

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

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**SAMHSA**  
Substance Abuse and Mental Health  
Services Administration

# Disclosure Information

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

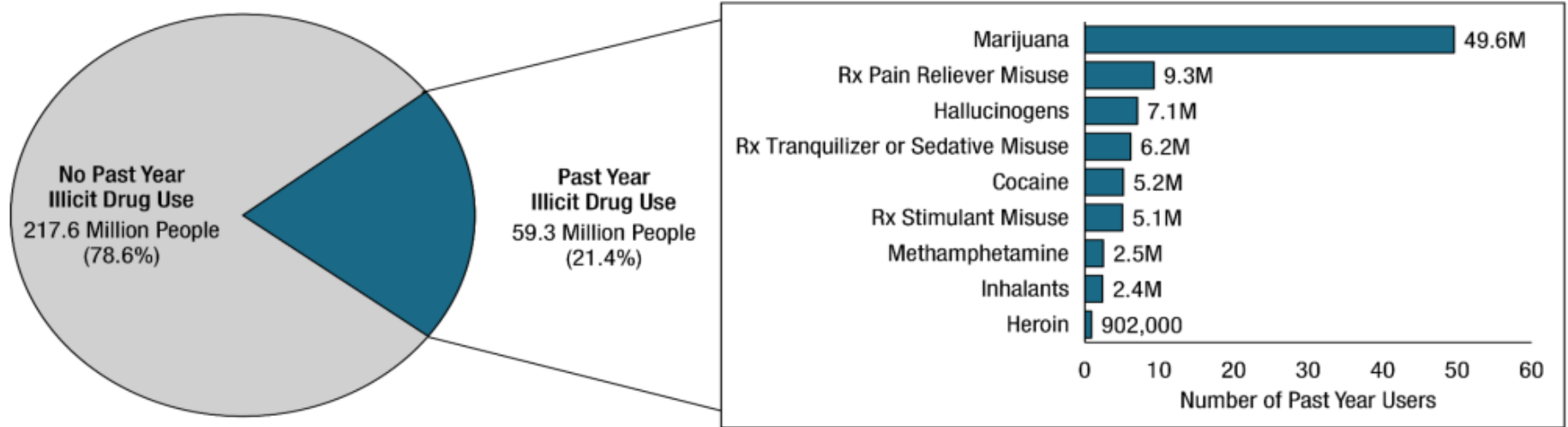
# Outline

- The current system is fragmented and does not promote integrated care
- The impact of COVID-19 on the provision of treatment
- COVID flexibilities put forth by the Substance Abuse and Mental Health Services Administration (SAMHSA), as well as program highlights
- Post-COVID considerations
- Questions

# The US Health System: Disjointed and Not Patient-Centered

- The U.S. health care system is not universally accessible:
  - It is a publicly and privately-funded patchwork of fragmented systems and programs
    - Insured Americans are covered by both public and private health insurance, with a majority covered by private insurance plans through their employers
    - Government-funded programs, such as Medicaid and Medicare, provide health care coverage to some vulnerable population groups
    - The government also publicly funds coverage through Indian Health Services and the military
- Health insurance typically covers substance abuse rehabilitation and various forms of mental health treatment.
  - The extent to which insurance will cover drug or alcohol rehab depends upon a variety of factors, including the policy's benefits, the treatment provider, and treatment need.

