Changes To Treatment Regulations During And After The COVID-19 Public Health Emergency

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Disclosure Information

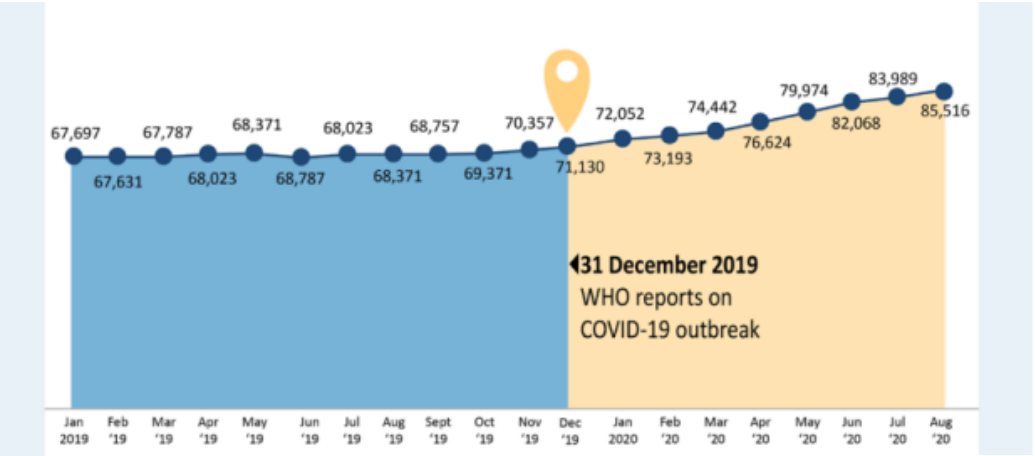
- Yngvild Olsen, MD, MPH, DFASAM has no disclosures to report
- Robert Baillieu, MD, MPH, FAAFP has no disclosures to report

Learning Objectives

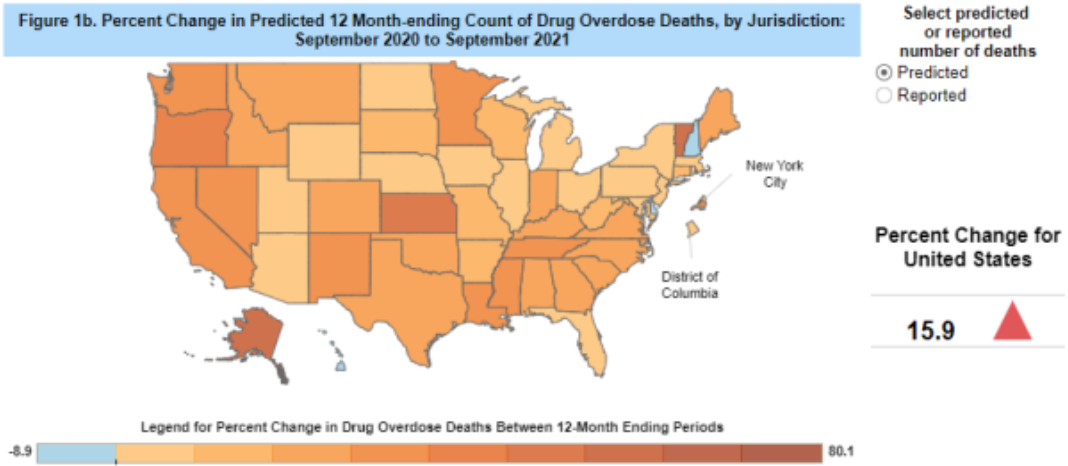
By the end of this session, participants should be able to:

- Review current trends related to substance use and substance use disorders
- Describe SAMHSA strategic priorities in the current environment
- Explain the COVID flexibilities put forth by the Substance Abuse and Mental Health Services Administration (SAMHSA)
- Examine post-COVID considerations

Overdose rates exceeding 100,000 over last 12 months



Source: Products - Vital Statistics Rapid Release - Provisional Drug Overdose Data (cdc.gov)



Most Overdose Deaths Involve One or More Illicit Drugs

	Co-involvement of other substances in drug overdose deaths involving Illicitly Manufactured Fentanyls (IMFs)	
	IMFs only*	40%
Other opioids co-involved	Rx opioids	15%
	Heroin	20%
	Any opioids other than IMFs**	30%
Other stimulants co-involved	Methamphetamine	20%
	Cocaine	28%
	Any stimulant***	42%
	Benzodiazepines	15%
	Gabapentin	5%
	Xylazine	5%

The 10 most frequently occurring opioid and stimulant combinations accounted for over 77% of overdose deaths

Fewer than 3% of deaths involved buprenorphine, and fewer than 4% of deaths involved methadone, across jurisdictions.

