# Welcome to the Opioid Settlement Technical Assistance Learning Series

## *Overview of the Opioid Settlements &*

## *Ensuring Compliance with the Opioid Settlement Agreements (Exhibit E)*

June 8, 2023 | 2:30 – 3:30 pm

MDHHS Michigan Department of Health & Human Services
GRETCHEN WHITMER, GOVERNOR | ELIZABETH HERTEL, DIRECTOR

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# HOUSEKEEPING ITEMS

- This Zoom event will be recorded
- Participants will be on mute when presenters are speaking
- To ask a question, please use the QA feature
- No legal guidance will be provided
- Any follow-up questions or requests for the Technical Assistance Collaborative (TAC), please email: MDHHS-opioidsettlementhelp@michigan.gov

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# About the TAC & Introduction of Presenters

Stella Resko, PhD
Professor, School of Social Work; Director and CADAS Coordinator
Wayne State University

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# ABOUT THE TAC

- Technical Assistance Collaborative (TAC) established in April 2023
- Comprised of MSU, U-M, and WSU
- Partnership with MDHHS
- Provides technical assistance and expertise to communities at the county, municipal, and township levels receiving opioid settlement funds
- Focus on evidence-based, best practices, promising programs and strategies to remediate opioid overdose deaths
- TA Learning Series is an opportunity for government officials, communities, and the public to hear from our TAC experts on a monthly basis

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# Presenters

- **Matthew Walker**, Assistant Attorney General; Corporate Oversight Division, specializing in opioids and antitrust matters.

- **Amy Bohnert**, PhD, MHS, University of Michigan; Professor in the Departments of Anesthesiology, Psychology, and Epidemiology; Co-Director, Opioid Research Institute and the Michigan Opioid Collaborative.

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**Matthew Walker, Assistant Attorney General**
Corporate Oversight Division

# *Overview of the Opioid Settlement*




# Background

- By 2017, over 2,000 federal lawsuits had been filed by government entities against opioid-related defendants. Among those defendants were opioid distributors and manufacturers.
- In 2017, a federal judicial panel consolidated these cases into multidistrict litigation (MDL).
  - The MDL was consolidated under one judge in the Northern District of Ohio.
- In 2019, after receiving pressure from the MDL judge, three of the nation's largest drug distributors—McKesson, Cardinal Health, and AmerisouceBergen—agreed to settlements. Janssen, an opioid manufacturer, also agreed to settlement.
- In 2021, the details of the settlement were released.
- This process has been replicated with pharmacal companies and others.

# What is being settled?

Many governments have agreed to release certain legal claims against these defendants, related to opioids.

In exchange for government's releasing those claims, the defendants have agreed to do certain things and pay money.

- Doing certain things is known as injunctive relief.
- Paying money is known as monetary payments.

# Opioid Settlements Overview

- The state of Michigan is slated to receive nearly $776 million over 18 years from two settlements, Distributors (McKesson, Cardinal Health and AmerisourceBergen) and J&J.
  - Tribal settlements are separate.
- Fifty percent (50%) of the settlement amount will be paid directly to county and local governments.
- Allocation percentages can be found in Exhibit A of the Michigan State-Subdivision Agreement for Allocation of Distributor Settlement Agreement and Janssen Settlement Agreement.
- 70% of funds must be used for future opioid remediation.
- Exhibit E outlines allowable uses for settlement funds.
- Distribution of funds began in January 2023.

# Injunctive Relief -
# What do the defendants have to do?

Janssen (Opioid Manufacturer), for 10 years, has agreed to:

- Stop selling and manufacturing opioids.
- Stop promoting opioids.
- Stop providing financial incentives to sales teams for opioid sales.
- Stop lobbying for federal, state, local, and regulatory provisions that encourage or require health care providers to prescribe opioids.
- Stop lobbying against federal, state, local, and regulatory provisions that:
    - Support non-opioid pain relief.
    - Prescribing the lowest effective dose.
    - Prescribing naloxone and using urine testing for those with opioid prescriptions.
    - Support evidence-based treatments (like MAT).

