

# Opioid Settlements

WHOLESALE DRUG DISTRIBUTORS AND JANSSEN

#### 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.

## Who is settling?

Three of the Nation's largest wholesale drug distributors: McKesson, Cardinal Health, and AmerisourceBergen

• This includes several thousand subsidiaries of these companies.

Opioid manufacturer Janssen, a subsidiary of Johnson and Johnson.

# 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.

#### 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)

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.

### What do the defendants have to pay?

The Distributors and Janssen will pay up to \$26 billion nationwide. Michigan will receive up to 3.4%, or approximately \$776 million over the course of 18 or less payments. Payments are unlikely to be the same from year to year because of certain options in the settlement agreement.

Michigan is a participating state and 269 of 278 eligible local subdivisions participated in the settlements

Participation of States and eligible local governments is key

#### **DISTRIBUTORS: Base and Incentives**

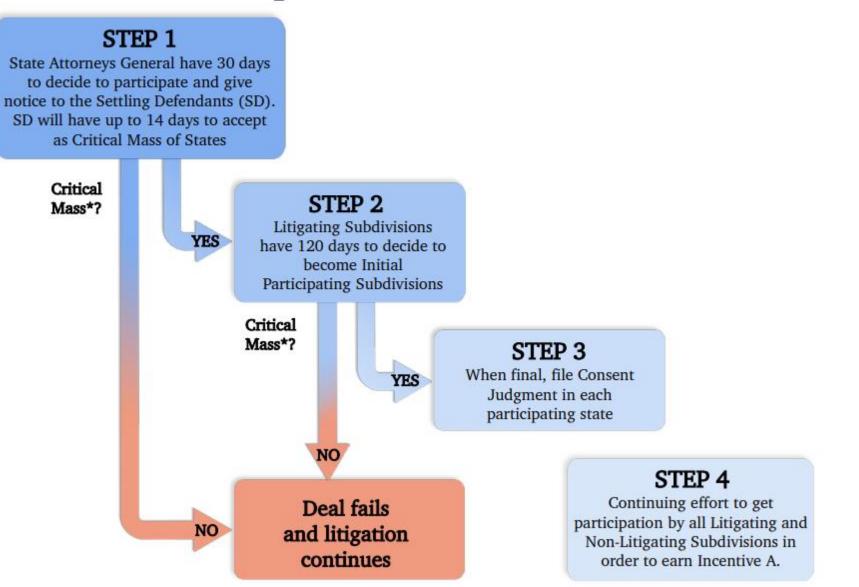
	Incentive A	Ince	ntive B		Inc	centiv	e C		Inc	entive D
Base 55% Incentives 45% Net Abatement Amount	Incentive A provides for payment of all but Incentive D payments in exchange for near full peace. Incentive A is earned by: • Passing a Statute or court	S • In • In ol	ncentive B is not r state earns Incent ncentive B is up to ncentive B is earn btaining releases ubdivisions.	ive A. o 25%. ed by	a	if a St Incent Incent gettin 30,00	ntive C is up ntive C is ea ng larger (po 00) non-litig	ncentive A. to 15%. arned by opulation of ating and an	Al pa th	% share of the State's total batement Fund allocation (see age 20). Payable starting in year 6 rough year 18. Qualifying Criteria
Incentives are earned by obtaining releases from subdivisions and limiting additional subdivisions from filing suit	<ul> <li>ruling that terminates existing and bars future claims by subdivisions (including special districts);</li> <li>Receiving releases on behalf of (i) all general purpose subdivisions above 10,000 population, (ii) larger school and hospital/health districts,</li> </ul>		Incentive B Slie Participation or Case- Specific Resolution Levels	Incentive B Award	_	cities Ince Par Re Re	to join the	iding Scale:		<ul> <li>State must have had no later Litigating Subdivisions bring suit and proceed past preliminary motions.</li> </ul>
filing suit.	and (iii) all currently litigating		85%	30%	_		70-74%	35%		
	subdivisions; or		86-90%	40%	_		75-79% 80-84%	40%		
	A combination of these		91-94%	50%	_		85-89%	55%		
During the first two years, States that settle are treated as if receiving full base	approaches that results in a complete bar of existing and future claims (e.g., legislation barring future claims combined with 100% participation by litigating subdivisions).		95-99%	60%	_	9	90-92%	60%		
			99-99.9%	95%			93%		١٨	/by/Dontinination
			100%	100%			94% 95-97%	75% 90%	V	Vhy Participation
and incentive.							98-99%	95%		is Important
Illustrative only- Executed		with I	tructured in time Incentive B under ement.		Th	ere is no	100% timing ele	100% ment.		

