MICHIGAN BOARD OF MEDICINE

July 18, 2018 MEETING

APPROVED MINUTES

In accordance with the Open Meetings Act, 1976 PA 267, the Michigan Board of Medicine met on July 18, 2018 at the Ottawa Building, Conference Room 3, 611 West Ottawa Street, Lansing, Michigan 48933.

CALL TO ORDER

Mohammed Arsiwala, MD, Chairperson called the meeting to order at 10:13 a.m.

ROLL CALL

Members Present:
Mohammed Arsiwala, MD, Chairperson
Louis Prues, Public Member, Vice Chairperson
Richard Bates, MD
Michael Chafty, MD (Left at 12:05 p.m.)
Stacey Frankovich, Public Member (Left at 11:55 a.m.)
Michelle Gormas, PA
Renee Johnston, Public Member
Cara Poland, MD
Venkat Rao, MD
James Rogers, MD
Traci Ruiz, Public Member
James Sondheimer, MD
Paul Sophiea, Public Member
Dennis Szymanski, MD
Shereen Tabrizi, Public Member
Rosalie Tocco-Bradley, MD, PhD (Left at 10:55 a.m.)

Members Absent:
Michael Chrissos, MD
Eric Stocker, Public Member
Terri Tahnoose, Public Member

Staff Present:
Weston MacIntosh, Analyst, Boards and Committees Section
Kiran Parag, Analyst, Compliance Section
LeAnn Payne, Board Support, Board and Committees Section
Michele Wagner-Gutkowski, Assistant Attorney General

Arsiwala Introduced Cara Poland, MD as a new professional member to the Board.

APPROVAL OF AGENDA

MOTION by Rogers, seconded by Sophiea, to approve the agenda as presented.

A voice vote followed.

MOTION PREVAILED

APPROVAL OF MINUTES

MOTION by Szymanski, seconded by Johnston, to approve the May 16, 2018 minutes, as presented.

A voice vote followed.

MOTION PREVAILED

Drug Enforcement Presentation

Cathy Gallagher and Leigh Ann Halas from the Drug Enforcement Administration presented on "Diversion Control: Combating the Supply", addressing the opioid abuse epidemic in Michigan (Addendum #1).

OLD BUSINESS

None

NEW BUSINESS

REGULATORY CONSIDERATIONS

Judith Cooper Andersen Berk, MD – Petition for Reinstatement

MOTION by Sophiea, seconded by Gormas, to discuss.

Sondheimer recused himself.

A voice vote followed.

MOTION PREVAILED

Discussion was held.

MOTION by Szymanski, seconded by Chafty, to accept the Petition for Reinstatement and place Petitioner on probation for one year, with the following terms: Petitioner must contact HPRP within 30 days and enter into a disciplinary regulatory monitoring agreement. Petitioner must also contact and enroll with the Center for Personalized Education for Professionals (CPEP) for a reentry clinical assessment of her professional skills and knowledge and comply with any CPEP recommendations. Failure to comply with the terms of the Order shall result in license suspension.

A roll call vote followed: Yeas: Bates, Chafty, Gormas, Johnston, Poland, Rao, Sophiea, Szymanski, Tabrizi, Prues, Arsiwala
Nays: Frankovich, Rogers, Ruiz
Recuse: Sondheimer

MOTION PREVAILED

Mark Kallaway, MD – Proposal for Decision

MOTION by Gormas, seconded by Rao, to discuss.

Bates recused himself.

A voice vote was held.

MOTION PREVAILED

Discussion was held.

MOTION by Rao, seconded by Johnston, to accept the Proposal for Decision and grant reinstatement to a limited license. Petitioner's license is limited for one day not to exceed one year. During the limitation, the Petitioner shall not engage in the practice medicine until he provides evidence to the Department of completing a reentry clinical assessment by CPEP with focus on anesthesiology, pain management and addiction medicine, and has been endorsed safe to practice by CPEP. Upon receipt by the Department of a satisfactory CPEP assessment and safety to practice endorsement, the Petitioner's limited license shall automatically be reclassified to a full and unlimited license status. Upon reclassification, Petitioner's shall be placed on probation for one year. During the probationary period Petitioner shall contact HPRP within 30 days and enter into a disciplinary regulatory monitoring agreement and continue to comply with any CPEP recommendations. In addition, Petitioner shall complete a total of 45 hours of live continuing education with 15 hours in each of the following areas: anesthesiology, pain management, and addiction medicine. Failure to comply with the terms of the Order shall result in license suspension.

