# Department of Defense (DoD)
# Opioid Prescriber Safety Training (OPST)Program:

# Risk Mitigation

# Presenter

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Department of Rehabilitation Medicine

Interdisciplinary Pain Management Center

Madigan Army Medical Center

Joint Base Lewis-McChord, Wash.

# Diane Flynn, M.D., M.P.H

- Dr. Flynn is a Family Physician in the Department of Rehabilitation Medicine at the Interdisciplinary Pain Management Center at Madigan Army Medical Center (MAMC).
- Point of Contact for the MAMC Opioid Education and Naloxone Distribution Training Program.
- Serves on the Controlled Substance Review Board at MAMC.
- Received her Medical Doctorate at Sydney Kimmel Medical College at Thomas Jefferson University in Philadelphia, PA.
- Completed her Family Medicine residency at Christiana Care in Wilmington, DE. Masters of Science in Epidemiology at Johns Hopkins, University in Baltimore, MD. Masters of Public Health at the University of Washington in Seattle, WA.

# Disclosures

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# Learning Objectives

At the conclusion of this activity, participants will be able to:

1. List opioid risk mitigation recommendations and increase use of risk mitigation tools and resources.
2. Explain key components of the Opioid Overdose Education and Naloxone Distribution (OEND) efforts to increase availability to naloxone to patients at risk.
3. Comprehend when an active duty beneficiary's controlled substance prescription will expire according to the new DoDI 1010.16.
4. Compare opioid safety and naloxone prescribing tools in CarePoint.

# Risk Mitigation Recommendations

Opioid use guidelines endorsed by Veteran Affairs (VA)/DoD, Centers for Disease Control (CDC) and Defense Health Agency (DHA)-6025.04 recommend the following approaches to mitigate risk of opioids

- Comprehensive biopsychosocial pain assessment
- Use alternatives to opioids when possible
- Assessment of risks and benefits before and during opioid use
- Periodic urine drug screening
- Use of prescription drug monitoring program (PDMP)
- Opioid informed consent
- Increase access to naloxone
- Consider opioid taper when risk exceeds benefits
- Assess for opioid use disorder

# Risk Mitigation Recommendations

Opioid use guidelines endorsed by VA/DoD, CDC and DHA-6025.04 recommend the following approaches to mitigate risk of opioids

- Comprehensive biopsychosocial pain assessment
  - Defense and Veterans Pain Rating Scale (DVPRS)
  - Pain Assessment Screening Tool and Outcomes Registry (PASTOR)
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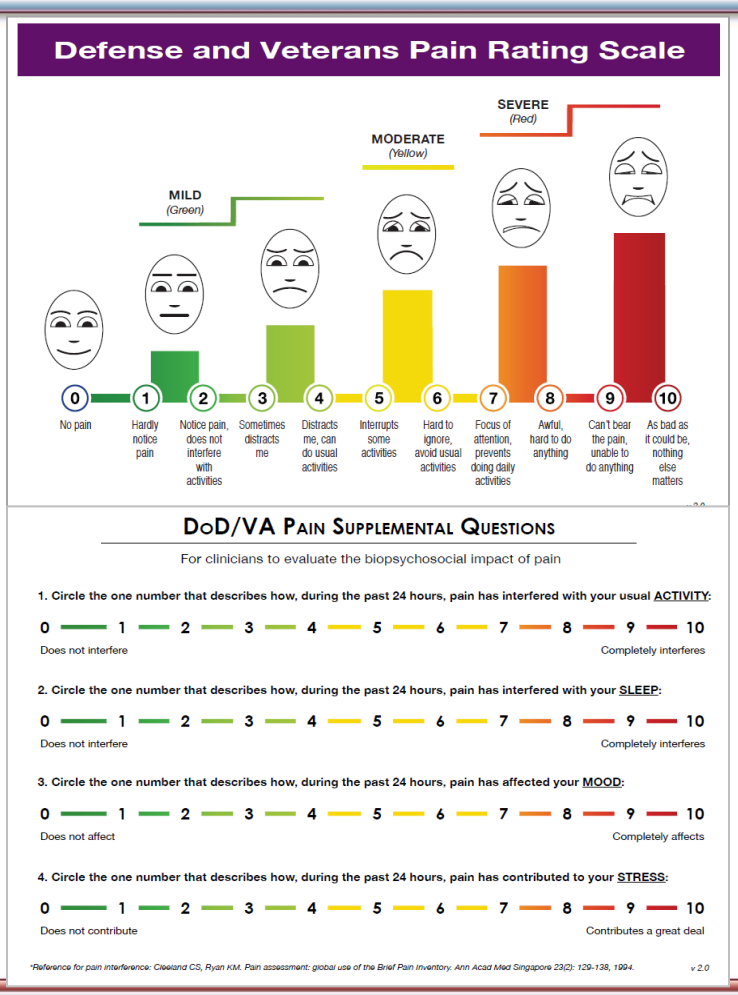
# Defense and Veterans Pain Rating Scale (DVPRS)

DVPRS components:

- Pain Intensity
- Pain Impact



## Defense and Veterans Pain Rating Scale



### DoD/VA Pain Supplemental Questions

For clinicians to evaluate the biopsychosocial impact of pain

1. Circle the one number that describes how, during the past 24 hours, pain has interfered with your usual ACTIVITY:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not interfere — Completely interferes

2. Circle the one number that describes how, during the past 24 hours, pain has interfered with your SLEEP:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not interfere — Completely interferes

3. Circle the one number that describes how, during the past 24 hours, pain has affected your MOOD:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not affect — Completely affects

4. Circle the one number that describes how, during the past 24 hours, pain has contributed to your STRESS:

0 — 1 — 2 — 3 — 4 — 5 — 6 — 7 — 8 — 9 — 10

Does not contribute — Contributes a great deal

*Reference for pain interference: Cleeland CS, Ryan KM. Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singapore 23(2): 129-138, 1994.

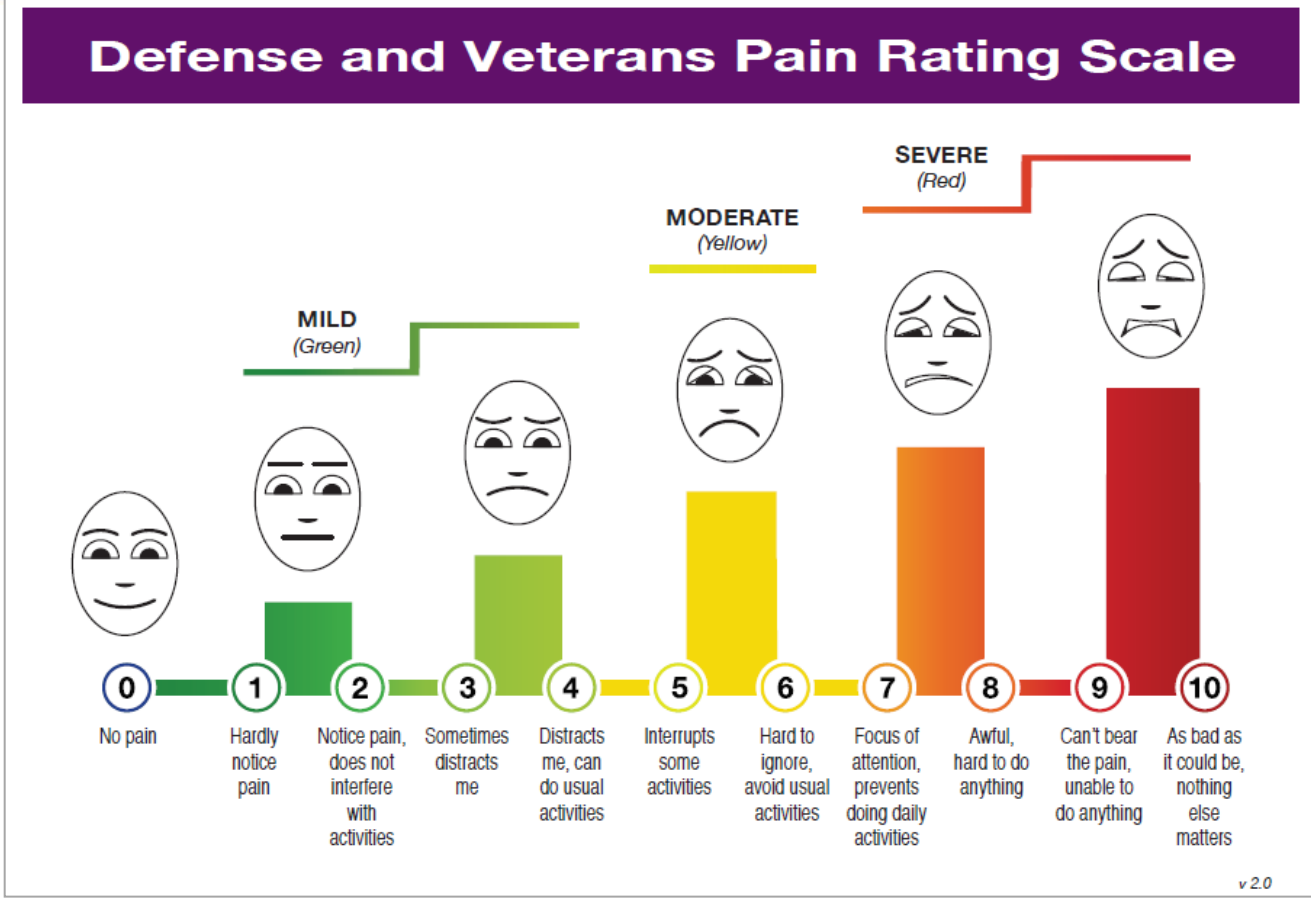
v 2.0

# Defense and Veterans Pain Rating Scale (DVPRS)

Defense Health Agency

## Pain Intensity

- Faces
- Color coded bars
- Word descriptors



# Defense and Veterans Pain Rating Scale (DVPRS)

Defense Health Agency

## Pain Impact

- Activity
- Sleep
- Mood
- Stress

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# The Pain Assessment Screening Tool and Outcomes Registry (PASTOR)

Defense Health Agency

Alerts

Pain map

DVPRS

Treatment history

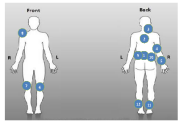
Assessments
- Depression
- Anxiety
- Anger
- Sleep
- Fatigue
- Pain interference
- Physical function
- Social roles
- Catastrophizing

Important activities impacted by pain

PASTOR

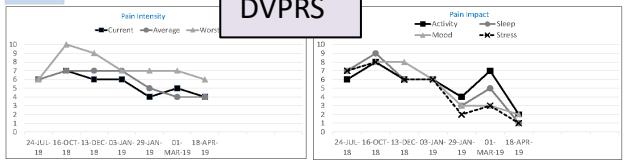
Name:
Date: 18-APR-2019
Record ID:

