

Pharmacists Society of the State of New York Midwinter Meeting 2021 Pharmacy Law Update

John J. Heaphy, R.Ph.
Mary K. Sutphen, R.Ph.
Pharmacy Consultants
NYS Bureau of Narcotic Enforcement



Conflict of Interest:

Mary Sutphen and John Heaphy have no conflicts of interest



OBJECTIVES

- Outline recent legislative changes and updates in controlled substance law and regulations
- Review the functionality and updates to the Prescription Monitoring Program (PMP)
- Describe new information related to the prescription drug take-back program
- Discuss selected topics of interest concerning controlled substances in New York
 State

Pre-Test Questions



Q: Is the prescribing practitioner required to indicate on the ONYSRx that he or she has been approved for a waiver from electronic prescribing?

A. Yes

B. No

C. Unsure



Q: A pharmacist may designate a pharmacy technician to consult the Prescription Monitoring Program on their behalf.

- A. True
- B. False
- C. True, if the technician has undergone a special training
- D. True, if the technician is certified



Q: Buprenorphine for substance use disorder may be prescribed by:

- A. Medical Doctors
- B. Nurse Practitioners
- C. Physician Assistants
- D. All of the above



Frequently Asked Questions



Q: If a Lyrica® prescription is written for a 90 day supply with Code C, and the insurance won't cover it, can I change it to 30 days with 2 refills?

- A. No, the prescriber must transmit a new prescription for #30 with 2 refills.
- B. Yes, if the total quantity matches the original, prescriber authorization is not required.
- C. No, changes are not permitted on controlled substance prescriptions.
- D. Yes, with prescriber authorization and proper documentation of the change.



A: If a Lyrica® prescription is written for a 90 day supply with Code C, and the insurance won't cover it, can I change it to 30 days with 2 refills?

D. Yes, with prescriber authorization and proper documentation of the change.

A pharmacist may not change the quantity or refills on a prescription without prescriber authorization. Oral authorization is permissible. The pharmacist shall annotate the change electronically (or if paper script, write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature). The following, however, may never be changed: practitioner's signature, date, drug name or name of the patient.



Information authorized to be added or changed by the pharmacist on an electronic prescription, **MUST** be annotated electronically and archived for 5 years.

Pharmacist's Add/Change Reference for Controlled Substance Prescriptions

| RPH ADD WITH Practitioner Authorization | RPH ADD WITHOUT Practitioner Authorization | NEVER ADD | RPH CHANGE WITH Practitioner Authorization | RPH CHANGE WITHOUT Practitioner Authorization | NEVER CHANGE |
|--|---|---------------------------|---|--|---------------------------|
| Practitioner DEA# | Patient Address | Patient Name | Practitioner DEA# | Patient Address | Patient Name |
| Institutional DEA #/suffix | Patient Sex | Practitioner Signature | Institutional DEA #/suffix | Patient Sex | Practitioner Signature |
| Directions | Patient Age | Date Written | Directions | Patient Age | Date Written |
| Code | | Drug Name | Code | | Drug Name |
| MDD | | Quantity | Quantity | | |
| Strength | | | MDD | 4 | |
| | | | Strength | | |
| | | | Dosage Form | 37 | |



Q: Can a Schedule II controlled substance have a partial fill based on the patient or practitioner's request?

A. Yes

B. No

C. Unsure



A: Can a Schedule II controlled substance have a partial fill based on the patient or practitioner's request?

B. No. Not at this time. The DEA has not yet finalized regulations defining the partial filling of a CII controlled substance requested by the patient or their prescribing practitioner.



Q: Can a Schedule III-V controlled substance have a partial fill?

A. Yes

B. No

C. Unsure



A: Can a Schedule III-V controlled substance have a partial fill?

B. Yes. Provided that each partial filling is recorded in the same manner as a refill, and the total quantity dispensed does not exceed the total quantity prescribed for a 30 day period.



Q:Does the supervising doctor's name need to be on a controlled substance prescription prescribed by a physician assistant?

A. Yes

B. No

C. Unsure



Q:Does the supervising doctor's name need to be on a controlled substance prescription prescribed by a physician assistant?

A. Yes. The prescription must include the name, address and telephone number of the supervising physician and the name of the licensed physician assistant.



A: Does the supervising doctor's name need to be on a controlled substance prescription prescribed by a medical resident?

A. Yes

B. No

C. Unsure



A: Does the supervising doctor's name need to be on a controlled substance prescription prescribed by a medical resident?

B. No. Interns, residents or foreign physicians may prescribe controlled substances under the DEA number of the institution and the code number (or suffix) assigned to them by the institution. The prescription does not need to be transmitted or written with the supervising practitioners name or DEA number.



Q: Is Epidiolex (cannabidiol) a controlled substance in New York State?

A. Yes

B. No

C. Unsure



Q: Is Epidiolex® (cannabidiol) a controlled substance in New York State?

A. Yes

B. No.

C. Unsure



New York State Controlled Substance Scheduling

Epidiolex ® (cannabidiol):

- ➤ An FDA approved cannabidiol medication indicated to treat seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or Tuberous Sclerosis Complex.
- ➤ is "a drug product in finished dosage formulation that has been approved by the FDA that contains cannabidiol derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols"



New York State Controlled Substance Scheduling

Epidiolex ® (cannabidiol):

- ➤ In May 2019, was added as a Schedule V controlled substance into 10NYCRR Part 80 Section 80.3, through an emergency regulation from the Commissioner of Health
- April 2020 DEA removed from federal controlled substance scheduling.
- ➤ In July 2020, Epidiolex ® (cannabidiol) was removed from 10NYCRR Part 80 Section 80.3 as a controlled substance through an emergency regulation from the Commissioner of Health.

Schedule II-V Medications Not Yet Scheduled in New York State

DEA Schedule II:

- > Dronabinol Oral Solution
- > Oliceridine

DEA Schedule III:

> Perampanel



Schedule II-V Medications Not Yet Scheduled in New York State

DEA Schedule IV:

- > Alfaxalone
- > Brexanolone
- > Eluxadoline
- Lamborexant
- > Lorcaserin.
- Remimazolam
- Solriamfetol
- > Suvorexant



Schedule II-V Medications Not Yet Scheduled in New York State

DEA Schedule V:

- Brivaracetam
- > Cenobamate
- > Lasmitidan





Drug Listing

This listing indicates brand names that are associated with the drugs listed on the patient search results. This list is not exhaustive and may include brands no longer available in the marketplace.

Last Updated: 07/13/2020 14:30:44 PM

| Drug | Brand Name | | Refillable |
|--|---|------|------------|
| Alfentanil | Alfenta® | CII | N |
| Alprazolam | Gabazolamine™, Niravam®, Sentrazolam AM™, Xanax®, Xanax XR® | CIV | N |
| Amobarbital | Amytal®, Tuinal® | | N |
| Amphetamine | Adderall®, Adderall XR®, Adzenys ER™, Adzenys ER ODT™, Dexedrine®, Dextrostat®, Dyanavel® XR, EVEKEO®, Mydayis™ | | N |
| Aprobarbital | Alurate® | | Y |
| Benzphetamine | Didrex® | CIII | Y |
| Buprenorphine | Belbuca®, Bunavail®, Buprenex®, Butrans®, Probuphine®, Sublocade™, Suboxone®, Subutex®, Zubsolve® | CIII | Y |
| Butabarbital | Butalbital/Aspirin (ASA)/Caffeine, Fiorinal®, Fiorital®, Butisol Sodium® | CIII | Y |
| Butalbital/Codeine | Ascomp® with Codeine, Fiorinal® w/ Codeine | CIII | Υ |
| Butorphanol | Stadol® | CIV | Y |
| Cannabidiol | Epidiolex® | CV | Y |
| Carisoprodol | Soma®, Prazolamine™ | CIV | Υ |
| Carisoprodol/Codeine/ASA | Soma® Compound with Codeine | CIII | Υ |
| Chloralhydrate | Aquachloral Supprettes®, Chloralum, Noctec®, Somnote® | CIV | Υ |
| Chlordiazepoxide | Librax®, Librium® | CIV | N |
| Clobazam | Frisium®, Onfi®, Sympazan™ | CIV | N |
| Clonazepam | Klonopin [®] | CIV | N |
| Clorazepate | Tranxene® | CIV | N |
| Cocaine | Cocaine, Goprelto | CII | N |
| Codeine-cii | Codeine | CII | N |
| Acetaminophen (APAP) w/Codeine #3, APAP w/Codeine #4, Fioricet® w/ Codeine, Theracodeine™, Tuxarin™. Tylenol w/Codeine #3®. Tylenol w/Codeine #4® | | CIII | Υ |



Electronic Prescribing



The E-Prescribing Mandate Public Health Law 281

No person shall issue any prescription in this state unless such prescription is made by electronic prescription from the person issuing the prescription to a pharmacy... **EXCEPT**



Exceptions to Electronic Prescribing

- Prescriptions issued by veterinarians
- > Temporary technological or electrical failure
- Use of electronic prescribing would impact the patient's medical condition
- Prescriptions issued by a practitioner to be dispensed outside of New York State



Non-Electronic Prescriptions

- Out of State practitioner, including Indian Reservations, VA hospitals & clinics, and other Federal Installations
- Practitioner Certification of 25 prescription or less annually
- Practitioners who received a waiver (economic hardship, technological limitations, other exceptional circumstance)
- Specific circumstances listed in Commissioner's Blanket Waiver



Exceptions to Electronic Prescribing Practitioner Certification with the DOH

Pursuant to §281(7) of the Public Health Law, a practitioner shall not be required to issue prescriptions electronically if he or she certifies to the Department that he or she will not issue more than twenty-five prescriptions during a twelve-month period. Prescriptions in both oral and written form for both controlled substances and non-controlled substances shall be included in determining whether the practitioner will reach the limit of twenty-five prescriptions.



Electronic Prescribing Waivers

- > Practitioners may apply for a waiver from the requirement to electronically prescribe controlled substances.
- Waivers may be requested online using the Health Commerce System, or by paper submission.
- 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.