A roll call vote followed: Yeas: Chafty, Gormas, Johnston, Poland, Rao, Sondheimer, Sophiea, Szymanski, Tabrizi, Prues, Arsiwala
Nays: Frankovich, Rogers, Ruiz
Recuse: Bates

MOTION PREVAILED

FSMB Update

Arsiwala informed the Board that he attended the FSMB training for new FSMB Board members and that Cheryl Pezon, the Bureau Director, attended training for new Executive Directors.

Monitoring Guidelines for Peer Review Reports

Arsiwala explained the process of Peer Review Reports. He informed the Board that he is developing a universal reporting template to assist in helping the process be more consistent.

Expert Reviewers

Arsiwala informed the Board of the need for more expert reviewers in many specialties. He advised members to email MacIntosh or himself with recommendations.

Chair Report

Activity from March 14th to June 30, 2018

Conferee assignments	2
Quarterly Reports Approved	4
CME/CPEP Courses approved	16
Face to Face Conferee	4
Settlement offers, and conferee conference issued	22
Violation of consent orders and suspension issued	1
Emergency Suspension issued	3
File Review	6
Physician Reviewer approved	2

Department Update

MacIntosh informed the Board that the Department has issued 1 special volunteer license since the last meeting.

MacIntosh announced that Cheryl Pezon has been named the Director of the Bureau of Professional Licensing.

MacIntosh announced that Kim Gaedeke has been named Deputy Director of the Department of Licensing and Regulatory Affairs (LARA).

Parag introduced Michael Draminski as the new Compliance Manager and Carla Chapman as the new analyst in the Compliance Section.

MacIntosh introduced Dawn Gage, Licensing Manager, Debi Haigh, Senior Analyst, and Justine Foy, Departmental Technician as the medicine profession licensing team.

COMMITTEE REPORTS

Investigations and Complaints

Rogers reported that the Investigations and Complaints Committee reviewed one hundred eight (108) files in June 2018. Sixty (60) files were authorized for investigation and forty- seven (47) files were closed. One (1) file was returned for additional records. There were three (3) reviewers.

The Investigation & Complaints Committee reviewed forty-seven (47) files in July 2018. Seventeen (17) files were authorized for investigation and thirty (30) files were closed. There were three (3) reviewers.

Arsiwala announced he appointed Cara Poland to the Investigations and Complaints Committee.

Rules Committee

MacIntosh informed that the Board the rules committee is still working on the rule set and has met twice since the last meeting.

Disciplinary Subcommittee

Johnston reported that the Disciplinary Subcommittee (DSC) met today and considered thirty-nine (39) matters: four (4) Administrative Complaints, two (2) Proposals for Decision, Twenty-six (26) Consent Orders and Stipulations, and seven (7) Requests for Dismissal.

PUBLIC COMMENT

Dr. Grace Jacek from the University of Detroit Mercy introduced herself to the Board and informed them that she brought a student with her to observe the meeting.

ANNOUNCEMENTS

The next regularly scheduled meeting will be held September 19, 2018 at 10:00 a.m., at the Ottawa Building, 611 West Ottawa Street, Upper Level Conference Center, Conference Room 3, Lansing, Michigan.

ADJOURNMENT

MOTION by Sondheimer, seconded by Sophiea, to adjourn the meeting at 12:15 p.m.

A voice vote followed.

MOTION PREVAILED

Minutes approved by the Board on: September 19, 2018.

Prepared by:
LeAnn Payne July 20, 2018
Bureau of Professional Licensing

Drug Enforcement Administration

Diversion Control: Combating the Supply

Michigan Board of Medicine Meeting
July 18, 2018

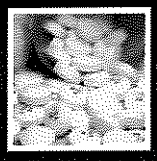
Cathy Gallagher
Diversion Program Manager
Detroit Division