# Substance Misuse In 2020

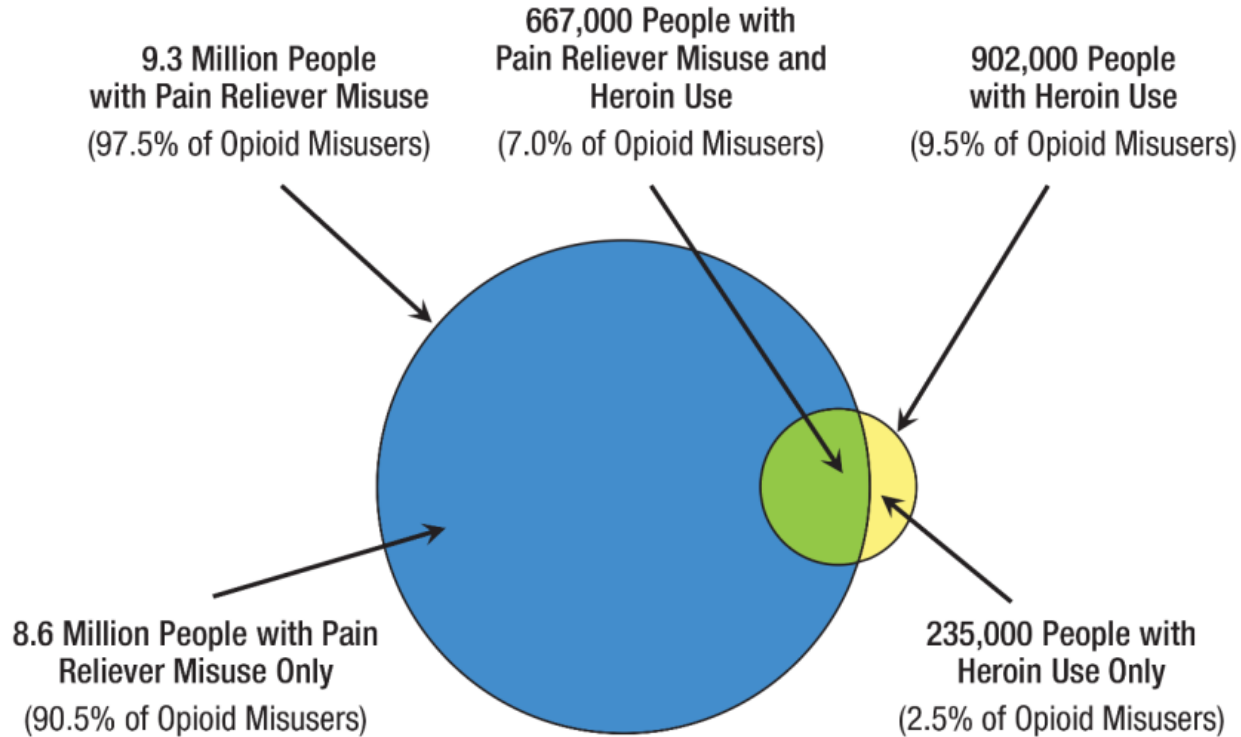


Rx = prescription.

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

# Past Year Opioid Misuse Among Those 12 and Older, 2020

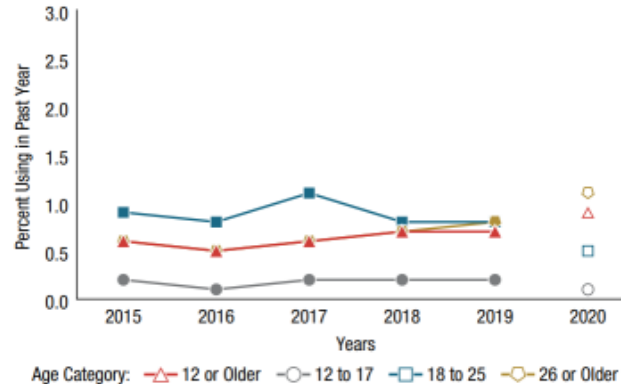


**9.5 Million People Aged 12 or Older with Past Year Opioid Misuse**

# Stimulant Misuse

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

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

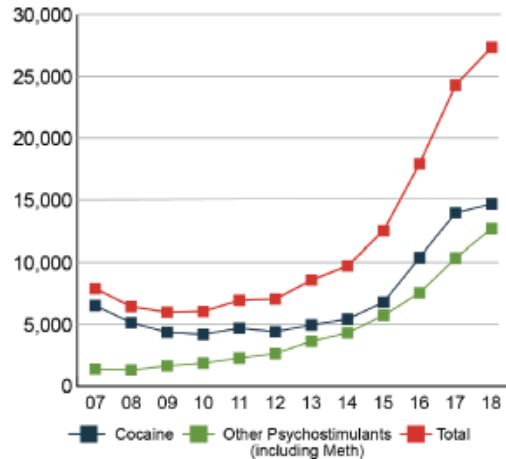


Note: There is no connecting line between 2019 and 2020 to indicate caution should be used when comparing estimates between 2020 and prior years because of methodological changes for 2020. Due to these changes, significance testing between 2020 and prior years was not performed.