Exceptions to Electronic Prescribing

- ➤ It is <u>NOT</u> mandatory for the practitioner to make a notation on an Official NYS Prescription indicating the circumstance for which it is being written.
- ➤ A pharmacist is <u>NOT</u> required to verify that a practitioner properly falls under one of the exceptions from the requirement to electronically prescribe. Pharmacists may continue to dispense medications from valid written, oral, or fax prescriptions that are consistent with current laws and regulations.



Commissioner of Health's Letter Additional Exceptional Circumstances

Provides a "Blanket Waiver" from electronic prescribing for the following additional exceptional circumstances:

- > Nursing home or RHCF defined in Article 2801 of the Public Health Law
- Complicated directions
- Directions longer than 140 characters
- Compounded prescriptions containing two (2) or more products
- Compounded infusion prescriptions containing two (2) or more products
- A prescription containing certain elements required by the Federal Food and Drug Administration (FDA), such as an attachment
- Approved protocols under expedited partner therapy
- Approved protocols under collaborative drug management
- Response to a public health emergency that would allow a non-patient specific prescription
- Approved research protocol
- > A non-patient specific prescription for an opioid antagonist



Q: Pharmacies must register their certified Electronic Prescribing of Controlled Substance (EPCS) software application with BNE, and renew their registration every years thereafter.

A. 2

B. 3

C. 5



A: Pharmacies must register their certified Electronic Prescribing of Controlled Substance (EPCS) software application with BNE, and renew their registration every years thereafter.

A. 2

B. 3

C. 5



Registration of a Certified Pharmacy Application

Note: BNE does not <u>certify</u> software applications

Registration is <u>required</u>, whichever occurs first:

- At least <u>every</u> two years, or whenever functionality related to controlled substance prescription requirements is altered with the computer application
- Registration process is available online through the Health Commerce System
- ➤ The online HCS application is called ROPES
- > Instructions can be found on the BNE website



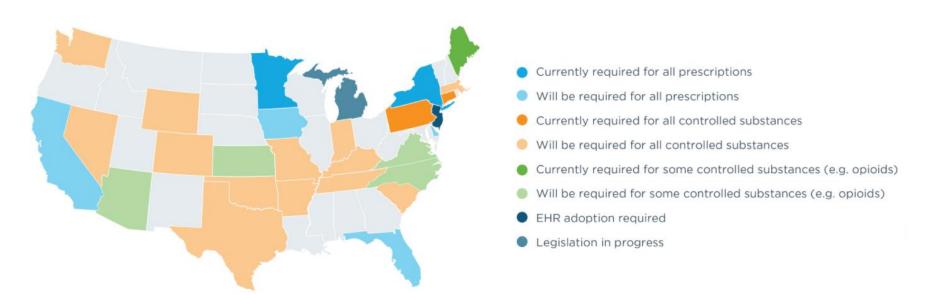
Electronic Prescribing

| Year | Electronic Prescriptions | Paper Prescriptions | Total Prescriptions | % Electronic Prescriptions |
|------|-----------------------------|------------------------|------------------------|----------------------------|
| 2014 | 30,237 | 23,915,517 | 23,945,754 | 0.13% |
| 2015 | 3,978,568 | 19,997,372 | 23,975,940 | 16.6% |
| 2016 | 16,859,189 | 6,547,127 | 23,406,316 | 72.0% |
| 2017 | 20,007,917 | 2,941,133 | 22,949,050 | 87.2% |
| 2018 | 19,975,212 | 2,282,113 | 22,257,325 | 89.7% |
| 2019 | 20,228,243 | 1,843,028 | 22,071,262 | 91.6% |

NEW YORK Department of Health

EPCS Readiness: Which States Lead the Charge?

WHERE IS E-PRESCRIBING REQUIRED BY LAW?



Policy:

The ISTOP law requires e-prescribing for all prescriptions.

- · Allows exceptions; waivers may be granted for one year and must be reapplied for annually
- Includes specific penalties for noncompliance



EPCS Readiness: Which States Lead the Charge?

New York maintained its longstanding position as the nation's leader in EPCS enablement, having required e-prescribing for all prescriptions since 2016.

Pharmacy Enablement:
98.5%

Prescriber Enablement:
81.6%

➤ Controlled Substances Prescribed Electronically: 88.3%





Prescription Monitoring Program (PMP)



A: A pharmacist may check the Prescription Monitoring Program when performing medication reconciliation

A. True

B. False



A: A pharmacist may check the Prescription Monitoring Program when performing medication reconciliation

A. True

B. False



Pharmacist Access to PMP Registry

Pharmacist may **NOT** access the PMP Registry for someone for whom they do **NOT** have a prescription



Utilizing the PMP Registry

Do NOT use the PMP to check on:

- Celebrities, sports or political figures,
- Neighbors, relatives,
- Employment screening,
- Medication reconciliation purposes,
- Medication therapy management

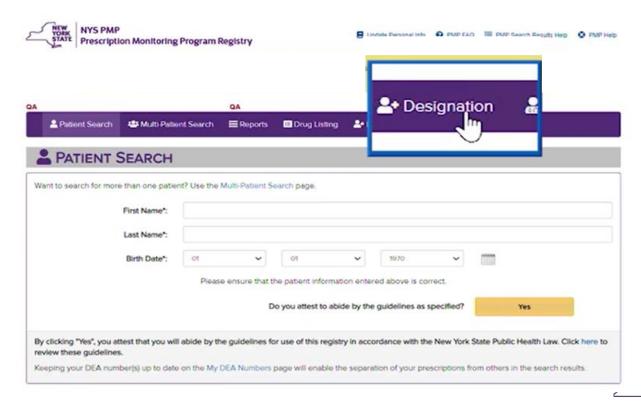


Pharmacist Access to PMP Registry

Pharmacists may designate ONLY another pharmacist or pharmacy intern

Pharmacy technicians and other pharmacy employees are **PROHIBITED** from access to the PMP Registry





| 2 Patie | ent Search | A Multi-Patient Search | ⊞ Reports | Drug Listing | ♣ Designation | | |
|----------------|----------------|--|------------------|---------------------|-----------------------|--|---|
| DESIG | NATION | | | | | | |
| his or her bel | nalf. The prac | | ensure that suc | h designee(s) acces | sses the registry onl | rize one or more designees to consult th y for purposes authorized in the New Yor | - |
| The selecte | ed designee l | has been removed. | | | | | |
| | | for User to Designate ter the designee's HCS ID: Enter the pharmacy in | 14 h | | Search | | |
| | | Designees | | | | | |
| | | Designators have designated you. | | | | | |



| A Patient Search | A Multi-Patient Search | ≣ Reports | ■ Drug Listing | ♣ Designation | |
|------------------|------------------------|------------------|----------------|---------------|--|
| | | | | | |
| DESIGNATION | | | | | |

Pursuant to Section 3343-a of the New York State Public Health Law, a practitioner or pharmacist may authorize one or more designees to consult the registry on his or her behalf. The practitioner or pharmacist shall ensure that such designee(s) accesses the registry only for purposes authorized in the New York State Public Health Law and at all times maintains security and confidentiality of the information contained therein.

| Search for User to Designate | |
|--|--|
| Enter the designee's HCS ID: | User ID # |
| Enter the pharmacy intern's permit number: | Permit/ Lic.# Search |
| Designate User Designate | |
| HCS User ID: User ID# User Na | me: Pmp Testuser Permit Number: Permit/Lic # |

Review Designees

No users have been designated.

Review Designators

No users have designated you.



| 🚣 Patient Search | A Multi-Patient Search | ≣ Reports | I Drug Listing | ♣ Designation | |
|------------------|------------------------|------------------|----------------|---------------|--|
| | | | | | |
| DESIGNATION | | | | | |

Pursuant to Section 3343-a of the New York State Public Health Law, a practitioner or pharmacist may authorize one or more designees to consult the registry on his or her behalf. The practitioner or pharmacist shall ensure that such designee(s) accesses the registry only for purposes authorized in the New York State Public Health Law and at all times maintains security and confidentiality of the information contained therein.

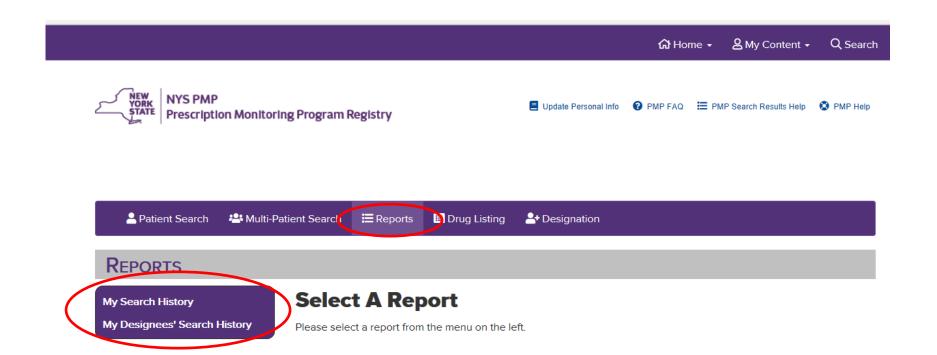
| Search for | User to De | signate | | | |
|------------|----------------|-----------------------------------|---|--------|--|
| Enter | the designee's | s HCS ID: | | | |
| | Enter the ph | armacy intern's permit number: | Search | | |
| Review Do | 5 | nat you have designated | to perform patient searches on your beh | alf. | |
| | HCS ID | User Name | Date Designated | Action | |
| | tcspnp1 | Pmp Testuser | 10/20/2020 13:55:43 PM | Remove | |
| | | | | | |



Utilizing the PMP Registry

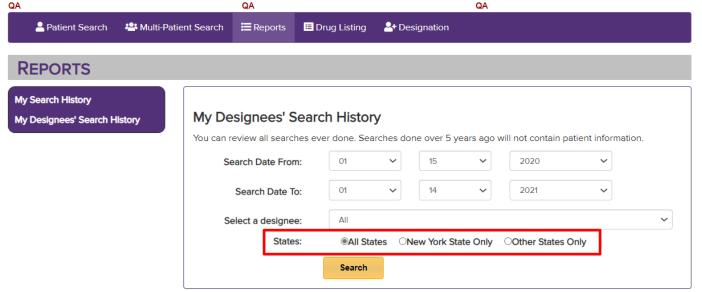
- It is important to note that the pharmacist is responsible for the searches done by a designee.
- Passwords are **NOT** to be shared!













