



Managing Pain and Opioid Use

An Educational Program on Compliance with
New York State Prescribing Laws

Boston University School of Medicine
Barry M. Manuel Continuing Medical Education Office



Obtaining your Educational Credits

At the conclusion of the program, you will be able to receive CME, CNE, and ABIM MOC Part II credit but you must take a post-test and complete an evaluation.

With a passing score of 70% or greater, you will be able to print your certificate.



Program Support

This program is provided by Boston University School of Medicine in partnership with the New York Chapter of the American College of Physicians.



Educational Objectives

At the conclusion of this activity, participants will be better able to:

- Describe New York State/Federal legislative updates regarding prescribing opioids and naloxone and certifying for medical cannabis.
- Explain relevant issues related to opioid misuse, opioid use disorder, and opioid overdose.
- Describe palliative care, palliative symptom management, and communication tools for end-of-life decision making and advance directive planning.



State and Federal Laws on the Prescribing of Controlled Substances

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Chair, Pain Management Task Force
New York Chapter American College of Physicians



Prescribing: Code of Federal Regulations - Title 21

All prescriptions for controlled substances shall

- Be signed and dated when issued
- Bear the full name and address of the patient
- Include medication name, strength, dosage form, quantity prescribed, directions for use
- List the name, address and registration number of the practitioner

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=1306&showFR=1> Accessed 11.1.2022



NYS Internet System for Tracking Over-Prescribing (I-STOP)

- The Prescription Drug Monitoring Program (PDMP) Registry provides practitioners and pharmacists with direct, secure access to view substance prescription history.
- Helps evaluate a patient's treatment as it pertains to controlled substance prescribing and dispensing.
- Practitioner (or designee) **must** consult the registry prior to prescribing or dispensing any controlled substance listed on schedule II, III or IV.
- Practitioners may consult the registry prior to prescribing or dispensing any other controlled substance.



Exception to the E-Prescribing Mandate

- No longer requires a notification to the New York State Department of Health.
- Practitioner must indicate in the patient's health record when they issue a non-electronic prescription for one of the approved exceptions below:
 - Temporary technological failure;
 - Temporary electrical failure;
 - To be dispensed by a pharmacy located outside the state, outside the country, or on federal property;
 - The practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition.

https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/practitioner_notification_requirement.htm Accessed 11.1.22.



Exceptions to the Duty to Consult PDMP

The duty to consult the registry shall not apply to:

- I. Veterinarians
- II. Methadone programs aka opioid treatment programs
- III. A practitioner administering a controlled substance
- IV. A practitioner prescribing or ordering a controlled substance for use on the premises of an institutional dispenser
- V. A practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity of controlled substance prescribed does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use



Exceptions to the Duty to Consult PDMP

The duty to consult the registry shall not apply to:

- VI. A practitioner prescribing a controlled substance to a patient under the care of hospice
- VII. A practitioner when:
 - A. it is not reasonably possible for the practitioner to access the registry in a timely manner;
 - B. no other practitioner or designee authorized to access the registry, pursuant to paragraph (b) of this subdivision, is reasonably available; and
 - C. the quantity of controlled substance prescribed does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;



Exceptions to the Duty to Consult PDMP

The duty to consult the registry shall not apply to:

- viii. A practitioner acting in compliance with regulations that may be promulgated by the Commissioner as to circumstances under which consultation of the 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;
- ix. A situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure, as set forth in regulation.

Exceptions to the Duty to Consult PDMP

The duty to consult the registry shall not apply to:

- x. A practitioner who has been granted a waiver due to technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner, pursuant to a process established in regulation, and in the discretion of the Commissioner.

Seven Day Limitation on Initial Opioid Prescribing for Acute Pain

- Practitioner initially may not prescribe more than a 7-day supply of an opioid medication for acute pain
 - Acute pain: resulting from disease, accidental or intentional trauma, or other cause, that the practitioner reasonably expects to last a short time
- Upon any subsequent evaluation for the same pain, the practitioner may order any appropriate renewal, refill, or new prescription for an opioid in accordance with existing rules and regulations

7
DAY SUPPLY

Seven-day limit does not include prescribing for chronic pain, pain being treated as a part of cancer care, hospice or other end-of-life care, or pain being treated as part of palliative care practices.

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Written Treatment Plan for Opioid Prescribing: NYS Public Health Law §3331

- Must have a written treatment plan if opioids are being initiated or maintained for pain which has lasted more than three months or past the time of normal tissue healing
- Exclusion if opioids used for:
 - cancer treatment that is not remission
 - hospice, palliative care, or other end-of-life care

<https://www.nysenate.gov/legislation/laws/PBH/3331> Accessed 11/1/2022

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American College of Physicians

Written Treatment Plan for Opioid Prescribing

Treatment plan must be done at least annually and include:

- goals for pain management and functional improvement based on diagnosis, and a discussion on how opioid therapy would be tapered to lower dosages or tapered and discontinued if benefits do not outweigh risks;
- a review with the patient of the risks of and alternatives to opioid treatment; and
- an evaluation of risk factors for opioid-related harms.

New York State Drug Take Back Act (DTB)

- Mandates that manufacturers establish, fund, and manage a New York State approved medication take back program(s) for the safe collection and disposal of unused covered medications.
- Pharmacies of 10 or more establishments within NYS and non-resident pharmacies that provide covered medications to NYS residents by mail must implement provide consumers with pre-approved method(s) of collection and disposal.

Chapter 120 Laws of 2018

https://www.health.ny.gov/professionals/narcotic/drug_take_back.htm
Accessed 11.1.2022

Pharmacies Must:

- Provide for the safe collection of medications by offering one or more of the following methods:
 - On-site collection, dropbox, or receptacle meeting federal standards
 - Mail-back collection by prepaid envelopes as authorized by federal law and regulation
 - Other Federal Drug Enforcement Agency approved methods of collection
- Provide collection at no cost to the consumer
- Display signage advertising the availability of medication collection to consumers
- Comply with all federal laws and regulations concerning the disposal of controlled substances.