Primary Care: Madigan AMC
Age: 36
Gender: Male



| | | |
|---|---|---|
| | Prescription Pain Medication Misuse | Negative Screen |
| | PTSD | Negative Screen |
| | Alcohol Concern | Negative Screen |
| | Depression | Negative Screen |
| | Anxiety | Negative Screen |
| | Neuropathic Pain Screen | Negative Screen |

DVPRS

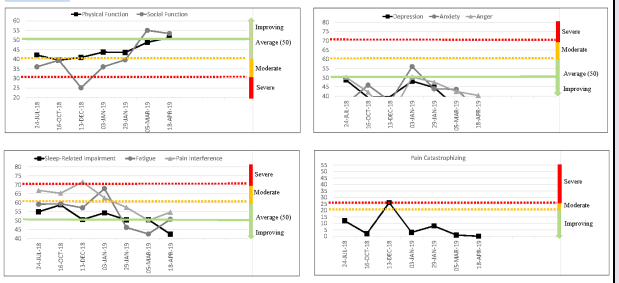



Treatment History and Effectiveness

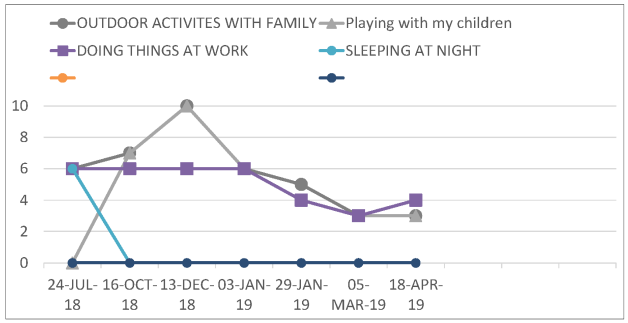
| Type of Treatment (examples) | When it was used | Effectiveness |
|---|---|---|
| Exercise, physical therapy or occupational therapy | Currently | No |
| Other physical treatments (heat, massage, TENS) | Currently | Slightly |
| Behavioral treatment (CBT, relaxation, distraction) | Currently | Slightly |
| Muscle relaxants (cyclobenzaprine, methocarbamol, diazepam, etc.) | Currently | Slightly |
| Non-steroidal anti-inflammatory medication (ibuprofen) and/or acetaminophen (Tylenol, etc.) | Currently | Slightly |
| Neuropathic pain medications (gabapentin, nortriptyline, duloxetine, etc.) | Currently | Moderately |
| Complementary and integrative therapies (acupuncture, yoga, etc.) | Currently | Slightly |
| Opioid medications (oxycodone, morphine) | 1-3 years ago | Slightly |
| Injection therapies (epidural steroid or joint injections, etc.) | Never | N/A |
| Orthopedic or neurosurgical surgeries (spinal fusion, arthroscopic joint surgeries, joint replacement, etc.) | Never | N/A |

PASTOR

PROMIS Scales




Important activities that are limited by pain...



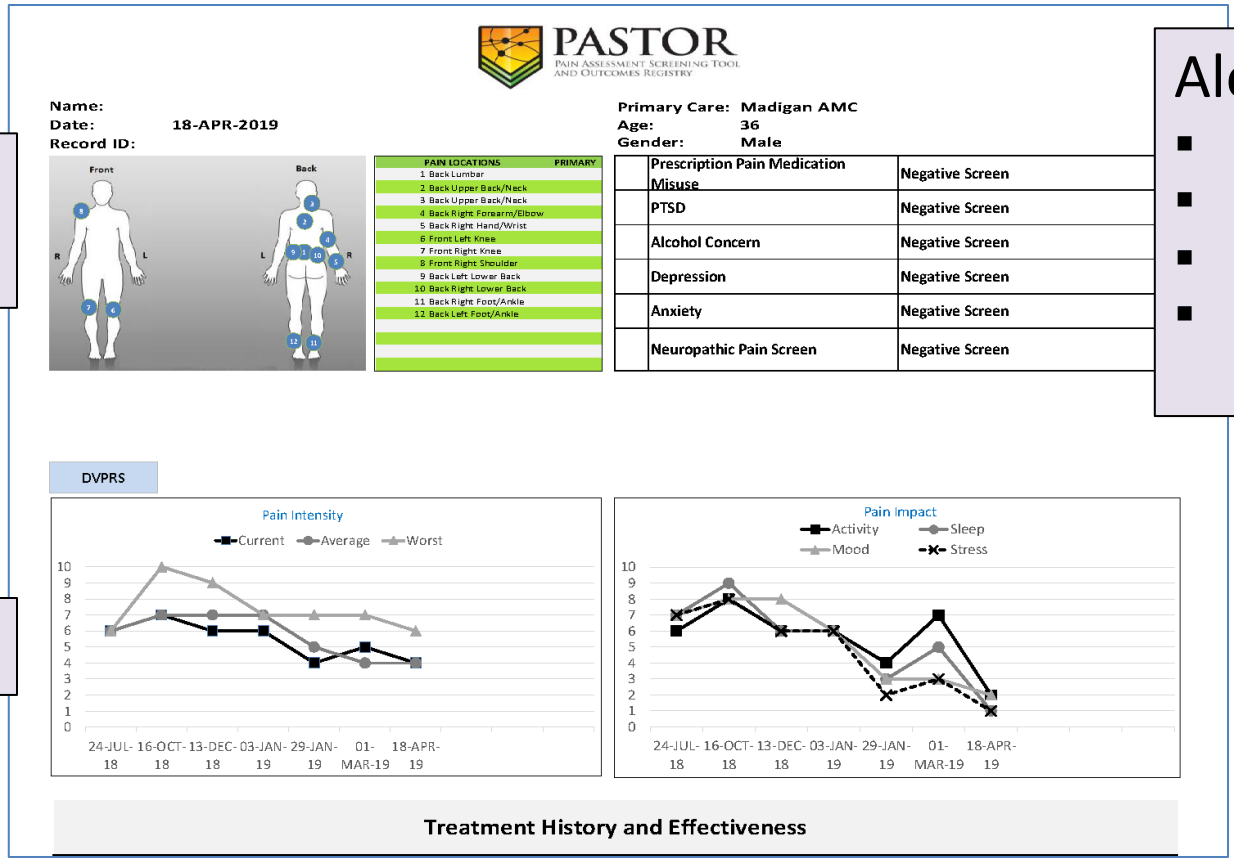

*"Medically Ready Force…Ready Medical Force"*

# The Pain Assessment Screening Tool and Outcomes Registry (PASTOR)

Defense Health Agency

Pain map

DVPRS




## Alerts

- Med. misuse
- PTSD
- Mood
- Neuropathic pain

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Defense Health Agency

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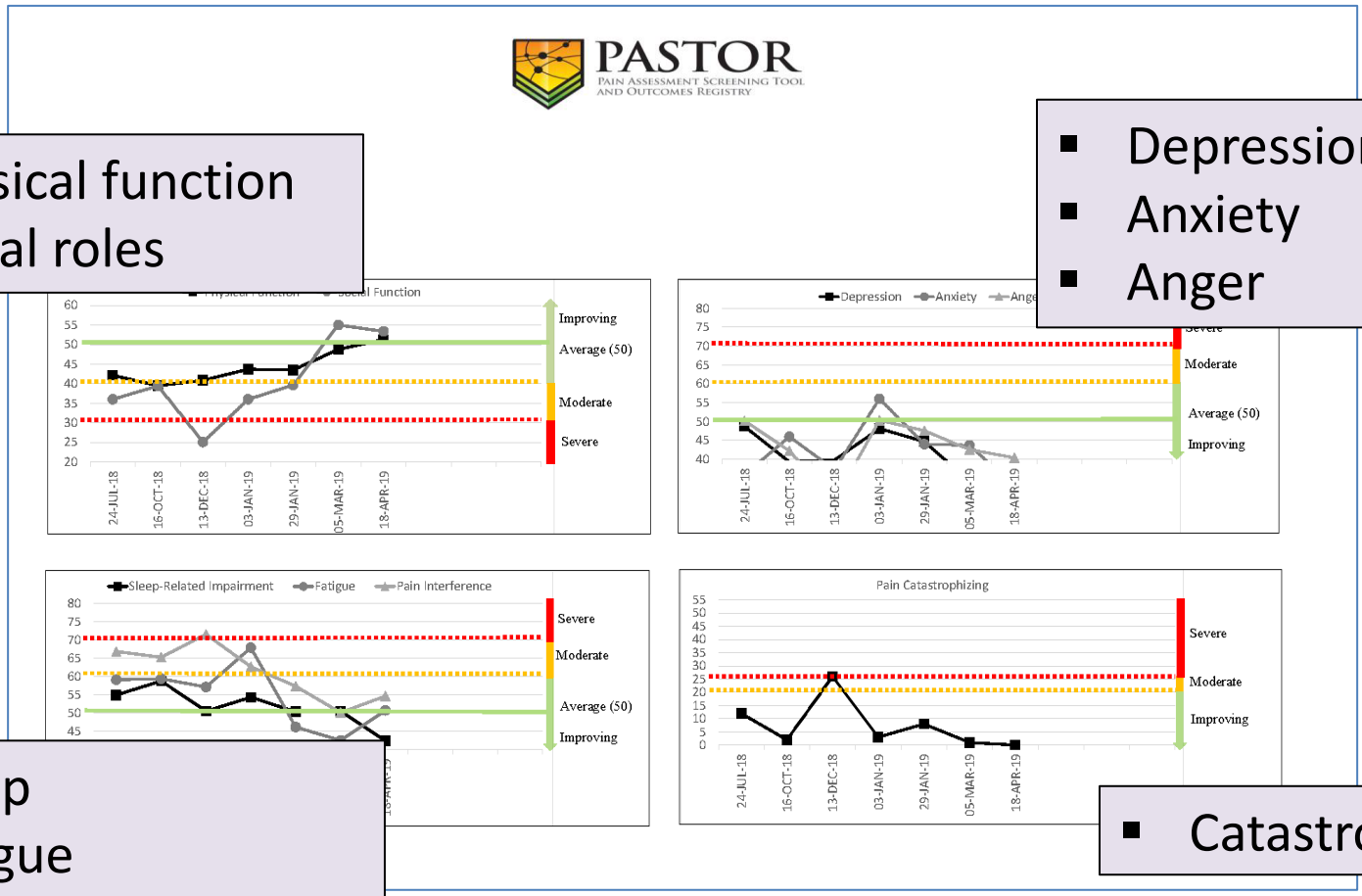
# The Pain Assessment Screening Tool and Outcomes Registry (PASTOR)