SOURCE: State Unintentional Drug Overdose Reporting System (SUDORS), 40 jurisdictions, 2020

*Includes fentanyl and fentanyl analogs, **Includes heroin, prescription opioids, and other illicit synthetic opioids, *** Includes cocaine, amphetamines, cathinones, and other central nervous system stimulants (e.g., atomoxetine, caffeine).

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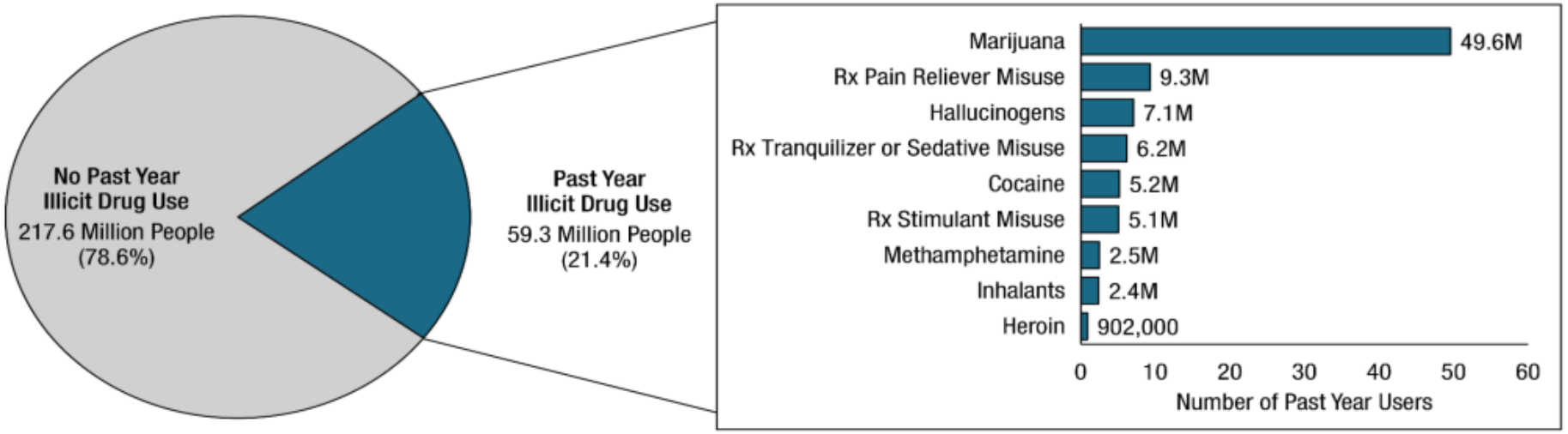
Substance Misuse In 2020



Rx = prescription.
Note: The estimated numbers of past year users of different illicit drugs are not mutually exclusive because people could have used more than one type of illicit drug in the past year.

Source: Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health

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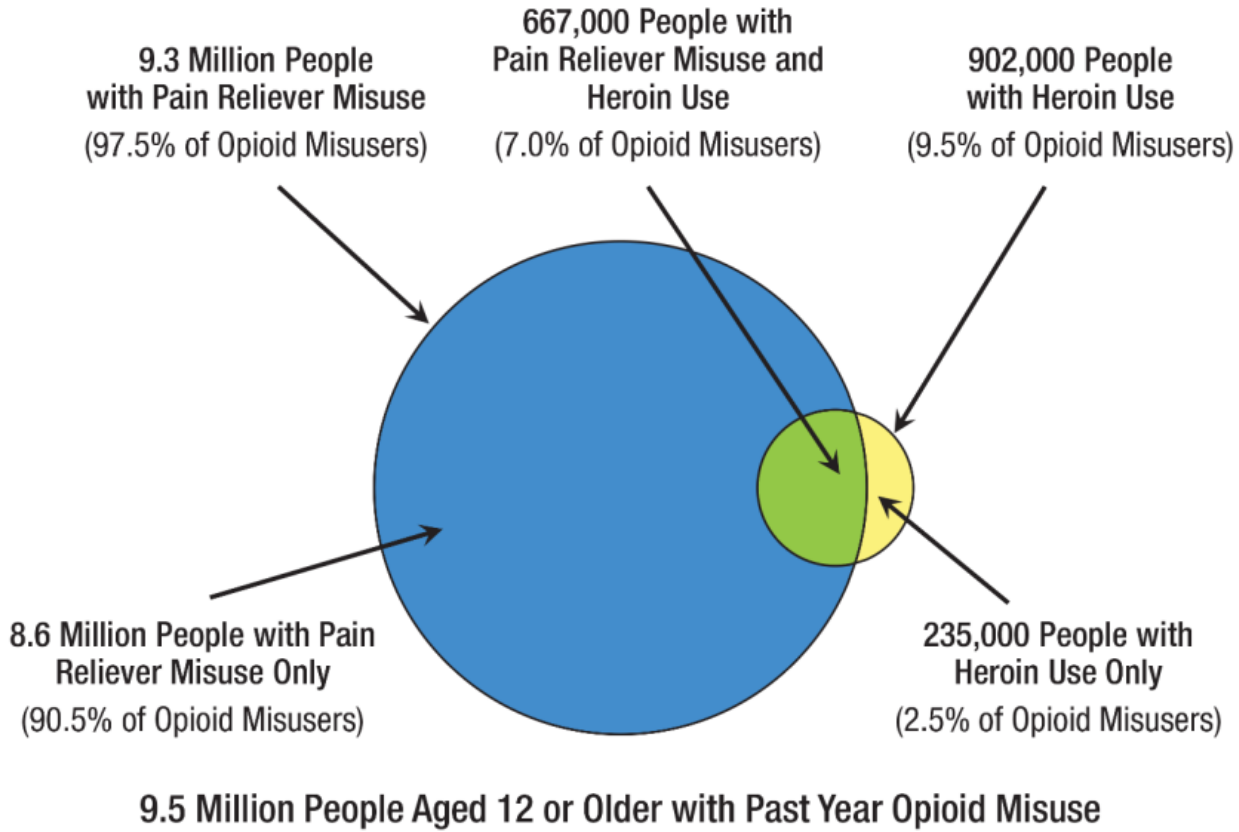
Past Year Opioid Misuse Among Those 12 and Older, 2020