Chapter 120 Laws of 2018

https://www.health.ny.gov/professionals/narcotic/drug_take_back.htm

Accessed 11.1.2022



Initial Physical Examination in Telemedicine Needed For Controlled Substances - New September 2022

- Although the Drug Enforcement Administration (DEA) has temporarily waived its requirement for an in-person physical exam during the COVID-19 federal public health emergency, NYS has not waived the requirement for an initial physical exam prior to prescribing controlled substances (except for buprenorphine).
- NYS law currently requires that a physical exam of the patient is required prior to prescribing a controlled substance (under most circumstances).
- The examination may vary "as indicated" to conform to generally accepted medical standards, including consideration of medication to be prescribed and the patient's condition & history.

Title 10 New York Codes, Rules and Regulations §§80.62 and 80.63

<https://www.health.ny.gov/professionals/narcotic/> Accessed 11.1.2022



Reliance on Record of Physical Exam

- Practitioners may prescribe a controlled substance to their own patient after a review of the patient's record IF the record contains the results of a physical examination performed by a consulting physician or hospital and such record warrants the prescribing.
- The examination of record must have been performed specific to the diagnosis for which the prescription is being considered.
- A new diagnosis may necessitate a new physical examination.
- Both practitioners must be licensed to practice in New York State (NYS).

<https://www.health.ny.gov/professionals/narcotic/> Accessed 11.1.2022



Exemption - Buprenorphine for Medication for Addiction Treatment for Opioid Use Disorder (OUD)

- Due to the federal public health emergency, the NYS Department of Health is permitting the prescribing of buprenorphine for medication for addiction treatment for opioid use disorder (OUD) without the physical examination of the patient.
- No other controlled substances are subject to this temporary exception to NYS's independent requirements.
- RESOURCE for Telemedicine for Buprenorphine:
https://www.health.ny.gov/diseases/aids/consumers/prevention/buprenorphine/docs/telemedicine_guidance.pdf

<https://www.health.ny.gov/professionals/narcotic/> Accessed 11.1.2022



Standing Order for Naloxone in Pharmacies

- Effective 8/15/22, all pharmacies in NYS may dispense naloxone through a [standing order](#) (non-patient specific order).
- This order enables more lay people in NY to have naloxone available to treat life-threatening opioid overdose.
- Info for lay people seeking naloxone in pharmacies:
 - No need to have a prescription for naloxone.
 - Simply request this medication at the pharmacy counter and present insurance information.
 - The [Naloxone Co-payment Assistance Program \(N-CAP\)](#) will cover co-payments of up to \$40 resulting in no or lower out-of-pocket expenses for most privately insured persons. There should be no co-pay for patients on Medicaid.

https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/pharmacy_standing_order.htm Accessed 11.1.2022



Prescribing Naloxone – Proposed Legislation

- With the first opioid prescription in a calendar year to a patient, the prescriber ALSO shall prescribe an opioid antagonist when risk factors are present:
 - (a) a history of substance use disorder;
 - (b) high dose or cumulative prescriptions that result in morphine 90mg equivalents or higher per day;
 - (c) concurrent use of opioids and benzodiazepine or nonbenzodiazepine sedative hypnotics.
- EXCLUSIONS: prescribing in a hospital or nursing home under article 28 or a facility under article 31 of the Mental Hygiene Law, or for hospice patients

<https://www.nysenate.gov/legislation/laws/PBH/3309> Accessed 11.1.2022



New York State's Medical Cannabis Program

- To issue certifications for patients to receive medical cannabis, health care providers must:
 - Be licensed, registered, or certified by New York State to prescribe controlled substances to humans within the State, such as physicians, nurse practitioners, physician assistants, dentists, podiatrists, and midwives.
- Complete at least a two-hour course before they certify patients for medical cannabis.
- The Medical Cannabis Data Management System (MCDMS) streamlines the patient certification process.

LINK TO COURSES:
<https://cannabis.ny.gov/practitioners>

<https://cannabis.ny.gov/practitioners>
 Accessed 11.1.2022



Pointers for Medical Cannabis

- Practitioners do not *prescribe* a specific formulation and dosage of cannabis; they *recommend* it. Choose:
 - “Per Pharmacist Consultation” to defer the selection of medical cannabis ratio to pharmacists in the dispensary
 - “Specific Recommendations” to select at least one product ratio
- Practitioners must consult the PDMP to check the controlled substance history before issuing or editing a patient’s medical cannabis certification.
- After certifying, make sure you print the ENTIRE document to include important instructions to the patient on how to register.



Eligible Conditions for Medical Cannabis in NYS

- Cancer
- HIV infection or AIDS
- Amyotrophic lateral sclerosis (ALS)
- Parkinson's disease
- Multiple sclerosis
- Spinal cord injury with spasticity
- Epilepsy
- Inflammatory bowel disease
- Neuropathy
- Huntington's disease
- Post-traumatic stress disorder
- Pain that degrades health and functional capability as an alternative to opioid use
- Substance use disorder
- Alzheimer's
- Muscular dystrophy
- Dystonia
- Rheumatoid arthritis
- Autism
- Or any other condition, at the discretion of the health care provider

Resource: <https://www.ncbi.nlm.nih.gov/books/NBK577724/>

<https://cannabis.ny.gov/medical-cannabis-program-faqs>

Accessed 11/1/2022



Brief Overview of Issues Related to Opioid Misuse, Opioid Use Disorder (OUD), Medication for Opioid Use Disorder (MOUD), and Overdoses

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Vulnerability Factors for Developing Substance Use Disorder (SUD)

- Genetic predisposition (40-60% of the vulnerability)
- History of trauma and/or abuse (most commonly preadolescent sexual trauma in females; witness to or victim of violence in all genders)
- Concomitant mental health diagnoses:
 - Bipolar disorder
 - Anxiety (GAD/PTSD/social anxiety)
 - Depression
 - ADHD
 - Specific personality disorders (borderline, antisocial)
 - Antisocial conduct disorder (diagnosed in adolescence)

Understand Intersectionality and Its Role in Identity, Oppression, and Privilege

INTERSECTIONAL IDENTITIES



thanks to Anita Ravi, MD for her slide and Jeoma Oluo for her concepts from the book So You Want to Talk About Race?