Defense Health Agency

- Physical function
- Social roles

- Depression
- Anxiety
- Anger




- Sleep
- Fatigue
- Pain interference

- Catastrophizing

*"Medically Ready Force…Ready Medical Force"*

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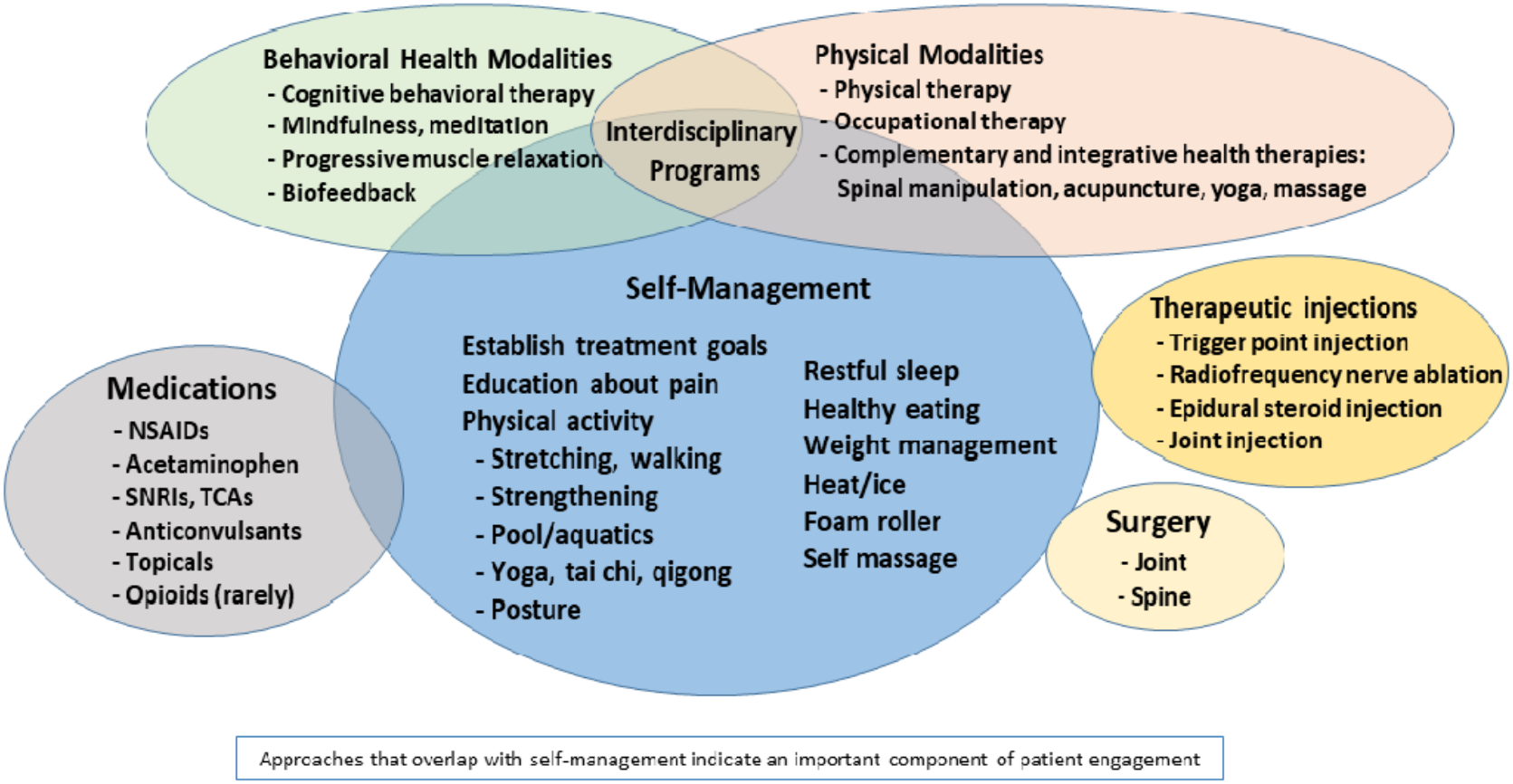
# Use Alternatives to Opioids as Initial Treatment of Pain




Approaches that overlap with self-management indicate an important component of patient engagement

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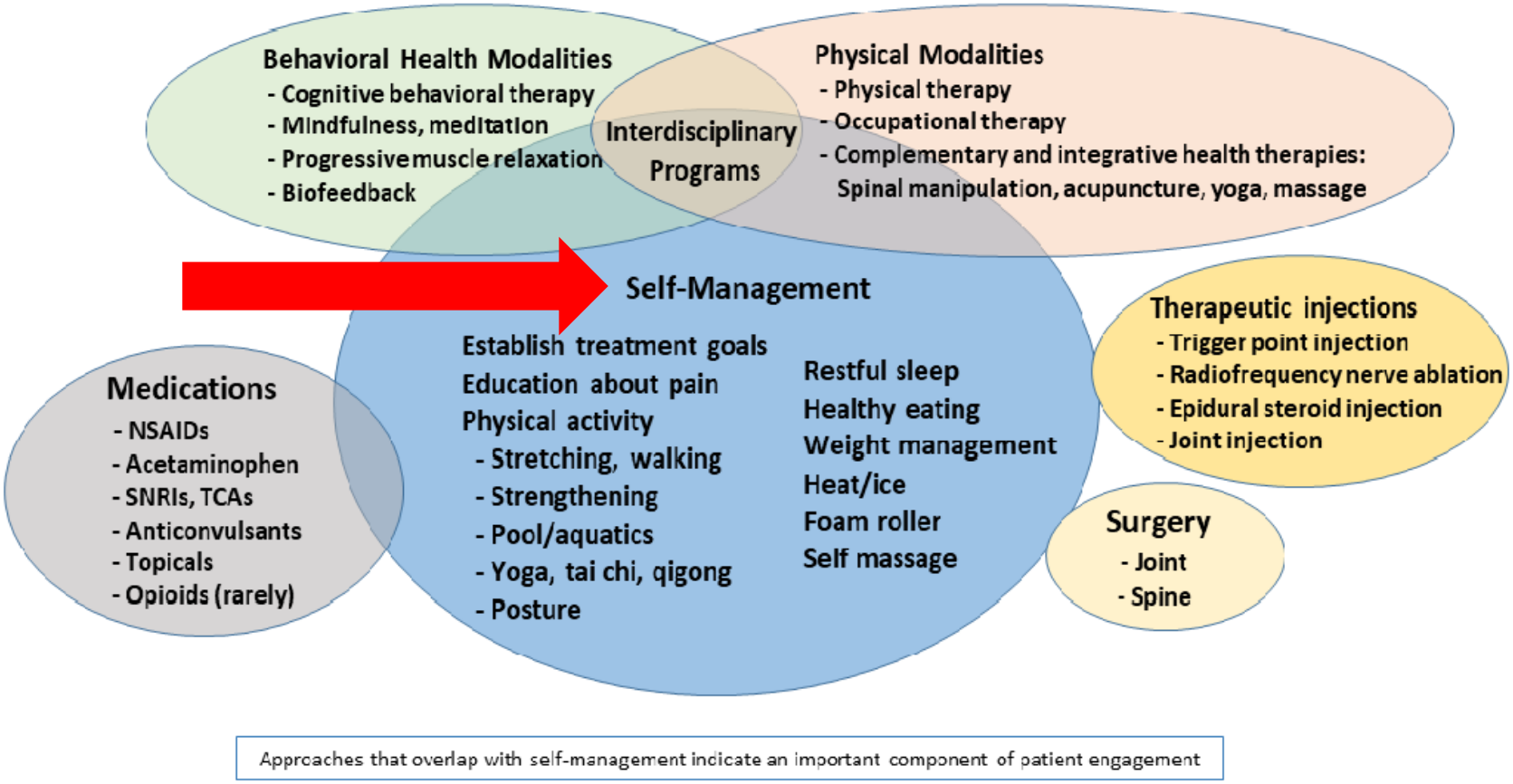

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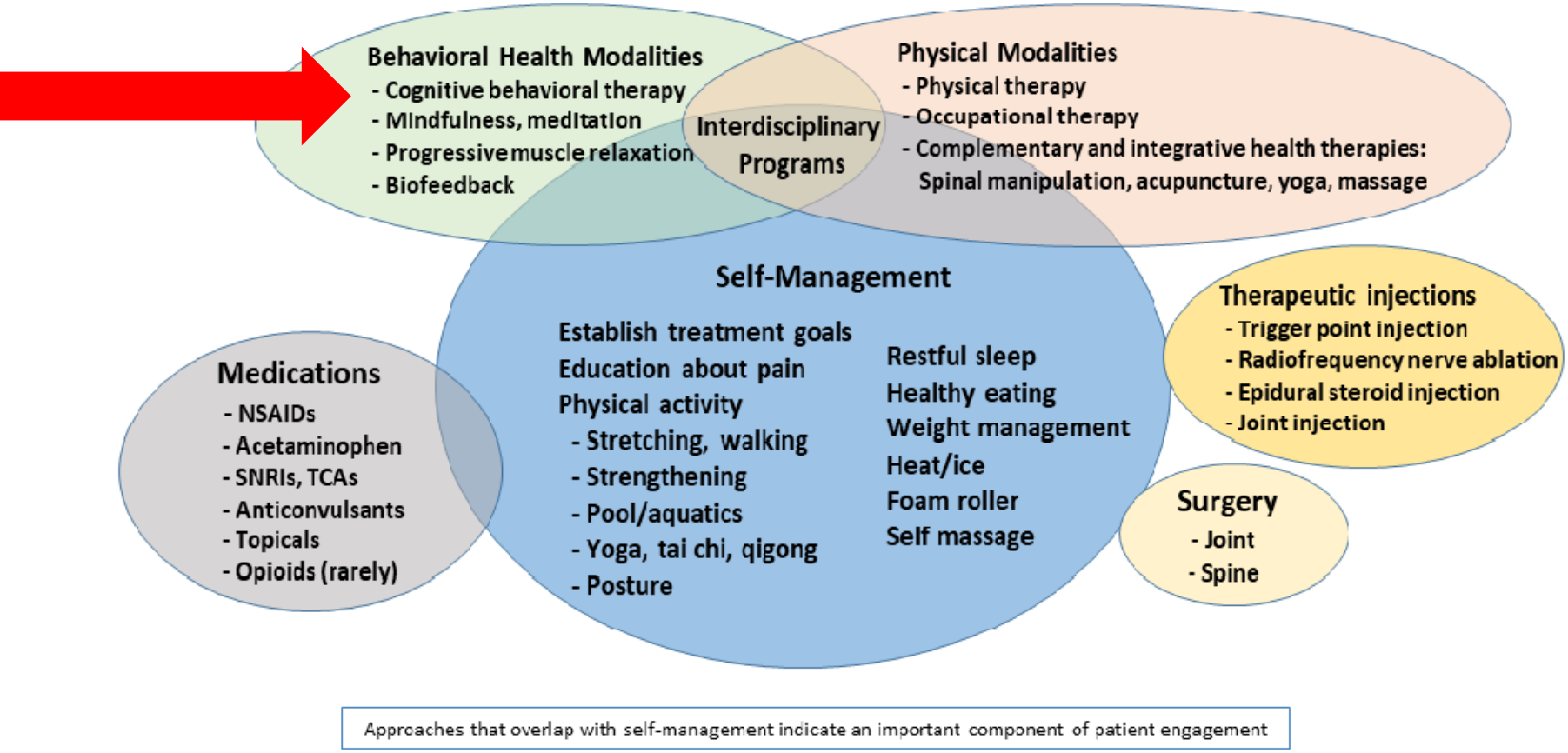