Illustrative only- Executed Agreements Control.

#### **JOHNSON & JOHNSON: Base and Incentives**

	Incentive A	Ince	entive B		Inc	entive C		Inc	entive D
Base 45% Incentives 55% Global Settlement Abatement	Incentive A provides for payment of all but Incentive D payments in exchange for near full peace. Earning Incentive A also causes substantial payments, the first three years of payments, accelerated and paid within 90 days.		<ul> <li>Incentive B is not relevant if a State earns Incentive A.</li> <li>Incentive B is up to 30%.</li> <li>Incentive B is earned from obtaining releases from litigat subdivisions.</li> </ul>			Incentive C is not a State earns Incent Incentive C is up to breaks Incentive C Incentive C is earn larger (population litigating and non-l and cities to join the awarded for obtain largest general p subdivisions (citi	ive A. 5 20%. It 5 in two parts. 6 ad by getting of 30,000) itigating coun 10 deal. 5% is 10 ng a State's 10 urpose	A p th ties ten	<ul> <li>% share of the State's total abatement Fund allocation (see age 20). Payable starting in year 6 brough year 18.</li> <li>Qualifying Criteria</li> <li>State must have had no later Litigating Subdivisions bring suit and proceed past</li> </ul>
Amount	<ul> <li>Passing a Statute or court ruling that terminates existing and bars future claims by subdivisions (including special districts);</li> </ul>		Incentive B Sli Participation or Case- Specific Resolution	ding Scale: Incentive B Award		Incentive C S Participation, Release, or Resolution Levels	Incentive C(1) Award		preliminary motions in the 5 years following the Effective Date.
Incentives are	<ul> <li>Receiving releases on behalf of</li> </ul>		Levels	50%/		<u>60%</u> 70%	40% 45%		
earned by obtaining	(i) all general purpose		75%	50% 52%		80%	45% 50%		
releases from	subdivisions above 10,000		77%	54%		85%	55%		
subdivisions and	population, (ii) larger school and hospital/health districts,		78%	56%		90%	60%		
limiting additional subdivisions from	and (iii) all currently litigating		79%	58%		91%	65%		
	subdivisions; or		80%	60%		92%	70%		
filing suit.	A combination of these		<u>85%</u> 90%	70% 80%		93%	80%		
	approaches that results in a		90%	90%		94%	90%		
	complete bar of existing and future claims (e.g., legislation barring future claims combined with 100%		100% 100% Timing element Incentive B is structured in time periods and states will receive a percentage of sliding scale payments depending on when they reach 75% of litigating			95% ere is no timing elen	100%	W	/hy Participation is Important
Illustrative only- Executed Agreements Control.	participation by litigating subdivisions).	scale; (b)	ons signed on: (a) 0-210 day ) 211-365 = 75% of sliding s m effective date = 50% of sl	cale; and (c) 366-2					

#### Implementation



2021.07.22 Subject to Update & Correction/Executed Agreements Control

### Michigan State-Subdivision Agreement Available at Michigan.gov/agopioids

- Controls the allocation of funds to the State and Local Subdivisions, instead of what is listed in Master Settlement Agreement.
  - 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.