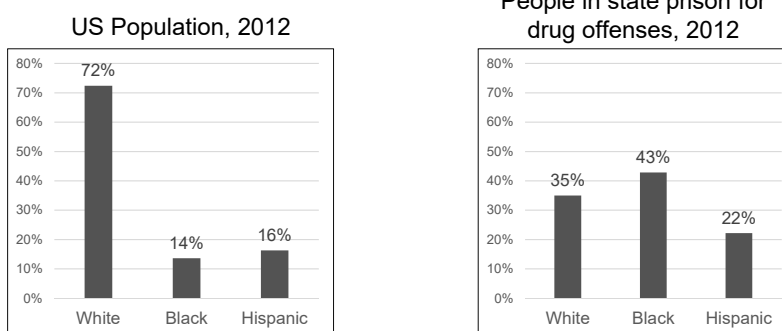
Intersectionality Framework:

- understand the impact of various systems of domination, including racism, sexism, classism, and how other forms of inequality “intersect”
- interpersonal experiences of discrimination based on gender, class, race, sexuality, disability, etc., stem from macro systems of inequality
- Interventions that are not sensitive to intersecting forms of identity can privilege some with access to resources and marginalize others who face barriers in access to care.

Link, B. G., & Phelan, J. (1995). Social conditions as fundamental causes of disease. *Journal of health and social behavior*, 80-94.

Crenshaw, Kimberle, 1991. "Mapping the Margins: Intersectionality, Identity Politics, and Violence Against Women of Color", *Stanford Law Review* 43: 1241-1299

Incarceration for Drug Offenses by Race and Ethnicity, 2012



Sources: US Census; Carson EA, Prisoners in 2013, US DOJ, 9/30/14.



CDC Provisional Total Estimated Overdose Deaths Through December 2021

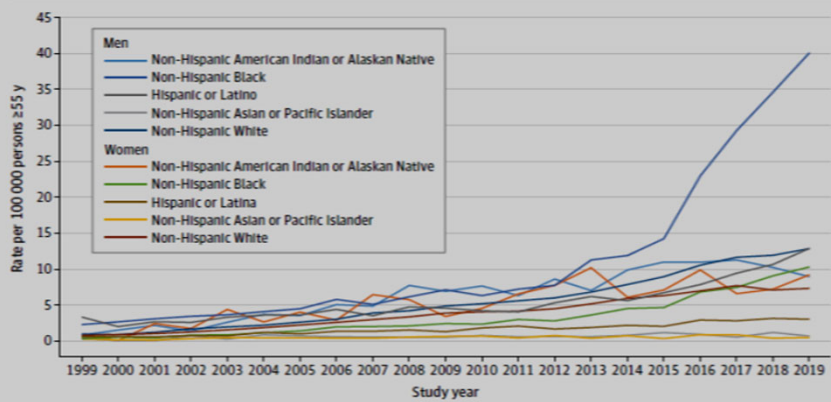
- Annual drug overdose deaths have reached another record high in the United States.
- An estimated **107,622 people** died of a drug overdose in the 12-month period ending December 2021, according to CDC provisional data published 5/11/2022.
- An overall 15% increase in deaths compared with 2020. About two-thirds of those deaths involved synthetic opioids such as illicitly manufactured fentanyl and its analogues. There were significant deaths due to methamphetamine use as well.

<https://www.whitehouse.gov/ondcp/briefing-room/2022/05/11/statement-from-dr-rahul-gupta-on-todays-cdc-overdose-death-data-4/>



Disparities by Sex and Race and Ethnicity in Death Rates Due to Opioid Overdose Among Adults 55 and Over, 1999-2019

Figure 2. Rates of Opioid Overdose Deaths per 100 000 Persons 55 Years and Older by Sex and by Race and Ethnicity, 1999 to 2019



<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787930> (Published 1/11/2022)



Disparities in Overdose Rates by Race and Ethnicity, 1999-2020

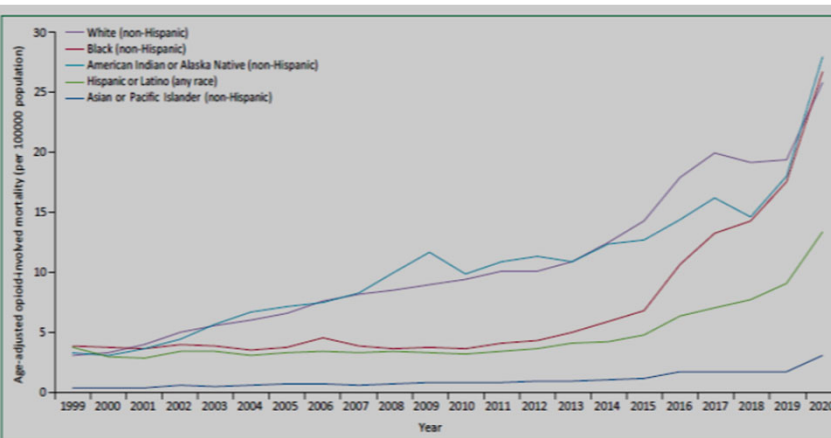


Figure 4: US age-adjusted opioid-involved mortality (per 100 000 population), 1999–2019

Data are from the US Centers for Disease Control and Prevention's Wide-Ranging Online Data for Epidemiologic Research.¹⁷

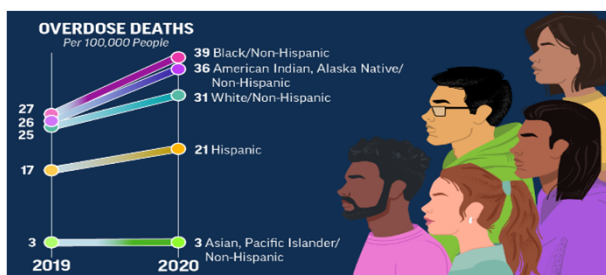
[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)02252-2/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02252-2/fulltext) (published 2/2/2022)



Drug Overdose Deaths, by Selected Sociodemographic and Social Determinants of Health Characteristics — 25 States and the District of Columbia, 2019–2020

- In just one year, overdose death rates (number of drug overdose deaths per 100,000 people) increased 44% for Black people and 39% for American Indian and Alaska Native (AI/AN) people.** Most people who died by overdose had no evidence of substance use treatment before their deaths. In fact, a lower proportion of people from racial and ethnic minority groups received treatment, compared with White people. Some conditions in the places where people live, work, and play can widen these disparities. Increasing access to proven treatment for all people who have substance use disorder(s) is a critical part of their care and recovery.

 - Harm reduction services can further reduce overdoses and save lives. Harm reduction services can include naloxone, fentanyl test strips, and referral to substance use disorder treatment. Syringe services programs can serve as a valuable way to reach people who inject drugs and provide them with overdose prevention education and opportunities to link to substance use disorder treatment.

