BUPRENORPHINE 201: IHRC SUMMIT 2019

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Tony Miller, MD
Andrea Weber, MD
Monica Wilke-Brown, LMSW
OUTLINE - 1:00 PM TO 5:00 PM

- Buprenorphine Review
- Updates in Buprenorphine: Populations, Maintenance Treatment, Chronic Pain
- Cases for Small Group Discussions

***Break***

- Harm Reduction in Clinical Practice
- IDPH Presentation – Treatment Programs
- Policy and Advocacy Breakout Discussions
581 MEN WITH HEROIN ADDICTION FOLLOWED 33 YEARS

Hser et al., 2001
OPIOID EPIDEMIC: 2\textsuperscript{ND} AND 3\textsuperscript{RD} WAVES

Drugs Involved in U.S. Overdose Deaths, 1999 to 2017

- Synthetic Opioids other than Methadone, 23,496
- Heroin, 15,958
- Natural and semi-synthetic opioids, 14,958
- Cocaine, 14,556
- Methamphetamine, 10,721
- Methadone, 3,295

Early addiction driven by REWARD

Late addiction driven by PUNISHMENT
high

normal

sick

Time →

Slide: A Miller (not part of PCSS training)
**MAJOR FEATURES OF METHADONE**

**Full Agonist at mu receptor**

**Long acting**
- Half-life ~ 15-60 Hours

**Weak affinity** for mu receptor
- Can be displaced by partial agonists (e.g. buprenorphine) and antagonists (e.g. naloxone, naltrexone), which can both precipitate withdrawal

**Monitoring**
- Significant respiratory suppression and potential respiratory arrest in overdose
- QT prolongation

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CSAT, 2005
**Partial agonist** at mu receptor
- Comparatively minimal respiratory suppression and no respiratory arrest when used as prescribed

**Long acting**
- Half-life ~ 24-36 Hours

**High affinity** for mu receptor
- Blocks other opioids
- Displaces other opioids
  - Can precipitate withdrawal

**Slow dissociation** from mu receptor
- Stays on receptor for a long time
**MAJOR FEATURES OF NALTREXONE**

**Full Antagonist** at mu receptor
- Competitive binding at mu receptor

**Long acting**
- Half-life:
  - Oral ~ 4 Hours
  - IM ~ 5-10 days

**High affinity** for mu receptor
- Blocks other opioids
- Displaces other opioids
  - Can precipitate withdrawal

**Formulations**
- Tablets: Revia®: FDA approved in 1984
- Extended-Release intramuscular injection: Vivitrol®: FDA approved in 2010

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[Graph showing dose vs. mu opioid effects with arrows indicating full agonist (e.g., morphine, methadone), partial agonist (buprenorphine), and antagonist (naloxone, naltrexone).]

SAMHSA, 2018
What is the primary reason buprenorphine is combined with naloxone?

A. To increase opioid blockade
B. To prevent overdose
C. To reduce diversion
D. To lower the euphoric effects of buprenorphine
UPDATES IN BUPRENORPHINE

Special Populations – Pregnancy, Adolescents
Maintenance treatment – Dosing, Duration
Chronic pain
Pregnancy Topics

Pilot Study
Naltrexone Treatment for Pregnant Women With Opioid Use Disorder Compared With Matched Buprenorphine Control Subjects

- Wachman, Elisha M. et al., Clinical Therapeutics, in press (2019)
- Single site, retrospective cohort study of 19 mother-infant dyads taking NTX(6) or BUP(13), compared pregnancy and infant outcomes

- Findings: 0 infants in the NTX group had NAS, 92% of infants in BUP group had NAS, no other statistically significant differences found
Receipt of Timely Addiction Treatment and Association of Early Medication Treatment With Retention in Care Among Youths With Opioid Use Disorder

Scott E. Hadland, MD, MPH, MS; Sarah M. Bagley, MD, MSc; Jonathan Rodean, MPP; Michael Silverstein, MD, MPH; Sharon Levy, MD, MPH; Marc R. Larochelle, MD, MPH; Jeffrey H. Samet, MD, MA, MPH; Bonnie T. Zima, MD, MPH

**Treatment retention:**
- 123 days (BUP), 150 days (NTX), 324 days (MMT),
- 67 days (no MAT).
- Any medication improved retention better than behavioral health services alone.