Source: Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health

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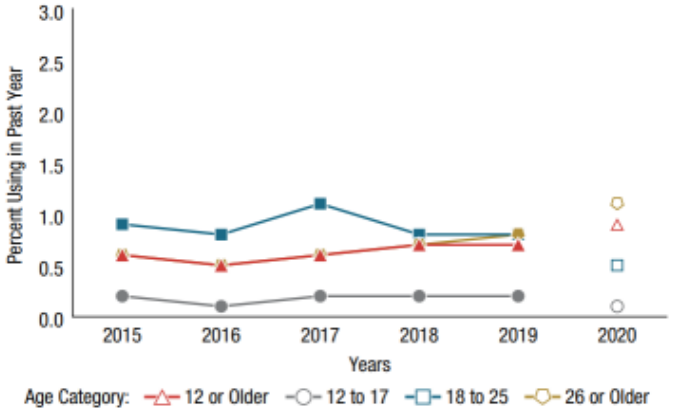
Stimulant Misuse

- In 2020, 5.2 million people in the United States aged 12 or older used cocaine
- Methamphetamine use is increasing, with 2.5 million people aged 12 or older using the substance in the past year - an increase of 600,000 people since 2018
- In 2018, the amount of cocaine and methamphetamines seized in parts of US exceeded that of opioids

Past Year Methamphetamine Use: Among People Aged 12 or Older; 2015-2020



Note: There is no connecting line between 2019 and 2020 to indicate caution should be used when comparing estimates between 2020 and prior years because of methodological changes for 2020. Due to these changes, significance testing between 2020 and prior years was not performed.

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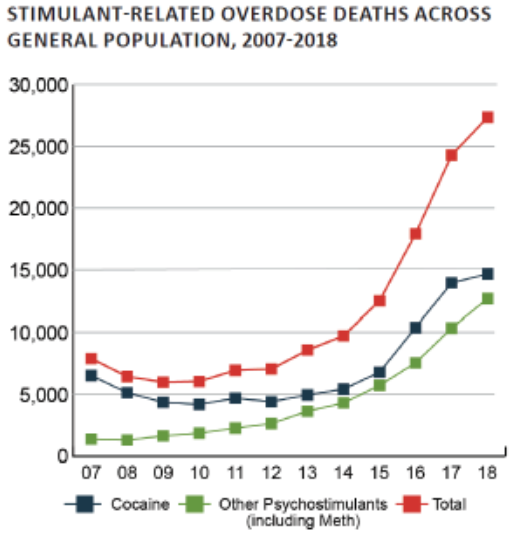
Stimulant Misuse

While the trend in overall stimulant use is concerning, increases in related overdose deaths may be even greater cause for alarm.



*Source: CDC WONDER; NCHS, National Vital Statistics System, Mortality

Cocaine misuse is highest among adults aged 18 to 25, while methamphetamine misuse is highest among those aged 26 to 49.

In recent years, more than 50 percent of all stimulant-related overdose deaths have also involved opioids.