DEA

Diversion Control Division

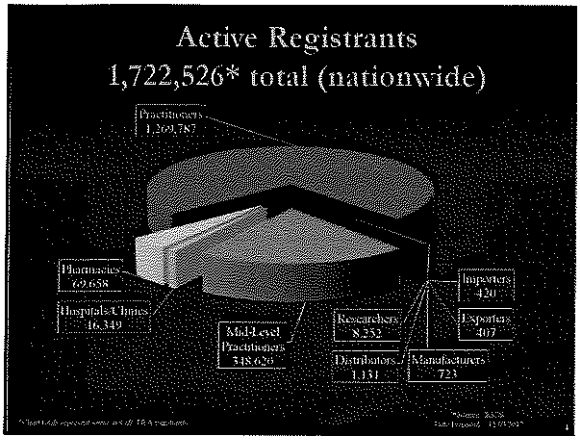
Diversion Control Division Mission

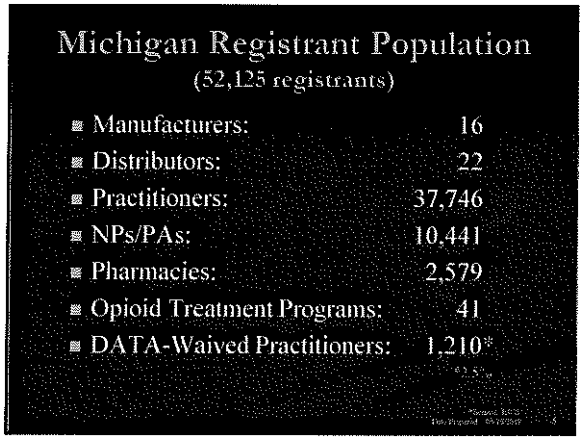
To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

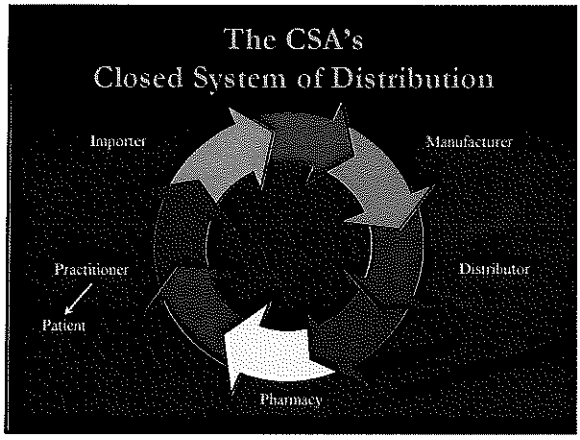


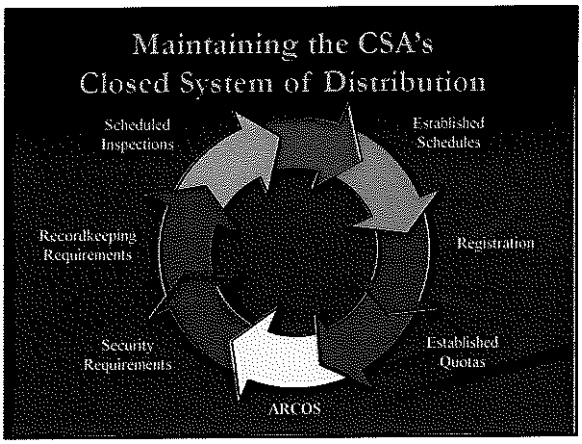
while

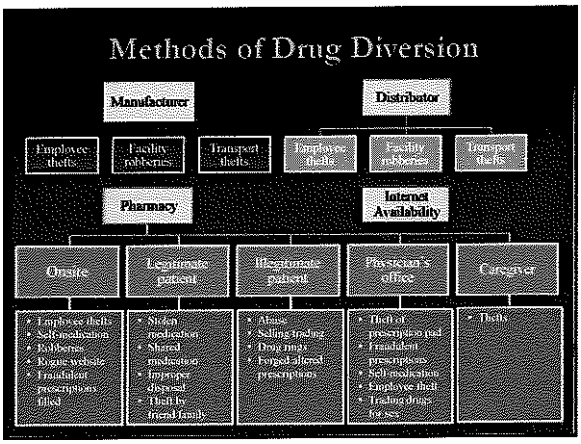
ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

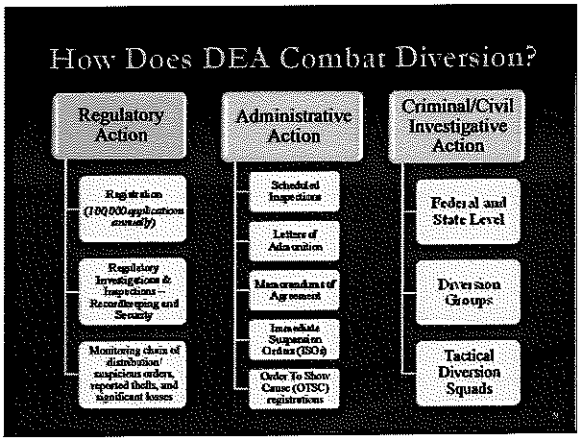

Active Registrants
1,722,526* total (nationwide)
Practitioners
1,269,787
Pharmacies
69,658
Hospitals/Clinics
16,349
Mid-Level
Practitioners
348,626
Researchers
8,252
Distributors
1,131
Manufacturers
723
Importers
420
Exporters
407