# Injunctive Relief - What do the defendants have to do?

The Distributors have agreed, for a period of 10 years, to:

- Create and implement a Controlled Substance Monitoring Program (CSMP).
  - CSMP is responsible for onboarding and approval of new controlled substance pharmacies, setting and adjusting pharmacy thresholds, setting and adjusting pharmacy thresholds, terminating or suspending pharmacies, and identifying red flags.
  - CSMP must conduct ongoing due diligence and conduct site visits, among other things.
- Create and implement a National Clearinghouse to receive and analyze data received from this injunctive relief
  - The Clearinghouse will allow Distributors to obtain comprehensive data from other Distributors , pharmacies, and other relevant sources.
  - States will have access to the data to query without limitation.

# Monetary Relief - What do the defendants have to pay?

**The Distributors will pay $631 million to Michigan governments over 18 years.**

- Payment amounts will vary from year to year, depending on overall payment amount and incentives.
- Governments should not expect the same amount each year.

**Janssen will pay $145 million over 9 years.**

- Payment amounts will vary from year to year.
- Governments should not expect the same amount each year.
- First 5 payments were accelerated into 1 payment in January.
- Payments should resume in 2026 (Payment 6).

# Legislative effort for Incentive A

Bills were passed to ensure Michigan receives Incentive A:

- SB 993 – Michigan Opioid Healing and Recovery Fund
- SB 994 – Opioid Advisory Commission
- SB 995 – Bar to new civil lawsuits against settling defendants

# Michigan State-Subdivision Agreement

## Available at Michigan.gov/agopioids

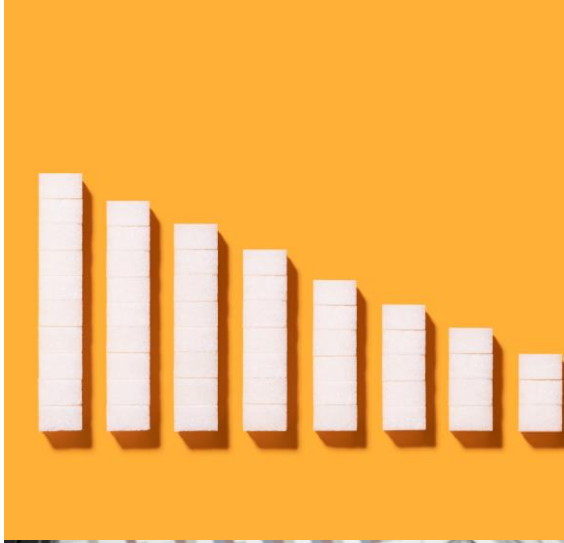
- Controls the allocation of funds to the State and Local Subdivisions.
  - Allocates 50% to Local Subdivisions and 50% to the State. This is instead of 15% to Local Subdivisions, 15% to the State, and 70% to a fund.
  - Deductions for an Administrative Fund, Litigating Local Government Attorney Fee Fund, and Special Circumstance Fund.
- Allocations to individual local subdivisions are determined by a nationally used formula, modified by a litigation adjustment.
- Individual local subdivisions with an allocation percentage of less than .0023% (approx. $7,500 or less in total) will receive their complete recovery in the first payment.
- Local subdivisions may voluntarily assign all or part of their allocation to another participating subdivision.

# Upcoming Settlements

- Mallinckrodt Bankruptcy began payments in May 2023.
- The following settlements are pending, and active payout should begin in 2023:
  - CVS
  - Walmart
  - Allergan
  - Teva
- Additional settlements are expected to take place with the following:
  - Purdue Pharma
  - Endo
  - Walgreens
- Distribution process, requirements on spending and reporting are expected to differ.
- Tribal settlements are separate.

# How to Spend the Money

- Settlement payments must be used for Opioid Remediation, per the Michigan State-Subdivision Agreement.
- 70% of the settlement payment must be used for future Opioid Remediation.



# Opioid Remediation - Definition

- Care, treatment, and other programs and expenditures (including reimbursement for past such programs or expenditures except where this Agreement restricts the use of funds solely to future Opioid Remediation) designed to:
  - **(1)** address the misuse and abuse of opioid products,
  - **(2)** treat or mitigate opioid use or related disorders, or
  - **(3)** mitigate other alleged effects of, including on those injured as a result of, the opioid epidemic.
- Exhibit E provides a non-exhaustive list of expenditures that qualify as being paid for Opioid Remediation. Qualifying expenditures may include reasonable related administrative expenses.