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Polysubstance Misuse

- Individuals report an average use of 3.5 substances, including both simultaneous and sequential polydrug use.[1]

Among individuals with…	Percentage of individuals who also have…				
	Alcohol use disorder	Marijuana use disorder	Cocaine use disorder	Prescription opioid use disorder	Heroin use disorder
Alcohol use disorder	-	9.5	3.3	3.9	0.9
Marijuana use disorder	38.7	-	4.8	7.9	1.3
Cocaine use disorder	59.8	21.3	-	16.4	13.4
Prescription opioid use disorder	35.2	17.6	8.2	-	11.2
Heroin use disorder	24.5	12.3	20.9	34.9	-

Source: National Institute on Drug Abuse. (2020, April). *Common comorbidities with substance use disorders research report: What are some approaches to diagnosis?* National Institutes of Health. https://www.drugabuse.gov/publications/research-reports/common-comorbidities-substance-use-disorders/what-are-some-approaches-to-diagnosis

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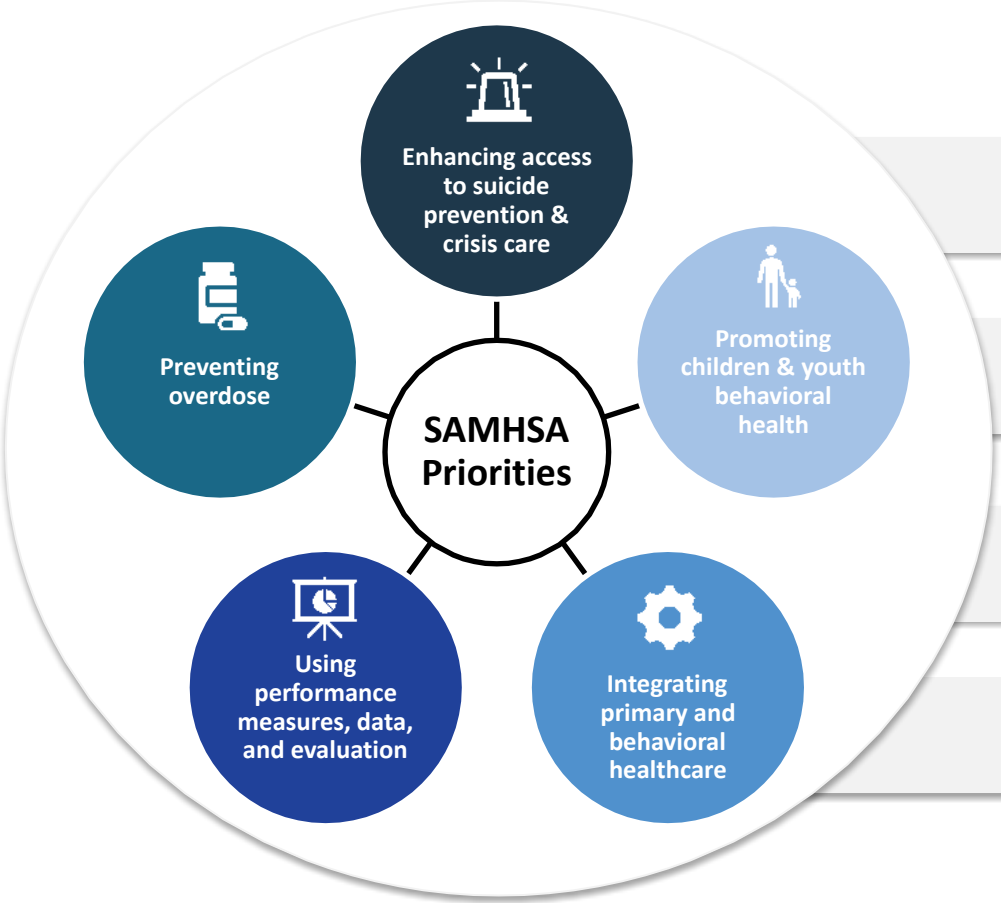
The Future Is Seen In The Present

- The COVID public health emergency called for rapid change
- Innovative treatment and intervention modalities rapidly rolled out
- Stress, isolation and limited access to resources associated with a rise in SUDs and mental health symptoms
- Situation demonstrated importance of integrating behavioral health care into emergency and primary care services
- Discussions using metrics and statistics became more commonplace