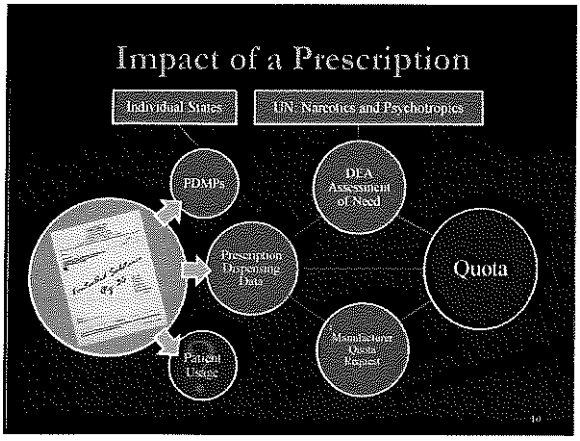

Michigan Registrant Population
(52,125 registrants)
Manufacturers: 16
Distributors: 22
Practitioners: 37,746
NPs/PAs: 10,441
Pharmacies: 2,579
Opioid Treatment Programs: 41
DATA-Waived Practitioners: 1,210*

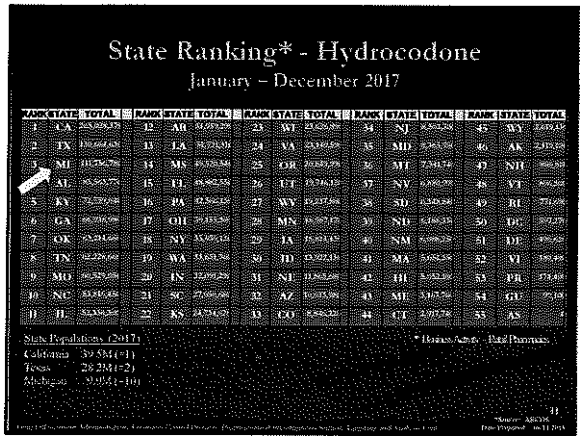

The CSA's
Closed System of Distribution
Importer
Manufacturer
Practitioner
Distributor
Patient
Pharmacy

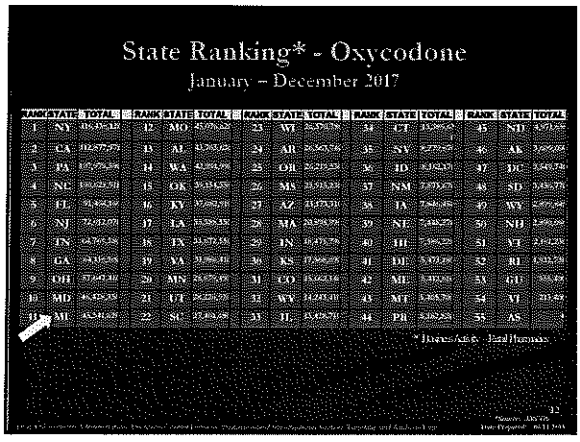

Maintaining the CSA's Closed System of Distribution
Scheduled Inspections
Established Schedules
Recordkeeping Requirements
Registration
Security Requirements
Established Quotas
ARCOS


Methods of Drug Diversion
Manufacturer
Distributor
Employee thefts
Facility robberies
Transport thefts
Employee thefts
Facility robberies
Transport thefts
Pharmacy
Internet Availability
Onsite
Legitimate patient
Illegitimate patient
Physician's office
Caregiver
• Employee thefts
• Self-medication
• Robberies
• Rogue website
• Fraudulent prescriptions filled
• Stolen medication
• Shared medication
• Improper disposal
• Theft by friend/family
• Abuse
• Selling/trading
• Drug mule
• Forged/altered prescriptions
• Theft of prescription pad
• Fraudulent prescriptions
• Self-medication
• Employee theft
• Trading drugs for sex
• Theft