# Stimulant Misuse

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

STIMULANT-RELATED OVERDOSE DEATHS ACROSS GENERAL POPULATION, 2007-2018



\*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.



# Polysubstance Misuse

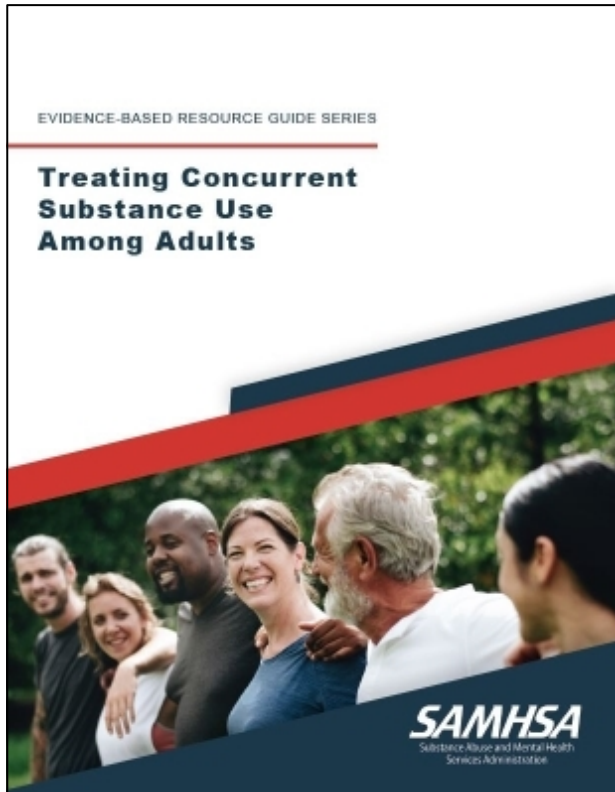
- Although drug addiction and its impacts are often centered around individual drugs, drug misuse is largely found to involve multiple substances
- Drug-dependent individuals report an average use of 3.5 substances, including both simultaneous and sequential polydrug use.<sup>1</sup>

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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# Polysubstance Misuse



- Prevalence rates
- Pregnant individuals
- Protective and risk factors
- Impacts

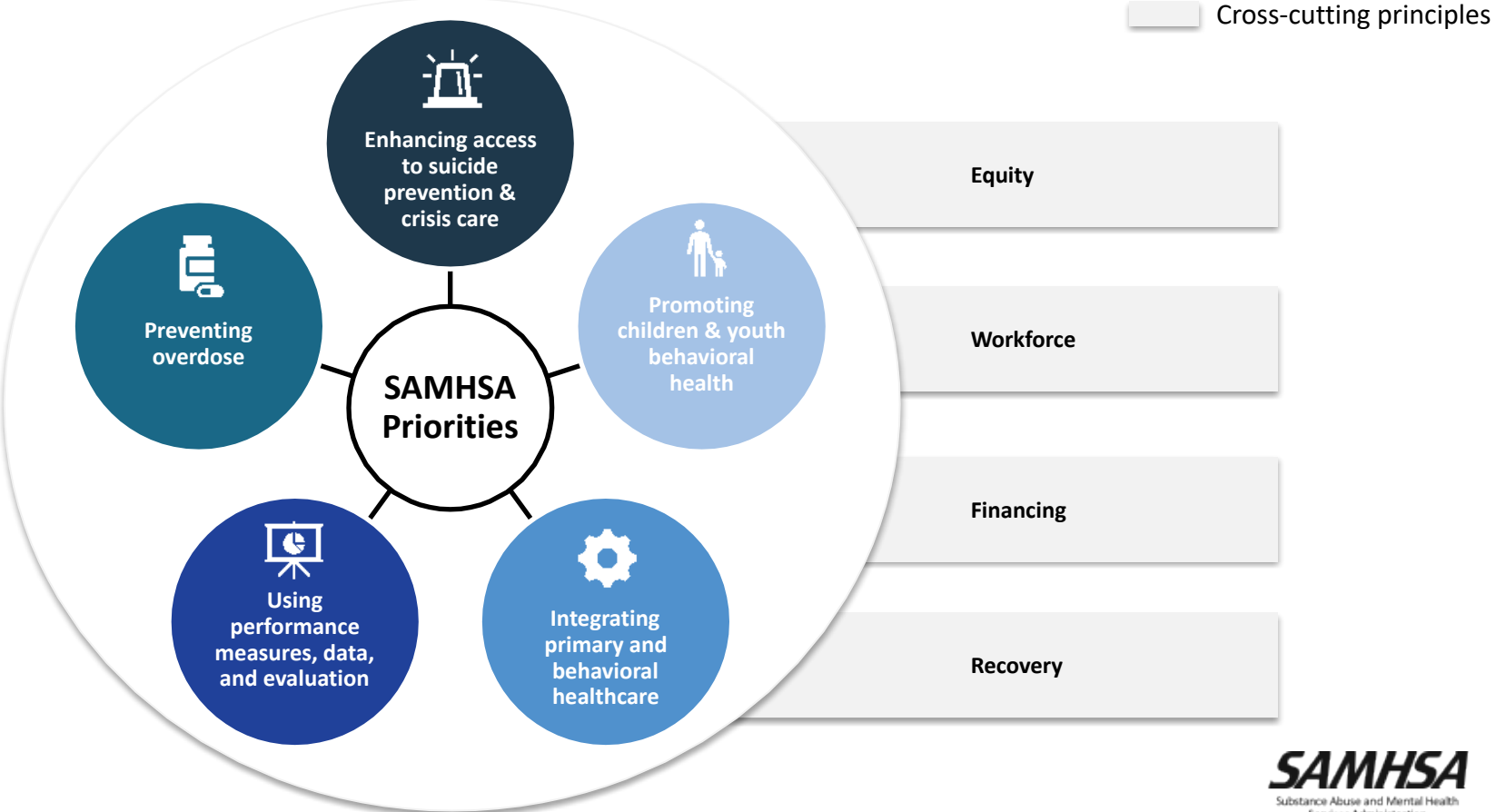
# Polysubstance Misuse – Treatment Strategies