SAMHSA Priorities and Cross-Cutting Principles



Cross-cutting principles

- Equity
- Workforce
- Financing
- Recovery

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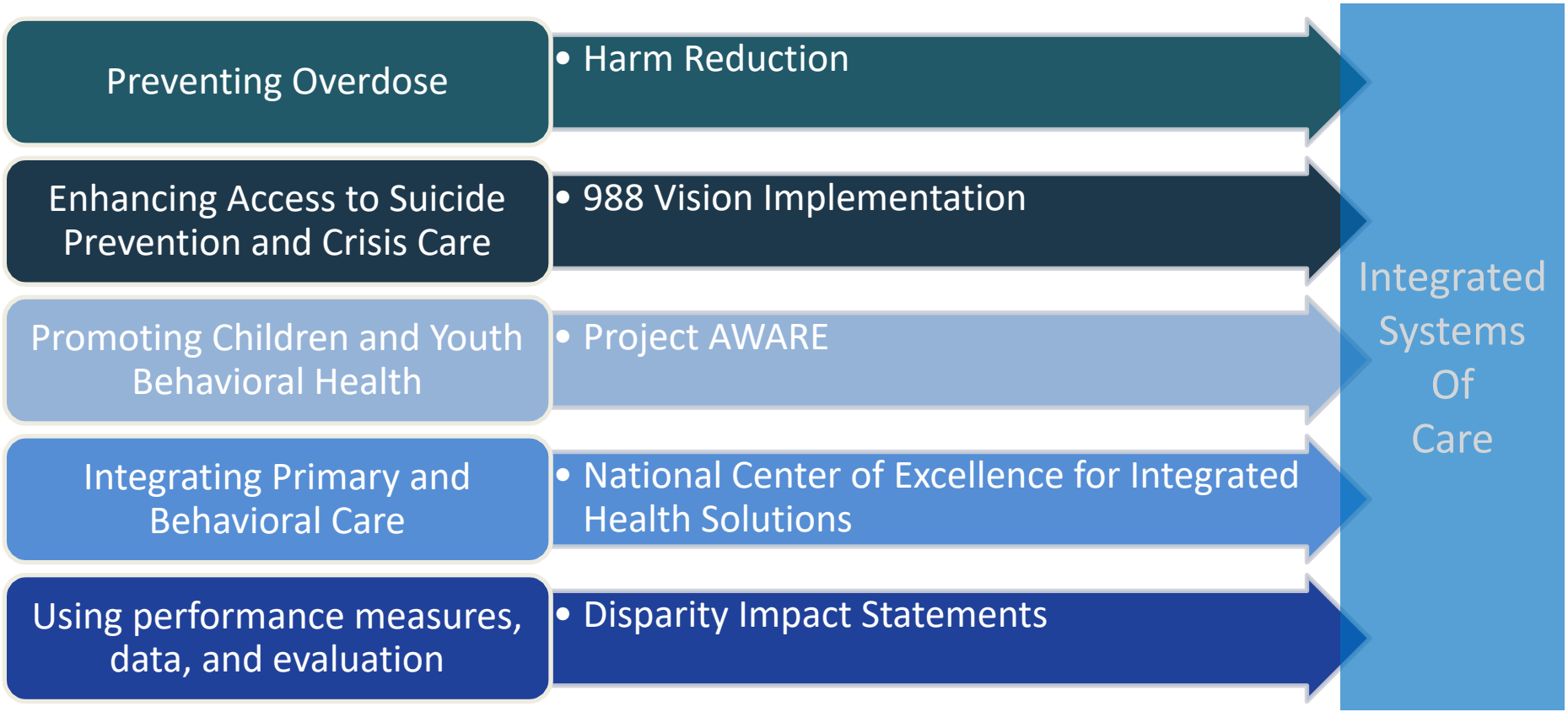
SAMHSA Priorities in Action



HHS Overdose Prevention Strategy

Increasing Access to MOUD Through Patient Centered Approaches

1. Flexibility in the provision of methadone:

    - Stable patients may receive up to 28 days of medication and less stable patients may receive up to 14 days of medication

    - 45 states have utilized this flexibility since early 2020

2. Flexibilities for the provision of buprenorphine in OTPs:

    - An OTP may treat new and existing patients with buprenorphine via telehealth (including audio-only)

3. Flexibilities for office based buprenorphine prescribers:

    - May start new patients on buprenorphine via telehealth (including audio-only).

SAMHSA's Telehealth Policies Enacted During the Pandemic

- Secretary of HHS, with the concurrence of the Acting DEA Administrator, designated a telemedicine exception that applied to all schedule II-V controlled substances

- The DEA also granted a "temporary exception" to its regulations that allows practitioners to prescribe controlled substances in states in which they are not registered

- Telemedicine is also used by (and therefore overseen, in part, by SAMHSA):
  - DATA-Waivered providers to prescribe buprenorphine
  - Counselors, social workers and support staff to provide treatment activities
  - Providers to link clients into care

Patient Level Implications

- Patients reporting high levels of satisfaction

- No significant differences between starting buprenorphine between telehealth and in-person on:
  - Rate of continued substance use
  - Retention in treatment
  - Engagement in services
  - The therapeutic alliance

- No significant reports of diversion, overdose or harm

Provider Level Implications

- Telehealth allows providers to meet patients where they are
- Virtual platforms allows providers to better access underserved areas, while also promoting flexible work schedules
- Methadone take home flexibilities allow for more patient-centered care