My Designees' Search History

Search Date Range: 01/15/2020 - 01/14/2021 **States:** All States

Report Date: 01/14/2021 04:36:16

Selected Designee: All

Only 500 rows will be displayed per search. To retrieve more records, narrow the date criteria and re-run the search.

| Search Date | Reference # | Designee ID | Designee Name | First Name | Last Name | Sex | Birth Date | States |
|------------------------|-------------|-------------|---------------|------------|-----------|-----|------------|--------|
| 10/20/2020 02:33:35 PM | 24424 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | CT,VT |
| 10/20/2020 02:30:38 PM | 41445 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/20/2020 02:00:32 PM | 41444 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/20/2020 01:58:04 PM | 41443 | tcspnp1 | Pmp Testuser | jack | spratt | | 01/01/1970 | NY |
| 10/20/2020 10:41:56 AM | 41437 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/20/2020 10:39:00 AM | 41436 | tcspnp1 | Pmp Testuser | jack | spratt | | 01/01/1970 | NY |
| 10/19/2020 05:07:04 PM | 41340 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/19/2020 05:04:47 PM | 41339 | tcspnp1 | Pmp Testuser | jack | spratt | | 01/01/1970 | NY |
| 10/19/2020 04:35:10 PM | 24376 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | CT,VT |
| 10/19/2020 04:32:54 PM | 41387 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/14/2020 06:20:48 PM | 24326 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | CT,VT |
| 10/14/2020 06:19:44 PM | 41286 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/14/2020 01:38:36 PM | 24325 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | CT,VT |
| 10/14/2020 01:38:24 PM | 41243 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |
| 10/07/2020 01:44:18 PM | 41090 | tcspnp1 | Pmp Testuser | sample | patient | | 08/08/1980 | NY |



Q: Can a pharmacist provide a copy of the PMP registry results of a patient for law enforcement, such as the DEA, local police or State Trooper?

A. Yes

B. No

C. Unsure



A: Can the pharmacist provide a copy of the PMP registry results of a patient for law enforcement, such as the DEA, local police or State Trooper?

B. No. Law enforcement must obtain the information through the subpoena process.



Pharmacist Access to PMP Registry

Pharmacists are **PROHIBITED** from providing a PMP report, upon request, for <u>any</u> law enforcement official, including a DEA agent



Q: How can a patient's suspicious activity be reported?

- A. Sending an e-mail to BNE
- B. From within the PMP
- C. A phone call to BNE
- D. All of the above



A: How can a patient's suspicious activity be reported?

- A. Send an e-mail to BNE
- B. From within the PMP
- C. Phone call to BNE
- D. All of the above



Others' Prescriptions

Patient Name: Sample Patient

Address: 00-00 1st Ave Somewhere, NY 99999

Birth Date: 08/08/1980

Sex: Male

| Rx Written | Rx Dispensed | Drug | Quantity | Days Supply | Prescriber Name | Payment Method | Dispenser |
|------------|-----------------|---------------------------|----------|----------------|--------------------|-------------------|------------------------|
| 10/09/2020 | 10/09/2020 | Alprazolam 1mg | 90 | 30 | Care, Yes I MD | Cash | Wehaveno Drugs |
| 10/04/2020 | 10/04/2020 | Hydrocodone/APAP 5/325 | 28 | 7 | Oncall, Im MD | Cash | Samestreet Pharmacy |
| 09/12/2020 | 09/12/2020 | Alprazolam 0.5mg | 45 | 15 | Oncall, Im MD | Cash | Samestreet Pharmacy |

Patient Name: Sample Patient

Address: 1234 Anywhere Ave Nowhere, NY 99999

Birth Date: 08/08/1980

Sex: Male

| Rx Written | Rx Dispensed | Drug \$ | Quantity \$ | Days Supply | Prescriber Name | Payment Method | Dispenser |
|------------|-----------------|----------------|-------------|----------------|-----------------|----------------|-------------------|
| 10/07/2020 | 10/10/2020 | OxylR 5mg | 120 | 30 | Doe, John R PA | Insurance | Notareal Pharmacy |
| 10/07/2020 | 10/10/2020 | Oxycontin 20mg | 60 | 30 | Doe, John R PA | Insurance | Notareal Pharmacy |
| 10/09/2020 | 10/10/2020 | Alprazolam 1mg | 270 | 90 | Doe, John R PA | Insurance | Notareal Pharmacy |

Patient Name: Sample Patient

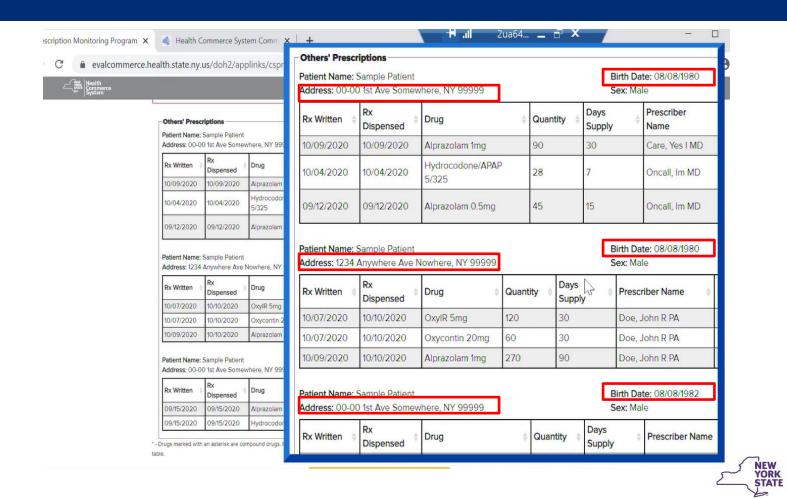
Birth Date: 08/08/1982

Address: 00-00 1st Ave Somewhere, NY 99999

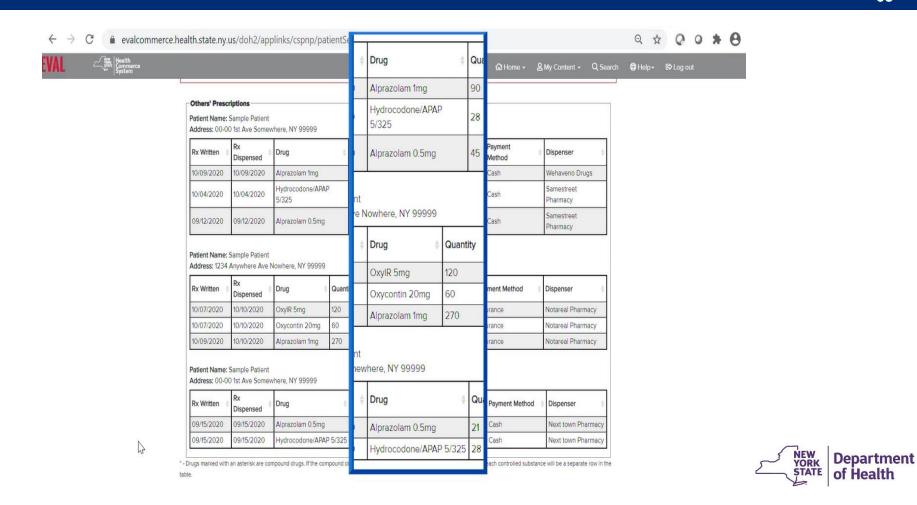
Sex: Male

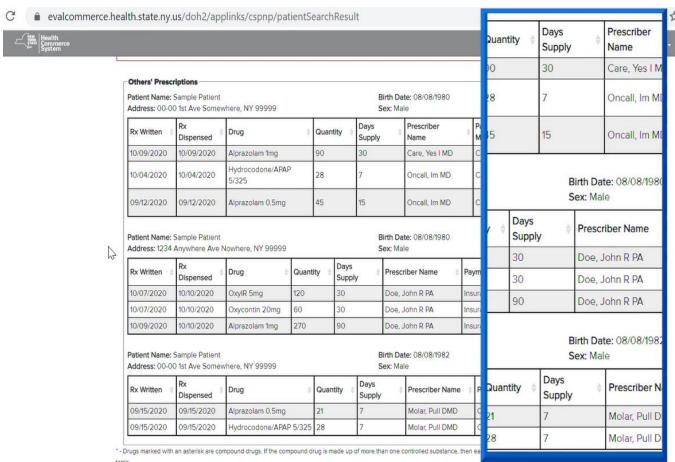
| Rx Written | Rx Dispensed | Drug # | Quantity | Days Supply | Prescriber Name | Payment Method # | Dispenser • |
|------------|-----------------|------------------------|----------|----------------|-----------------|------------------|--------------------|
| 09/15/2020 | 09/15/2020 | Alprazolam 0.5mg | 21 | 7 | Molar, Pull DMD | Cash | Next town Pharmacy |
| 09/15/2020 | 09/15/2020 | Hydrocodone/APAP 5/325 | 28 | 7 | Molar, Pull DMD | Cash | Next town Pharmacy |