- SAMHSA recently reviewed evidence underlying treatment for polysubstance misuse
  - The Evidence-Based Practice Guide on ‘Treating Concurrent Substance Use Disorders’ provides insight into treatment strategies
- Evidence on treating polysubstance misuse is fragmented and evolving
- Best practices include:
  - Co-location of treatment activities and treating providers
  - The use of FDA-approved pharmacotherapy and counseling
  - The use of contingency management together with FDA approved medications and counseling
  - Twelve step facilitation together with FDA approved pharmacotherapy and counseling

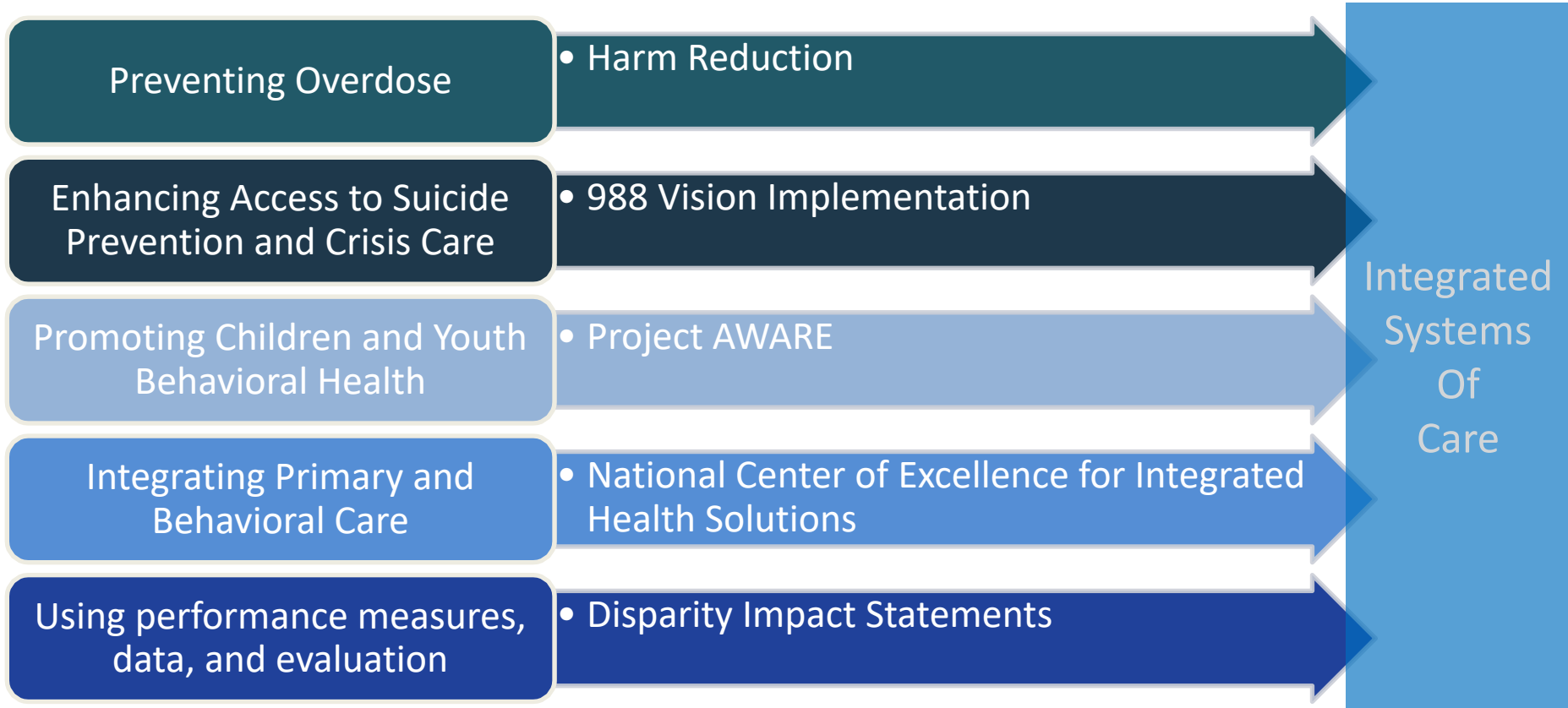
# Federal Agencies Close Gaps In Care

- Federal agencies such as SAMHSA close gaps in care through provision of:
  - Funds to support treatment, the workforce and interventions
  - Promulgating evidence-based practice
  - Promoting policies to expand access to care
- Agencies such as The National Institutes of Health engage in research
- The Centers for Disease Control promotes evidence-based practice and information sharing
- Agencies such as the Administration for Community Living protect the interests of different populations and groups

# SAMHSA Priorities and Cross-Cutting Principles



# SAMHSA Priorities in Action



# HHS Overdose Prevention Strategy



HHS.gov

# The Future Is Seen In The Present

- The COVID public health emergency called for rapid change that has benefitted patients, providers and systems of care
- Innovative treatment and intervention modalities were rapidly rolled out
- The stress, isolation and limited access to resources that the public health emergency imposed on so many, saw a rise in SUDs and behavioral health illnesses