Few studies on medications for OUD in adolescents.

- MMT appears to promote treatment retention with heroin use disorders.
- BUP improves likelihood of abstinence from opioids and treatment retention.
- Limited data suggests NTX is safe and feasible for adolescents.

- **Risks of untreated OUD FAR OUTWEIGH the risks of any of the medications.**
**DURATION OF TREATMENT**

- Controlled trials comparing durations of buprenorphine treatment uniformly support longer treatment over shorter treatment
  - POATS main trial 12 wk > 4 wk (Weiss & Rao *Drug Alc Dep* 2017; 273:S48-54)
  - Yale primary care 14 wk > 4 wk (Fiellin et al *JAMA IM* 2014; 174: 1947-1954)

- Improved outcomes in consistent treatment over a year vs. shorter or discontinuous treatment.
  - Pennsylvania Medicaid Observational Data (Lo-Ciganic et al *Addiction* 2016; 111:892–902)

- What about longer than a year? How much longer?
# Duration of Treatment

<table>
<thead>
<tr>
<th>Study</th>
<th>Follow-up</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>POATS Follow-up Study (Weiss &amp; Rao <em>Drug Alc Dep</em> 2017; 273:S48-54)</td>
<td>3.5 year</td>
<td>“80% of participants receiving opioid agonist treatment at both months 18 and 42 had abstained from illicit opioids in the previous month, compared to abstinence rates of 37% and 50% among those not receiving agonist treatment at months 18 and 42, respectively”</td>
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<tr>
<td>French primary care, buprenorphine (Dupuoy et al <em>Ann Fam Med</em> 2017; 15:355-358)</td>
<td>7 year</td>
<td>Mean duration of treatment: 680 days “ Compared with being in treatment, being out of treatment was associated with a markedly increased risk of death (hazard ratio = 29.04)”</td>
</tr>
<tr>
<td>START Study, methadone vs buprenorphine (Hser et al <em>Addiction</em>. 2016; 111:695–705)</td>
<td>2-8 year</td>
<td>Treatment with methadone or buprenorphine associated with decreased opioid use compared to not in treatment</td>
</tr>
</tbody>
</table>
MAINTENANCE DOSE

• Too little dose – too early discontinuation? (Observational study n=89)
  • Muruganadam et al *Asian J Psychiatry* 2019; 44:58-60
  • Treatment adherence 3 times higher on ≥ 6 mg/day compared to < 6 mg/day in initial 6 weeks of treatment.

• Review of claims data (2982 matched pairs drawn from pop of 15206)
  • Khemiri et al *Postgraduate Medicine* 2015; 126:113-120
  • >15 mg per day “had a significantly lower probability of discontinuing treatment, lower probability of psychiatric hospitalizations, and fewer inpatient psychiatric hospitalization days compared with lower dosed patients.”
Additional research is required:

- Ideal length of treatment with opioid agonists
- Optimal tapering strategies after long-term remission and wish to discontinue agonist treatment
- Efficacy of non-pharmacotherapy treatment options (including residential treatment).
CHRONIC PAIN

- “Legacy patients” – chronic opioid use, without obvious use disorder, prior to new CDC opioid prescribing guidelines 2016

- Offer/recommend taper strategy to balance benefits vs harms
  - Reduce risk vs taper to discontinuation

- Pain often does not worsen and often decreases
  - Opioid induced hyperalgesia, sedation, mood effects
  - Taper individually and add adjunctive therapy PRN to minimize withdrawal
  - Abrupt withdrawal: pain, insomnia, dysphoria, suicidality

CHRONIC PAIN - BUPRENORPHINE

- Transdermal and Buccal forms – FDA approved for moderate-to-severe chronic pain
- All other versions of buprenorphine – off-label for chronic pain
- If using buprenorphine ONLY for chronic pain (without an opioid use disorder), do NOT need a DATA waiver.
- Subjective improvements in pain, function, sleep, and constipation.
- Kappa opioid receptor antagonism – anti-anxiety/anti-depressant properties?

OVERALL: Buprenorphine similar in outcomes as other opioids with chronic pain, but with better side effect profile reduced harm.

