Safe Opioid Prescribing: Maximizing Benefits and Minimizing Risks

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Southeastern Consortium on Substance Abuse Training
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J. Paul Seale, MD, Disclosures

- The authors have no relevant financial conflicts of interest to disclose.

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Target Audience

- The overarching goal of PCSS-O is to offer evidence-based trainings on the safe and effective prescribing of opioid medications in the treatment of pain and/or opioid addiction.
- Our focus is to reach providers and/or providers-in-training from diverse healthcare professions including physicians, nurses, dentists, physician assistants, pharmacists, and program administrators.

Educational Objectives

At the conclusion of this activity participants should be able to:

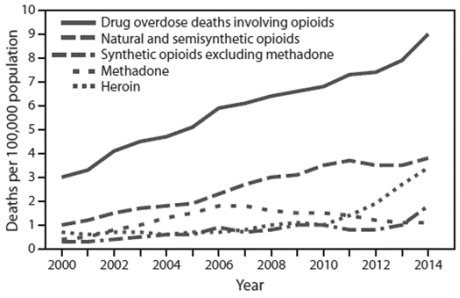
- Describe negative consequences that may occur in patients who receives prescriptions for opioid medication
- Construct an initial assessment and baseline measurement of a patient requesting opioid therapy
- Use a monitoring framework to protect the safety of patients receiving ongoing opioid therapy
- Address concerning behaviors of patients on chronic opioid therapy

New for 2016

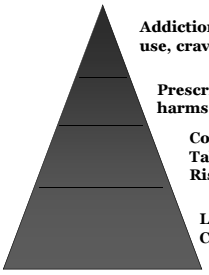
- New CDC guidelines advocating fewer opioids, risk stratification and dosing limitations
- Naloxone prescriptions for high risk patients (> 50 MME/day)
- Increasing heroin overdoses (unintended consequence of tighter guidelines)—offer treatment when refusing to prescribe opioids!
- Evidence of decreased pain in patients switched to buprenorphine

CDC Report on Opioid Epidemic

- In 2014, 28,647 deaths involved some type of opioid, including heroin.
- New Mexico showed a 20.8% increase in the rate of drug overdose deaths from 2013-2014 at 20.8%.
- In 2014, the five states with the highest rates of drug overdose deaths were West Virginia (35.5 deaths per 100,000), New Mexico (27.3), New Hampshire (26.2), Kentucky (24.7), and Ohio (24.6). (CDC MMWR Jan 2016 / 64(50);1378-82)



Opioid User's Pyramid



Addiction (4 Cs: Loss of control, compulsive use, craving, continued use despite harm)

Prescription Drug Misuse (recurrent harms related to use)

Concerning (Aberrant) Medication Taking Behaviors &/or Multiple Risk Factors

Low Risk Patient with No Concerning Behaviors

Level 1: Low Risk Patient with No Concerning Behaviors

- Initial risk assessment identifies patient as low risk
- No requests for early refills or dose escalation
- Keeps regularly scheduled appointments
- Brings medication container
- Medication counts always correct
- UDS results are as expected
  - "right drug" is present
  - "wrong drugs" are absent

Level 2: Concerning (Aberrant) Medication Taking Behaviors--*The Spectrum of Severity*

- Illegal activities – forging scripts, selling opioid prescription, buying drugs from illicit sources
- Multiple "lost" or "stolen" opioid prescriptions
- Non-adherence with monitoring requests (e.g. pill counts, urine drug tests)
- Deterioration in function at home and work
- Resistance to change therapy despite adverse effects (e.g. over-sedation)
- Running out early (i.e., unsanctioned dose escalation)
- Requests for specific opioid by name, "brand name only"
- Requests for increased opioid dose
- Non-adherence with other recommended therapies (e.g., physical therapy, behavioral therapy, etc.)

Butler et al. Pain. 2007

Note: for most of these, need to track pattern & severity over time

Level 3: Prescription Drug Misuse/ Abuse

- **Recurrent problems** related to prescription drug use
  - Failure to fulfill major role obligations at work, school, or home
  - Use in physically hazardous situations
  - Substance-related legal problems
  - Continued use despite persistent or recurrent substance-related social or interpersonal problems (for example, arguments with spouse, physical fights, etc.).