## Michigan State-Subdivision Agreement

Available at Michigan.gov/agopioids

- Attorney fees are limited to 15% of an individual Litigating Local Government's recovery and offset by a National Fee Fund.
  - For example, Subdivision A contracted with Attorney X for a 30% contingency fee. Attorney X's fee is limited to 15% of Subdivision A's recovery by the Michigan State-Subdivision Agreement and by order of the Court. The National Fee Fund pays 7% and the remainder is paid by the Litigating Local Government Attorney Fee Fund. Fees are paid over the course of 7 years.
- Special Circumstance Fund: Local subdivisions may apply for additional funding for any local impact that is not captured by a Local Government's allocation percentage.
  - The application deadline is March 30, 2022, but there is active effort to move this date back because everything is taking longer than expected.

## How may settlement funds be used?

Governed by "opioid remediation" as defined in the Distributor and Janssen Settlements; Guided by "Exhibit E" of the Distributor and Janssen Settlements

- Opioid Use Disorder (OUD) Treatment
- Treatment and **Recovery Support**
- Connecting People to Help
- Address Needs of Criminal Justice-Involved Persons

## How may settlement funds be used?

#### Continued

- Address Needs of Pregnant Women, Infants, and Parents
- Prevention
- First Responder **Support**
- Leadership Planning
- Training
- Research

## When will payments begin?

## Payment #1 as early as

April 2022

## Payment #2

as early as July 2022

Subsequent payments will be received annually in July.

## MICHIGAN OPIOID SETTLEMENT: STATE STRATEGY AND NEXT STEPS

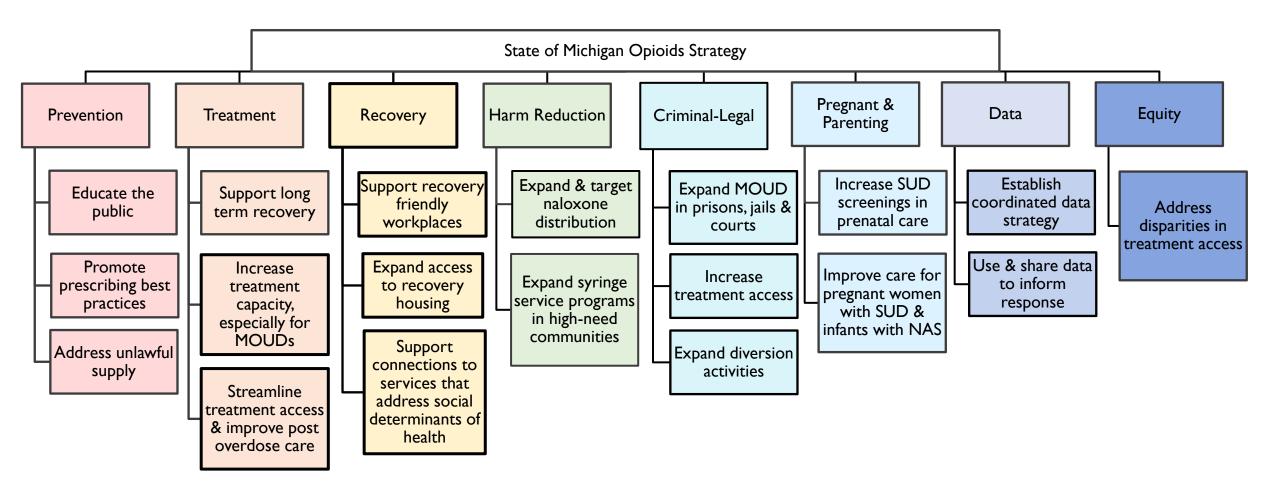
MARCH 2, 2022



#### **KEY PRINCIPLES**

Settlement funding planning will follow three key principles identified by the state:

- I. Align settlement funding with the State of Michigan Opioid Strategy
- 2. Address systemic barriers to services
- 3. Provide equitable distribution of funding