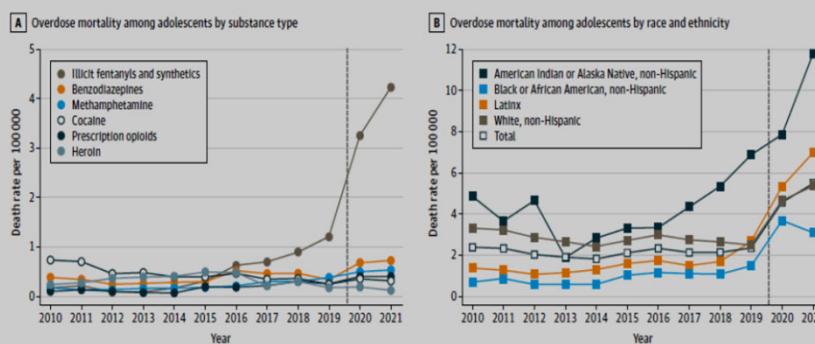


<https://www.cdc.gov/vitalsigns/overdose-death-disparities/index.html> (published online 7/19/2022)



Trends in Drug Overdose Deaths Among US Adolescents, January 2010 to June 2021

Figure. Adolescent Overdose Deaths, 2010-2021



Drug overdose rates per 100 000 adolescents are shown by (A) substance involved and (B) race and ethnicity. The year 2021 refers to January to June 2021, and rates have been annualized. The vertical dashed lines delineate the prepandemic and pandemic periods of observed data.

<https://jamanetwork.com/journals/jama/article-abstract/2790949> (4/8/2022)



NYS DOH Opioid Prevention Program: Data to Action: Overdose Deaths Involving Methamphetamine With and Without Fentanyl in NYS, Outside of NYC, 2016-2020, Demographic Data on Race and Ethnicity

- The average annual crude rates of overdose death involving methamphetamine in NYS outside of NYC for 2019 and 2020 were highest among those aged 25-44 years (3.2 per 100,000), males (1.6 per 100,000), and White non-Hispanic individuals (1.4 per 100,000) (Figure 2).

Figure 2

Overdose deaths involving methamphetamine, average annual crude rate per 100,000 population, by sub-population, New York State outside of New York City, 2019-2020^a



^a2020 data is provisional and subject to change

*White NH = White non-Hispanic. Black NH = Black or African American non-Hispanic. Other NH = Asian, Pacific Islander and all other non-Hispanic.

** Rate is suppressed due to fewer than 10 events in the numerator.

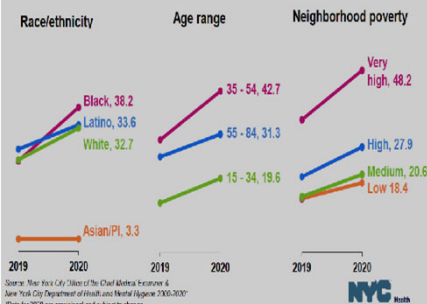
NYS DOH: Opioid Prevention Program: Data to Action: Overdose Deaths Involving Methamphetamine With and Without Fentanyl in NYS, Outside of NYC, 2016-2020 (January 2022)



Disparities in NYC Overdose Deaths by Race/Ethnicity, Age Range, and Neighborhood Poverty, 2019-2020

Change in rates of drug overdose death, 2019 to 2020 (per 100,000 residents)

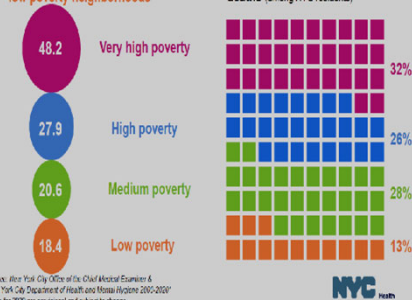
Large increase in rates of overdose among Black New Yorkers, those aged 35-54, and residents of very high poverty neighborhoods



Very high poverty neighborhoods have higher burden of overdose

Overdose fatality rates in very high poverty neighborhoods more than double low poverty neighborhoods

Residents of very high poverty neighborhoods account for nearly 1 out of 3 overdose deaths (among NYC residents)



NYC Health Epi Data Brief Unintentional Drug Poisoning (Overdose) Deaths in NYC in 2020 (November 2021, No 129)



Who Is at Risk for Opioid Overdose?

- Reduced tolerance
- Using alone (a risk factor for fatal OD)
- Chronic medical condition
- Unstable housing/unhoused
- Concomitant mental health condition
- Polysubstance use
- Changes in the illicit substance supply
- History of a previous nonfatal overdose
- Doses \geq 90 mg morphine-equivalent doses
- Injecting versus sniffing (though someone may overdose via any administration route)

New York State's Good Samaritan Law

Protects:

- The individual who experiences an overdose and
- The person who summons EMS (calls 911)

Prevents prosecution for:

- Possession of up to 8 oz of a controlled substance
- Alcohol (for underage drinkers)
- Cannabis (any amount) (cannabis is now legal in NYS for adults 21 years and older)
- Substance paraphernalia offenses
- Sharing of drugs (in NYS, sharing can be a "sales" offense)

How Does Naloxone Work?

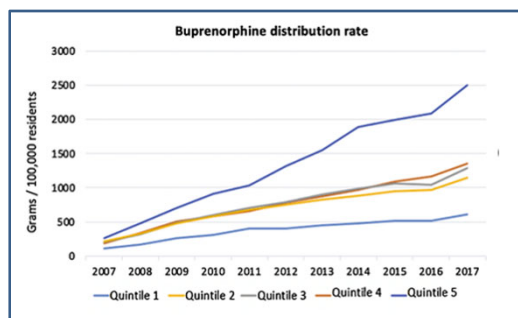
Naloxone: Mechanism of Action

- **Reverses opioid overdose and prevents fatalities**
- Mu-opioid receptor antagonist
 - No clinical effect in the absence of opioid agonists
 - Inert: no medication-medication interactions
 - Displaces opioids from the mu opioid receptors
- Takes effect in 2-3 minutes
 - May cause acute opioid withdrawal
 - Lasts for 30-90 minutes (longer for newer formulations)
- **Hepatic metabolism; renal excretion**
- **Safe in children**
- **Evidence thus far indicates no additional naloxone needed to reverse overdoses with fentanyl involvement**

Goals for MOUD

- Decrease risk for opioid related mortality (overdose) and all cause mortality (methadone and buprenorphine)
- Alleviate physical withdrawal symptoms
- Alleviate opioid cravings
- Normalize brain changes: anatomy
- Normalize brain physiology: neurotransmitters
- Improve functionality for the patient: goals are individualized
- Decrease potential harm (incidence of transmissible infections: HIV/HCV/HBV, incidence of injection-related infections: endocarditis/abscesses/osteomyelitis, etc.)