How Does DEA Combat Diversion?
Regulatory Action
Administrative Action
Criminal/Civil Investigative Action
Registration (100,000 applications annually)
Regulatory Investigations & Inspections – Recordkeeping and Security
Monitoring chain of distribution/ suspicious orders, reported thefts, and significant losses
Scheduled Inspections
Letters of Admonition
Memorandum of Agreement
Immediate Suspension Orders (ISOs)
Order To Show Cause (OTSC) registrations
Federal and State Level
Diversion Groups
Tactical Diversion Squads


Impact of a Prescription
Individual States
UN: Narcotics and Psychotropics
PDMPs
DEA Assessment of Need
Prescription Dispensing Data
Quota
Manufacturer Quota Request
Patient Usage
40


State Ranking* - Hydrocodone
January – December 2017
RANK STATE TOTAL
1 CA
2 TX
3 MI
4 AL
5 KY
6 GA
7 OK
8 TN
9 MO
10 NC
11 IL
12 AR
13 LA
14 MS
15 FL
16 PA
17 OH
18 NY
19 WA
20 IN
21 SC
22 KS
23 WI
24 VA
25 OR
26 UT
27 WV
28 MN
29 IA
30 ID
31 NE
32 AZ
33 CO
34 NJ
35 MD
36 MT
37 NV
38 SD
39 ND
40 NM
41 HI
42 MA
43 ME
44 CT
45 WY
46 AK
47 NH
48 VT
49 RI
50 DC
51 DE
52 VI
53 PR
54 GU
55 AS
State Populations (2017)
California 39,584 (#1)
Texas 28,284 (#2)
Michigan 9,945 (#10)
* Dosage Units – Retail Pharmacies
31


State Ranking* - Oxycodone
January – December 2017
RANK STATE TOTAL
1 NY
2 CA
3 PA
4 NC
5 FL
6 NJ
7 TN
8 GA
9 OH
10 MD
11 MI
12 MO
13 AL
14 WA
15 OK
16 KY
17 LA
18 TX
19 VA
20 MN
21 UT
22 SC
23 WI
24 AR
25 OR
26 MS
27 AZ
28 MA
29 IN
30 KS
31 CO
32 WV
33 IL
34 CT
35 NV
36 ID
37 NM
38 IA
39 NE
40 HI
41 DE
42 ME
43 MT
44 PR
45 ND
46 AK
47 DC
48 SD
49 WY
50 NH
51 VT
52 RI
53 VI
54 GU
55 AS
* Dosage Units – Retail Pharmacies
32

State Ranking* - Oxymorphone

January – December 2017

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	TN	[illegible]	12	OK	[illegible]	23	WV	[illegible]	34	ID	[illegible]	45	MN	[illegible]
2	NC	[illegible]	13	VA	[illegible]	24	AR	[illegible]	35	DE	[illegible]	46	WY	[illegible]
3	PA	[illegible]	14	GA	[illegible]	25	WA	[illegible]	36	NV	[illegible]	47	NH	[illegible]
4	FL	[illegible]	15	OH	[illegible]	26	IL	[illegible]	37	NE	[illegible]	48	MT	[illegible]
5	MI	[illegible]	16	NJ	[illegible]	27	KS	[illegible]	38	IA	[illegible]	49	DC	[illegible]
[illegible]	NY	[illegible]	17	SC	[illegible]	28	AZ	[illegible]	39	HI	[illegible]	50	VT	[illegible]
7	CA	[illegible]	18	KY	[illegible]	29	MA	[illegible]	40	ME	[illegible]	51	RI	[illegible]
8	TX	[illegible]	19	MS	[illegible]	30	WI	[illegible]	41	NM	[illegible]	52	AS	0
9	LA	[illegible]	20	UT	[illegible]	31	CO	[illegible]	42	SD	[illegible]	53	GU	0
10	MD	[illegible]	21	MO	[illegible]	32	CT	[illegible]	43	AK	[illegible]	54	PR	0
11	AL	[illegible]	22	IN	[illegible]	33	OR	[illegible]	44	ND	[illegible]	55	VI	0