- Considerations of transitioning to/using buprenorphine for pain:
  1. Not tolerating opioid taper
  2. Risk of use disorder in someone with indications for buprenorphine
  3. Medical co-morbidities increasing overdose risk
  4. Multiple side effects from chronic opioid use
  5. Non-adherence to the treatment plan
  6. Concern for hyperalgesia in current opioid plan
  7. Patient preference

Babu et al. NEJM 2019.
# MAT and Pregnancy

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<th>Methadone</th>
<th>Buprenorphine</th>
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<tbody>
<tr>
<td>Can be used in pregnancy?</td>
<td>Yes</td>
<td>Yes (with or without naloxone)</td>
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<tr>
<td>Dose adjustments?</td>
<td>May need to split and/or increase</td>
<td>May need to split and/or increase</td>
</tr>
<tr>
<td>Delivery issues?</td>
<td>Epidural ok; anesthesia should be aware if c-section; routine post-op pain management</td>
<td>Epidural ok; anesthesia should be aware if c-section; could increase buprenorphine if needed for post-op pain mgmt</td>
</tr>
<tr>
<td>Neonatal withdrawal?</td>
<td>Yes</td>
<td>Milder, shorter</td>
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<tr>
<td>Breastfeeding?</td>
<td>Yes</td>
<td>Yes</td>
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</tbody>
</table>

It is NOT recommended to stop or switch MAT treatment during pregnancy.
SMARTPHONE APP: BUPRENORPHINE HOME INDUCTION

Frequently Asked Questions

- Buprenorphine is used in medication-assisted treatment (MAT) to help people reduce or quit their use of heroin or other opioids, such as pain relievers like morphine.
- How does buprenorphine work?
- What are the side effects of buprenorphine?
- Is there a potential for misuse?
- Who is the ideal candidate to take buprenorphine?
- What are the safety precautions?
- Should I take buprenorphine if I am pregnant or breastfeeding?
- How many phases of buprenorphine treatment are there?
- Which phases of buprenorphine treatment does this app focus on?

What's New

Version 1.1
7mo ago

General Updates

Preview

Day 1
I started taking buprenorphine yesterday.

Day 2
I started taking buprenorphine at least two days ago.

Day 3+

You’ve taken 0mg of buprenorphine today.
FENTANYL

- High potency, synthetic opioid
- Strong receptor affinity
- Half life is ~7 hours
- Lipophilic, can build up in adipose tissue

**Pearl:** Despite the short half-life, the high potency and lipid storage of fentanyl can lead to ongoing withdrawal symptoms during buprenorphine induction that can last for days to a week.
ATYPICAL OPIOIDS: TRAMADOL

- A synthetic 4-phenyl-piperidone analogue of codeine
- Opioid agonist, also inhibits noradrenaline and serotonin reuptake

**Pearls:** Opioid withdrawal syndrome + SNRI-like withdrawal syndrome
**ATYPICAL OPIOIDS: KRATOM**

- A tropical tree, native to Southeast Asia; leaves are swallowed/chewed/smoked/brewed
- Readily available to order on internet, not currently illegal
- Opioid like effects at lower dose
- Stimulant like effects at higher dose
- No treatments have been tested for treatment of kratom addiction

**Pearl:** Very short acting
Full agonist (e.g. morphine, methadone)

Partial agonist (buprenorphine)

Antagonist (naloxone, naltrexone)

- Methadone 30 mg/day (ish)
- Methadone 100 mg/day
Reminder that all of these can cause repolarization delay (QT prolongation):

- Methadone
- Citalopram
- Hydroxyzine
How long should someone stay on MAT?
FAQ’S

What if my patient on buprenorphine has a positive urine toxicology for:

- Cocaine?
- Marijuana?
- Another opioid?
FAQ’S

▪ What do I need to know about Prior Authorizations?
HARM REDUCTION IN CLINICAL PRACTICE WITH BUPRENORPHINE
Learning about treatment options
- Access to information
- Online, easy navigation
- Does not require case manager/referral

Finding treatment
- Options
- Transportation accessible
- Allow for work, childcare, etc.