Level 4: Addiction

- A clinical syndrome presenting as…
  - Loss of **C**ontrol
  - **C**ompulsive use
  - **C**ontinued use despite harm
  - **C**raving

  } **Concerning Medication-Taking Behaviors**

- Not equal to physical dependence, which develops in most patients on chronic opioids

Savage SR et al. J Pain Symptom Manage 2003

SBIRT Approach

- **Screening**
  - **Initial Assessment**: before prescribing, check PMP & medical records, assess for risk factors & obtain baseline measures using the PEG/6 A's
  - **Implement Universal Precautions:** agreement, UDS, pill counts
  - **Monitor for benefit & concerning/aberrant behaviors**
- **Brief Intervention**:
  - **Address concerning/aberrant behaviors:** express concern, ask pt to explain
  - **Increase monitoring**
  - **Taper** if there's no benefit or behaviors continue
- **Referral to Treatment**: if abuse/addiction, refer for formal treatment, buprenorphine or methadone

Screening

Screening: 3 Steps

- **Perform an Initial Assessment**
- **Implement a Monitoring Framework as part of Your Universal Precautions**
- **Monitor for benefit & concerning (aberrant) behaviors**

Initial Assessment

Starts before the office visit:

- Obtain records from previous MDs
- Check state Prescription Monitoring Program
- Scan available hospital &/or clinic records
- Defer prescribing if data are unavailable
- Talk about treatment options when you refuse to fill/refill, opioids

OPIOID RISK TOOL

		Mark each box that applies	Item Score If Female	Item Score If Male
1. **Family History of Substance Abuse**	Alcohol	[ ]	1	3
	Illegal Drugs	[ ]	2	3
	Prescription Drugs	[ ]	4	4
2. **Personal History of Substance Abuse**	Alcohol	[ ]	3	3
	Illegal Drugs	[ ]	4	4
	Prescription Drugs	[ ]	5	5
3. **Age** (Mark box if 16 – 45)		[ ]	1	1
4. **History of Preadolescent Sexual Abuse**		[ ]	3	0
5. **Psychological Disease**	Attention Deficit Disorder, Obsessive Compulsive Disorder, Bipolar, Schizophrenia	[ ]	2	2
	Depression	[ ]	1	1
		TOTAL	____	____

Total Score Risk Category: Low Risk 0-3, Moderate Risk 4-7, Hi Risk ≥ 8

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Ongoing Assessment: The PEG/ACA (6 A's)

- Analgesia (PAIN)
- Affect (ENJOYMENT)
- Activity (GENERAL ACTIVITY)

} **P E G**

- Adverse effects
- Adjuncts
- Concerning (Aberrant) behaviors

Jackman RP & Mallett BS, *AFP* 2008; 78: 1155-1162

PEG: A Validated Ongoing Assessment Instrument

1. **What number best describes your <u>Pain on average in the past week</u>? *(0=No pain – 10=Pain as bad as you can imagine)***
2. **What number best describes how, during the past week, pain has interfered with your <u>Enjoyment of life</u>? *(0=Does not interfere – 10=Completely interferes)***
3. **What number best describes how, during the past week, pain has interfered with your <u>General activity</u>? *(0=Does not interfere – 10=Completely interferes)***

*Add these 3 numbers to generate a validated measure you can follow over time

Krebs EE, et al. J Gen Intern Med 2009

Adverse Effects of Opioids

- CONSTIPATION
- Nausea
- Sedation
- Decreased cognition
- Loss of control
- Hyperalgesia
- Hypogonadism
- Urinary retention

Adjuncts

- "What else have you done to try to reduce or manage your pain?"
  - Non-opioid drugs (NSAIDs, anticonvulsants, etc.)
  - Exercise with flexibility training
  - Nondrug treatments
    - Physical therapy
    - Complimentary therapies
    - Cognitive behavioral therapy
  - Injections
  - Pumps

Concerning (Aberrant) Medication Taking Behaviors
The spectrum of Severity

- Illegal activities – forging scripts, selling opioid prescription, buying drugs from illicit sources
- Multiple "lost" or "stolen" opioid prescriptions
- Non-adherence with monitoring requests (e.g. pill counts, urine drug tests)
- Deterioration in function at home and work
- Resistance to change therapy despite adverse effects (e.g. over-sedation)
- Running out early (i.e., unsanctioned dose escalation)
- Requests for specific opioid by name, "brand name only"
- Requests for increase opioid dose
- Non-adherence with other recommended therapies (e.g., physical therapy, behavioral therapy)