- The public health emergency demonstrated the importance of integrating mental health care into emergency and primary care services
- The general public unfortunately renewed their understanding of stress, fear and a lack of access
- Discussions using metrics and statistics became more commonplace



# Increasing MAT Access Through Patient Centered Approaches

The COVID public health emergency necessitated flexibility in the provision of methadone:

- Stable patients may receive up to 28 days of medications and Less stable patients may receive up to 14 days of medication
- 45 states have utilized this flexibility

Flexibilities for the provision of buprenorphine at OTPs were also instituted:

- An OTP may treat new and existing patients with buprenorphine via telehealth (including use of telephone, if needed)
- An office based buprenorphine provider may induct new patients with buprenorphine using a telehealth platform.

Impact at The Provider Level

- In the COVID era, practitioners can now make treatment decisions that are more individualized, but are potentially more complicated.
- Equity in patient care may not be assured in the same way as it was pre-COVID-19.
  - Implicit biases and previous experiences with patients, as well as patient co-morbidities, impact application of flexibilities.

Impact at The Patient Level

- Extended take-home doses of Methadone allow clients to engage in recovery, employment and activities of daily living.
- Though OTP daily attendance has benefits for patients who require a structured setting, increasing required OTP attendance can interrupt daily routines and serve as a barrier to treatment engagement.