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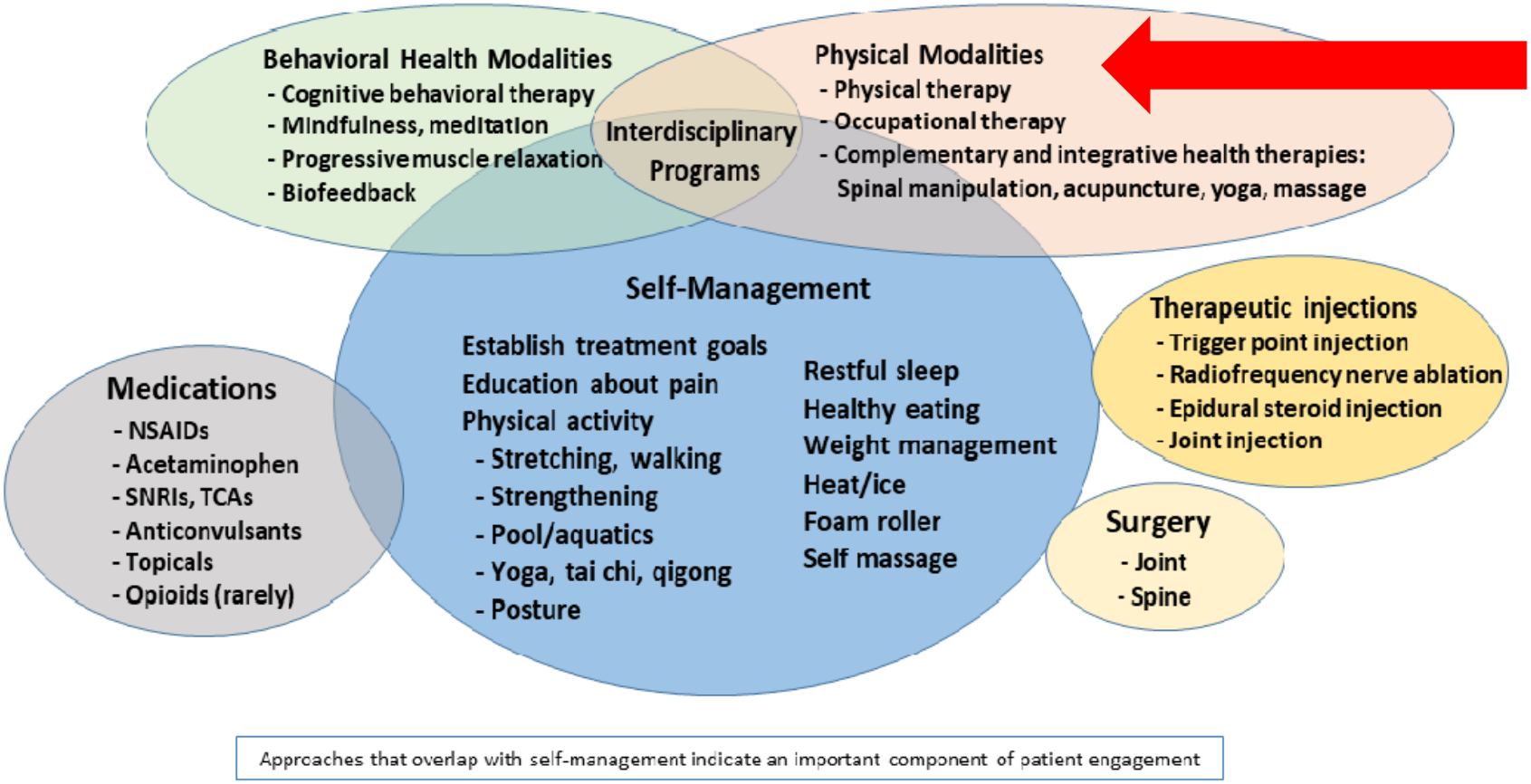

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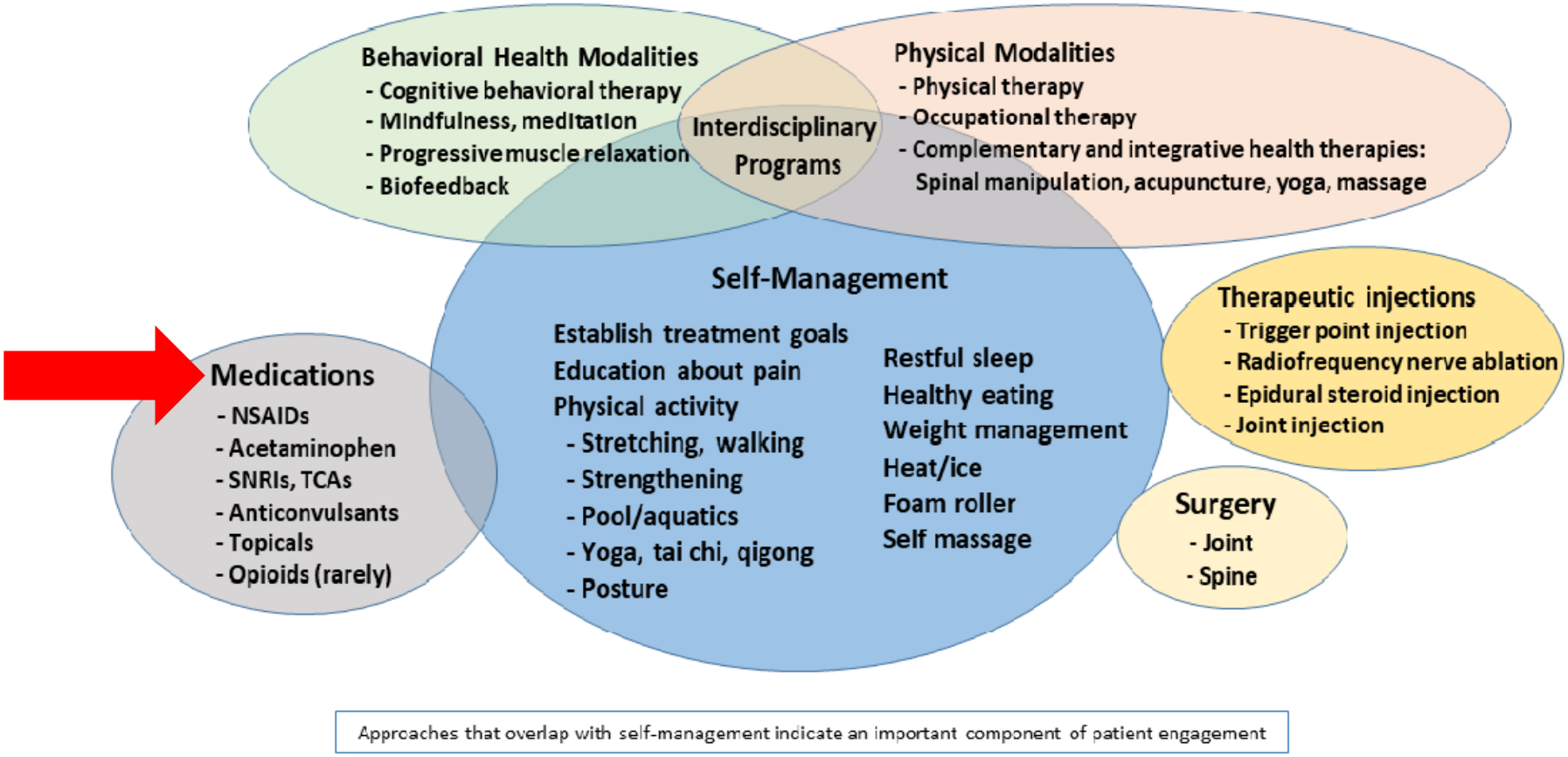


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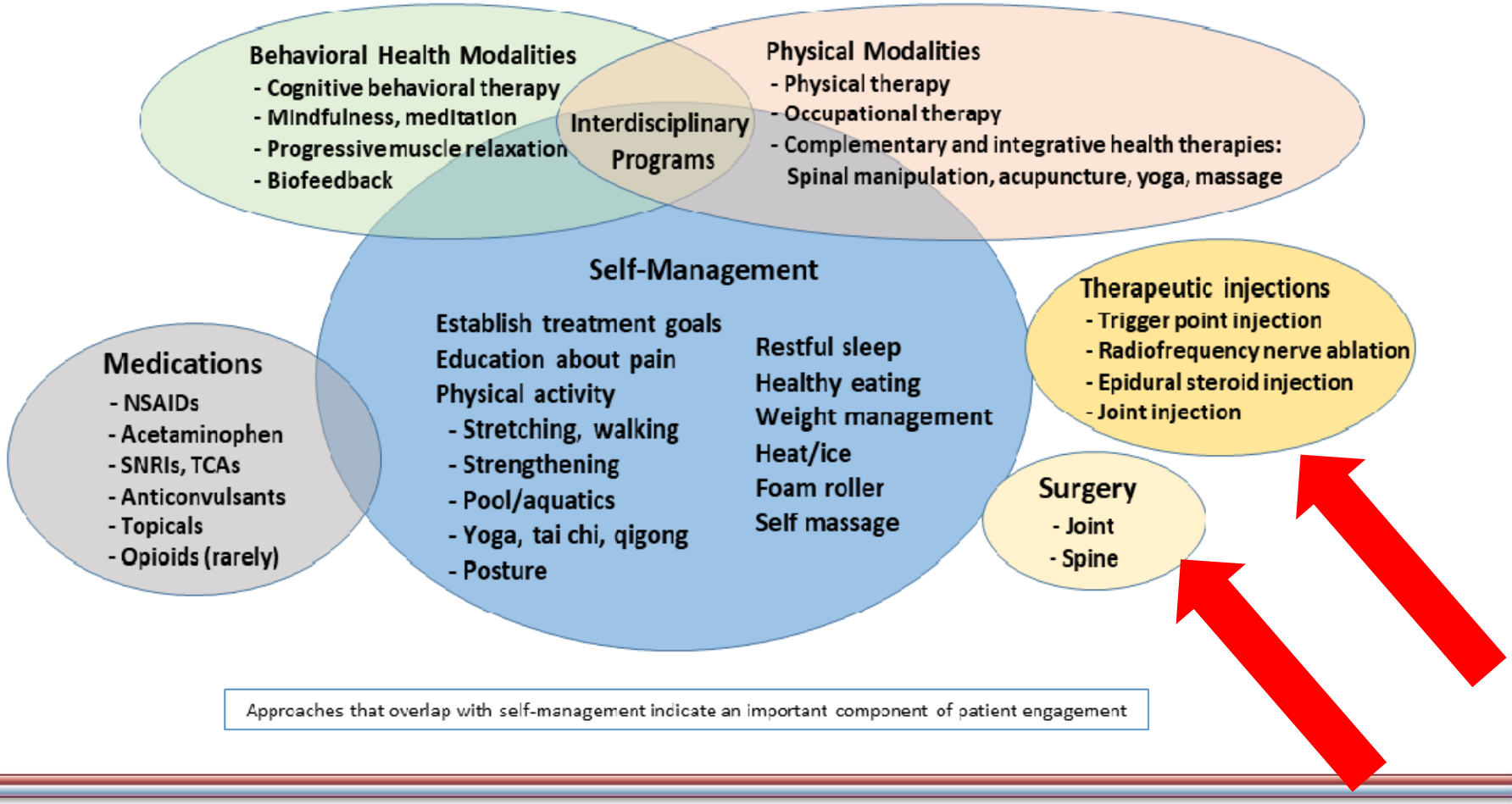