# Ensuring Compliance with Opioid Settlement Agreements

Amy Bohnert, PhD
University of Michigan

# Speaker Info

- PhD in Public Health
- Expert in opioid use disorder, opioid misuse, overdose, prevention, treatment
- Research and program funding from NIH, VA, BCBS, MDHHS, CDC

- Have served as an expert witness in opioid litigation

- *How I approached this talk – what would I say if I served as an expert witness?*

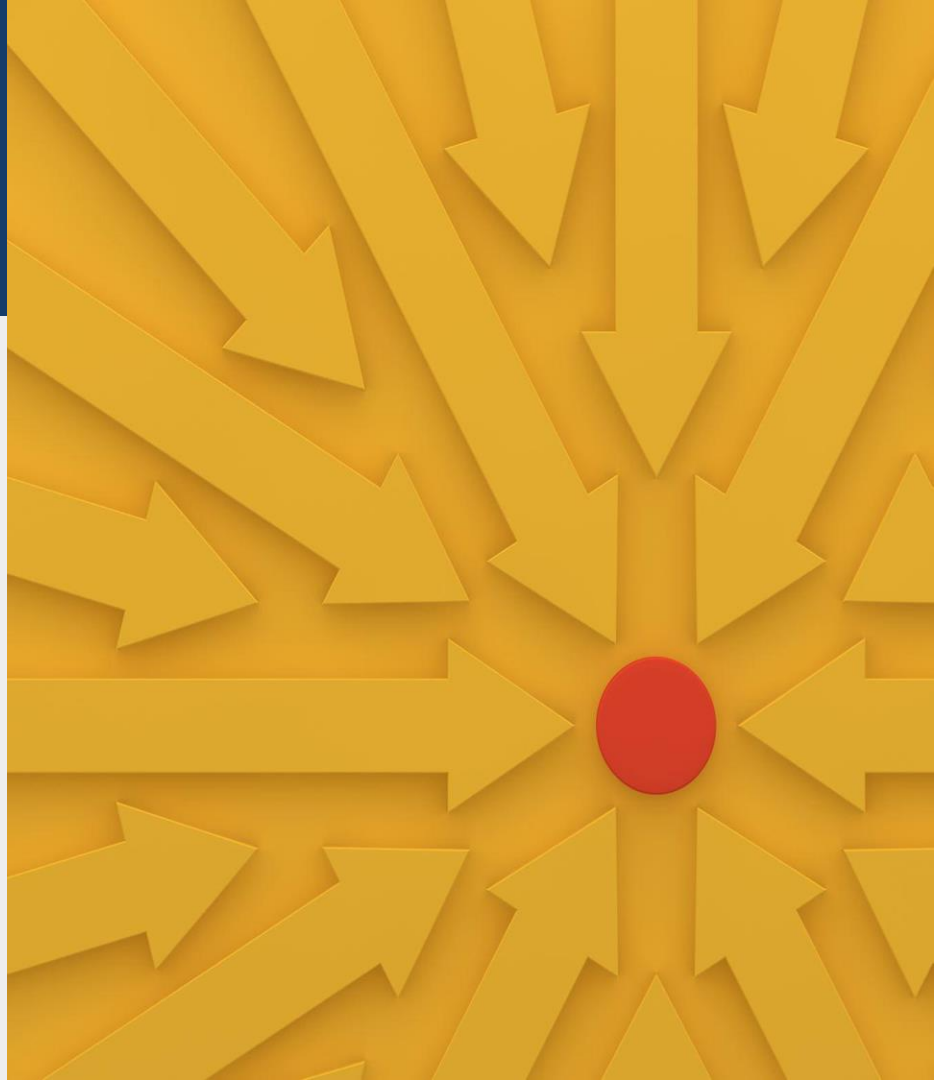
# Exhibit E

- Schedule A – Abatement Core Strategies
- Schedule B – Approved Uses
- Examples
- Q/A