# SAMHSA's Telehealth Policies Enacted During the Pandemic

- In April 2020, SAMHSA exempted OTPs from the requirement to perform an in-person physical evaluation for any patient who will be treated by the OTP with buprenorphine
- Prior to this, the Secretary of HHS, with the concurrence of the Acting DEA Administrator, designated that the telemedicine exception 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

# SAMHSA's Methadone Take Home Flexibility

- On March 16, 2020, SAMHSA issued an exemption to Opioid Treatment Programs (OTPs) whereby a state could request:  
  
“a blanket exception for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient’s medication for opioid use disorder.” States could also “request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.”
- An extension, for one year after the COVID-19 PHE ends, was issued on November 18, 2021
- The extension allows for SAMHSA to consider ways by which the extension might be made permanent

# Patient Level Implications

- Telehealth can be an effective tool in integrating care and extending the reach of specialty providers
- Among those requiring treatment with buprenorphine and receiving extended take home medications, there are high levels of satisfaction
- Research reveals no significant differences between telehealth and in-person buprenorphine induction in:
  - The 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 clients where they are (quite literally)
- The use of virtual platforms also allows providers to better access underserved areas, while also promoting flexible work schedules
- Methadone take home flexibilities allow for more patient-centered care and provider autonomy

# System Level Implications

- The COVID public health emergency called for rapid change that has benefitted patients, providers and systems of care
- Innovative treatment and intervention modalities were rapidly brought to scale
- Previously held beliefs, such as the need to see many methadone patients almost daily, have been dispelled during the pandemic
- Telehealth has allowed treatment teams to remain in close contact with vulnerable patients
- Rapid evaluation has demonstrated the efficacy of this modality
- It is likely here to stay, but this will require regulatory reform that will outlast the possible end of the Public Health Emergency
  - Temporary extensions must be implemented while rule making occurs
    - This allows for review of the evidence and thoughtful discussions with federal partners
    - Clients and the treatment community must be included in these discussions as changes affect them directly
    - On-going evaluation efforts are also important to monitor implementation and to consider how other new technologies might be integrated into care
    - In this way, regulators must be flexible and responsive

Considering the methadone take home flexibility and buprenorphine telehealth flexibility, what has worked well, and what might work better?

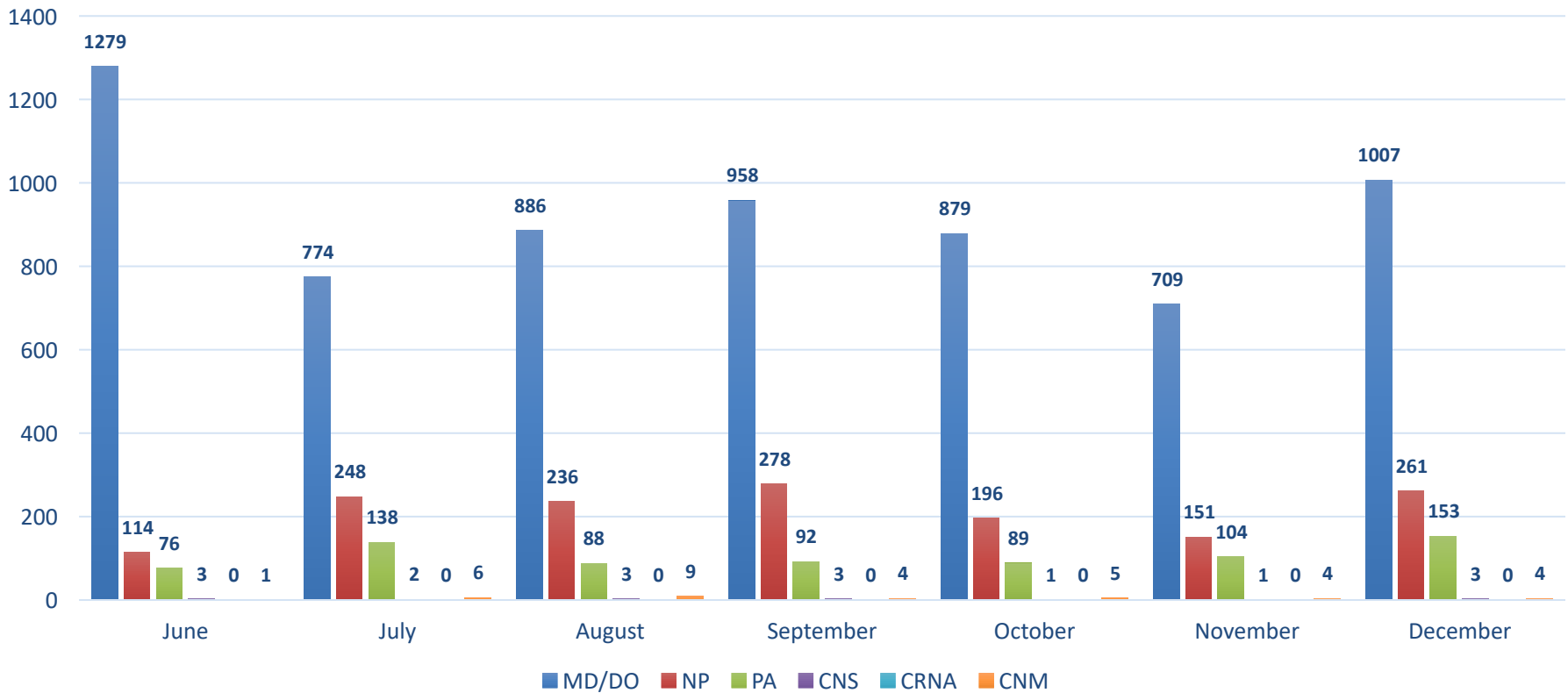
# Expanding Treatment: Medication-Assisted Treatment