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# Opioid-related Risks

- Possible side effects
  - Sleepiness, Slow thinking, Mental confusion
  - Constipation, intestinal blockage
  - Itching
  - Sweating
  - Nausea or vomiting
  - Decreased sex hormones, Irregular or no menstrual periods
  - Depression
  - Dry mouth, tooth decay
  - Allergies
- Other risks
  - Sleep apnea
  - Worsening of pain
  - Impaired driving
  - Tolerance
  - Withdrawal symptoms
  - Addiction
  - Adverse drug interactions
  - Pregnancy-related risks
  - Death

(Veterans Affairs Informed Consent for Long Term Opioid Therapy for Pain, 2014)

# Assessing Risk of Opioid Overdose

Factors associated with increased risk of opioid overdose

- History of non-fatal opioid overdose
- Higher doses of opioids
- Concomitant use of opioids with benzodiazepines or other sedating medications and substances
- Psychological conditions
- Chronic medical conditions
- Trauma
- Inpatient hospitalization, Emergency Room (ER) visits

(Zedler et al., 2015)

# Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD) Assessment Tool

Defense Health Agency

1. Calculate Risk Index for Overdose or Serious Opioid-Induced Respiratory Depression (RIOSORD) using chart provided below.

| RIOSORD Questions | Circle for "YES" Response |
|---|---|
| **In the past 6 months, has the patient had a health care visit (outpatient, inpatient, or ED) involving:** | |
| Opioid dependence? | 15 |
| Chronic hepatitis or cirrhosis? | 9 |
| Bipolar disorder or schizophrenia? | 7 |
| Chronic pulmonary disease? (e.g., emphysema, chronic bronchitis, asthma, pneumoconiosis, asbestosis) | 5 |
| Chronic kidney disease with clinically significant renal impairment? | 5 |
| Active traumatic injury, excluding burns? (e.g., fracture, dislocation, contusion, laceration, wound) | 4 |
| Sleep apnea? | 3 |
| **Does the patient consume:** | |
| An extended-release or long-acting (ER/LA) formulation of any prescription opioid or opioid with long and/or variable half-life? (e.g.,OxyContin, Oramorph-SR, methadone, fentanyl patch, levorphanol) | 9 |
| Methadone? (Methadone is a long-acting opioid, so also circle for "ER/LA formulation") | 9 |
| Oxycodone? (If it has an ER/LA formulation [e.g., OxyContin], also circle for "ER/LA formulation") | 3 |
| A prescription antidepressant? (e.g., fluoxetine, citalopram, venlafaxine, amitriptyline) | 7 |
| A prescription benzodiazepine? (e.g., diazepam, alprazolam) | 4 |
| **Is the patient's current maximum prescribed opioid dose: (Use Opioid Daily Dose Conversion Table provided on the next page)** | |
| >100 mg morphine equivalents per day? | 16 |
| 50-100 mg morphine equivalents per day? | 9 |
| 20-50 mg morphine equivalents per day? | 5 |
| **In the past 6 months, has the patient:** | |
| Had 1 or more ED visits? | 11 |
| Been hospitalized for 1 or more days? | 8 |
| TOTAL SCORE: | |

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| Is the pa | |
| >100 mg | |
| 50-100 m | |
| 20-50 mg | |
| In the pa | |
| Had 1 or | |
| Been hos | |
| TOTAL SCORE: | |

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# Risk Index for Overdose or Serious Opioid-induced Respiratory Depression (RIOSORD) Assessment Tool

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| RIOSO | |
|---|---|
| In the p | |
| Opioid | |
| Chronic | |
| Bipolar | |
| Chronic | |
| Chronic | |
| Active t | |
| Sleep a | |
| Does th | |
| An exte or varia | |
| Methac | |
| Oxycod | |
| A presc | |
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| TOTAL SCORE: | |

Maximum score=115

2. Determine Opioid Induced Respiratory Depression (OIRD) Probability based on Calculated Risk Index.

*NOTE: Score of more than 32/14% indicates a high risk and naloxone prescription is indicated.*

| Risk index score | OIRD probability (%) |
|---|---|
| 0-24 | 3 |
| 25-32 | 14 |
| 33-37 | 23 |
| 38-42 | 37 |
| 43-46 | 51 |
| 47-49 | 55 |
| 50-54 | 60 |
| 55-59 | 79 |
| 60-66 | 75 |
| ≥67 | 86 |

**Naloxone Indicated**

# Assessment of Risks and Benefits

- Opioid adverse effects and risks
- Factors associated with increased risk of opioid overdose
- To assess benefits, measures outcomes
  - Physical function, emotional status, quality of life
  - Continue opioids only if improvement is demonstrated and outweighs risks

# Periodic Urine Drug Screening

- Standard of care for patients on long-term opioid therapy
- At least annually; more frequently when indicated
- When results are unexpected, follow-up with confirmatory testing

# Risk Mitigation Recommendations

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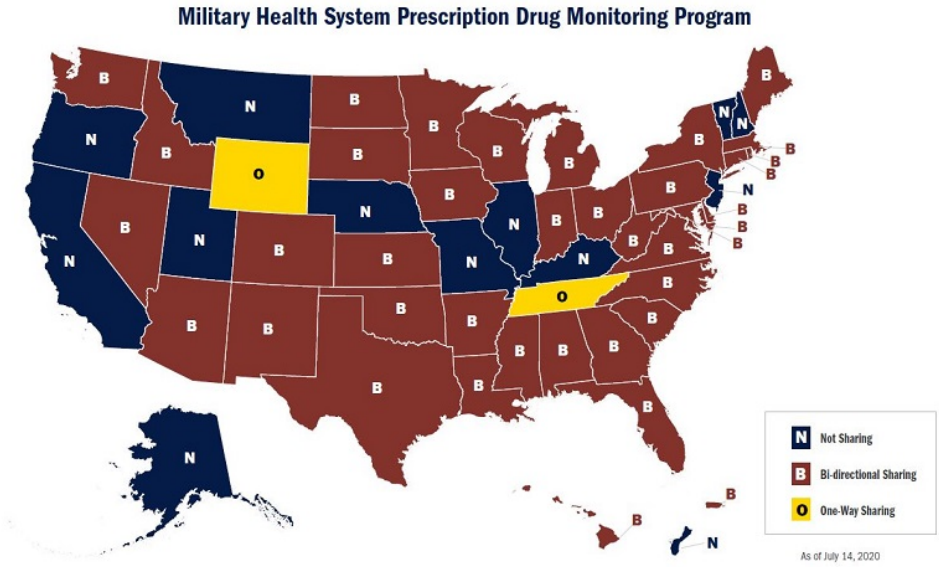
# Prescription Drug Monitoring Program

- Tool to help identify patients who may be misusing controlled substances, particularly opioids
- Military Health System (MHS) also has a PDMP
  - Bi-directional sharing: 38 PDMPs*
  - One-way sharing: 2
  - Not sharing: 13




*As of 14 July 2020

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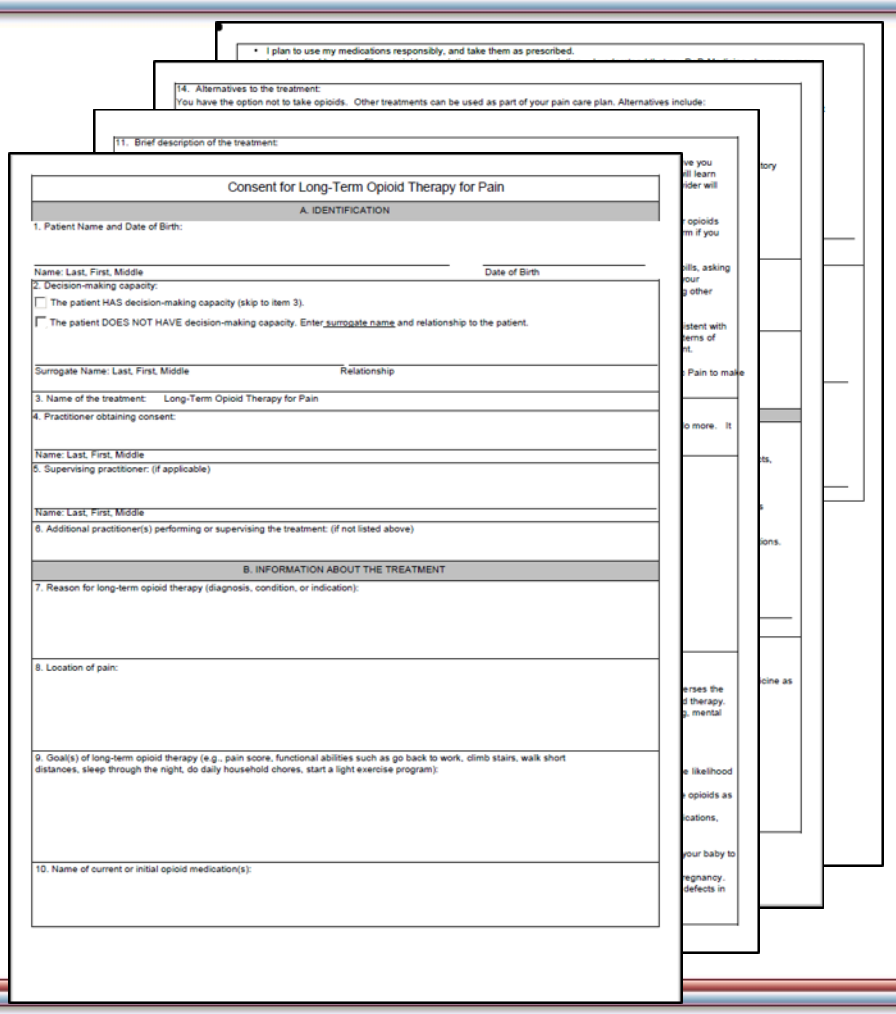
# DHA Informed Consent for Opioid Therapy



Consent for Long-Term Opioid Therapy for Pain

A. IDENTIFICATION

1. Patient Name and Date of Birth:

Name: Last, First, Middle — Date of Birth

2. Decision-making capacity:

☐ The patient HAS decision-making capacity (skip to item 3).

☐ The patient DOES NOT HAVE decision-making capacity. Enter surrogate name and relationship to the patient.