* Business Activity - Retail Pharmacies

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*Source: ARCOS

State Ranking* - Methadone

January – December 2017

RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL	RANK	STATE	TOTAL
1	CA	[illegible]	12	OH	[illegible]	23	IN	[illegible]	34	NV	[illegible]	45	ND	[illegible]
2	FL	[illegible]	13	NJ	[illegible]	24	MN	[illegible]	35	CO	[illegible]	46	DE	[illegible]
3	NY	[illegible]	14	VA	[illegible]	25	IL	[illegible]	36	CT	[illegible]	47	SD	[illegible]
4	MI	[illegible]	15	MO	[illegible]	26	TN	[illegible]	37	IA	[illegible]	48	NM	[illegible]
[illegible]	TX	[illegible]	16	KY	[illegible]	27	KS	[illegible]	38	HI	[illegible]	49	WY	[illegible]
6	PA	[illegible]	17	LA	[illegible]	28	SC	[illegible]	39	AK	[illegible]	50	DC	[illegible]
7	GA	[illegible]	18	AR	[illegible]	29	WI	[illegible]	40	NE	[illegible]	51	RI	[illegible]
8	NC	[illegible]	19	OK	[illegible]	30	MS	[illegible]	41	ME	[illegible]	52	PR	[illegible]
9	AL	[illegible]	20	UT	[illegible]	31	ID	[illegible]	42	NH	[illegible]	53	GU	[illegible]
10	WA	[illegible]	21	MA	[illegible]	32	AZ	[illegible]	43	VT	[illegible]	54	VI	[illegible]
11	MD	[illegible]	22	OR	[illegible]	33	WV	[illegible]	44	MT	[illegible]	55	AS	0

* Business Activity - Retail Pharmacies

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*Source: ARCOS

Medication-Assisted Treatment

Federal Requirements

Opioid Treatment Programs (OTPs)

- **Registration**:
  - *State (OTP)*
  - *DEA*
    - *Dispensing (methadone, buprenorphine)*
- **Recordkeeping**:
  - *Accountability*

DATA-Waived Physicians (DWPs)

- **Registration**:
  - *Medical Board*
  - *LARA*
  - *DEA*
- **Process**
  - *Apply to CSAT*
    - *Verify training*
  - *DEA issues UIN*
- **Recordkeeping**:
  - *Prescription requirements*
  - *Accountability*

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Obtaining a DATA Waiver: Physicians

- Under Drug Addiction Treatment Act of 2000 (DATA 2000), qualified physicians may apply for waivers to treat opioid dependency with approved buprenorphine products in any setting in which they are qualified to practice.
- A "qualified physician," as defined by DATA 2000, is:
  - Licensed under state law
  - Registered with DEA to dispense controlled substances
  - Required to treat no more than 30 patients at a time within the first year
  - Qualified by training and/or certification
- To maintain a waiver, a physician must also be capable of referring patients to counseling and other services

Source: SAMHSA (2016) 36

DATA Waivers

- Approximately 2.5% of Michigan practitioners are DATA-waived
- Learn more about buprenorphine and how to qualify for a physician waiver at:
  - https://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver

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Obtaining a DATA Waiver: NPs and PAs

- The Comprehensive Addiction and Recovery Act (CARA) extends buprenorphine prescribing privileges in office-based settings to qualified NPs and PAs until October 1, 2021.
- NPs and PAs must complete 24 hours of required training and can treat up to 30 patients.
- NPs and PAs may send copies of their training certificates to infobuprenorphine@samhsa.hhs.gov or fax them to 301.576.5237.
- SAMHSA forwards waiver applications to the DEA, which will assign the NP or PA a special identification number. All buprenorphine prescriptions for opioid dependency treat must include this specialized number.

Source: SAMHSA (2016) 38

Obtaining a DATA Waiver

SAMHSA verifies physician requirements

DEA assigns a special identification number in addition to a physician's regular DEA number

Individual physician can apply to treat:

Year 1: up to 30 patients | Year 2: up to 100 patients | Year 3 + beyond: up to 275 patients

Source: SAMHSA (2016)

DEA Application and Renewal

Registrants

Registrant is a term used to describe an individual or business entity that holds a DEA registration number authorizing the handling of controlled substances and/or List 1 chemical products.

Combined, they are often referred to as the *regulated community*.

Mid-Level Practitioners

Under the Controlled Substance Act (CSA), the term "mid-level practitioner" (MLP) means an individual practitioner other than physician, dentist, veterinarian, or podiatrist, who is licensed, registered, or otherwise permitted by the United States or jurisdiction in which he/she practices, to dispense administer, and prescribe a controlled substance in the course of professional practice.

Examples include:

Nurse Practitioners	Physician Assistants	Optometrists
Registered Pharmacist	Medical Psychologist	Nursing Home
Homeopathic Physician	Naturopathic Physician	Doctors of Oriental Medicine
Ambulance Service	Animal Shelter	Euthanasia Technicians

Registration with DEA is not required for a MLP who only administers controlled substances on behalf of a registered practitioner so long as the activity is in the practitioner's presence.