Buprenorphine Distribution Rate



Population-weighted rates of buprenorphine distribution in Medicaid expansion states from 2007-2017, stratified by 3-digit zip code quintile. (Quintile 1=highest % of white residents; Quintile 5=lowest % of white residents)

Source: Schuler MS, et. al., Drug Alcohol Depend. 2021.



Urine Toxicology Testing by Race

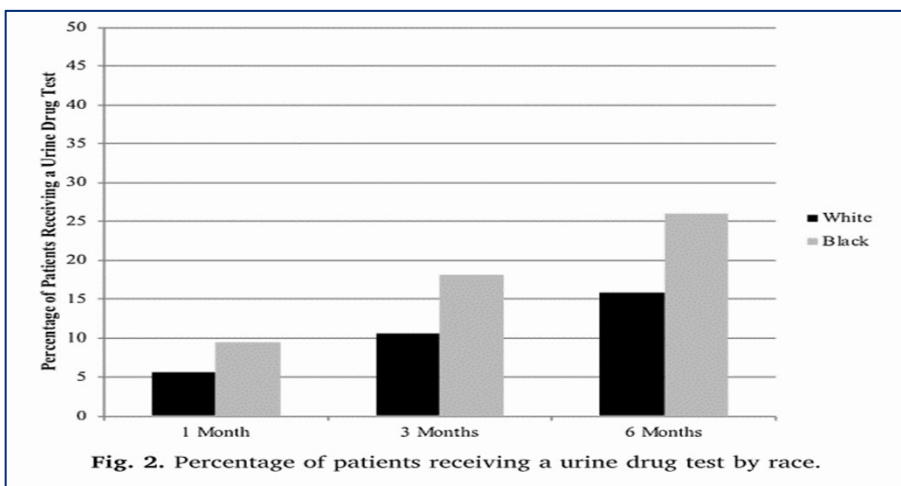


Fig. 2. Percentage of patients receiving a urine drug test by race.

Source: Gaither J, et. al., Drug Alcohol Depend. 2018



Become a Buprenorphine Waivered Practitioner

- Qualified practitioners can offer buprenorphine for the treatment of opioid use disorders (OUD).
- To receive a practitioner waiver to administer, dispense, and prescribe buprenorphine practitioners must notify SAMHSA's Center for Substance Abuse Treatment (CSAT) of their intent to practice this form of MOUD. The [notification of intent \(NOI\), or buprenorphine waiver application](#), must be submitted to SAMHSA before the initial dispensing or prescribing of MOUD.
- Qualified practitioners include Physicians, Nurse Practitioners (NPs), Physician Assistants (PAs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetist (CRNAs), and Certified Nurse-Midwives (CNMs).



Become a Buprenorphine Waivered Practitioner

- Recent changes have allowed for an alternative NOI for those seeking to treat **up to 30 patients**. The alternative type of NOI allows those providers who wish to treat up to 30 patients to forego the training requirement, as well as certification to counseling and other ancillary services (i.e., psychosocial services). Practitioners utilizing this training exemption are limited to treating no more than 30 patients at any one time (time spent practicing under this exemption will not qualify the practitioner for a higher patient limit).



Checking the PDMP

- Required:
 - Before writing any controlled prescription in New York State
- Optional, but Informative:
 - Consider checking the PDMP on all patients every visit
 - It can be informative: your patient may be on controlled medications, and you were unaware (potential medication-medication interactions, at risk for misuse or development of an SUD)
 - Caveat: methadone (or buprenorphine) received for the treatment of OUD (i.e., dispensed at an OTP) will NOT be listed in the PDMP
 - the only way to know is if your patient tells you



What Can You Do as a Healthcare Provider to Combat Disparities in Overdoses and Access to Treatment?

- **Raise awareness about overdose disparities and take action to remedy disparities in access to MOUD, harm reduction services, and overdose prevention strategies.** Culturally competent care, awareness of biases, and nonjudgmental communication can help address treatment access barriers, such as stigma and mistrust in health care systems.
- **Integrate substance use disorder and harm reduction services into routine clinical care, including in emergency departments and inpatient hospital care.**
- **Implement innovative service delivery models**, such as telehealth and remote initiation of MOUD, co-locating health and harm reduction services, and linking and retaining persons with opioid and other substance use disorders to care.
- **Strengthen collaboration between health care systems, public safety, and public health** to implement a holistic community response to overdose prevention.
- **Acknowledge that disparities in overdose deaths are exacerbated by underlying social determinants of health, structural racism, and historical trauma that contribute to increased risk for multiple health-related outcomes, including substance use and overdose, and can serve as substantial barriers to lifesaving care.**

<https://jamanetwork.com/journals/jama/fullarticle/2794593> (July 19, 2022)



Resources

- www.pcssnow.org
- www.psam.org
- www.harmreduction.org
- <https://oasas.ny.gov/training/clinical-support>
- <https://oasas.ny.gov/learning-thursdays>
- <https://oasas.ny.gov/harm-reduction-office-hours>
- https://www.health.ny.gov/diseases/aids/consumers/prevention/buprenorphine/docu/bupe_best_practices_2019.pdf (currently being revised)
- https://oasas.ny.gov/system/files/documents/2021/02/medications_maintenance_for_oud.pdf
- https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/
- <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#DATA-2000>
- <https://www.samhsa.gov/medication-assisted-treatment/statutes-regulations-guidelines#support>
- <https://www.samhsa.gov/medication-assisted-treatment/about-dpt>
- <https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php>
- <https://www.federalregister.gov/documents/2021/04/28/2021-08961/practice-guidelines-for-the-administration-of-buprenorphine-for-treating-opioid-use-disorder>
- <https://www.samhsa.gov/medication-assisted-treatment/become-buprenorphine-waivered-practitioner>



Palliative Medicine

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 Member, Pain Course Task Force
 New York Chapter American College of Physicians



Palliative Care in NYS Law

Two laws enacted in 2011.