Surrogate Name: Last, First, Middle — Relationship

3. Name of the treatment: Long-Term Opioid Therapy for Pain

4. Practitioner obtaining consent:

Name: Last, First, Middle

5. Supervising practitioner: (if applicable)

Name: Last, First, Middle

6. Additional practitioner(s) performing or supervising the treatment: (if not listed above)

B. INFORMATION ABOUT THE TREATMENT

7. Reason for long-term opioid therapy (diagnosis, condition, or indication):

8. Location of pain:

9. Goal(s) of long-term opioid therapy (e.g., pain score, functional abilities such as go back to work, climb stairs, walk short distances, sleep through the night, do daily household chores, start a light exercise program):

10. Name of current or initial opioid medication(s):

11. Brief description of the treatment:

14. Alternatives to the treatment:
You have the option not to take opioids. Other treatments can be used as part of your pain care plan. Alternatives include:

• I plan to use my medications responsibly, and take them as prescribed.

*"Medically Ready Force…Ready Medical Force"*

# DHA Informed Consent for Opioid Therapy

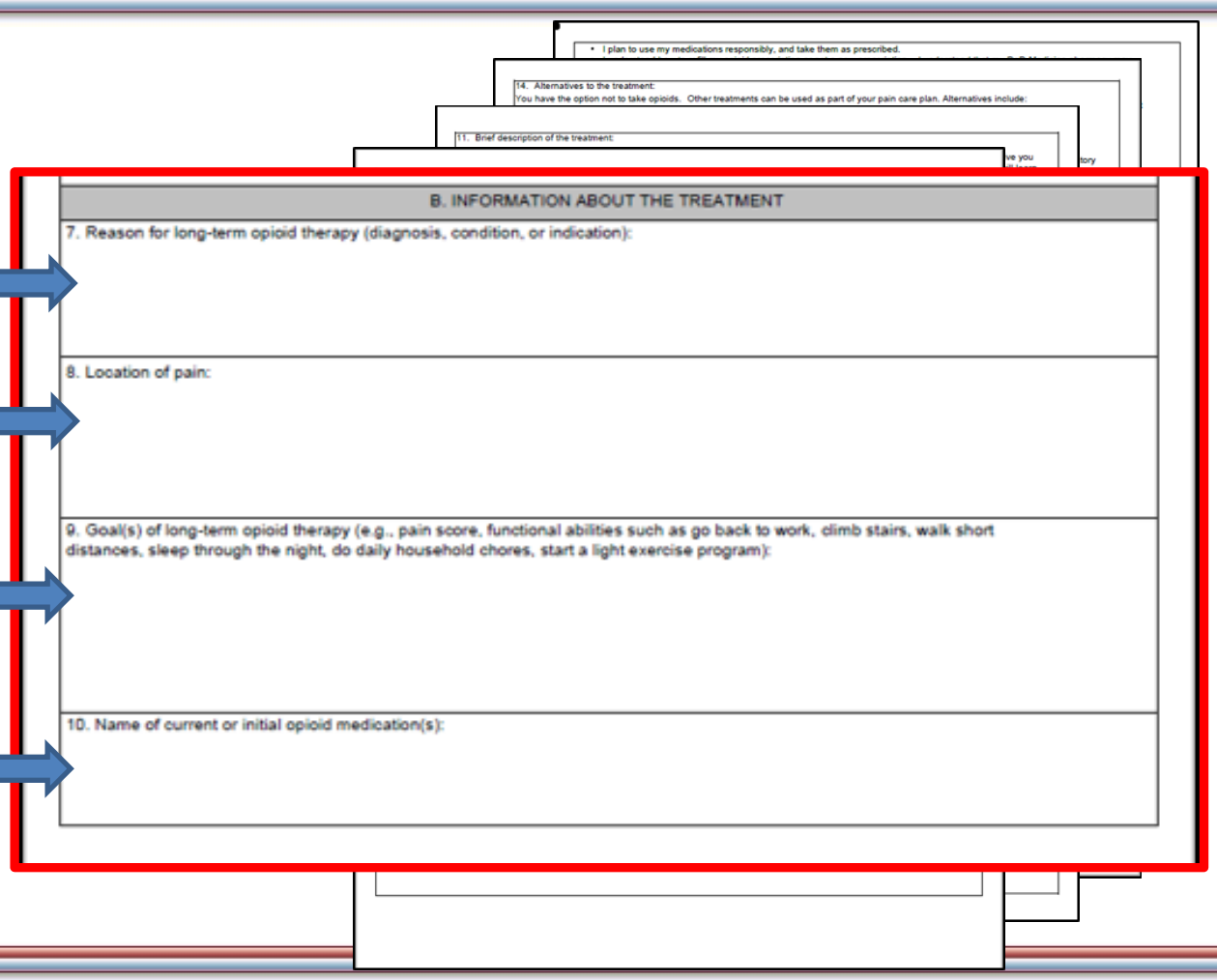
- Page 1 includes

Indication for opioids

Location of pain

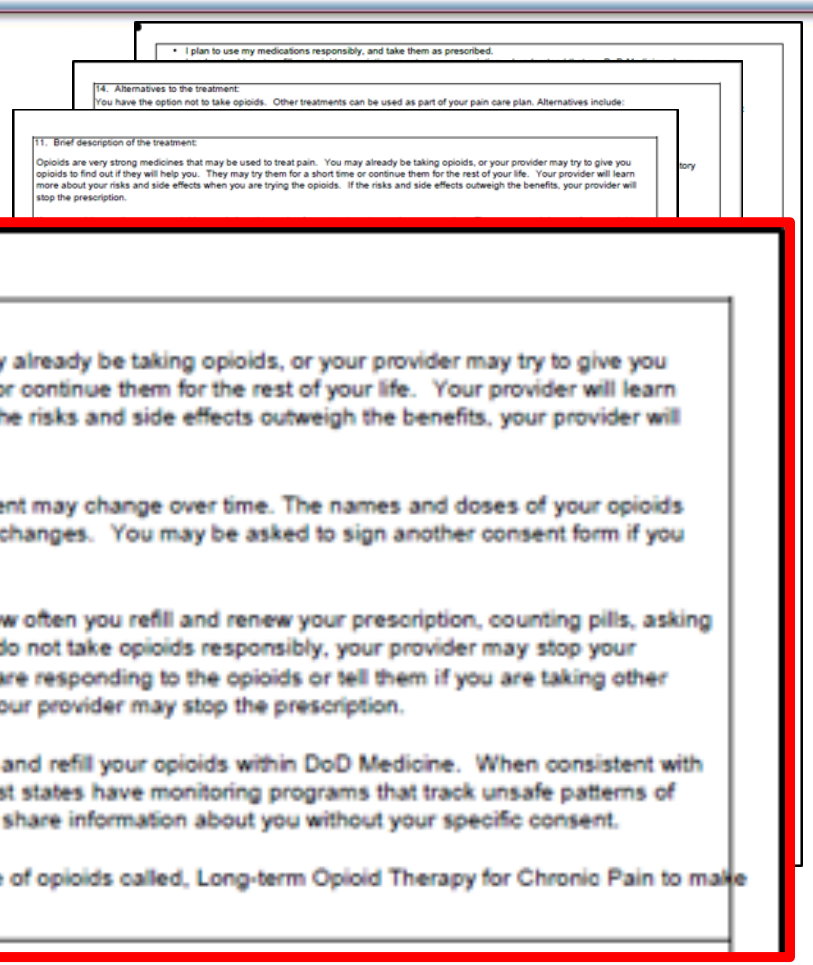
Goal of opioid therapy

Name of opioid



# DHA Informed Consent for Opioid Therapy

- Page 2 includes brief description of opioid therapy



11. Brief description of the treatment:

Opioids are very strong medicines that may be used to treat pain. You may already be taking opioids, or your provider may try to give you opioids to find out if they will help you. They may try them for a short time or continue them for the rest of your life. Your provider will learn more about your risks and side effects when you are trying the opioids. If the risks and side effects outweigh the benefits, your provider will stop the prescription.

If your provider continues your opioid prescription, the goals of your treatment may change over time. The names and doses of your opioids may also change. You will not need to sign another consent form for these changes. You may be asked to sign another consent form if you seek opioid pain care from another DoD Medicine provider.

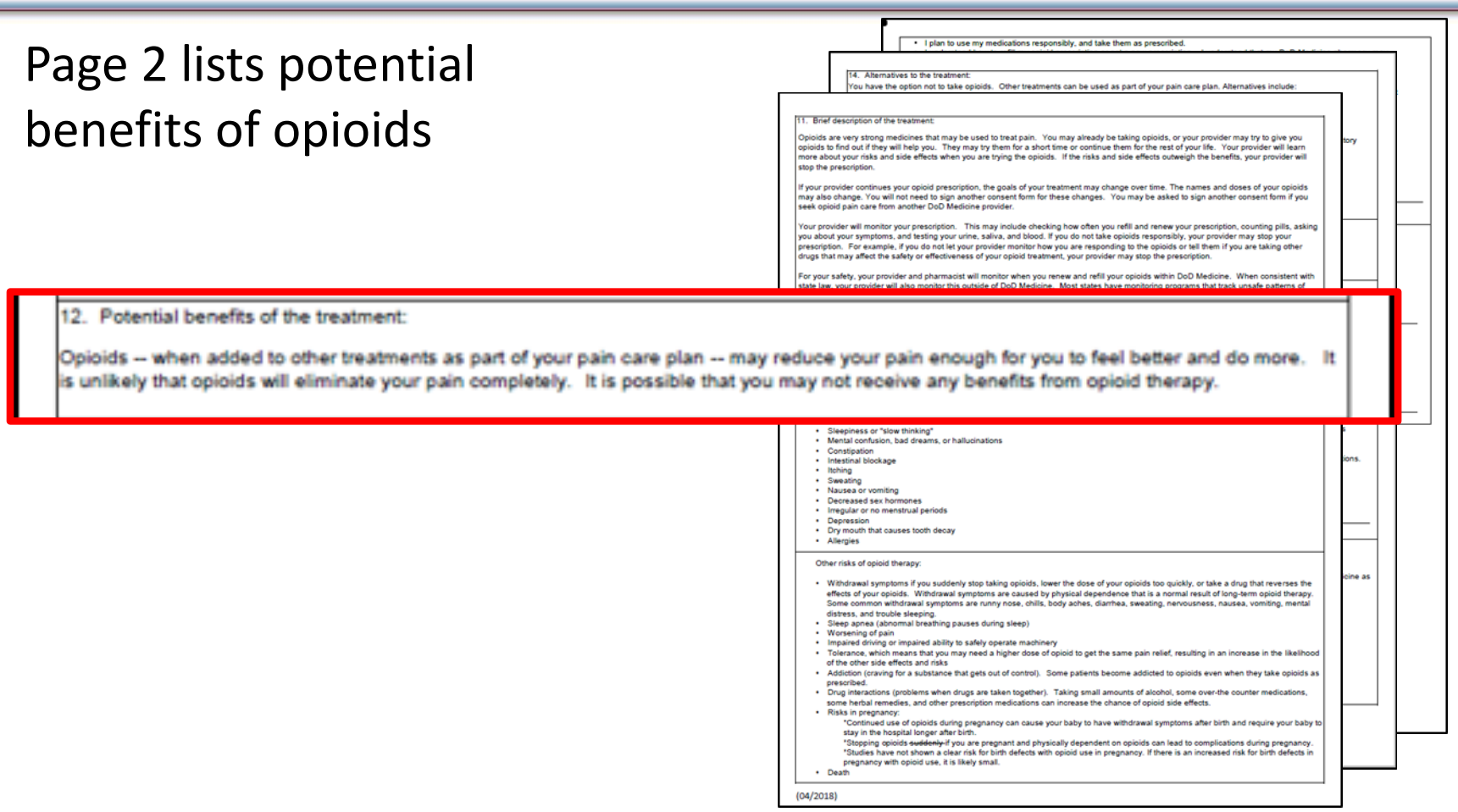
Your provider will monitor your prescription. This may include checking how often you refill and renew your prescription, counting pills, asking you about your symptoms, and testing your urine, saliva, and blood. If you do not take opioids responsibly, your provider may stop your prescription. For example, if you do not let your provider monitor how you are responding to the opioids or tell them if you are taking other drugs that may affect the safety or effectiveness of your opioid treatment, your provider may stop the prescription.