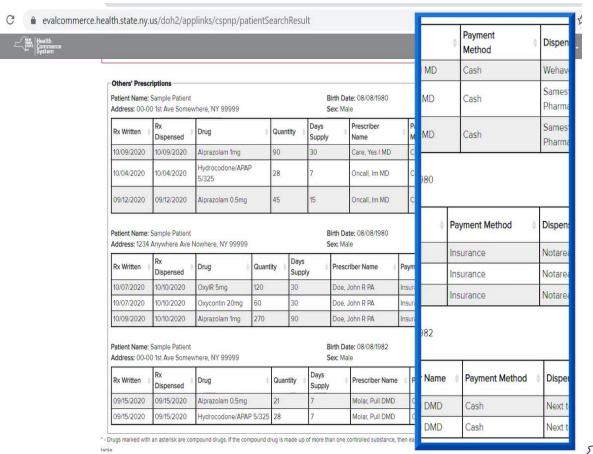


Department of Health

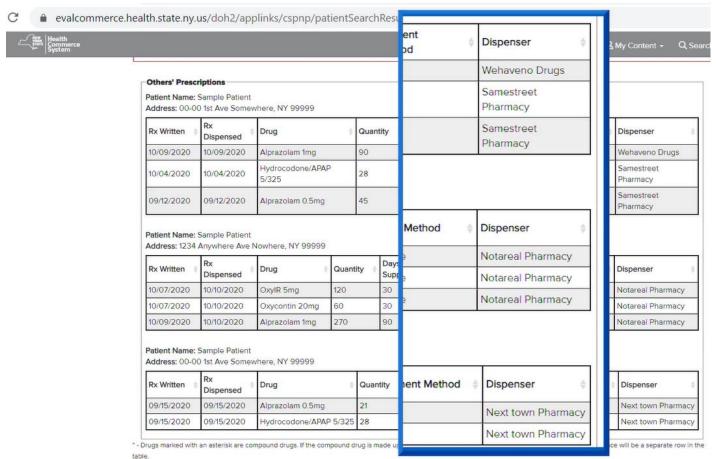




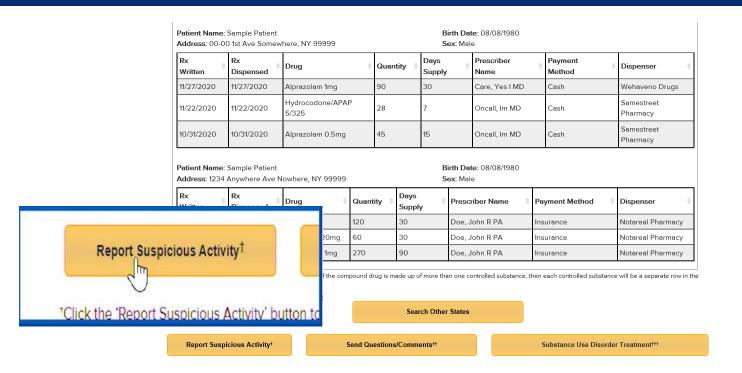




NEW YORK Department of Health









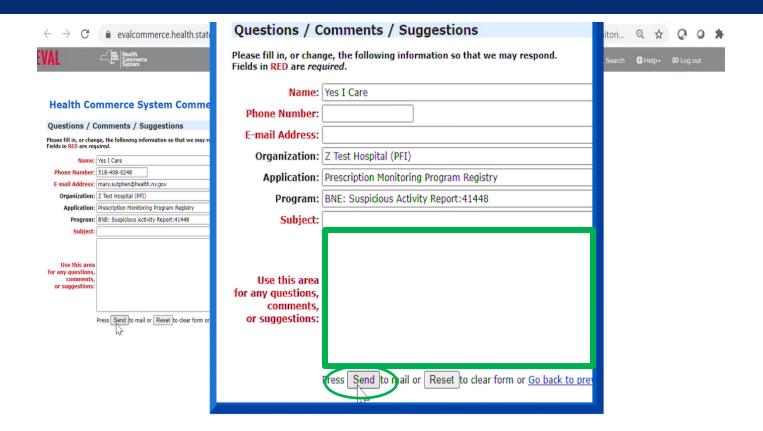
Health Commerce System Comments Form

Questions / Comments / Suggestions

Please fill in, or change, the following information so that we may respond. Fields in RED are required.

| Name: | Yes I Care | |
|---|---|----|
| Phone Number: | | |
| E-mail Address: | | |
| Organization: | Z Test Hospital (PFI) | |
| Application: | Prescription Monitoring Program Registry | |
| Program: | BNE: Suspicious Activity Report:41448 | |
| Subject: | | |
| Use this area for any questions, comments, or suggestions: | Press Send to mail or Reset to clear form or Go back to previous screen | // |





NEW YORK Department of Health

nue 4 or 5

Patient Name: Sample Patient

Birth Date: 08/08/1980

Address: 00-00 1st Ave Somewhere, NY 99999

Sex: Male

| Rx Written | Rx Dispensed | Drug \$ | Quantity • | - · | 0 | Payment Method | Dispenser \$ |
|---------------|-----------------|---------------------------|------------|-----|----------------|-------------------|------------------------|
| 11/27/2020 | 11/27/2020 | Alprazolam 1mg | 90 | 30 | Care, Yes I MD | Cash | Wehaveno Drugs |
| 11/22/2020 | 11/22/2020 | Hydrocodone/APAP 5/325 | 28 | 7 | Oncall, Im MD | Cash | Samestreet Pharmacy |
| 10/31/2020 | 10/31/2020 | Alprazolam 0.5mg | 45 | 15 | Oncall, Im MD | Cash | Samestreet Pharmacy |

Patient Name: Sample Patient

Address: 1234 Anywhere Ave Nowhere, NY 99999

Birth Date: 08/08/1980

Sex: Male

| Rx Written | Rx Dispensed | Drug \$ | Quantity | Days Supply | Prescriber Name | Payment Method | Dispenser \$ |
|---------------|-----------------|----------------|----------|----------------|-----------------|----------------|-------------------|
| 11/25/2020 | 11/28/2020 | OxylR 5mg | 120 | 30 | Doe, John R PA | Insurance | Notareal Pharmacy |
| 11/25/2020 | 11/28/2020 | Oxycontin 20mg | 60 | 30 | Doe, John R PA | Insurance | Notareal Pharmacy |
| 11/27/2020 | 11/28/2020 | Alprazolam 1mg | 270 | 90 | Doe, John R PA | Insurance | Notareal Pharmacy |

* - Drugs marked with an asterisk are compound drugs. If the o table.

Send Questions/Comments^{††}

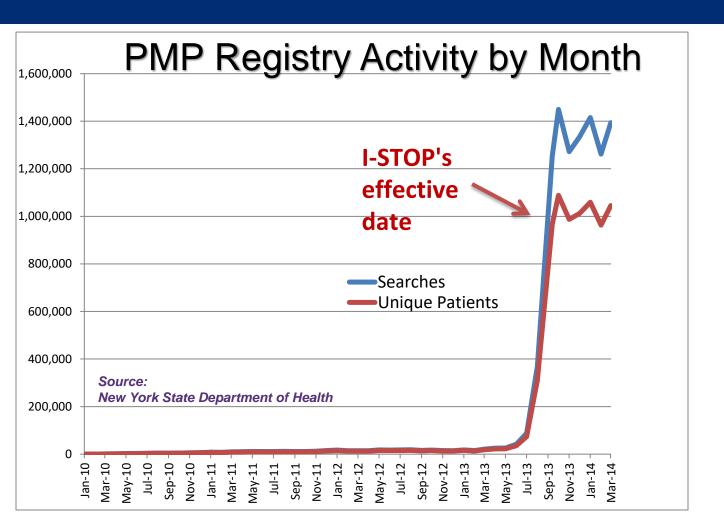
Substance Use Disorder Treatment^{†††}

Report Suspicious Activity†

Send Questions/Comments^{††}

Substance Use Disorder Treatment***







PMP Utilization

- **Before Mandatory Duty to Consult**
- 2/16/2010 through 8/26/13
 - 19,000 users performed 950,000 searches for 202,714 patients
- After Mandatory Duty to Consult

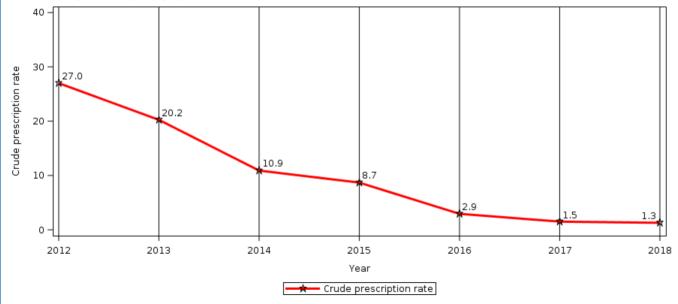
| | | Number of | Number of | |
|------|------------|--------------|------------------------|--|
| | Number of | Unique Users | Unique Patients | |
| Year | Searches | Searching | Searched | |
| 2014 | 16,810,573 | 68,291 | 5,974,020 | |
| 2015 | 18,145,771 | 69,598 | 4,704,346 | |
| 2016 | 18,364,788 | 70,722 | 4,564,881 | |
| 2017 | 18,739,213 | 73,322 | 4,490,047 | |
| 2018 | 19,076,547 | 72,731 | 4,411,199 | |

Over 47 searches have been handled per second



Doctor Shopping Activity in New York

New York State - Patients prescribed opioid analgesics from five or more prescribers and dispensed at five or more pharmacies, crude rate per 100,000 population







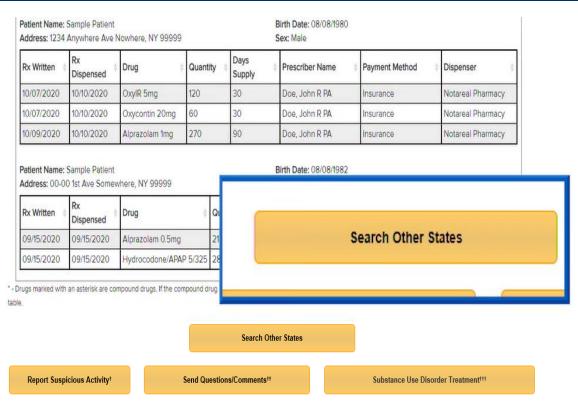
Interstate Sharing of Prescription Monitoring Program



Access to Other States PMP Data

- > Not all states share their PMP data with other states
- Practitioners or users/designees in New York may or may not have access to view other states' PMP data, and that access depends on what access is legally allowed in the other states. For example, some states may not allow a designee or pharmacist access.
- In New York State's PMP, the other states' data will display in the same manner as the New York data appears.
- ➤ The information New York requires may not be displayed in the other state's data if that information is not required by the other state. Such as:
 - Certain schedules other states may only require CII data
 - Payment Type



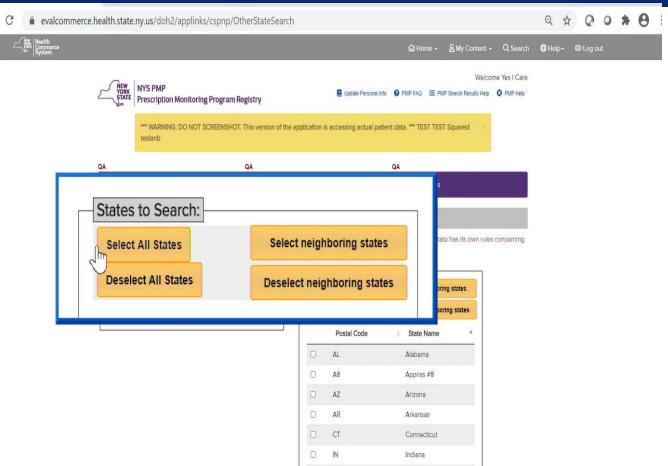


*Click the 'Report Suspicious Activity' button to report information related to controlled substance suspicious activity to the Bureau of Narcotic Enforcement.

