded safe-disposal options for consumers

# Contact Information

Bureau of Narcotic Enforcement  
New York State Department of Health

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[www.health.ny.gov](http://www.health.ny.gov)