- Palliative Care Information Act—requires the attending practitioner to offer patients with a terminal illness information about their prognosis, appropriate options (including risks and benefits), and the patient’s “legal rights to comprehensive pain and symptom management at the end of life.”
- Palliative Care Access Act—requires that hospitals, nursing homes, and other agencies and facilities provide appropriate information about palliative care to patients or surrogates and facilitate appropriate consultation.

https://www.health.ny.gov/professionals/patients/patient_rights/palliative_care/



What is Palliative Care?

- Specialized medical care for people living with serious illness
- Focused on providing relief from the symptoms and stress of a serious illness
- To improve quality of life for both the patient and the family
- Provided by a team of palliative care doctors, nurses and other specialists who work together with a patient’s other doctors to provide an extra layer of support
- Appropriate at any age and at any stage in a serious illness and can be provided along with curative treatment.

www.capc.org/about/palliative-care



Who Can Palliative Care Help?

- Patients with a serious, chronic illness
- Patients with metastatic or locally advanced cancer progressing despite systemic treatments with or without weight loss and functional decline
- Patients with complicated ICU courses and poor prognosis
- Patients presenting to the ED for recurrent or chronic severe problems with poor prognosis, esp. if considering ICU
- Patients and/or families whose distress is impairing decision-making

<https://getpalliativecare.org/resources/clinicians/>



Palliative Care Leads to Better Patient Outcomes

- 2020 meta-analysis of 28 studies of palliative care in non-cancer diagnoses (eg COPD, HF) showed that patients receiving palliative care services had:
 - Reduced ED use,
 - Fewer hospitalizations,
 - Lower symptom burden, and
 - More frequently participated in advance care planning

Quinn KL, Shurrab M, Gitau K, et al. Association of receipt of palliative care interventions with health care use, quality of life, and symptom burden among adults with chronic noncancer illness: a systematic review and meta-analysis. JAMA 2020; 324(14):1439–1450. doi:10.1001/jama.2020.14205



Palliative Care – When is it time?

- Palliative care is about **addressing the patient’s symptoms and psychosocial burden**—it is not prognosis-based.
- It is almost never “too soon” to introduce palliative care, AND physician prognosis is unreliable, and often overly optimistic—especially when there is a longstanding physician-patient relationship

Smith A. Communication of Prognosis in Palliative Care, in UpToDate
<https://www.uptodate.com/contents/communication-of-prognosis-in-palliative-care>, accessed 12/28/22



Enhancing Patient Communication

- Discuss the patient’s agenda first
- Attend to the patient’s emotional state. Check their understanding of what you are telling them. Watch for “shutdown”
- Present choices for treatment and express empathy
- Speak with the patient about what CAN be done prior to sharing why something cannot be done
- Outline long term goals first and available treatments options second
- Give patients your undivided attention, even if only briefly



Questions to Ask Your Patients

- What do you understand about your illness/diagnosis and its implications for the future?
- What frightens you?
- What are you worried about?
- What does your future look like (i.e. priorities, goals, challenges, etc.)?
- What do you think will happen now?
- How can I help you talk with your family?

What Is Hospice Care?

- Palliative care for patients who appear to have a life expectancy of 6 months or less
- It is covered under Medicare Part A. Many commercial insurance plans and NYS Medicaid also provide hospice benefits
- Provided by hospice care agencies, in coordination with the patient's primary physician

When to Consider Hospice Care

“Would you be surprised if your patient died some time within the next six months?”

Ira Byock, M.D.
Professor of Medicine and Community & Family Medicine
Geisel School of Medicine at Dartmouth, Hanover, NH
Founder/Chief Medical Officer
Institute for Human Caring of Providence Health and Services
Torrance, CA



Addressing Serious News

- Make sure you have privacy
- Minimize distractions and interruptions
- Check the patient’s understanding before you start
- Ask for permission before sharing new information
- Use empathy
- Check the patient’s understanding again, before you finish



Talking About Prognosis

- Acknowledge the uncertainty
- Use ranges of time
 - Months to a few years
 - Weeks to a few months
 - Days to a few weeks
 - Hours to a few days
- Use empathy
- Consider using, “I wish...” rather than, “I’m sorry...”

End-of-Life Care

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New York Chapter American College of Physicians

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Care of Actively Dying Patients

- Stop any IV fluids
 - Recognize that not eating or drinking is a natural part of dying process
 - Recognize that giving IVF while someone is actively dying usually causes burden without benefit (increased strain on heart and kidneys while causing dyspnea, pleural effusions, and edema)
- Dyspnea management
 - Turn on a fan or open the window
 - Flow of air eases breathing
 - Avoid NIPPV as it does not resolve underlying issue and can be very uncomfortable
- Limit vital sign checking
 - Only monitor HR and RR as markers of distress (goal HR<100, RR<24)
 - Checking BP is uncomfortable

Refocus Care

- As patients near end-of-life, stop medical treatments that:
 - Will not improve quality of life
 - Cause pain
 - Are expensive for the patient
 - Cause burdens or side effects that outweigh the benefits
- Eliminate unnecessary medications/treatments that may no longer be beneficial:
 - Cholesterol medications, dementia medications, vitamins, protein supplements, minerals, DVT prophylaxis, compression devices, antibiotics, anti-diabetic meds

Medications for Dying Patients at EOL

- Morphine IV or SL or SQ
 - Initial dose for opioid naive patient
 - Oral morphine (2.5-5 mg)
 - Parenteral (IV/SQ) morphine (1-2 mg)
 - When dyspnea is acute and severe, parenteral is the route of choice:
 - 2-5 mg IV every 5-10 minutes until relief
 - A continuous opioid infusion, with a PRN dose will provide the timeliest relief in the inpatient setting
- Lorazepam (Ativan®) IV or SL
 - Anxiolytics can reduce anxiety component of dyspnea
 - Starting dose usually 0.5mg IV q8h PRN
 - Oral liquid dose is 2mg/ml, so give 0.5mg (0.25ml) SL q6h prn

Non-pharmacological Interventions

- Offer social work or pastoral services
 - Usually appropriate at end of life and other potentially difficult times of illness
- Update caregivers/family
 - Provide realistic expectations and emotional support
 - Explain that not eating/drinking is a natural part of the dying process and it is not uncomfortable for the patient or a “starvation” state
- Encourage families on how to express their love and concern
 - Hand holding, music therapy, massage, reading

Advance Directives – Planning

- Complete a Health Care Proxy form
- Living Will – outline expectations for end-of-life care
- Organ Donation
- Power of Attorney – financial and other non-health care decisions
- MOLST – Medical Orders for Life Sustaining Treatment
- Non-Hospital DNR
- Planning tools like PREPARE for your care can help (prepareforyourcare.org)

Why Are Advance Directives Important?