System Level Implications

- Innovative treatment and intervention modalities were rapidly bought to scale
- Previously held beliefs have been dispelled
- Telehealth has allowed treatment teams to remain in close contact with vulnerable patients
- Rapid evaluation has demonstrated effectiveness and safety
- Flexibilities likely here to stay in some form -- requires regulatory reform that will outlast the possible end of the Public Health Emergency
- Temporary extensions must be implemented while rule making occurs
    - An extension of the methadone take home flexibilities, for one year after the COVID-19 PHE ends, was issued on November 18, 2021

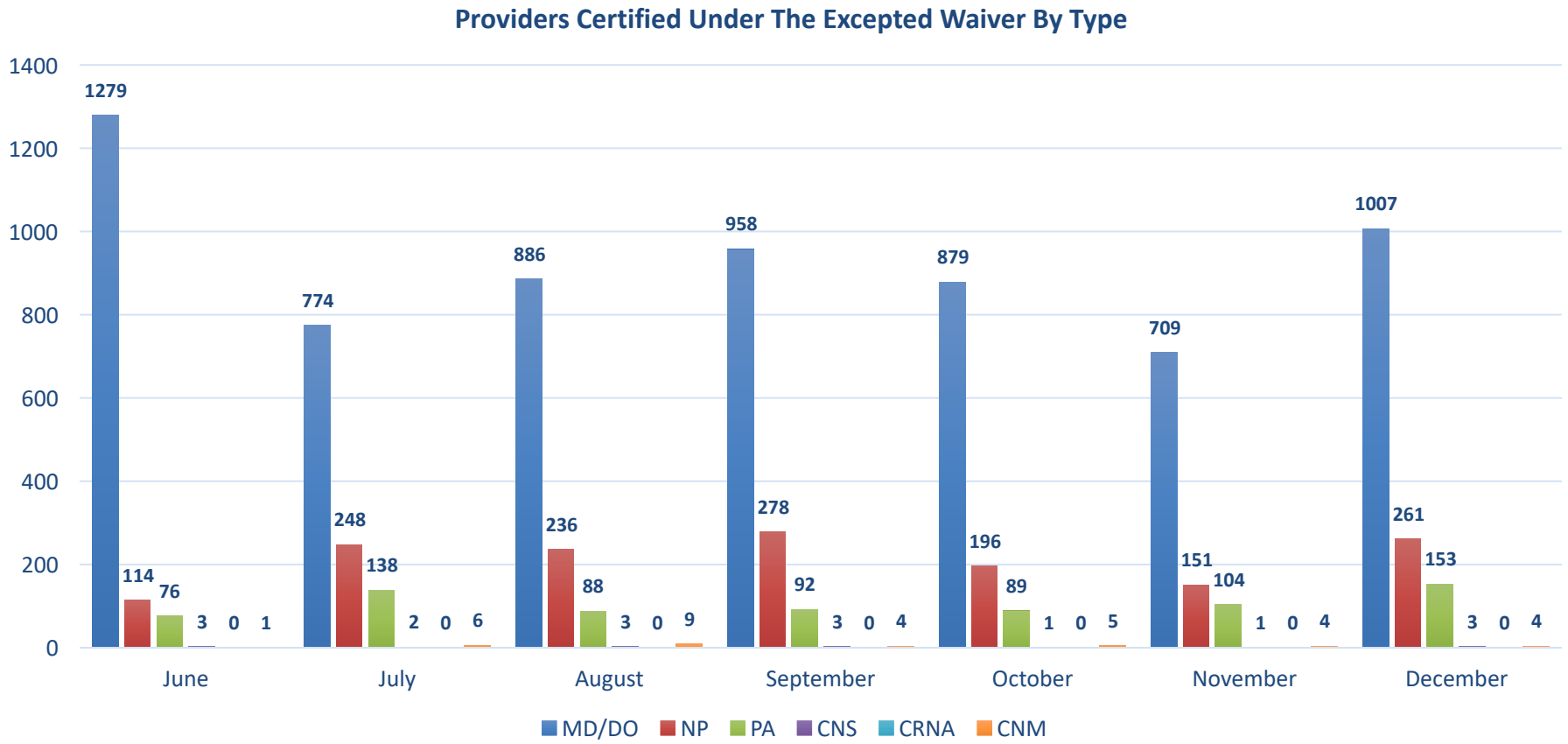
Other Initiatives To Expand Access

- On July 28, 2021, the DEA authorized OTPs to add a “mobile component” to their existing registration, eliminating a separate registration requirement for mobile medication units of OTPs

- 42 C.F.R. § 8.11(i) provides that OTPs certified by SAMHSA may establish medication units (as defined under 42 C.F.R. § 8.2) that are authorized to dispense opioid agonist treatment medications.