- Medications for Opioid Use Disorder are most effective when delivered as part of patient-centered services that includes counseling, case management and other services that seek to improve the social determinants of health
- Grantees have shown innovation in the use of funds:
  - The Medication-Assisted Treatment - Prescription Drug and Opioid Addiction (MAT-PDOA) grant expands/enhances access to MAT services for persons with an opioid use disorder who seek or receive this treatment



# Reducing Barriers to MAT access- Buprenorphine Practice Guidelines

Providers Certified Under The Excepted Waiver By Type



# Other Initiatives To Expand Access

- On July 28, 2021, the Drug Enforcement Administration (DEA) authorized Opioid Treatment Programs to add a “mobile component” to their existing registration, eliminating a separate registration requirement for mobile medication units of OTPs
- This is an opportunity to expand access to medications for treatment of OUD, especially in remote or underserved areas
- 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

# 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
- Coming soon.....
  - American Rescue Plan Act Funding of \$30M to SAMHSA for Harm Reduction grants
    - NEW funding opportunity posted soon!
  - SAMHSA is working with CDC to collaborate on Harm Reduction Technical Assistance
  - Supplemental block grant dollars available to states can be used for Harm Reduction activities

# GPRRA Changes

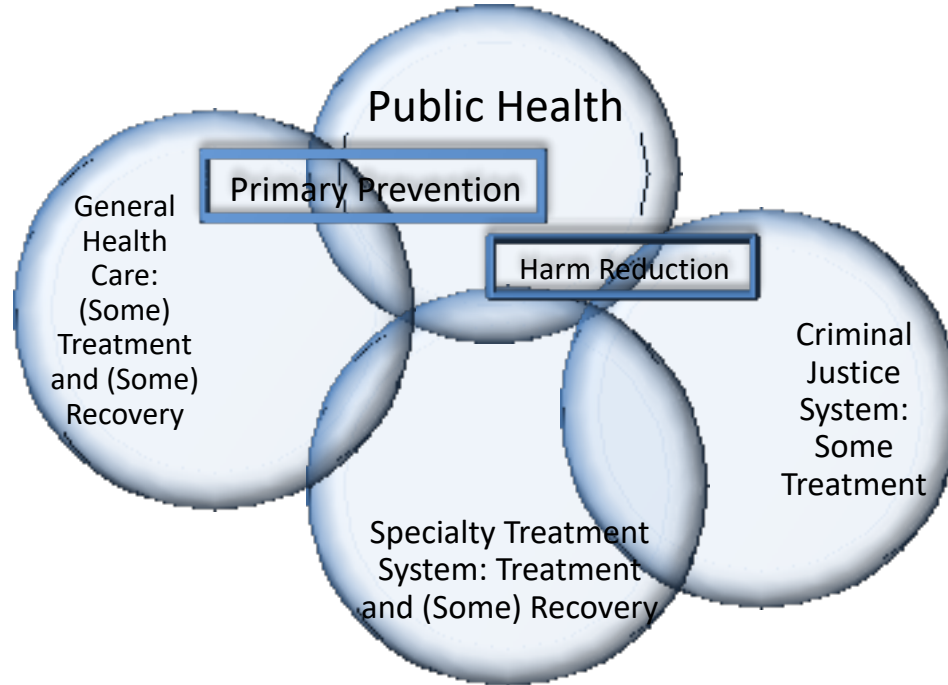
- An important initiative has been to review the GPRRA tool, to make it easier to administer, while also being cognoscente that not all substance use is misuse
- Revisions to the tool under consideration also include a more trauma informed and inclusive approach
- SAMHSA has also convened a GPRRA workgroup to reimagine data collection and to collect data that is meaningful, free of burden and supportive of different treatment modalities such as low threshold treatment