"Click the 'Send Questions/Comments' button to send questions about this report to the Bureau of Narcotic Enforcement, or call 1-866-811-7957.

""Click the 'Substance Use Disorder Treatment' button to go to the Office of Addiction Services and Supports website, www.oasas.ny.gov or call 1-877-846-7369.





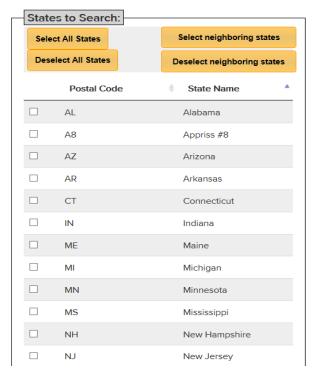
Maino



OTHER STATE PMP SEARCH

The NYS PMP will submit your request, but some or all data from certain other states may be unavailable to you. Each individual state has its own rules concerning who may search its registry and what data it provides.







OTHER STATE CONFIDENTIAL DRUG UTILIZATION REPORT

 Search Terms:
 jack spratt, 01/01/1970
 Search Date:
 09/23/2016 09:54:21 AM
 Searching on behalf of:
 Myself

 States Searched:
 CT, MN, NJ

The Drug Utilization Report below displays the controlled substance prescriptions, if any, that were dispensed in the indicated state(s). The information displayed on this report is compiled from requests submitted to other states' PMPs, and accurately reflects the information as returned by them. Blank fields indicate data not provided by other state.

This report was requested by: John W Hoey | Reference #: 10432

Prescriptions Dispensed in Connecticut

This state's PMP has indicated that you do not have permission to perform this search.

Prescriptions Dispensed in Minnesota

There are no results for the search terms that you entered.

Prescriptions Dispensed in New Jersey

This state's PMP has indicated that it encountered an error while performing the search.

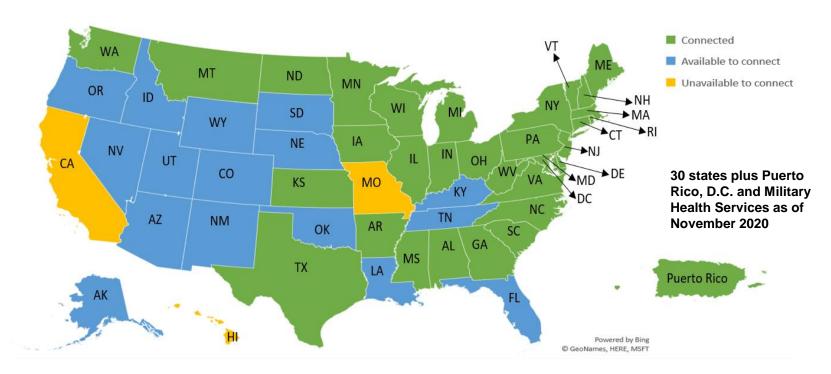
* - Drugs marked with an asterisk are compound drugs. If the compound drug is made up of more than one controlled substance, then each controlled substance will be a separate row in the table.

To report suspicious activity related to controlled substances, please click here and provide any relevant information.

To send questions or comments about this report to the Bureau of Narcotic Enforcement, please click here or call 1-866-811-7957 (Option 1).

For information regarding substance abuse rehabilitation treatment, please visit www.oasas.ny.gov or call 1-877-846-7369.

NEW YORK STATE PMPI DATA SHARING







Prescription
Monitoring Program
Webinars/
Enhancement





EDUCATING LEADERS IN PHARMACY AND PHARM

Need Help Registering?

Program Information

Login to Existing Account

Register for New Account

Home Study The New York State Prescription Monitoring Program (PMP)

Welcome to this enduring program. Please review the complete program information by selecting the above information tab before registering.

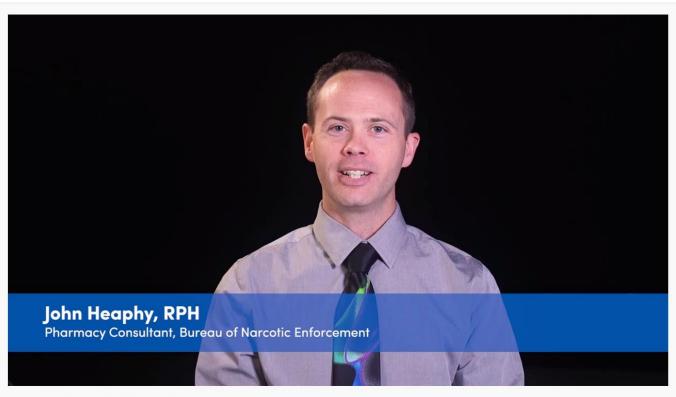
Attention Prescribers - How to Register: (There is no fee associated with this program)

In order to ensure receiving your ACCME credit and letter of completion, before registering for this program you must create an account in order for us to complete your credit claim document. You only need to complete this step once, and then you will be on file for all future programs. Simply click on "Register" in the upper right hand corner of this page and enter your information. Make sure to choose the appropriate account type-MD, DDS NP, PA, etc... Once you have set-up your UB CE account, you can then enroll and begin the program.

Prescribers and medical residents please note you are listed below as "All Other" in the payment section below.

Attention Pharmacists - Be sure you have an account. Once you successfully complete all components of the program your ACPE credit will be automatically uploaded to the CPE Monitor.

The New York State Prescription Monitoring Program - School of Pharmacy and Pharmaceutical Sciences - University at Buffalo



New York State Prescription Monitoring Program

© Unlisted



Topic Webinars

- Suspicious Activity
- > Assigning a Designee
- Practitioner Reports
- ➤ New to Practice- Medical Residents and Interns



Upcoming Enhancements

Morphine Milligram Equivalent (MME) calculator as a tool within the Prescription Monitoring Program Registry





The Opioid Crisis in NYS







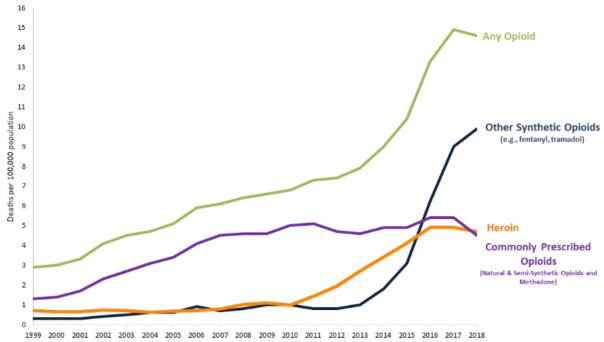
Opioid Use Disorder (OUD)



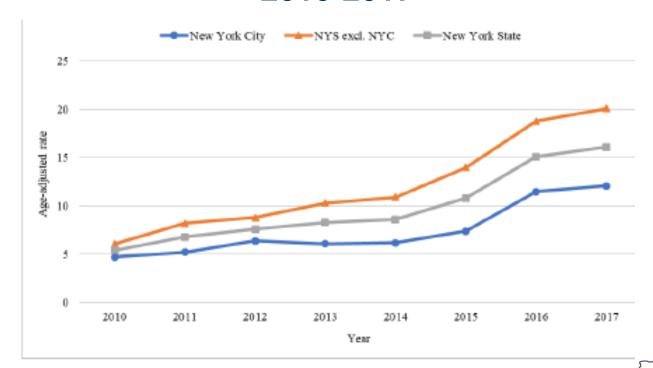




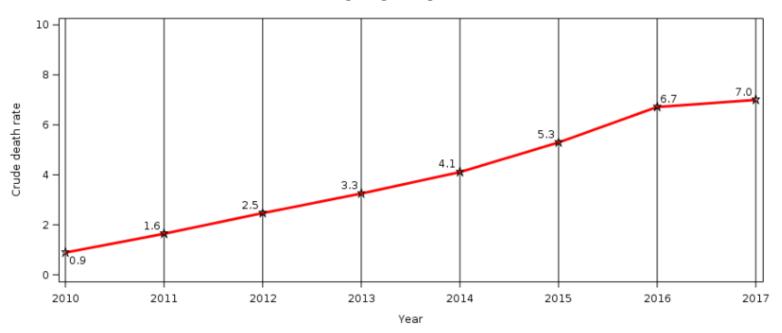
United States Overdose Opioid Deaths By Type 1999-2018