For your safety, your provider and pharmacist will monitor when you renew and refill your opioids within DoD Medicine. When consistent with state law, your provider will also monitor this outside of DoD Medicine. Most states have monitoring programs that track unsafe patterns of prescription drug use. DoD Medicine and these programs may obtain and share information about you without your specific consent.

Your provider will review with you a patient education guide on the safe use of opioids called, Long-term Opioid Therapy for Chronic Pain to make sure that you know how to take your medication safely.

# DHA Informed Consent for Opioid Therapy

- Page 2 lists potential benefits of opioids



12. Potential benefits of the treatment:

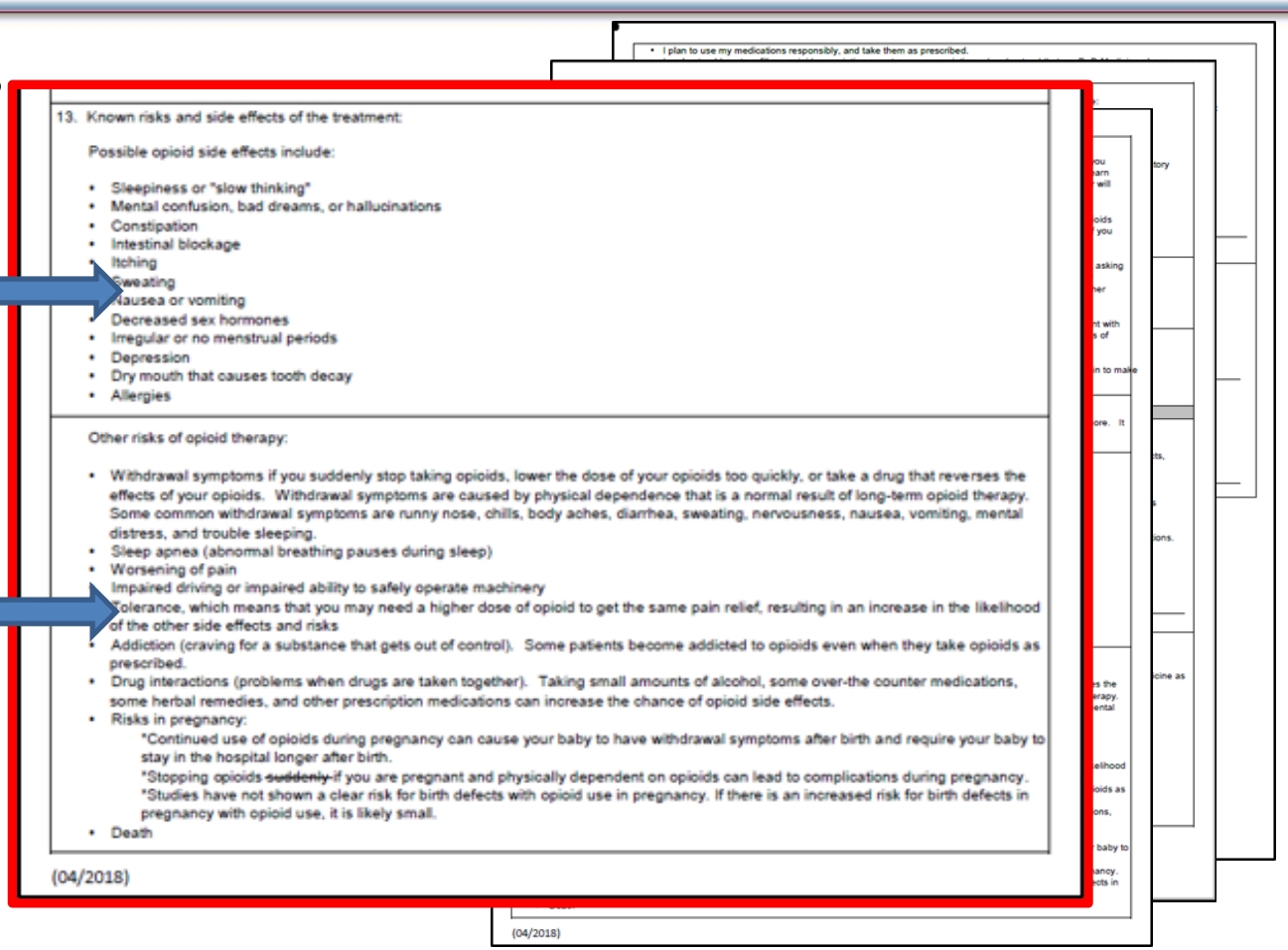
Opioids -- when added to other treatments as part of your pain care plan -- may reduce your pain enough for you to feel better and do more. It is unlikely that opioids will eliminate your pain completely. It is possible that you may not receive any benefits from opioid therapy.

# DHA Informed Consent for Opioid Therapy

- Page 2 includes

Side effects

Other risks



13. Known risks and side effects of the treatment:

Possible opioid side effects include:

- Sleepiness or "slow thinking"
- Mental confusion, bad dreams, or hallucinations
- Constipation
- Intestinal blockage
- Itching
- Sweating
- Nausea or vomiting
- Decreased sex hormones
- Irregular or no menstrual periods
- Depression
- Dry mouth that causes tooth decay
- Allergies

Other risks of opioid therapy:

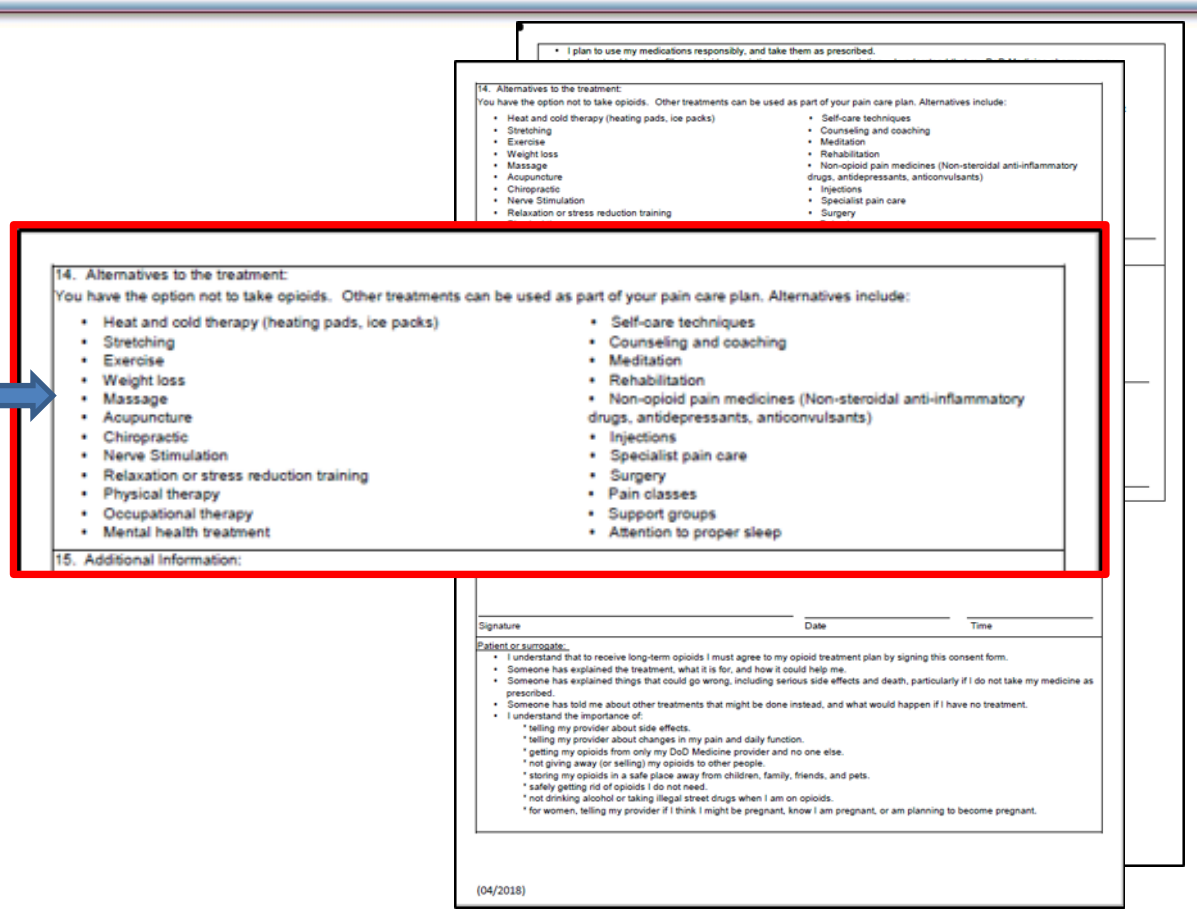
- Withdrawal symptoms if you suddenly stop taking opioids, lower the dose of your opioids too quickly, or take a drug that reverses the effects of your opioids. Withdrawal symptoms are caused by physical dependence that is a normal result of long-term opioid therapy. Some common withdrawal symptoms are runny nose, chills, body aches, diarrhea, sweating, nervousness, nausea, vomiting, mental distress, and trouble sleeping.
- Sleep apnea (abnormal breathing pauses during sleep)
- Worsening of pain
- Impaired driving or impaired ability to safely operate machinery
- Tolerance, which means that you may need a higher dose of opioid to get the same pain relief, resulting in an increase in the likelihood of the other side effects and risks
- Addiction (craving for a substance that gets out of control). Some patients become addicted to opioids even when they take opioids as prescribed.
- Drug interactions (problems when drugs are taken together). Taking small amounts of alcohol, some over-the counter medications, some herbal remedies, and other prescription medications can increase the chance of opioid side effects.
- Risks in pregnancy:
  - *Continued use of opioids during pregnancy can cause your baby to have withdrawal symptoms after birth and require your baby to stay in the hospital longer after birth.
  - *Stopping opioids ~~suddenly~~ if you are pregnant and physically dependent on opioids can lead to complications during pregnancy.
  - *Studies have not shown a clear risk for birth defects with opioid use in pregnancy. If there is an increased risk for birth defects in pregnancy with opioid use, it is likely small.
- Death