Separate Registrations for Separate Locations

CFR 1301.12:

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person.

Obtaining Applications

- **ON-LINE:** submitted via the DEA Diversion website at: www.deadiversion.usdoj.gov

  (only 225, 363, & 510 applications can be downloaded)
  DEA Form 224 and 224a *cannot* be downloaded

- **PAPER FORMS:** obtained by calling 800-882-9539 or by writing to:

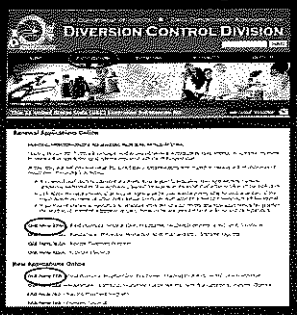
  DEA Headquarters
  Attn: Registration Section/ODR
  PO Box 2639
  Springfield, VA 22152-2639

Application for Registration

CFR 1301.13:

- Applications may be submitted anytime.
- Applicant must receive approval and certificate before engaging in business
- Renewal applications: accepted within 60 days of expiration for most registrants; bulk manufacturers and importers may renew within 120 days of expiration
- Registration period
- Registration fees

Application for Registration



www.deadiversion.usdoj.gov

Modification in Registration

CFR 1301.51:

Any registrant may apply to modify his/her registration to authorize the handling of additional controlled substances or to change his/her name or address, by submitting a letter of request to the Registration Unit, DEA.

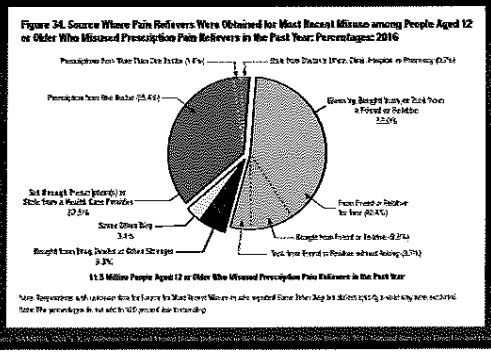
- Letter must include: registrant's name, address, and registration number as printed on the certificate of registration, and the substances and/or schedules to be added to his/her registration or the new name or address.
- Letter shall be signed in accordance with Sec.1301.13(j).
- Mailing addresses can be found in Sec. 1321.01.

Renewal Applications

- Mailed 60 days prior to expiration of current registration
- Mailed to bulk manufacturers 120 prior to expiration of current registration
- If registrant does not receive renewal application within 45 days of expiration date, registrant must notify, in writing, the Registration Unit of the Administration at the address previously noted.

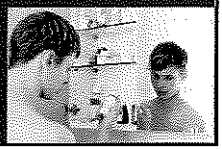
Secure and Responsible Drug Disposal Act of 2010

Sources of Supply



Medicine Cabinets: Easy Access

- More than half of teens (73%) indicate that it is easy to get prescription drugs from their parent's medicine cabinet
- Half of parents (55%) say anyone can access their medicine cabinet
- Almost four in 10 teens (38%) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet



Source: 2013 Partnership Attitude Tracking Study (2014)

Patient Education

Monitor
- Note how many pills are in your home
- Keep track of refills
- Control drugs prescribed to teens
- **NEVER** share

Secure
- Protect prescriptions like valuables
- Secure medication in a place only you know about

Dispose
- Properly dispose of unused or expired medicine

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Why Security and Disposal Matter

Accidental Use
- Approxunlldy 60,000 department visits ay=by cliil.&cn wider5 .are:aresult of unintentional medication ovecdoses

Intentional Misuse
- Prescription drugs canbe misused to get high
- Can lead to development of clmmi, sulmance abuse dison:ler
- **Primary source: medicine cabinets**

Health Risks
- **Different dosage: Medications are prescribed on a per-patient basis; sharing is never safe**
- **The safety or ingredients of shared medications cannot be guaranteed**

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Resources for Drug Disposal

- DEA Diversion website: www.deadiversion.usdoj.gov (click "Drug Disposal Information," then "Search for an Authorized Collector Location")
- Rx Drug Drop Box: www.rxdrugdropbox.org
- Dispose My Meds: www.disposemymeds.org
- U.S. Food and Drug Administration: www.fda.gov (search "disposal")

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Collection Receptacle Locations

Search for a disposal location online at: apps.deadiversion.usdoj.gov/pubdispsearch

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Disposal for Practitioners

- Promptly destroy controlled substance in accordance with 21 CFR § 1317.05(a) using an on-site method of destruction;
- Promptly deliver controlled substance to a DEA-registered reverse distributor by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;
- For returns or recalls: promptly deliver controlled substance to the registered person from whom it was obtained, the registered manufacturer of the substance, or other registrant authorized by the manufacturer to accept returns/recalls on manufacturer's behalf
- Request assistance from the Special Agent in Charge of the Administration in the area where the practitioner is located.