Opioid Deaths per 100,000 in NYS 2010-2017

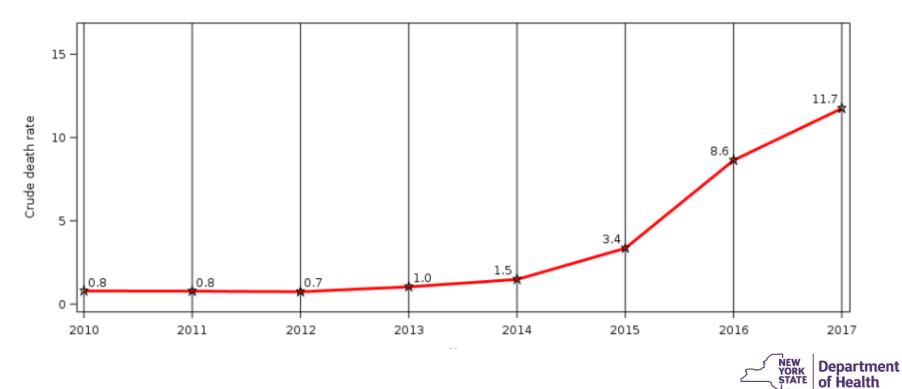


Heroin Deaths per 100,000 in NYS 2010-2017





Synthetic Opioid Deaths per 100,000 in NYS 2010-2017



Opioid Data Statistics

NEW YORK STATE

Services

News

Local

www.health.ny.gov/statistics/opioid/

Department of Health

Regional, County & Sub-county

evention Agenda Dashboard

Community Health Indicator Reports (CHIRS)

Race/Ethnicity (CHIRE)

Leading Causes of Death

Asthma in New York

Opioid-related Data in New York

New York State Cancer Registry

Environmental Public Health

Individuals/Families

Providers/Professionals

Engilities Co

Search

ou are Here: Home Page > Data & Reports > Opicid-related Data in New York State

Opioid-related Data in New York State

In response to the growing opioid-public health crisis and recommendations to improve the timeliness of reporting opioid-related data, the New York State Department of Health (NYSDOH) Opioid Prevention Program provides opioid-related data to support statewide prevention efforts. These efforts include improving timely opioid overdose reporting to key stakeholders. This information is a valuable tool for planning and can help identify where communities are struggling, help tailor interventions, and show improvements.

as website is designed to provide comprehensive. Useful data and information regarding opioid use and misuse. New resources will be added often. Please check back frequently

New York State Opioid Dashboard

The control of the Dashboard is an interactive visual presentation of indicators tracking opioid data at state and county favor tracking opioid data at for a positive for a state of the county favor tracking opioid data at for a positive for a state of an ounty favor tracking opioid data at for a positive for a state of the county favor tracking opioid data for a positive for a state of the county favor tracking opioid data for previous for a state of the profest of a sease specified previous for a state of the county favor tracking opioid data for a positive final factor for previous tracking opioid data for previous for a state of provide specified opioid and set of factors. Each county in the state hast so two master and opioid data for previous for a state of provide specified opioid and set of factors. Each county in the state hast so two master and opioid data for previous for a state opioid data for a state

New York State Opioid Summary Reports

- New York State Opioid Annual Report 2019 (PDF)
- New York State Opioid Annual Report 2018 (PDF)
- New York State Opioid Annual Report 2017 (PDF)
- Opioid Poisoning, Overdose and Prevention: 2015 Report to the Governor and NYS Legislature (PDF)

New York State County Opioid Quarterly Reports

In accordance with the recommendations of the New York State Herica and Opicid Task Force and 2018 legislation, the NYSDOH is providing opicid overdose information (deaths, emergency department (ED) visits, and hospitalizations) by county in quarterly reports. The report and cause are because on the country of residence. Opicids mode both preceding no pick pain relevens such as hydrocodone, on ordination of the precision of the precision of the precision of the burden of opicid advances in New York State in event of precision and opicid overedose information (seaths, emergency department (ED) visits, and hospitalizations) by county in quarterly reports. The report access are based on the country of residence. Opicids mode both precision opicid point and opicid overedose information (and should be usual and interpreted with causion, because used access part reports. The requirement of precision and opicid overedose information (and the precision opicid point and interpreted with opicid or access are based on the country of residence. Opicids mode to the country of residence Opicids mode to the country of residence Opicids mode to the country of residence on the country of residence Opicids mode to the country of residence of the country of res

- County Opioid Quarterly Report For New York State Counties Published July 2020 (PDF) (Data in excel)
- Archived New York State County Opioid Quarterly Reports

New York State Opioid Data to Action Reports

The Data to Action Reports are short communications on important topics that provide specific opioid-related data to mobilize public health action. Reports include key messages, quick facts describing the topics, figures illustrating relevant data, language describing recommendations, evidence-based approaches, and suggested actions and resources.

. Fentanyl-related deaths in New York State outside of New York City. 2015-2017

Technical Assistance for Opioid Data Indicators

This section contains resources to help users navigate the data website, understand the indicators, and interpret the data. Additional resources will be added periodically

- Opioid data sources and indicators
- Opioid mortality data technical assistance webinar recording

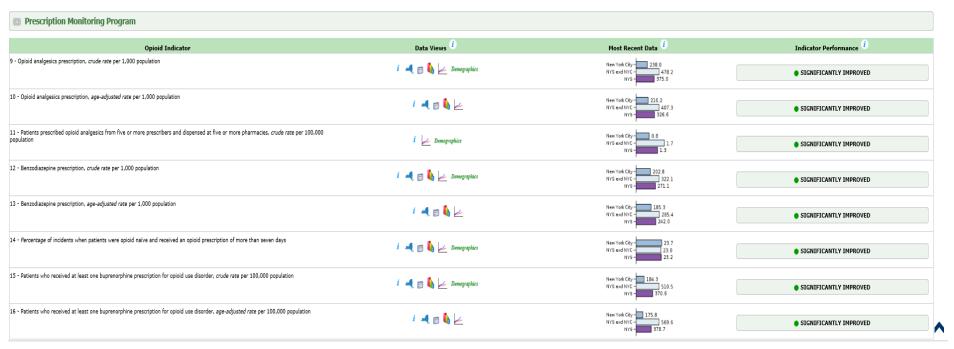


New York State Opioid Data Dashboard - State Level

| State Dashboard | County Dashboard | Sub-County | About This Site | Opioid Related Data in New York State |
|--|--|------------------|-----------------|---------------------------------------|
| State Dashboard Ho | <u>me</u> Data Table F | lealth Data NY | | |
| Filter indicators by Sta | ate Status on: Apply Improved No Chang | _ | . i | |
| Indicator Performance: | Improved No Chang | e 🗌 🔻 Worsened 🗀 | | |
| Opioid Data Overview | | | | |
| ■ Prescription | Monitoring Program | n | | |
| Overdose De | eaths Related to Opi | ioids | | |
| Emergency Department Visits Related to Opioids | | | | |
| Hospital Discharges Related to Opioids | | | | |
| Office of Add | diction Services and | Supports | | |
| Youth Risk B | Behavior Surveilland | e System | | |
| National Sur | vey on Drug Use an | d Health | | |



Opioid Data Dashboard





Opioid Use Disorder (OUD) Signs and Symptoms

Physical Signs

- > Change in appetite
- ➤ Pupil size
 - Small: opioid intoxication
 - Large: opioid withdrawal
- > Nausea
- Vomiting
- Sweating

Behavioral Signs

- ➤ Change in personality/attitude
- > Change in friends
- ➤ Change in activities, sports, hobbies
- ➤ Poor attendance / grades
- ➤ Increased isolation; secrecy
- ➤ Wearing long sleeved shirts
- ➤ Moody, irritable, nervous, giddy, or nodding off

 NEW Departm of Healt

What is Naloxone?

Naloxone is an emergency medicine that can reverse an opioid overdose





Opioid Overdose Prevention Naloxone In Action

- Reverses opioid effects of sedation and respiratory depression
- Causes sudden withdrawal– unpleasant feeling
- Wakes the person who is overdosing in 3-5 minutes
- Works for approx., 30-90 minutes
- > Safe, highly effective

- Routinely used by EMS (larger doses)
- No harm if an opioid is not present
- Available at pharmacies
- No potential for abuse



New York State's 911 Good Samaritan

Call 911 without fear of arrest if someone is having a drug or alcohol overdose

The following are signs of an overdose. CALL 911 if the person:

- Is passed out and cannot be woken up;
- Is not breathing, breathing very slowly, or making gurgling sounds;
- Has lips that are blue or grayish color.

Why should you care about the 911 Good Samaritan Law?

- > The law empowers an individual to save a person's life.
- ➤ The law encourages anyone to call 911 when they see or experience a drug or alcohol overdose.

AIDS Institute



Services

Government

Department of Health

Individuals/Families

Providers/Professionals

Health Facilities

HIV, STDs, & Hepatitis C

HIV and AIDS

Sexually Transmitted Diseases



General Information

1-800-541-2437 1-800-233-7432 Spanish

PEP Hotline Services NYC 1-844-373-7692 Rest of NYS 1-844-737-4669

Uninsured Care Programs 1-800-542-2437

 1-844-682-4058
 HIV Confidentiality Hotline 1-800-962-5065

CEI Programs & Services (212) 417-4778 or visit

a toll-free number for clinician

in NYS to discuss PEP, PrEP, HIV. HCV & STD management

This line supports inquiries from

clinicians only (MD, NP, PA, RN, PharmD or DDS) and is not intended for natient or consumer questions.

are Here: Home Page > AIDS Institute

AIDS Institute

The New York State Department of Health, AIDS Institute has lead responsibility for coordinating state programs, services and activities relating to HIVIAIDS, sexually transmitted diseases (STDs) and hepatitis C.

- · About the AIDS Institute
- AIDS Institute Priorities 2019-2020 (PDF)
- 2016 2020 AIDS Institute Strategic Profile (PDF)
- 2017 AIDS Institute Center at a Glance (PDF)
- The AIDS Institute Celebrates 30 years (1983-2017)
- The AIDS Institute Celebrates 25 years (1983-2008)

What's New on the AIDS Institute's web site?