How can SAMHSA reimagine GPRA so that it is less burdensome, while also providing information on program activities and client outcomes?

# Education and Funding To Promote a Robust Workforce

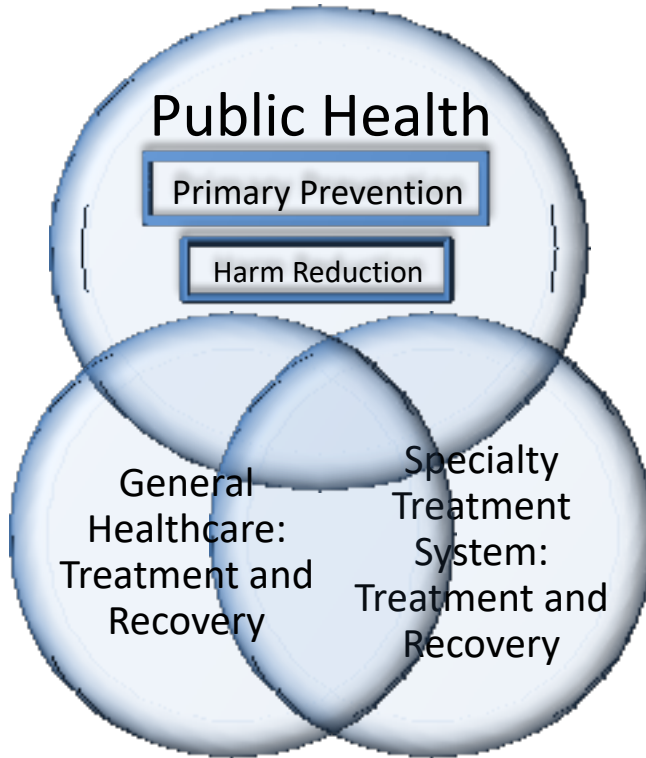
- Stigma and treatment hesitancy can be overcome through education
  - All medical schools, professional schools and residency programs should have a comprehensive and longitudinal curriculum on substance misuse and behavioral health
- Education at the community level brings individuals into treatment and helps to reduce stigma
- Funding more vocational, college and university places for addiction, behavioral health and peer specialists closes the workforce shortage gap
- Funding resources that promulgate evidence-based practice promotes equity and quality care for all

# 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.

# 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).



# 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

# SAMHSA and HHS priorities → CSAT Actions

Prevent overdoses	Inform and promote models and strategies that infuse continuous care practices with harm reduction, treatment, and recovery services (e.g., harm reduction services in OTP and CJ programs, recovery housing)
Integrate primary care and behavioral health	Establish and strengthen collaboration and coordination within CSAT and within and external to SAMHSA to bring continuous care practices, including recovery supports and language change, to the work
Enhance access to suicide prevention and crisis care	Work with partners such as NASADAD to promote SUD crisis services in the 988 continuum
Expand access to services for youth and their families impacted by behavioral health	Partner within SAMHSA on cross-cutting youth agenda initiative
Use performance measures, data, and evaluation to advance the behavioral health field	Build a robust data-driven story– where are we compared to where we want to go? Who are we serving? What services are they getting? What impact is it having? Who and what services are we missing? How is the SUD workforce expanding?

What is needed from SAMHSA to facilitate integrated systems of care and to improve client outcomes?

# All Federal Agencies Work To Close Gaps In Care

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# 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 services and behavioral health
- Treatment services available across different sites, and using different modalities
- Promote on-going research for the treatment of substance use disorders.

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***Thank you!***

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