Butler et al. Pain. 2007

Note: for most of these, need to track pattern & severity over time

https://www.youtube.com/watch?v=VFKGEqSMZzc

View Video 1—Pain Management: Assessment with the PEG/ACA (6 A's)

Observe this physician-patient assessment encounter with a 46 year-old new patient whose records from her previous physician showed occasional escalation of dose due to complaints of increased pain and no urine drug screening. The Prescription Monitoring Program showed prescriptions only from her gastroenterologist. Her score on the Opioid Risk Tool (ORT) is 3 (low risk).

<u>https://www.youtube.com/watch?v=VFKGEqSMZzc</u>

Why Implement a Monitoring Framework?

- Increasing evidence that structured care programs can assist patients in reducing or resolving concerning/aberrant behaviors

Outcomes of Structured Care

- Wiedemer et al (2007): 77/171 (45%) of pts with concerning/aberrant behaviors who received structured opioid care (agreement, UDS, etc.) adhered to the agreement and resolved concerning behaviors
- Jamison et al (2010): high risk pts who received structured care – monthly UDS, compliance checklists, motivational counseling – showed markedly reduced positive scores on Drug Misuse Index (PDUQ, ABC, urine screens)
  - High-Risk control patients – 73.7%
  - High risk structured care - 26.3%
  - Low risk controls - 25%

Weidemer et al, Pain Medicine, 2007; Jamison et al, Pain 2010

Steps for Implementing a Monitoring Framework

1. Have a risk/benefit discussion about opioids (include in your agreement)
2. Explore non-opioid treatment options
3. If appropriate, talk about an opioid "test/trial"
4. Define treatment goals
5. Encourage patient responsibility
6. Explain opioid monitoring measures, emphasizing patient safety issues

Step 1: Have a Benefit/Risk Discussion About Opioids

Potential Benefits	Potential Risks
▪ Analgesia	▪ Toxicity/side effects
▪ Function	▪ Functional impairment
▪ Quality of life	▪ Physical dependence
	▪ Abuse/addiction
	▪ Overdose
	▪ Increased pain sensitivity

Dose-Related Risk: How Much Opioid Is too Much?

- Patients receiving ≥**100 morphine mg equivalents (MME)** had an 8.9-fold increase in overdose risk with a 1.8 percent annual overdose rate.
- Patients receiving ≥ **120 MME** doubled the risk of substance-related health services utilization encounters (withdrawal, intoxication, overdoses).
- CDC Guidelines: use additional precautions at ≥ 50 mg MME and generally avoid doses ≥ 90 mg MME

Dunn et al., 2010; Braden et al., 2010; http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0001

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Step 2: Explore Nonopioid Treatment Options

- Nonopioid drugs
- Exercise with flexibility training
- Nondrug treatments
  - Physical therapy
  - Complementary therapies (yoga, meditation, guided imagery, etc.)
    - Guided imagery http://www.healthjourneys.com/kaiser/easePain_flash.asp
  - Cognitive behavioral therapy
- Injections
- Pumps

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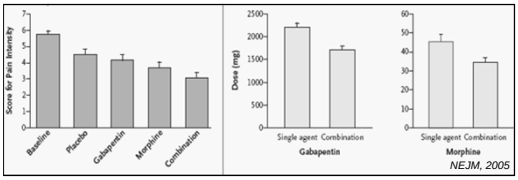
Exploit Synergism of Opioids + Anticonvulsants

Morphine, Gabapentin, or Their Combination for Neuropathic Pain

Ian Gilron, M.D., Joan M. Bailey, R.N., M.Ed., Dongsheng Tu, Ph.D., Ronald R. Holden, Ph.D., Donald F. Weaver, M.D., Ph.D., and Robyn L. Houlden, M.D.