- Health Advisories
- · Health Advisory: Increased Number of HIV Diagnoses in Monroe County 2020
- 2020 World AIDS Day & Ending the Epidemic
- On World AIDS Day, Governor Cuomo Announces New York State Has "Bent The Curve" on the HIV Epidemic

Our web site contains information regarding HIV/AIDS, STDs and hepatitis C. You will find information regarding our many programs, initiatives and services. Please choose a subject below to begin your search:

Information for Consumers

- Ending the Epidemic
- Resources for People Living with HIV/AIDS
- · Drug Use Resources and HIV/AIDS, STD & Hepatitis C Prevention
- HIV/AIDS and STD Testing
- Pre & Post Exposure Prophlyaxis (PEP, PrEP)
- · NYS Condom Program (NYSCondom)
- LGBTQ Health
- Hepatitis C

Information for Providers

- Ending the Epidemic
- Training for Providers
- Prevention Resources
- · HIV, STD, Viral Hepatitis Consumer & Provider Materials
- Corrections and HIV/AIDS

- Hepatitis C Testing Information



www.health.ny.gov/diseases/aids



Pharmacy Dispensing

- Significant steps have been taken in the last few years to increase pharmacy dispensing of naloxone
- Currently over 2,600 pharmacies with standing orders in NYS

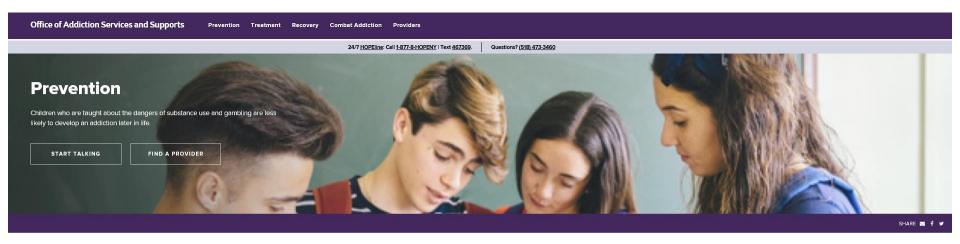


To Find the Nearest Participating Pharmacy:





Office of Addiction Services and Supports (OASAS) www.OASAS.ny.gov



PREVENTION WORKS

Addiction prevention in New York State is based on a risk and protective factor framework. Protective factors for children and young adults include:

- ${\boldsymbol \cdot}$ Open communication with family members, teachers, and other adults in their lives
- · A strong sense of family, positive experiences and role models; and
- . The attitudes and conditions of their community.

rence NEW YORK Department of Health

Find Addiction Treatment



Services

News Go

Government

Local

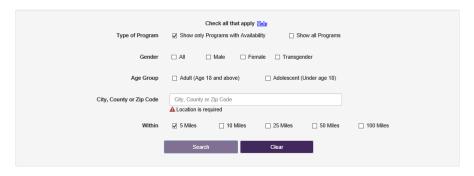
Q Search

Office of Addiction Services and Supports

OASAS Certified Treatment Service Descriptions for levels of substance use disorder care.

NYS OASAS Treatment Availability Dashboard

Search For State Certified Outpatient Or Bedded Programs



Visit New York: State HOPEline, by calling 1-877-946-7389 or texting HOPENY (467369) for help and hope 24 hours a day, 385 days a year for alcoholism, drug abuse and problem gambling.

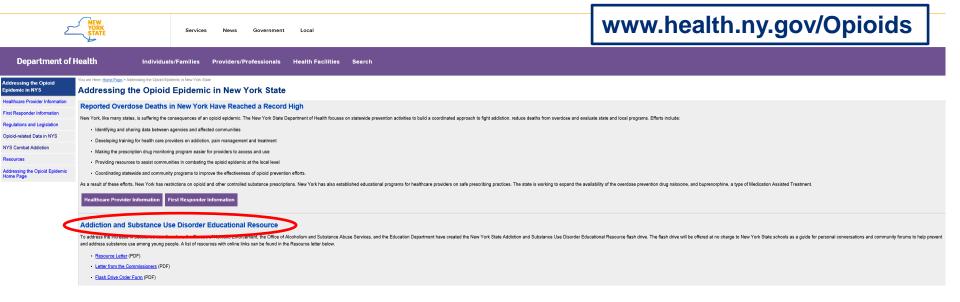
Comments or Questions? Send us an email:

StatewideFO@oasas.ny.gov

Privacy Policyl Disclaimed Accessibility



Opioid Information





Addiction & Substance Use Disorder (SUD) Educational Resource

- Posters, presentations, videos, and discussion guides about the opioid and heroin epidemic.
- > Facts on prescription drugs, their potential for misuse, and how to dispose of unused medications.
- Information on where to find prevention, treatment, and recovery services.
- Details on NYS laws that allow schools to provide and maintain naloxone on-site, to save the life of someone overdosing on opioids.
- Information on how school personnel can implement an opioid overdose prevention program.

Addiction & Substance Use Disorder (SUD) Educational Resource

NYS OASAS NYS BNE NYSED

Combat Addiction Combat Heroin Good Samaritan law

Hope Line 1-877-8HOPENY

Kitchen Table Toolkit Naloxone Information

Opioid Information

Opioid Overdose Prevention Toolkit and Resources-

NYS Center for School Health

Opioid Panel Presentation -NYSED

Prescription Drug Abuse Awareness

Safe Medication Disposal Spotlight on Synthetics Student Support Services Talk2Prevent

Treatment Availability Dashboard

www.oasas.ny.gov

www.health.ny.gov/professionals/narcotic/

www.nysed.gov/

http://www.oasas.ny.gov/CombatAddiction/index.cfm

http://www.combatheroin.ny.gov/

http://www.combatheroin.ny.gov/prevention http://www.oasas.ny.gov/accesshelp/index.cfm

http://www.combatheroin.ny.gov/kitchen-table-toolkit

www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/

directories.htm

www.health.ny.gov/professionals/narcotic/opioid_treatment_guidelines/

http://www.schoolhealthny.com/OpioidOverdose

http://www.regents.nysed.gov/video/board-regents-meeting-opioid-

panel-january-9-2017

www.health.ny.gov/professionals/narcotic/prescription_drug_abuse_aw

areness/

www.health.ny.gov/professionals/narcotic/safe_disposal/ http://www.oasas.ny.gov/AdMed/drugs/Synthetics.cfm

www.p12.nysed.gov/sss/ www.talk2prevent.ny.gov/

http://www.findaddictiontreatment.ny.gov/



Medication Assisted Treatment (MAT)



A Can a community pharmacist fill a methadone prescription?

- A. Yes, it should be treated as any other CII medication.
- B. Yes, if it is being prescribed for pain.
- C. No, methadone can only be administered in a clinic setting.



A Can a community pharmacist fill a methadone prescription?

- A. Yes, it should be treated as any other CII medication.
- B. Yes, if it is being prescribed for pain.
- C. No, methadone can only be administered in a clinic setting.



Acronyms

- **DATA** Drug Addiction Treatment Act of 2000
- **CARA** Comprehensive Addiction & Recovery Act of 2016
- **OTP** Opioid Treatment Program
- NTP Narcotic Treatment Program
- **MMTP** Methadone Maintenance Treatment Program
- **MAT** Medication-Assisted Treatment
- **OASAS** Office of Addiction Services and Supports
- SAMHSA Substance Abuse and Mental Health Services

Administration

Opioid Withdrawl

- May 2018- Lofexidine (Lucemyra) approved by FDA
- First FDA approved non-opioid treatment for the management of opioid withdrawl symptoms
- Approved for a maximum of 14 day treatment period
- \triangleright Decreases symptoms by reducing the release of norepinephrine. (α -2 adrenergic receptor agonist.)



FDA Approved Medications for Opioid Use Disorder

- Methadone- given in clinics, withdrawal is not required to start, stringent requirements for admission
- Naltrexone- anyone licensed to prescribe in NYS may prescribe naltrexone, must be abstinent from narcotics for 7 to 10 days
- Buprenorphine- office based opioid treatment, withdrawal is not required to start



Buprenorphine for Opioid Use Disorder

- Effective February 2017, Nurse Practitioners (NPs) and Physician Assistants (PAs) became able to prescribe buprenorphine as qualifying other practitioners.
- ➤ The SUPPORT Act of 2018 added clinical nurse specialists, registered nurse anesthetists, and certified nurse midwives who meet certain qualifications to be qualifying other practitioners until October 2023.
- Qualifying other practitioners must complete 24 hours of required training to prescribe buprenorphine for Opioid Use Disorder (OUD).



Buprenorphine for Opioid Use Disorder

- Practitioners can initially treat up to 30 patients, or 100 patients under certain conditions.
- Qualified practitioners who had a waiver to prescribe buprenorphine for up to 100 patients for a year or more, can obtain a waiver to treat up to 275 patients with additional credentialing.

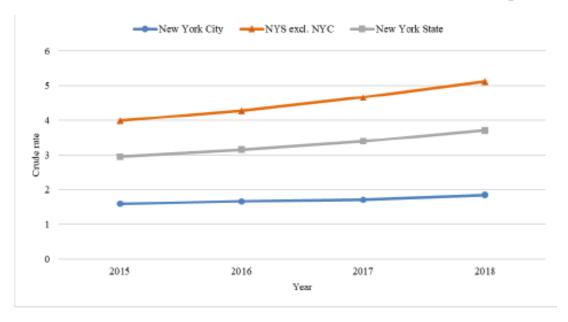


Title 10 Part 80 Rules & Regulations on Controlled Substance Section 80.84 Amendments

What are the amendments?

- ➤ The word "physician" was removed and the words "authorized practitioner" were inserted, which means that all authorized practitioners; physicians, NPs & PAs etc. may treat OUD with Buprenorphine in an office-based setting.
- The 30-patient limit was removed and points to the federal government patient limits.

Buprenorphine Prescribing

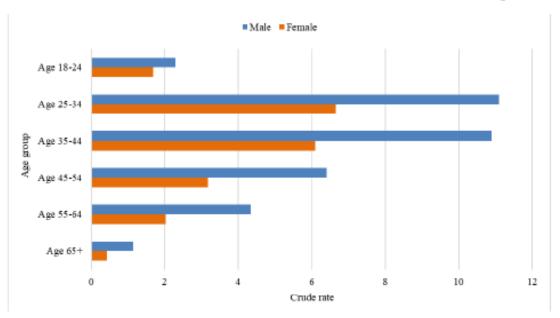


NYS Buprenorphine prescriptions for OUD per 1,000 population



Data Source: NYS PMP

Buprenorphine Prescribing



NYS Buprenorphine prescriptions for OUD per 1,000 population 2018



Data Source: NYS PMP

Q:Can a vendor pharmacy dispense Suboxone® to a nursing home (class 3a facility) for Medication Assisted Treatment (MAT)?