#### PREVENTION

- Launching targeted media campaigns ongoing
- Funding academic detailing and prescribing best practices programs
- Providing educational materials and expert consultation services for prescribers to promote best practices, especially for high-risk areas or medical specialties
- Supporting and promoting prescription drug takeback events
- Use Michigan Automated Prescribing System (MAPS) to monitor controlled substance prescriptions and identify potential inappropriate prescribing practices

#### TREATMENT

#### **Increased Treatment Capacity**

- Michigan Opioid Collaborative (MOC) provide technical assistance and support to buprenorphine prescribers – ongoing
- Emergency department MOUD Partnering with Michigan Opioid Partnership to expand MOUD in emergency departments across the state – ongoing

#### **Reducing Administrative Barriers**

- Removed Medicaid prior authorization for buprenorphine – Late 2019
- Updated Medicaid Reimbursement Policy for Office Based Opioid Treatment - 2021
- Received federal approval to change Essential Health Benefits Plan to expand access to treatment and naloxone in public and private health insurance – 2020

#### RECOVERY

- OUD/SUD Treatment Costs, Case Management, and Transportation- covers costs for individuals with SUD/OUD to access treatment, transportation to treatment, and offers case management to individuals – ongoing
- Peers in emergency departments, outpatient treatment, and community settingsintegrates peer support specialists in different treatment settings – ongoing
- Recovery Housing- cover recovery housing costs for individuals with SUD/OUD ongoing
- Certification of Recovery Residences- Certify recovery residences in Michigan according to National Association of Recovery Residence standards – ongoing

#### HARM REDUCTION

- Promoting naloxone distribution in key locations & expand scope of standing order
  - Naloxone portal has bulk orders of naloxone throughout Michigan
- Promoting adoption of EMS leave behind programs & require licensed EMS vehicles be equipped with naloxone
- Expanding SSPs and increase service delivery in communities of need
  - 81 locations operating in Michigan
- Conducting street outreach in high-need communities

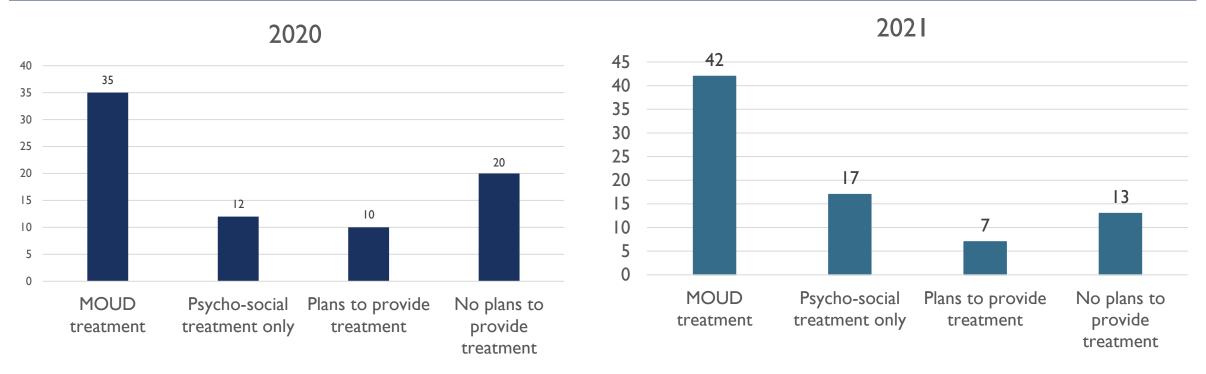
#### CRIMINAL-LEGAL

- Assessing MOUD use in jails and courts to inform funding
- Providing technical assistance to MDOC MOUD pilots
- Expanding the number of treatment courts
- Supporting MOUD use in treatment courts, through TA, education, & funding
- Supporting training for judges, prosecutors, and defense counsel on science of addiction, MOUDs, and ADA requirements