(04/2018)

# DHA Informed Consent for Opioid Therapy

- Page 3 includes

Alternatives to opioids



14. Alternatives to the treatment:
You have the option not to take opioids. Other treatments can be used as part of your pain care plan. Alternatives include:

- Heat and cold therapy (heating pads, ice packs)
- Stretching
- Exercise
- Weight loss
- Massage
- Acupuncture
- Chiropractic
- Nerve Stimulation
- Relaxation or stress reduction training
- Physical therapy
- Occupational therapy
- Mental health treatment
- Self-care techniques
- Counseling and coaching
- Meditation
- Rehabilitation
- Non-opioid pain medicines (Non-steroidal anti-inflammatory drugs, antidepressants, anticonvulsants)
- Injections
- Specialist pain care
- Surgery
- Pain classes
- Support groups
- Attention to proper sleep

15. Additional Information:

Signature Date Time

Patient or surrogate:

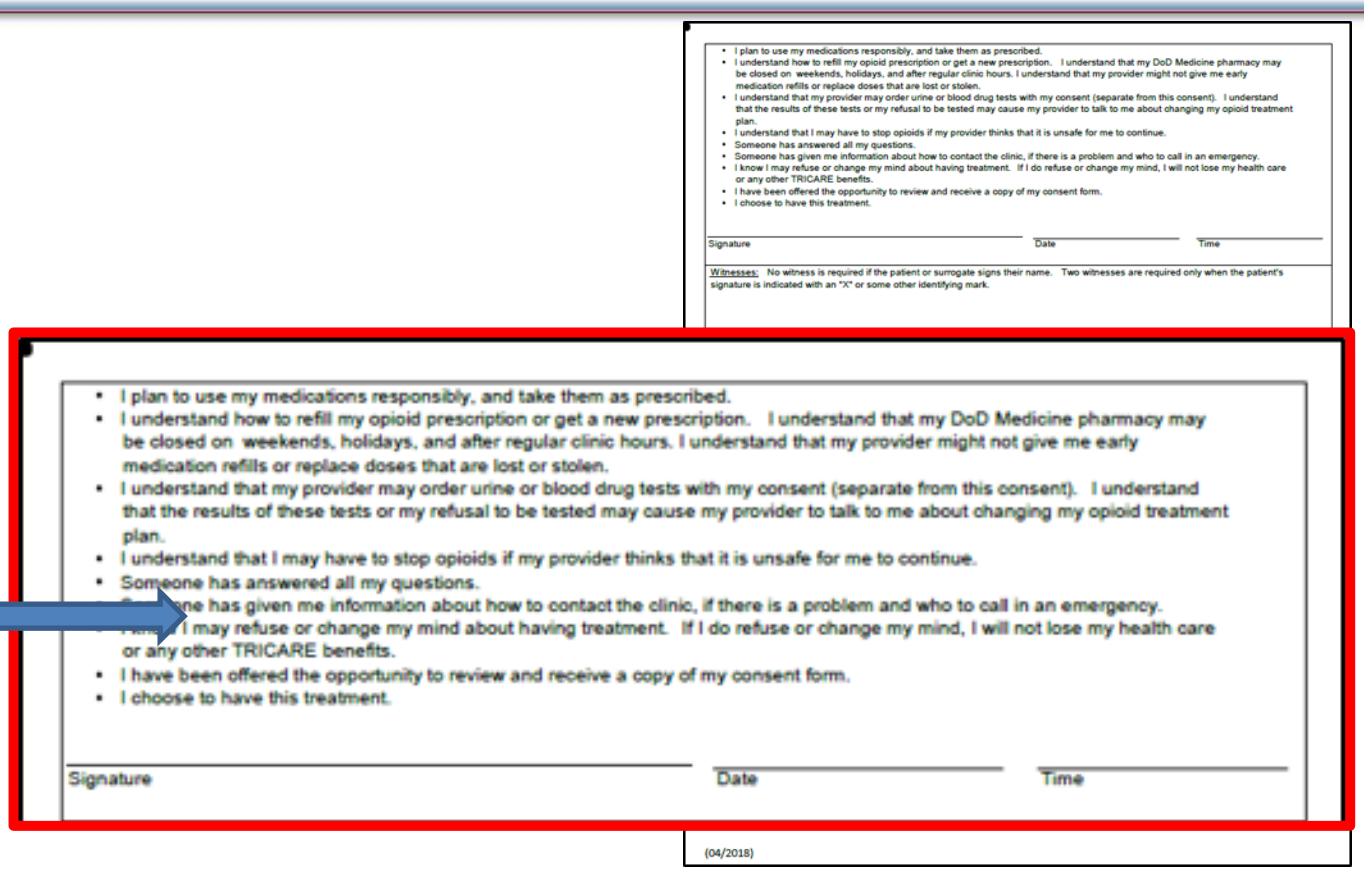
- I understand that to receive long-term opioids I must agree to my opioid treatment plan by signing this consent form.
- Someone has explained the treatment, what it is for, and how it could help me.
- Someone has explained things that could go wrong, including serious side effects and death, particularly if I do not take my medicine as prescribed.
- Someone has told me about other treatments that might be done instead, and what would happen if I have no treatment.
- I understand the importance of:
  - * telling my provider about side effects.
  - * telling my provider about changes in my pain and daily function.
  - * getting my opioids from only my DoD Medicine provider and no one else.
  - * not giving away (or selling) my opioids to other people.
  - * storing my opioids in a safe place away from children, family, friends, and pets.
  - * safely getting rid of opioids I do not need.
  - * not drinking alcohol or taking illegal street drugs when I am on opioids.
  - * for women, telling my provider if I think I might be pregnant, know I am pregnant, or am planning to become pregnant.

(04/2018)

# DHA Informed Consent for Opioid Therapy

- Page 4

Urine drug screening; Opioid monitoring



- I plan to use my medications responsibly, and take them as prescribed.
- I understand how to refill my opioid prescription or get a new prescription. I understand that my DoD Medicine pharmacy may be closed on weekends, holidays, and after regular clinic hours. I understand that my provider might not give me early medication refills or replace doses that are lost or stolen.
- I understand that my provider may order urine or blood drug tests with my consent (separate from this consent). I understand that the results of these tests or my refusal to be tested may cause my provider to talk to me about changing my opioid treatment plan.
- I understand that I may have to stop opioids if my provider thinks that it is unsafe for me to continue.
- Someone has answered all my questions.
- Someone has given me information about how to contact the clinic, if there is a problem and who to call in an emergency.
- I know I may refuse or change my mind about having treatment. If I do refuse or change my mind, I will not lose my health care or any other TRICARE benefits.
- I have been offered the opportunity to review and receive a copy of my consent form.
- I choose to have this treatment.

Signature Date Time

Witnesses: No witness is required if the patient or surrogate signs their name. Two witnesses are required only when the patient's signature is indicated with an "X" or some other identifying mark.

(04/2018)

# Risk Mitigation Recommendations

Opioid use guidelines endorsed by VA/DoD, CDC and DHA-6025.04 recommend the following approaches to mitigate risk of opioids

- Comprehensive biopsychosocial pain assessment
- Use alternatives to opioids when possible
- Assessment of risks and benefits before and during opioid use
- Periodic urine drug screening
- Use of prescription drug monitoring program (PDMP)
- Opioid informed consent
- Increase access to naloxone
- Consider opioid taper when risk exceeds benefits
- Assess for opioid use disorder

# Naloxone

- Opioid antagonist that can reverse the potentially fatal effects of an opioid overdose
- Recommended
  - Morphine equivalent daily dose (MEDD) ≥50 mg
  - Opioid / Benzodiazepine combination
  - RIOSORD score >32
  - Long-term opioid therapy
  - Provider clinical judgment
  - Others patients, upon request


Nasal Spray
*Narcan*[R]

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- Assess for opioid use disorder (OUD)

# Tapering/Discontinuation

- Consider tapering when:
  - Dose exceeds 90 mg morphine equivalent daily dose (MEDD)
  - Patient is prescribed both opioids and benzodiazepines (taper one or both medications).
  - RIOSORD score >32
  - Risks exceed benefits
- Tailor tapering approach to specific characteristics:
  - Opioid dose, duration of therapy, and type of opioid formulation
  - Psychiatric, medical, and Substance Use Disorders (SUD) comorbidities
  - Other risk factors (e.g., non-adherence, high-risk medication related behavior, social support, coping)
- When safety allows, taper gradually (e.g., by 5-20% every 4 weeks) to allow time for neurobiological, psychological, and behavioral adaptations.

(VA/DoD Diagnosis and Treatment of Low Back Pain Work Group, 2017)

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# Opioid Use Disorder and Medication Assisted Therapy

- Risk for OUD starts at any dose and increases in a dose dependent manner
- OUD Features
  - Loss of control over use
  - Continued use despite harm
- Consider medication assisted treatment

**Table C-1: DSM-5 Diagnostic Criteria for OUD [197]**

| DSM-5 Diagnostic Criteria for OUD |
|---|
| 1. Craving or strong desire or urge to use opioids |
| 2. Recurrent use in situations that are physically hazardous |
| 3. Tolerance |
| 4. Withdrawal (or opioids are taken to relieve or avoid withdrawal) |
| 5. Using larger amounts of opioids or over a longer period than initially intended |
| 6. Persisting desire or unable to cut down on or control opioid use |
| 7. Spending a lot of time to obtain, use, or recover from opioids |
| 8. Continued opioid use despite persistent or recurrent social or interpersonal problems related to opioids |
| 9. Continued use despite physical or psychological problems related to opioids |
| 10. Failure to fulfill obligations at work, school, or home due to use |
| 11. Activities are given up or reduced because of use |

**Table C-2: DSM-5 Diagnostic Criteria for Severity of OUD [197]**

| Severity of OUD | Number of Symptoms |
|---|---|
| Mild | Presence of 2-3 symptoms |
| Moderate | Presence of 4-5 symptoms |
| Severe | Presence of 6 or more symptoms |

DSM-5 OUD Diagnostic criteria

(Psychological Health Center of Excellence (PHCoE), 2018)

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(PHCoE, 2018)

# Opioid Use Disorder and Medication Assisted Therapy

- Risk for OUD starts at any dose and increases in a dose dependent manner
- As opioid dosage increases monitor for OUD
- OUD Features
  - Loss of control over use
  - Continued use despite harm
- Consider medication assisted treatment for patients

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# Risk Mitigation Recommendations Key Takeaways

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