A. Yes, if the practitioner is DATA waived.

B. No

C. Unsure



A: Can a vendor pharmacy dispense Suboxone® to a nursing home (class 3a facility) for Medication Assisted Treatment (MAT)?

A. Yes. The federal Drug Addiction Treatment Act of 2000 (DATA 2000) allows a practitioner to prescribe, administer or dispense a controlled substance approved by the FDA for narcotic addiction. Currently, buprenorphine is the only such approved controlled substance. A pharmacist may dispense buprenorphine for the treatment of opioid use disorder pursuant to a prescription issued by an authorized practitioner.

Q: What is the maximum day supply of buprenorphine for Opioid Use Disorder (OUD) that can be filled?

A. 90

B. 30

C. 180



A: What is the maximum day supply of buprenorphine for Opioid Use Disorder (OUD) that can be filled?

B. 30 day supply is the maximum. There is no condition code that would allow for greater than a 30-day supply for OUD treatment with buprenorphine.



Q: Can a buprenorphine prescription for Opioid Use Disorder (OUD) be refilled?

A. Yes

B. No

C. Unsure



A: Can a buprenorphine prescription for Opioid Use Disorder (OUD) be refilled?

A. Yes. Buprenorphine is a Schedule III controlled substance and can be written for up to 5 refills.



Safe Disposal Program



Q: In non-medical use of prescription pain relievers, which source accounts for half?

- A. Obtained from a healthcare provider
- B. Bought from a "dealer"
- C. Obtained from a friend or relative

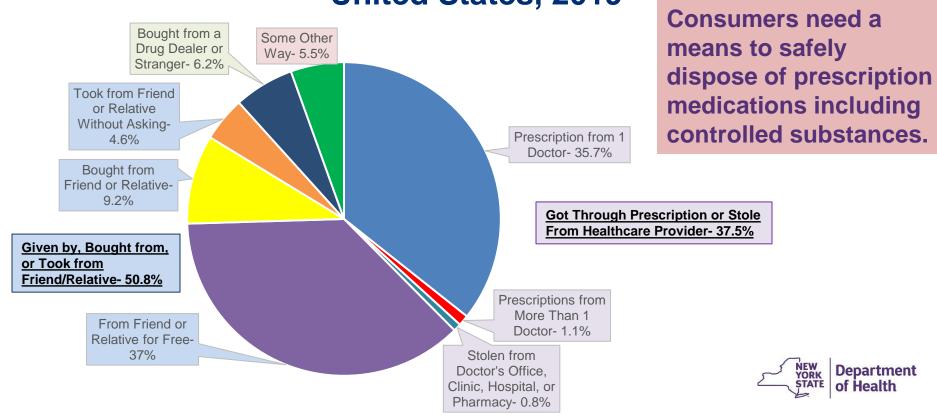


A: In non-medical use of prescription pain relievers, which source accounts for half?

- A. Obtained from a healthcare provider
- B. Bought from a "dealer"
- C. Obtained from a friend or relative



Sources for Nonmedical Use of Prescription Drugs
United States, 2019



Safe Disposal

- Consumers need a means to safely dispose of prescription medications including controlled substances
- Public Health Law §3343-b: disposal must be in accordance with federal law and NYS Public Health Law Article 2-B



Safe Disposal Program New York State

- > NYS Law Enforcement Drug Collection Event
- NYS Law Enforcement Medication Drop Box Program
- DEA Drug Take Back Event
- DEA Approved Collector (i.e. retail pharmacy, hospital/clinics with an on-site pharmacy, NTP)
- DEA Mail-Back Program
- Drug Take Back Act



Medication Drop Boxes by County



http://www.health.ny.gov/professionals/ narcotic/medication_drop_boxes/



Safe Disposal Program New York State

- The NYS Department of Health, Bureau of Narcotic Enforcement authorizes all activities allowed under the federal DEA's Disposal of Controlled Substances Final Rule. http://www.deadiversion.usdoj.gov/drug_disposal/index.html
- Retail pharmacies may apply directly to the DEA for registration as a "Collector" to place an approved drop box in their pharmacy.
- > The pharmacist may not handle the controlled substance, the ultimate user must place their unwanted drugs directly into the drop box.
- Allows a vendor pharmacy to place a DEA approved drop box in the RHCF to discard the resident's discontinued drugs



Drug Take Back Act (DTB)



Drug Take Back Act

- ➤ Public Health Law (PHL) §§290-294
- Implemented and Administered by the Bureau of Narcotic Enforcement, with the Department of Environmental Conservation
- Effective Date: January 6, 2019



Drug Take Back Act

- All wholesalers that sell in or into the state must provide DOH with a list of manufacturers that produce covered drugs
- Manufacturers' proposed drug take back programs must be submitted to DOH



Drug Take Back Act

DOH must approve or deny proposed plan, in consultation with DEC

- If the proposed plan is not approved by DOH, a revised plan must be submitted
- No defined date for when collection must be up and running



Drug Take Back Act - PHL §§290-294

- ➤ §290 Definitions
- ➤ §291 Drug Take Back
- §292 Collection
- §293 Violations
- §294 Jurisdiction



Drug Take Back Act – PHL §290 Definitions

- (1) Authorized collector
- (2) Covered drug
- (3) Manufacturer
- (4) Pharmacies
- (5) Drug take back organization
- (6) Wholesaler
- (7) Repackager



Drug Take Back Act - PHL §291

Manufacturers of covered drugs must either:

- (a) operate a drug take back program approved by DOH individually or jointly with other manufacturers;
- (b) enter into an agreement with a drug take back organization which shall operate a drug take back program approved by DOH; or
- (c) enter into an agreement with DOH to operate a drug take back program on its behalf.

Minimum Requirements §291(a)-(h)

Certifies the drug take back program will accept all covered drugs regardless of who produced them;

➤ Details a collection system to provide convenient, ongoing collection services to all persons seeking to dispose of covered drugs pursuant to section two hundred ninety-two of this article that is geographically distributed in a way to ensure access in rural and underserved areas;

Minimum Requirements

➤ Manufacturers bear all costs – collection, transportation, disposal.

➤ Manufacturers bear all state costs – administration, enforcement.

➤ Manufacturers must update plans at least every 3 years.



Drug Take Back Act – PHL §292 Collection

Pharmacies must provide for safe collection of drugs by one or more of the following:

- On-Site Collection/Drop boxes
- Mail-back envelopes
- Other DEA-approved methods

Also must have signage to notify.



Drug Take Back Act – PHL §292 Collection

- Pharmacies that chose to offer mail-back collection must provide a voucher for a prepaid envelope upon dispensing a covered drug.
- ➤ The voucher must include information on drug take back and safe drug disposal methods.



Convenience Standard

- ➤ For any city with a population of 125,000 or more as of the last census, the commissioner shall establish by regulation a distribution plan that ensures that on-site collection receptacle or dropbox placement shall be reasonably accessible to all residents and that provides for program cost efficiency.
- > NYC, Yonkers, Syracuse, Rochester, and Buffalo.



One size does not fit all

- What works for the Bronx is different from what's effective in the Adirondacks
- ➤ The Act provides the flexibility to give appropriate considerations to factors including geography, population, cost efficiency and pharmacy locations



Drug Take Back Act – PHL §294 Jurisdiction

- New York State has exclusive jurisdiction over all drug disposal matters in the DTBA.
- All conflicting county and local laws, rules, and regulations are preempted.



Bureau of Narcotic Enforcement

Riverview Center 150 Broadway Albany, NY 12204 Phone: (866)- 811-7957

www.nyhealth.gov/professionals/narcotic/

E-mail: <u>narcotic@health.ny.gov</u>

Regional Offices:

NYC: (212) 417-4103

Buffalo: (716) 847-4532

Syracuse: (315) 477-8459

Rochester: (585) 423-8043



Resources

10 NYCRR Part 80 Rules Article 33 PHL

http://www.health.ny.gov/professionals/narcotic/laws_and_regulations/

Controlled Substance Frequently Asked Questions

http://www.health.ny.gov/professionals/narcotic/faq/

State Education Department Office of the Professions

http://www.op.nysed.gov/prof/



Resources

Drug Enforcement Administration (DEA) http://www.deadiversion.usdoj.gov/877-883-5789

NYS Office of Addiction Services and Supports (OASAS)

<u>www.oasas.ny.gov</u> 1-877-8 HOPENY (1-877-846-7369)

Substance Abuse and Mental Health Services Administration (SAMHSA)

http://www.samhsa.gov/ 866-287-2728



Post-Test Questions



Q: Is the prescribing practitioner required to indicate on the ONYSRx that he or she has been approved for a waiver from electronic prescribing?

A. Yes

B. No

C. Unsure



A: Is the prescribing practitioner required to indicate on the ONYSRx that he or she has been approved for a waiver from electronic prescribing?

B. No. A prescriber is not required to indicate a waiver of the ONYSRx. Pharmacists should be vigilant and verify the authenticity of any prescription presented to them.



Q: A pharmacist may designate a pharmacy technician to consult the Prescription Monitoring Program on their behalf.

- A. True
- B. False
- C. True, if the technician has undergone a special training
- D. True, if the technician is certified



A: A pharmacist may designate a pharmacy technician to consult the Prescription Monitoring Program on their behalf.

- A. True
- B. False
- C. True, if the technician has undergone a special training
- D. True, if the technician is certified



Q: Buprenorphine for substance use disorder may be prescribed by:

- A. Medical Doctors
- B. Nurse Practitioners
- C. Physician Assistants
- D. All of the above



Q: Buprenorphine for substance use disorder may be prescribed by:

- A. Medical Doctors
- B. Nurse Practitioners
- C. Physician Assistants
- D. All of the above



Questions?