#### CRIMINAL-LEGAL

- Streamlining Medicaid re-activation for eligible individuals leaving prisons or jails; provide access to CC360
- Establishing data sharing procedures between Medicaid, MDOC, and county jails
- Piloting LEAD program and secure diversion spaces
- Expanding the Angels Program and explore additional opportunities for diversion from criminal-legal system to treatment

#### CRIMINAL-LEGAL – SURVEY OF MICHIGAN JAILS



- Providing funding through the PIHPs to expand jail-based access to MOUD and prison access to MAT
- Michigan Department of Corrections (MDOC) oversees all state prisons
- County sheriffs oversee local jails



#### PREGNANT AND PARENTING WOMEN INITIATIVES

#### **Rooming-In for Infants with Neonatal Abstinence Syndrome (NAS)**

• War Memorial Hospital in Sault Ste. Marie, Hurley Medical Center in Flint, and Munson Medical Center in

Traverse City received funding to retrofit space for rooming-in care

#### High Touch, High Tech (HT2)

 HT2 project uses a tablet-administered app to screen pregnant women for mental health and substance use disorders and connect them to treatment

Michigan awarded State Pilot Grant Program for Treatment of Postpartum Women (PPW-PLT)

Grant provides up to \$900,000/yr. for three years to PIHP Region 2 and Region 7 to support P/PW with a
primary SUD diagnosis as well as direct additional funding to HT2 project



#### ADDRESSING DISPARITIES

#### In 2020, overdose data showed alarming racial disparities:

- The opioid overdose death rate for Black residents, increased from 29.1 deaths per 100,000 in 2019 to 37.5 deaths per 100,000 in 2020.
- The opioid overdose death rate for Hispanic residents, increased from 15 deaths per 100,000 in 2019 to 22.3 deaths per 100,000 in 2020.
- Michigan Opioid Task Force set to launch a Racial Equity Workgroup to address these disparities.
  - Support culturally competent community outreach in majority-minority communities
  - Promote MOUD in majority-minority communities
  - Conduct analysis to identify key drivers of disparities



#### MDHHS OPIOID SETTLEMENT SURVEY 2021-22: Initial Findings

Priorities for opioid settlement funding	% ranked #I priority
<b>Recovery support services</b> , including peer support and wrap-around services for individuals with Substance Use Disorder (SUD) and co-occurring mental health diagnoses	36%
Prevention programming	19%
<b>Expanding access to Medications to treat Opioid Use Disorder</b> (MOUD) and other opioid-related treatment	16%
<b>Support for pregnant &amp; post-partum women</b> affected by substance use, and infants with Neonatal Abstinence Syndrome (NAS)	9%
Naloxone distribution and training	7%
Treatment for incarcerated population	6%
Syringe Service Programs (SSP)	4%
Research and evaluation of abatement strategies	3%



#### MDHHS OPIOID SETTLEMENT SURVEY 2021-22: Initial Findings

Treatment and Recovery Support Services	% ranked #1	Prevention Activities	% ranked #1	
Residential/inpatient treatment programming	24%	Evidence-based prevention programs in k-12 schools	28%	
Wrap-around service programs to address spectrum of social factors (transportation, housing, employment, etc.)	20%	Training for first-responders on programming to connect at-risk individuals with services and supports	27%	
Access to Medications to treat Opioid Use Disorder (MOUD), including methadone, buprenorphine, and naltrexone	19%	Medical provider education and outreach around opioid prescribing best practices	25%	
Harm Reduction Activities	% ranked	Population/ Communities	% ranked	
	#1		#1	
Expand programming to divert/deflect individuals from criminal-legal system		Individuals with co-occurring mental health diagnoses and/or other Substance Use Disorders (SUD)	#1 41%	
		Individuals with co-occurring mental health diagnoses and/or other Substance Use Disorders		



#### NEXT STEPS AND QUESTIONS

- Webinars starting in April to inform best practices on services for opioid use disorder
  - $\circ$  Prevention
  - Treatment
  - $\circ$  Recovery
  - Harm reduction
- Future partnerships will be ongoing, and more information will be available later
- Questions?