Going to treatment
- Walk-in availability, realistic hours
- Applications? Approvals prior to starting?
- Case manager support over barriers

Providers
- Abstinence required?
- Participate only when sober?
- Individualize treatment plan/goal
- Therapy required for other services (medications)
CLINICAL HARM REDUCTION STRATEGIES

- Patient-dictated therapeutic focus and goals of care along a continuum
- Investigate the “whys” of different drug use
- Focus on patient’s relationship with the drug (vs. the person or the drug)
- Education about safe injection practices
- Provide culturally competent educational materials
- Be affirming of goals, resilience, and successes to date
- Encourage drug checking
- Ensure naloxone availability (prescription, IHRC contact)
Harm Reduction Continuum

— Substance use and behaviors occur along a continuum from no use to chaotic use

Adapted from Patti Denning's book "Practicing Harm Reduction Psychotherapy"
CLINICAL HARM REDUCTION STRATEGIES

- Any Positive Change
- Do NOT require participation in 12-step fellowships
- Use non-stigmatizing language
- Investigate past experiences with healthcare providers – boundaries, relationship building
- Clarify re: patient health information accessibility – Insurance? Family? Law enforcement?
- Eliminate rules for engagement – unconditional regard and support
- Investigate reasons for any hostility, anger, silence, etc. openly and honestly
# Language Matters

**Language is powerful**—especially when talking about alcohol and other drugs and the people who use them. Stigmatizing language reinforces negative stereotypes.

*Person-centred* language focuses on the person, not their substance use.

## 4 Guidelines to Using Non-Stigmatizing Language

1. **Use People-first language**
   - **Person who uses opioids**
     - **VS.** Opioid user OR Addict
   - **Person experiencing problems with substance use**
     - **VS.** Abuser OR Junkie

2. **Use language that reflects the medical nature of substance use disorders**
   - **Person experiencing barriers to accessing services**
     - **VS.** Unmotivated OR Non-compliant

3. **Use language that promotes recovery**
   - **Positive test results** OR **Negative test results**
     - **VS.** Dirty test results OR Clean test results

4. **Avoid slang and idioms**
   - **Drug use, non-prescribed use**
     - **VS.** Abuse, misuse, problem use, non-compliant use
   - **Person who uses/injects drugs**
     - **VS.** Drug user, drug abuser
   - **Person with a dependence on...**
     - **VS.** Addict, junkie, drug user, alcoholic
   - **Person experiencing drug dependence**
     - **VS.** Struggling with addiction, has a drug problem
   - **Person who has stopped using drugs**
     - **VS.** Clean, sober, drug-free
   - **Person with lived experience of drug dependence**
     - **VS.** Ex-Addict, former addict, used to be a...
   - **Person disagrees**
     - **VS.** Unwilling, resistant, uninterested
   - **Treatment has not been effective/doesn’t work**
     - **VS.** Drug resistant, non-compliant
   - **Person’s needs are not being met**
     - **VS.** Drug resistant, manipulative, quitting
   - **Currently using drugs**
     - **VS.** Using again, fallen off the wagon, had a relapse
   - **No longer using drugs**
     - **VS.** Clean, dry, maintained recovery
   - **Positive/negative urine drug screen**
     - **VS.** Clean urine, drug-free
   - **Used/unused syringes**
     - **VS.** Clean needles, dirty
   - **Pharmacotherapy is treatment**
     - **VS.** Replacing one drug for another

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*Adapted from Non-Language: Patients from the National Council on Alcoholism and Drug Abuse and Health, United States (2002) and Mataro, Bali, New Zealand (2006)*

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NALOXONE

- Likely responsible for the reduction in opioid overdose deaths in 2018
- Offer it to all of your patients
- Higher doses than usual or repeat dose may be needed, especially if the person has been exposed to fentanyl

- What do you tell your patients about how to get naloxone?
- What do you tell your patients about how to use naloxone?
SAFER INJECTING COUNSELING

- Demonstrates nonjudgemental care, compassion, and overall concern for safety
- Helps establishes trust in treatment relationship
- Education frames around existing practices and knowledge of the patient

Basics:
1. Frequency of injection use
2. Site of injection use
3. Needle type (gauge, length)
4. Tourniquet used? How?
5. Injection angle
6. Filtering practices
7. Sterile injection practices
8. Managing inflammation after a “miss”
IDPH — TREATMENT PROGRAMS

Monica Wilke-Brown, LMSW
Treatment Program Directors
Iowa Prescription Monitoring Program (PMP) Opioid prescriptions per 100 people in 2018