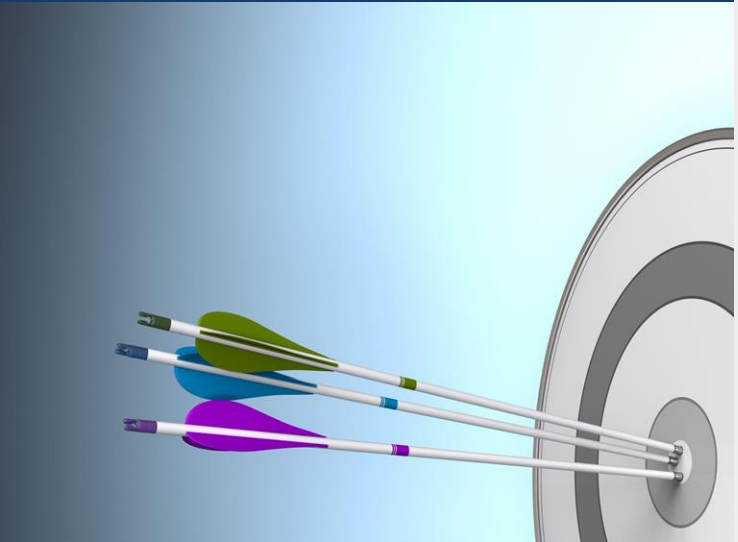
# Schedule A Core Strategies

Priority shall be given to the nine core strategies listed in **Schedule A**

- Outlines the priority areas to deploy specific strategies with the goal of remediating opioid use disorder in communities



# Core Strategies



1. Naloxone for overdose reversal
2. Medication-assisted treatment (MAT) and other opioid-related treatment
3. Pregnant & postpartum women
4. Expanding treatment for neonatal abstinence syndrome (NAS)
5. Expansion of “warm hand-off” programs and recovery services
6. Incarcerated population
7. Prevention programs
8. Syringe service programs
9. Evaluation of programs

# Naloxone or other FDA-approved drug to reverse opioid overdoses

- Expand training for first responders, schools, community support groups and families
- Increase distribution to uninsured or whose insurance does not cover

# Medication-Assisted Treatment (MAT)

MAT

- Increase distribution of MAT to uninsured and whose insurance does not cover
- Support forms of MAT as approved by FDA

Other opioid-related treatment

- Prevention and education
- Training and awareness
- Treatment and recovery



# Medication-Assisted Treatment (MAT)

MAT - Comparison of Medications for Opioid Use Disorder (OUD)

| | **Methadone** | **Naltrexone** | **Buprenorphine** |
|---|---|---|---|
| **Mechanism** | Agonist | Antagonist | Partial agonist |
| **Clinical uses** | Medically supervised withdrawal, maintenance | Prevention of relapse to opioid dependence, following medically supervised withdrawal | Medically supervised withdrawal, maintenance |
| **Administration** | Oral | Oral, intramuscular injection | Oral tablet or film, subdermal implant |
| **Prescribing and dispensing** | SAMHSA-certified Opioid Treatment Programs (OTPs) dispense methadone for daily administration on site or at home (stable patients). | Any individual licensed to prescribe medicines may prescribe and/or order administration by qualified staff. | Physicians outside OTPs must complete special training and certification to qualify for a federal waiver to prescribe. Any pharmacy can fill the script. |
| **Other considerations** | Stigma associated with treatment, potential for misuse/diversion | Lowers opioid tolerance and can increase overdose risk | Potential for misuse/diversion |

# Pregnant & postpartum women

- Expand Screening, Brief Intervention, and Referral to Treatment (SBIRT) services
- Expand comprehensive evidence-based treatment for uninsured for up to 12 months postpartum
- Provide comprehensive wrap-around services to individuals with OUD, including housing, transportation, job placement/training, and childcare

# Expanding treatment for Neonatal Abstinence Syndrome (NAS)

- Expand comprehensive evidence-based and recovery support for NAS babies
- Expand services for better continuum of care with infant-need dyad
- Expand long-term treatment and services for medical monitoring of NAS babies and their families

# Prevention Programs

- Media campaigns to prevent opioid use (FDA's "Real Cost" campaign to prevent youth from misusing tobacco)
- Evidence-based prevention programs in schools
- Medical provider education and outreach regarding best prescribing practices for opioids consistent with the 2016 CDC guidelines, including providers at hospitals (academic detailing)
- Community drug disposal programs
- Training first responders to participate in pre-arrest diversion programs, post-overdose response teams, or similar strategies connecting at-risk individuals to behavioral health services and supports

# Expanding syringe service programs

- Provide comprehensive syringe service programs with more wrap-around services, including linkage to OUD treatment, access to sterile syringes and linkage to care and treatment of infectious diseases

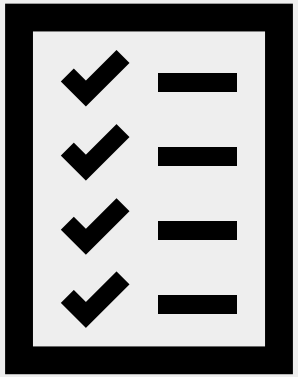
# Evidence-based data collection and research analyzing effectiveness of abatement strategies within the State