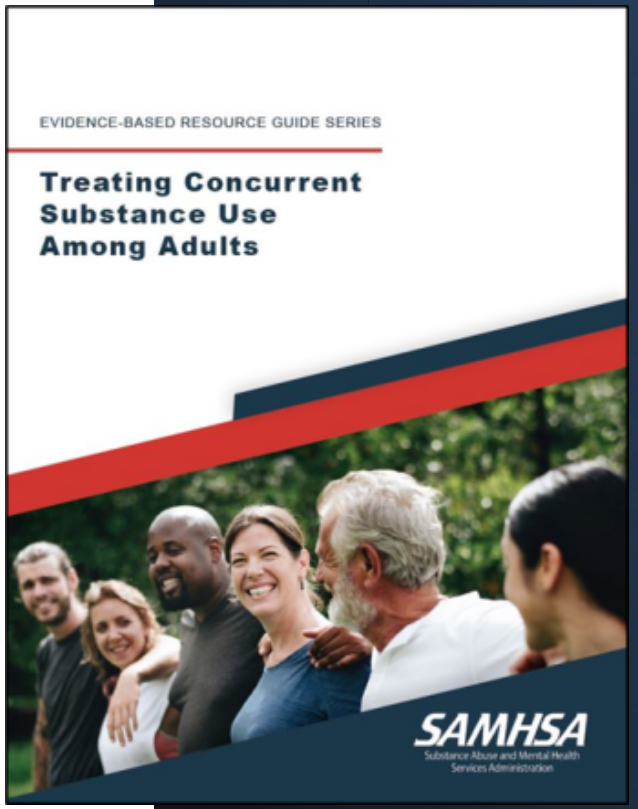
- SAMHSA publicized this in a letter on September 21, 2021

Reducing Barriers to Access- Buprenorphine Practice Guidelines



Polysubstance Misuse – Treatment Strategies

- The Evidence-Based Practice Guide on “Treating Concurrent Substance Use Disorders”
  - Evidence on treating polysubstance misuse is fragmented and evolving
  - Best practices include:
    - Co-location of treatment activities and treating providers
    - Use of FDA-approved pharmacotherapy and counseling
    - Use of contingency management together with FDA approved medications and counseling
    - Twelve step facilitation together with FDA approved pharmacotherapy and counseling



Harm Reduction Initiatives

- New initiatives:
  - SAMHSA grant funds can be used to purchase Fentanyl Test Strips
  - Overdose reversal drugs can be purchased with SAMHSA funds
  - SAMHSA grants that address education and resources for groups like EMS helping to prevent death from overdose
  - American Rescue Plan Act Funding of $30M to SAMHSA for Harm Reduction grants
  - SAMHSA working with CDC on Harm Reduction Technical Assistance Center

Education and Funding To Promote a Robust Workforce

- Stigma and treatment hesitancy overcome through education
  - All medical schools, professional schools and residency programs should have a comprehensive and longitudinal curriculum on substance use and substance use disorders

- Education at the community level brings individuals into treatment and helps to reduce stigma

- Supporting a peer specialists workforce helps close the workforce shortage gap

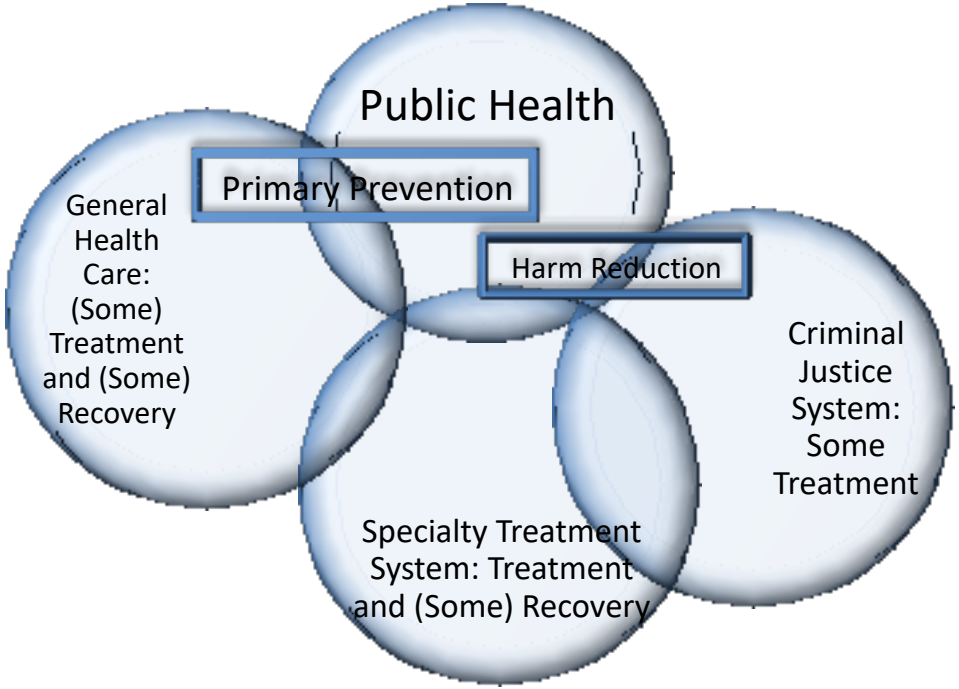
- Funding resources that promulgate evidence-based practice promotes equity and quality care