Prescriptions / 100 persons:
- 0 - 34.0[16]
- 34.1 - 61.1[56]
- 61.2 - 69.2[9]
- 69.3 - 76.9[9]
- 77.0 - 91.2[6]
- 91.3 - 96.7[3]

Iowa Department of Public Health, 2019
State of Iowa, Opioid Related Death Rate Per 100,000 Persons, 2015-2017

Deaths / 100K persons
- 0 [26]
- 0.1 - 2.9 [19]
- 3.0 - 4.8 [23]
- 4.9 - 8.5 [24]
- 8.6 - 13.2 [7]

Iowa Department of Public Health, 2019
"Unfortunately, when relapse occurs many deem treatment a failure. This is not the case: Successful treatment for addiction typically requires **continual evaluation and modification** as appropriate, similar to the approach taken for other chronic diseases."

ADDITIONAL GRANT FUNDED EFFORTS

- RFPs currently open on Iowagrants.gov
- National Governor’s Association Learning Lab on working with DOC to improve buprenorphine access
- Integrated Provider Network MAT access/capacity building, staff and community trainings
- Naloxone distribution: Tele-Naloxone partnership with UIHC Specialty Pharmacy
- Statewide Media campaigns
yourlifeiowa.org

Supporting your life.

24/7

YourLifeIowa.org / 855.581.8111
<table>
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<tr>
<th>Service Area</th>
<th>Contractor</th>
<th>Service Area</th>
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<td>1</td>
<td>Jackson Recovery Centers, Inc., Spencer</td>
<td>13</td>
<td>Crossroads Behavioral Health Services, Creston (4)</td>
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<tr>
<td></td>
<td>Phone: 800-472-9018</td>
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<td>Phone: 641-782-8457</td>
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<td>Prairie Ridge Integrated Behavioral Healthcare, Mason City (1)</td>
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<td>Broadlawns Medical Center, Des Moines (1)</td>
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<td></td>
<td>Phone: 866-429-2391</td>
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<td>Phone: 515-282-6610</td>
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<td>Northeast Iowa Behavioral Health, Decorah (4)</td>
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<td>House of Mercy, Des Moines (1,3)</td>
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<td></td>
<td>Phone: 800-400-8923</td>
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<td>Phone: 515-643-6500</td>
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<td>Prelude Behavioral Services, Des Moines (1)</td>
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<td>Phone: 800-472-9018</td>
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<td>Phone: 515-262-0349</td>
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<td>Community Opportunities DBA New Opportunities, Carroll</td>
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<td>UCS Healthcare, Des Moines (4)</td>
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<td>Phone: 712-792-9266</td>
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<td>Phone: 515-280-3860</td>
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<td>House of Mercy, Newton (1)</td>
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<td>Phone: 866-801-0085</td>
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<td>Phone: 641-792-0717</td>
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<td>7</td>
<td>Substance Abuse Treatment Unit of Central Iowa, Marshalltown</td>
<td>15</td>
<td>UCS Healthcare, Knoxville</td>
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<td></td>
<td>Phone: 641-752-5421</td>
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<td>Pathways Behavioral Services, Inc., Waterloo (1, 4)</td>
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<td>Southern Iowa Economic Development Association (SIEDA), Ottumwa (4)</td>
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<td>Phone: 319-235-6571</td>
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<td>Phone: 800-622-8340</td>
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<td>Substance Abuse Services Center (SASC), Dubuque</td>
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<td>Prelude Behavioral Services, Iowa City (1)</td>
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<td>Phone: 563-582-3784</td>
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<td>Phone: 319-351-4357</td>
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<td>Area Substance Abuse Council, Inc. (ASAC), Cedar Rapids (1, 2, 3, 4)</td>
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<td>Alcohol &amp; Drug Dependency Services (ADDS), Burlington (1, 4)</td>
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<td>Phone: 319-390-4611</td>
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<td>Center for Alcohol &amp; Drug Services, Inc. (CADS), Davenport (1)</td>
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<td>Phone: 563-322-2667</td>
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<td>Zion Recovery Services, Inc., Atlantic (1), Phone: 712-243-5091</td>
<td>19</td>
<td>Robert Young Center, Muscatine, Phone: 563-264-9409 (4)</td>
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Additional Specialized Treatment Statewide Services
(1) Adult Residential Treatment  (2) Juvenile Residential Treatment  (3) Women and Children Treatment  (4) Methadone Treatment

*The IPN contractors (providers) are funded by IDPH to provide substance use and problem gambling services to eligible Iowans. For more information about the providers listed, click on the provider name or call the phone numbers listed. For more information about other treatment and prevention programs visit: [http://www.yourlifeiowa.org/finder](http://www.yourlifeiowa.org/finder). September 2019
IOWA'S GOOD SAMARITAN LAW PROTECTS YOU

DON'T RUN CALL 911!