- Michigan Department of Health and Human Services (MDHHS) is coordinating to assist counties, municipalities and townships
- Technical Assistance Collaborative providing additional guidance and assistance
- Michigan Association of Counties (MAC) is working with NACo and Vital Strategies on an evaluation tool
- Important to have standard metrics to measure and evaluate impact

# Schedule B
# Approved Uses

**Grantees shall choose from the abatement strategies or allowable uses listed in Schedule B**

- List of allowable uses of the opioid settlement funding
- Focuses on **evidence-based or evidence-informed** programs or strategies
- Three sections: **Treatment, Prevention and Other**



# Treatment (5 Categories)

- Treat Opioid Use Disorder (OUD)
- Support People in Treatment and Recovery
- Connections to Care
- Criminal Justice-Involved Persons
- Pregnant or Parenting Women and Their Families, Including Babies with Neonatal Abstinence Syndrome (NAS)

# Treat opioid use disorder (OUD)

Expand availability for OUD treatment and any co-occurring SUD/MH conditions, including:

- All forms of MAT approved by FDA, counseling, psychiatric support, and other treatment and recovery support services
- Reimbursement of evidence-based services
- Telehealth
- Peer recovery coaches
- Treatment of trauma for individuals with OUD and family members

*Challenges – how to integrate with reimbursement*

# Treat opioid use disorder (OUD)

Expand Workforce Capacity

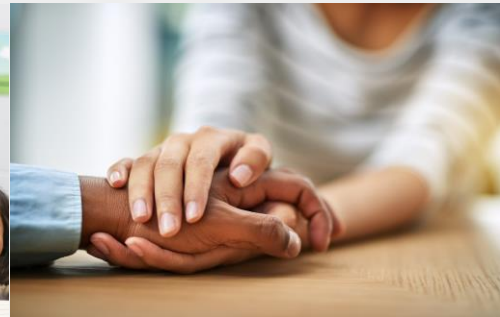
- Training of health care providers, first responders, students, or other supporting professionals (e.g., peer recovery coaches, recovery outreach specialists, including telemonitoring for community-based providers in rural or underserved areas) on MAT
- Scholarships and supports for behavioral health practitioners or workers, including fellowships, training, scholarships, loan repayment, or other incentives for providers working in rural or underserved areas
- Web-based training curricula and motivational interviewing

# Support people in treatment and recovery

For people in recovery from OUD and any co-occurring SUD/MH conditions:

- Housing, housing, housing
- Transportation
- Education (recovery high school and higher ed), job placement, job training
- Childcare
- Counseling, peer-support, recovery case management, and residential treatment with access to medications
- Legal services





# Connections to Care

- Train health care providers on screening and counseling
- Navigators and on-call teams to begin MAT in hospital emergency departments
- Hospital programs that transition persons with OUD to treatment
- Peer supports in key settings
- Crisis stabilization centers that serve as an alternative to hospital emergency departments
- EMS, including peer support specialists, to connect individuals to treatment or other appropriate services following an opioid overdose or other opioid-related adverse event
- Workplace programs
- Centralized call centers

# Criminal justice-involved persons

- Pre-arrest or pre-arraignment diversion and deflection strategies
- Treatment and recovery courts, with MAT
- Treatment in jail/prison and after release

# Prevention (3 Categories)

- Appropriate Prescribing and Dispensing of Opioids
- Prevent Misuse of Opioids
- Prevent Overdose Deaths and Other Harms (Harm Reduction)

# Prevent over-prescribing and ensure appropriate prescribing and dispensing of opioids

Use evidence-based or evidence-informed programs or strategies that may include, but are not limited to, the following:

- Medical provider education
  - “Academic detailing”
- Training for health care providers regarding safe and responsible opioid prescribing, dosing, and tapering patients off opioids
- Providing support for non-opioid pain treatment alternatives, including training providers to offer or refer multi-modal, evidence-informed treatment of pain
- Education on dispensing

# Community-Based Prevention

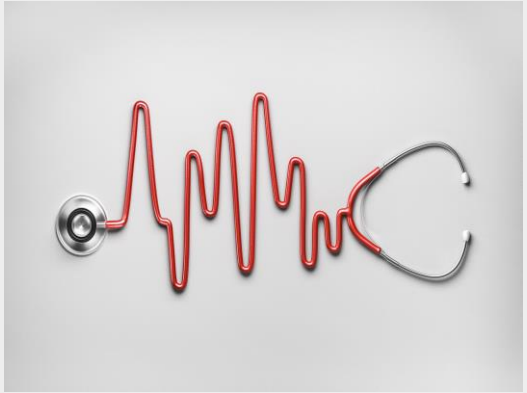
- Funding media campaigns to prevent opioid misuse
- Drug take-back disposal or destruction programs
- Funding community anti-drug coalitions that engage in drug prevention efforts