GPRA Data Collection Tool Changes

- Revision of CSAT GPRA data collection tool is underway
  - Easier to administer
  - Not all substance use is associated with a substance use disorder
  - Attention paid to who is administering the tool
  - Aiming for more trauma informed and inclusive approach

- SAMHSA continuing to reimagine data collection and data that is meaningful and supportive of different treatment modalities such as low threshold treatment

Our Nemesis: Disorganized Systems



In the community: people living with SUD at different stages of recovery and their families with many trying to navigate their way through barely coordinated systems.

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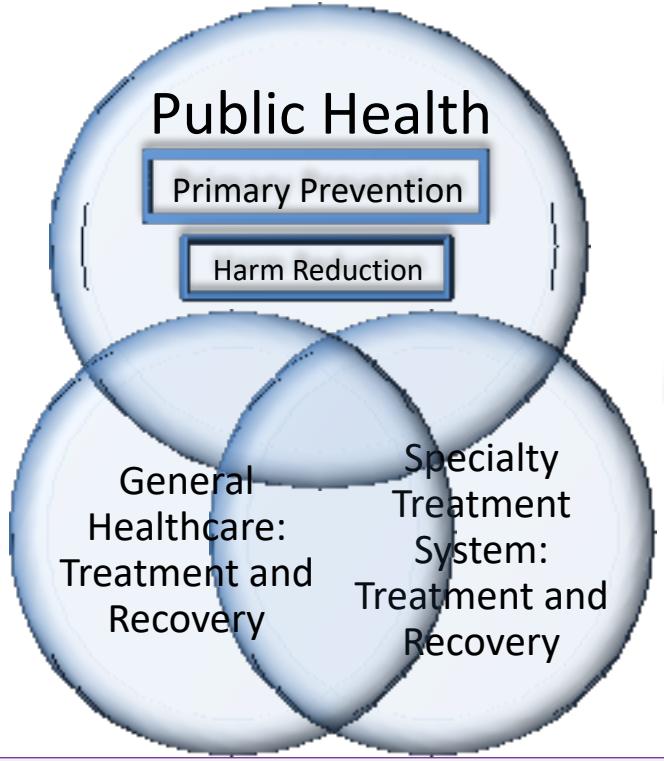
Wouldn't It Be Better If…..?



CSAT's Work: Expand access to and quality of effective care in a coordinated, integrated system that includes general healthcare and specialty treatment settings (and for now the criminal justice system) to save and improve the lives of people with substance use disorders and related conditions, recognizing the contributions of their families and communities.

In the community: With family, people living with SUDs at different stages of recovery, no wrong door when needed, and (they get to fill in the blank).

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Framework for a coordinated, integrated SUD health care system

- Continuous care model
- Built on values of equity, dignity, respect, and non-discrimination
- Grounded in the science of substance use disorders as health conditions, a health professional workforce that embraces that, and partners that support it

All Federal Agencies Work To Close Gaps In Care

- SAMHSA closes gaps in care through provision of:
  - Funds to support treatment, the workforce and effective public health interventions
  - Promulgating evidence-based practice
  - Promoting policies to expand access to care

- The Centers for Medicare and Medicaid support medically necessary services

- The National Institutes of Health/NIDA/NIAAA engages in research

- The Centers for Disease Control provides public health surveillance, data, and information sharing

- Administration for Community Living protect the interests of different populations and groups

Bringing The Threads Together

- Evidence driven decision making that supports patients, providers and communities
- Understanding how funding impacts patients, and moving high-value services to scale
- Readily available and high-quality education for those wishing to pursue careers in addiction-related services
- Treatment services available across different sites, and using different modalities
- Promote on-going research for continuum of harm reduction, treatment, and recovery support services

Imagining The Future Together: Questions for Discussion

- Considering the methadone take home flexibility and buprenorphine telehealth flexibility, what has worked well, and what might work better?
- What is needed from SAMHSA to facilitate integrated systems of care and improve patient outcomes?
- How can SAMHSA reimagine GPRA so that it is less burdensome, while also providing information on program activities and patient outcomes?

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