- People are living longer with chronic illnesses
- Health care technology can prolong survival but often comes with trade-offs
- This results in more complex decisions to be made about medical interventions and procedures
- Decisions are more stressful in times of crises
- Advanced planning allows patients to express their goals and values, so they can be honored even when patients can't speak for themselves

When to Address Advance Directives?

- Initial or annual outpatient visit
- Prior to hospitalization for elective surgery or procedure
- Any acute hospitalization
- Return visit after a recent hospitalization
- Follow up office visit, especially if chronic illness
- Diagnosis of serious or life threatening illness

*Basically – consider the discussion
at any clinical interaction*

Medicare Pays for Advance Care Planning

CPT Code 99497

- Advance care planning including explanation and discussion of advance directives by physician or other qualified health care professional
- First 30 minutes, face-to-face with patient, family member(s), and/or surrogate

Appropriate documentation:

- An account of discussion with regarding the voluntary nature of the encounter
- Documentation indicating the explanation of advance directives (along with completion of those forms, when performed)
- Who was present
- Time spent in face-to-face encounter

CPT Code 99498

- Each additional 30 minutes
List separately, in addition to code 99497

Does the beneficiary/practice have to complete an advance directive to bill the service?

- No, the CPT code descriptors indicate "when performed," so completion of an advance directive is not a requirement for billing the service

Advance Directives for Adults

Health Care Proxy (HCP)

- Legal document that appoints a Health Care Agent to make decisions in the event patient is unable to do so due to illness or injury

Living Will

- In case of a terminal or irreversible condition, provides guidance about medical procedures that a patient might or might not want when they are unable to say
- In NYS, not a binding legal document. It can help establish clear and convincing evidence of patient's preferences

Health Care Proxy

(1) I, _____ hereby appoint _____ (name, home address and telephone number)

as my health care agent to make any and all health care decisions for me, except to the extent that I state otherwise. This proxy shall take effect only when and if I become unable to make my own health care decisions.

(2) **Optional: Alternate Agent**
If the person I appoint is unable, unwilling or unavailable to act as my health care agent, I hereby appoint _____ (name, home address and telephone number)

as my health care agent to make any and all health care decisions for me, except to the extent that I state otherwise.

(3) Unless I revoke it or state an expiration date or circumstances under which it will expire, this proxy shall remain in effect indefinitely. (Optional: If you want this proxy to expire, state the date or conditions here.) This proxy shall expire (specify date or conditions): _____



Actionable Medical Orders: MOLST

Medical Orders for Life-Sustaining Treatment

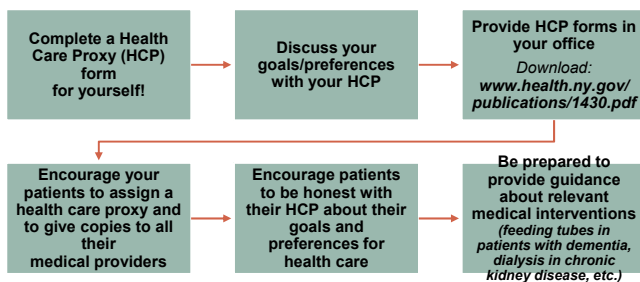
Documents a patient's treatment preferences concerning life-sustaining treatment

- Only authorized NYS form for documenting both non-hospital DNR and DNI orders
- Provides specific medical orders (feeding tube, IVF, antibiotics, DNH)
- Clinician would NOT be surprised if the patient died in the next year
- Patient has one or more advanced chronic conditions or a serious new illness with a poor prognosis

<https://www.health.ny.gov/forms/doh-5003.pdf>



Health Care Proxy Steps



Resources

Stephanie Jones, MD, FACP
Member, Pain Course Task Force
New York Chapter American College of Physicians



Resources – State and Federal Laws

- **NYS Internet System for Tracking Over-Prescribing (I-STOP) E Prescribing Updates:**
<http://www.nvacp.org/i4a/pages/index.cfm?pageid=3700>
- **NYS Prescription Monitoring Program**
https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/
- **NYS E-Prescribing**
https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/
<http://www.nvacp.org/i4a/pages/index.cfm?pageid=3700>
- **NYS Prescription Monitoring Program and E-Prescribing Help-Desk**
1-866-811-7957
- **Federal Prescribing Requirements**
<https://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm>



Resources – Palliative Medicine

- **Palliative Care Information Act**
https://www.health.ny.gov/professionals/patients/patient_rights/palliative_care/information_act.htm
 - **Palliative Care Access Act**
http://www.health.ny.gov/professionals/patients/patient_rights/palliative_care/phl_2997_d_memo.htm
 - **Appointing a Health Care Proxy in NYS**
<https://health.ny.gov/publications/1430.pdf>
 - **Who Can Palliative Care Help?**
<https://getpalliativecare.org/resources/clinicians>
- SPIKES - Buckman R. Breaking Bad News: A Guide for Health Care Professionals. Baltimore: Johns Hopkins University Press, 1992:15



Resources – Palliative Medicine

- **When Should Patients Get Palliative Care**

J Temel, et al, Early palliative care for patients with metastatic non-small-cell lung cancer, *N Engl J Med.* 2010 Aug 19;363(8):733-42
Enhancing Patient Communication

A Back, R Arnold, J Tulskey, *Mastering Communication with Seriously Ill Patients: Balancing Honesty with Empathy and Hope*, Cambridge University Press, 2009

- **Questions to Ask Your Patients**

Adapted from A Gawande, *Being Mortal: Medicine and What Matters in the End*, Metropolitan Books (Henry Holt), New York, 2014

- **How Do You Know It Is Time for Palliative Care**

Warm E. Prognostication. 3rd Edition. Fast Facts and Concepts. May 2015; 30.
Available at: <http://www.mypcnw.org>

Christakis NA, Lamont EB. Extent and Determinants of Error in Doctor's Prognoses in Terminally Ill Patients: Prospective Cohort Study. *BMJ.* 2000; 320:469-472