# Youth-Focused Prevention

- Funding evidence-based prevention programs in schools or evidence-informed school and community education programs and campaigns for students, families, school employees, school athletic programs, parent-teacher and student associations, and others
- Youth mental health prevention programs and services
- Key Evidence-Based Program: Strengthening Families

# Harm Reduction

- Naloxone (basically anywhere)
- Overdose education
- Software and applications for overdoses/naloxone revivals
- Syringe service programs and other evidence-informed programs to reduce harms associated with intravenous drug use, including supplies, staffing, space, fentanyl checking, HCV treatment



# Other Strategies (4 Categories)

First Responders

Leadership, Planning and Coordination

Training



Research

# First Responders


In addition to items in section C, D and H (opioid settlement agreement) relating to first responders, support the following:

- Education of law enforcement or other first responders regarding appropriate practices and precautions when dealing with fentanyl or other drugs
- Provision of wellness and support services for first responders and others who experience secondary trauma associated with opioid-related emergency events

# Leadership, planning and coordination

Support efforts to provide leadership, planning, coordination, facilitations, training and technical assistance to abate the opioid epidemic through activities, programs, or strategies that may include, but are not limited to, the following:

- Statewide, regional, local or community regional planning to identify root causes of addiction and overdose
- Goals for reducing harms related to the opioid epidemic
- Areas and populations with the greatest needs for treatment intervention services
- Support training, technical assistance and other strategies to abate the opioid epidemic described in the opioid abatement strategy list

# Examples

- Alabama – court software
- Kentucky – research on psychedelics

- *Key Questions:*
  - *Would experts agree it fits an allowable use?*
  - *How much funding is it?*

JUSTICE AND PUBLIC SAFETY

# Alabama Court Requests Opioid Settlement Funds for Software

Limestone County District Attorney Brian Jones is hoping a portion of the money Limestone County has received from the opioid settlement can benefit the county's court system.

The county has received approximately $300,000 from the state's settlement, and Jones is requesting $100,000 of it for Grand Jury software.

"We are in a situation right now where the Grand Jury software and the Case Manager software we are currently using is failing. For instance, the last Grand Jury, we had a problem where the software was switching the defendant's name with the victim's name," Jones said.

The money the county is receiving from the Opioid Settlement is to help address problems caused by opioid addiction. Jones believes the software will benefit the county as it tracks the cases more precisely and quickly.

"With this software, if you call me and want to know how many fentanyl cases you prosecuted last year, I can hit a button and tell you in five minutes," Jones said.

Key points:

- Planning and coordination?
- 1/3 of total budget

# A Surprising Southern State Journeys from Opioids to Ibogaine

By Reilly Capps May 31, 2023

## Kentucky Will Use Opioid Settlement Money to Develop Psychedelic Into FDA-approved Drug

"Kentucky will explore the possibility of devoting no less than $42 million over the next six years to the creation of public private partnerships which can incubate, support and drive the development of ibogaine all the way through the FDA approval process," said W. Bryan Hubbard, executive director of Kentucky Opioid Abatement Advisory Commission. Hubbard called ibogaine "Kentucky's breakthrough opportunity."

Kentucky received $842 million from the settlements. By using some of its settlement money to explore ibogaine, Kentucky becomes the first state to use its resources to legalize a psychedelic.

Key points:

- "Research," but not really a research question
- $42m of $842M (~5%)

# Summary

- Avoid a potential challenge of how funding was spent
- Stick with evidence-based or evidence-promising programs and strategies that have a connection in helping individuals with an OUD or co-occurring SUD/MH conditions and those at risk of these conditions
- In general, training to improve services or reduce stigma cuts across all domains
- Reach out to the TAC and MDHHS along with your county, municipal and township statewide organizations as resources and for expertise

# Thank you for listening!

# Thank You!

For questions and to make requests to the TAC, please email **MDHHS-opioidsettlementhelp@michigan.gov**

The next TAC Learning Series will be held in July, details will be sent soon.

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