IF YOU WITNESS A DRUG OVERDOSE

GENERALLY, YOU CANNOT BE ARRESTED, CHARGED OR PROSECUTED FOR:

- Possession of a controlled, dangerous substance
- Possession or use of drug paraphernalia, and
- Calling 911 WILL NOT affect your parole or probation status

Iowa's law does not protect against arrest for open warrants and crimes not listed above.
For additional details regarding Iowa's Good Samaritan Law, see Iowa Code Sections 120.418.

FOR MORE INFORMATION VISIT YourLifelowa.org

September 2018
Thanks to Maryland Department of Health
POLICY AND ADVOCACY BREAKOUT SESSIONS

Payor/Medicaid
Department of Corrections
Emergency/Inpatient Hospital roles
Current Waiver Requirements
POLICY AND ADVOCACY

1. Payor/Medicaid
2. Department of Corrections
3. Emergency/Inpatient Hospital roles
4. Current Waiver Requirements
MEDICAID PRIOR AUTHORIZATION

- Sample forms.

- Experience?
- Barriers?
- Revisions?
- Other payor issues?

- States without Prior Authorization: New York
DEPARTMENT OF CORRECTIONS

- Continuing medications for opioid use disorders
- Starting medications in jail/prison
- Starting/continuing medications in halfway housing
- Attitudes of corrections officers re: medications for opioid use disorders
UIHC ED INDUCTION PROTOCOL

- Sample protocol.

- Screening for opioid use disorders and severity
- 24/7 access to induction on buprenorphine
- 2 weeks supply via Zubsolv company coupon
- Follow-up in UIHC MAT Clinic as soon as possible
CURRENT DEA WAIVER REQUIREMENTS

- DATA 2000
- CARA 2016
- SUPPORT 2018
Allowed certified physicians to prescribe and dispense opioid use disorders with Schedule III, IV, and V medications that have FDA-approval for treatment of OUD in treatment setting outside of an opioid treatment program (OTP).

- Requires state medical license, DEA registration number, specialty/subspecialty within ABMS, ASAM, or AOA
- 8 hours training from a certified provider, application for new DEA number
- Treat up to 30 patients with opioid use disorder within first year
- After 1 year, can apply to have limit increased to 100 patients
Expanded prescribing privileges to NPs and PAs for 5 years (until 2021).
- 24 hours of training
- Supervised by/work with qualifying physician as per state law

Excluded patients getting buprenorphine directly administered from patient limit
- i.e. OTP patients receiving directly administered buprenorphine
Expanded qualifying practitioners to certified nurse midwives, clinical nurse specialists, certified registered nurse anesthetists
- 24 hours of training

All qualified practitioners can treat up to 100 patients in the first year if:
- They are board-certified in addiction medicine or addiction psychiatry –OR-
- They provide MAT in a qualified practice setting

After 1 year, qualified practitioners can request permission to treat up to 275 patients if:
- They have maintained the 100-patient limit waiver for at least 1 year –AND-
- They are board certified in AP or AM –OR- provide MAT in a qualified practice setting –AND-
- They have not had Medicare enrollment and billing privileges revoked
QUALIFIED PRACTICE SETTING?

- Provides **professional coverage for patient medical emergencies** during hours when the practitioner's practice is closed.

- Provides access to **case-management services** for patients including referral and follow-up services for programs that provide, or financially support, the provision of services such as medical, behavioral, social, housing, employment, educational, or other related services.

- Uses health information technology systems such as **electronic health records**.

- Is registered for their State prescription drug monitoring program (**PDMP**) where operational and in accordance with Federal and State law.

- Accepts **third-party payment** for costs in providing health services, including written billing, credit, and collection policies and procedures, or Federal health benefits.
THANK YOU FOR ATTENDING!!!