Resources – End of Life/Advance Care Planning

- **NYS MOLST and E-MOLST**

https://www.health.ny.gov/professionals/patients/patient_rights/molst/

<http://www.nyacp.org/i4a/pages/index.cfm?pageid=3790>

- **8 Step MOLST Protocol**

http://www.compassionandsupport.org/pdfs/homepage/MOLST_8_Step_Protocol_revised_032911_.pdf

- **Comprehensive Resources for Support at End of Life**

<http://www.compassionandsupport.org>

- **NYS Non-Hospital DNR Form**

<https://www.health.ny.gov/forms/doh-3474.pdf>



Resources – End of Life/Advance Care Planning

- **Advance Care Planning Continuum**

Bomba PA, Orem K. Lessons learned from New York's community approach to advance care planning and MOLST. *Ann Palliat Med* 2015;4(1):10-21. doi: 10.3978/j.issn.2224-5820.2015.01.05 -

<http://www.compassionandsupport.org/pdfs/research/Bomba.Orem.LessonsLearnedNY.ACP.MOLST.0115.pdf>

Bomba PA, Vermilyea D. Integrating POLST into Palliative Care Guidelines: A Paradigm Shift in Advance Care Planning in Oncology. *Journal of the National Comprehensive Cancer Network* 2006;4(8):819-829.

http://www.compassionandsupport.org/pdfs/professionals/training/Integrating_POLST_into_PC_Guidelines.pdf

Bomba PA. Medical Orders for Life-Sustaining Treatment (MOLST): A Paradigm Shift in Advance Care Planning. *NYSBA Health Law Journal* 2006;11(3):29-51.

http://www.compassionandsupport.org/pdfs/research/Bomba_article_NYSBA_Health_Law_Journal.pdf

Bomba PA. Advance Care Planning along the Continuum. *The Case Manager* 2005;16(4):68-72.

<https://www.ncbi.nlm.nih.gov/pubmed/15818349>



Resources – Other

- **The Community Principles of Pain Management (CPPM), posted on CompassionAndSupport.org, include:**

- **Pain Management – Professionals:**

http://www.compassionandsupport.org/index.php/for_professionals/pain_management

- **Opioid Use Disorder**

http://www.compassionandsupport.org/index.php/for_professionals/pain_management/addiction_misuse

- **Pain Management – Patients and Families**

http://www.compassionandsupport.org/index.php/for_patients_families/pain_management

<https://www.osc.state.ny.us/reports/continuing-crisis-drug-overdose-deaths-new-york>

www.pcssnow.org

www.asam.org

www.harmeduction.org

http://icg.utoronto.ca/tools/ace_download.shtml

www.hivguidelines.org/substance-use



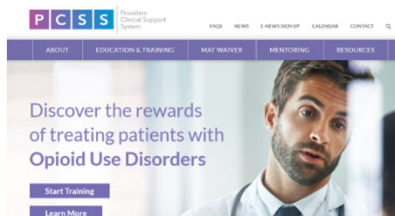
Frequently Asked Questions

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How Can I Learn More About Opioid Use Disorder?

- There are myriad resources online for learning about opioid use disorder: screening, diagnosis, treatment, etc.
- www.pcssnow.org (Providers Clinical Support System)
 - Education and Training modules:
 - SUD (Substance Use Disorder) 101
 - Chronic Pain
 - Webinars, videos, and “Success Stories”
 - Resources:
 - clinical tools
 - clinical resources
 - family/patient resources
 - mentoring opportunities

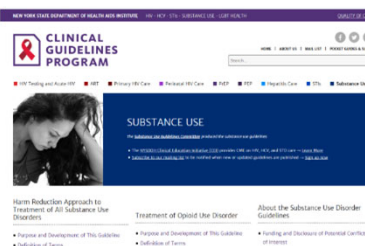


How Can I Learn More About Opioid Use Disorder?

- NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE: Clinical Guidelines Program
www.hivguidelines.org/substance-use/

- Updated SUD Guidelines**

- “Harm Reduction Approach to Treatment of All SUD”
- “Treatment of OUD”
- The Guidelines are geared towards primary care providers and other non-addiction medicine specialists interacting with patients using opioids, misusing opioids, or with OUD
- Comprehensive and can be utilized by providers while with patients
- Is extensively referenced



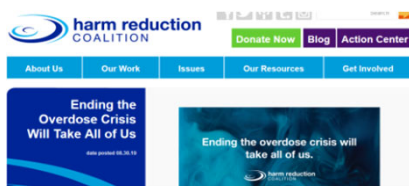
How Can I Learn More About Opioid Use Disorder?

- NEW YORK STATE OFFICE OF ADDICTION SERVICES AND SUPPORTS:
- Learning Thursdays Recorded Webinars:
- <https://oasas.ny.gov/learning-thursdays>
- Clinical Support Trainings:
- <https://oasas.ny.gov/training/clinical-support>
- Harm Reduction Office Hours:
- <https://oasas.ny.gov/harm-reduction-office-hours>



What Else Should I Understand When Treating Patients Misusing Opioids or With OUD?

- Harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with substance use
- Harm reduction is also a movement for social justice built on a belief in, and respect for, the rights of people who use substances
- As medical providers, we do harm reduction with all our patients routinely
- We need to apply the same principles to our patients who are PWUD (people who use drugs)



www.harmreduction.org

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What Else Should I Understand When Treating Patients Misusing Opioids or With OUD?

- Trauma-Informed Care
 - Individual trauma results from an event, series of events, or set of circumstances experienced as physically or emotionally harmful or life-threatening with lasting adverse effects on the individual's functioning and mental, physical, social, emotional, or spiritual well-being.
 - Health care providers need to recognize that trauma is highly prevalent, can impact a person at any time during their lifespan, and may present as mental health, substance use or physical health conditions.
 - Ensuring that the physical and emotional safety of an individual is addressed is the first important step to providing Trauma-Informed Care.
 - 5 Principles: Safety, choice, collaboration, trustworthiness, and empowerment



<https://www.thenationalcouncil.org/program/center-of-excellence/>
<https://www.thenationalcouncil.org/program/?search=trauma%20informed%20care>

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Acknowledgements

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Thank You

Thank you for participating in Managing Pain and Opioid Use: An Educational Program on Compliance with New York State Prescribing Laws. You can receive CME, CNE, and ABIM MOC Part II credit, you must take a post-test and complete an evaluation. With a passing score of 70% or greater, you'll be able to print your certificate.