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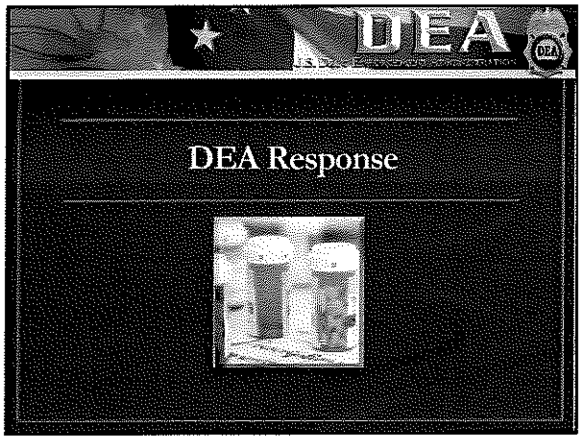
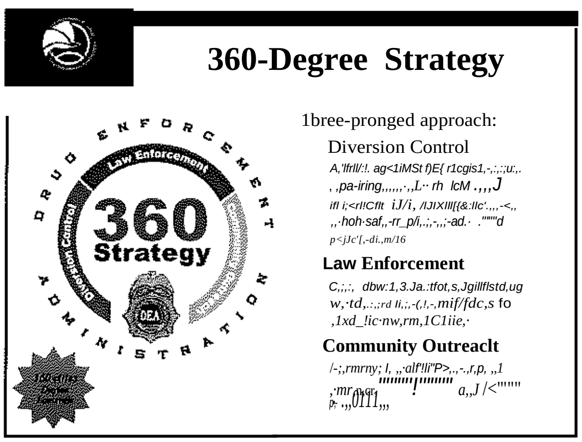
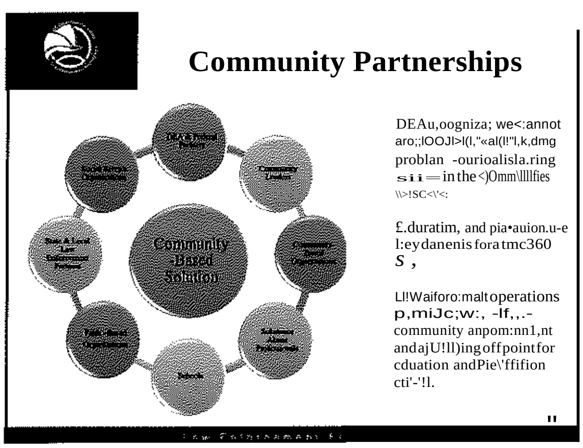
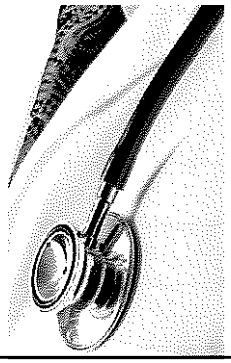

DEA
DEA Response


360-Degree Strategy
Diversion Control
Law Enforcement
Community Outreaclt
360
Strategy
DRUG ENFORCEMENT ADMINISTRATION


Community Partnerships
Community Based Solution

Registrant Outreach Initiatives

- Physician training
- Pharmacy outreach initiative



Comments / Questions?

U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Contact Information

- Complaints
  - Local Police: Immediate threats to human health/safety
  - Consumer complaints (LARA): 517-373-9196; BPLhelp@michigan.gov
  - DEA: Report prescription drug diversion by doctor/pharmacy www.deadiversion.usdoj.gov/tips_online.htm
  - HHS: Hotline 1-800-HHS-TIPS; OIG.HHS.gov/report-fraud
- State PDMP
  - Michigan Automated Prescription System (MAPS) help: www.michigan.gov/mimapsinfo
- Recovery
  - 1-800-662-HELP (4357)
  - https://findtreatment.samhsa.gov