NEJM, 2005

3
1

Step 3: If Appropriate, Offer an Opioid "Test/Trial"

- We lack strong accurate predictors:
  - Who will experience lasting benefit from chronic opioid analgesics
  - Who will be harmed by chronic opioid analgesia
- Current evidence suggests that a 3-6 month trial may be appropriate
  - In patients with no contraindications
  - If not continued past the point of obvious failure
- Offer opioid prescriptions/changes as a **"test"** of the medication

Opioid Efficacy in Chronic Pain

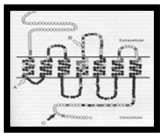
- Most literature surveys & uncontrolled case series
- RCTs are short duration <4 months with small sample sizes <300 pts
- Mostly pharmaceutical company sponsored
- Pain relief modest
- Modest to no functional improvement
- **Not all chronic pain is opioid responsive**

Balantyne JC, Mao J. NEJM 2003
Martell BA et al. Ann Intern Med 2007
Eisenberg E et al. JAMA. 2005

Variability in Response to Opioids

Mu Receptor

- >100 polymorphisms in the human mu opioid receptor gene
- Mu receptor subtypes
  - Not all patients respond to same opioid in same way
  - Not all pain responds to same opioid in the same way
  - Incomplete cross-tolerance between opioids



Mu receptor genome

Smith H, Pain Physician, 2008

Long-Term Opioids Can Increase Pain Sensitivity *(in some patients)*

- Some patients obtain **pain relief** when tapered off opioids
- Animal studies chronic opioids increased pain sensitivity
- Methadone maintenance pts w/ increased pain sensitivity
- ? neuroadaptation to chronic opioids
- Opioid withdrawal mediated pain
- Opioid-induced hyperalgesia

www.sbirtonline.org

Li X et al. Brain Res Mol Brain Res 2001
Doverty M et al. Pain 2001
Angst MS, Clark JD. Anesthesiology 2006

Step 4: Define Treatment Goals

- Work with patient to identify **specific measurable realistic** functional goals
- Use these goals jointly to measure benefit
- Remind patient that pain is unlikely to go away completely

Step 5:
Encourage Patient Responsibility & Safety

- Explain legal responsibilities
  - Safeguarding (lock box), disposing, not sharing or selling
- Encourage the patient to look out for early signs of harm
  - Am I safe to drive or operate heavy machinery?
  - Am I having trouble controlling the use of my medication?
- Give Rx for naloxone for OD reversal

Naloxone Prescription Instructions

Intramuscular

- Rx: Naloxone 0.4 mg/mL
- Quantity: 2-4 single-use 1 mL vials or 1 X 10 mL multi-use vial
- Sig: for suspected opioid overdose, inject 1 mL in shoulder or thigh. Repeat after 3 minutes if no or minimal response
- Refills: prescriber preference

Intra-Nasal

- Rx: Naloxone 1mg/1mL
- Quantity: 2-4 x 2 mL prefilled Luer-Jet™ Luer-Lock needleless syringe
- Sig: For suspected opioid overdose, spray 1 mL (half of the syringe) into each nostril. Repeat after 3 minutes if no or minimal response
- Refills: prescriber preference

Auto-Injector

- Rx: Naloxone 0.4 mg/mL
- Quantity: 1 kit containing 2 auto-injectors
- Sig: View instructional video. For suspected opioid overdose, inject 1 mL in thigh. Repeat after 3 minutes if no or minimal response
- Refills: prescriber preference

Step 6:
Explain Opioid Monitoring & Why We Do It

- Focus on patient safety
- Designed to help protect patient from getting harmed by medications.
  - Diuretic-potassium monitoring analogy
- A standard policy used with all patients
  - Note: set **level of** monitoring to match risk (more frequent visits & monitoring in higher risk patients)

"Universal Precautions"
Protect Patients & Help Detect Concerning (Aberrant) Behaviors

- Agreements ("contracts")
- Urine Drug Testing
- Pill Counts
- Prescription Monitoring Programs
- Phone Follow up

Agreements (Contracts)

- Educational and informational, articulating rationale and risks of treatment
- Spell out monitoring (pill counts, etc.) and action plans for concerning/aberrant medication taking behavior
- Universal use takes "pressure" off provider to make individual decisions (Our clinic policy is…)

Fishman SM, Kreis PG. Clin J Pain 2002
Arnold RM et al. Am J of Medicine 2006
Starrels JL et al. Ann Intern Med 2010

Monitoring: Urine Drug Tests

- **Evidence of therapeutic adherence**
- **Evidence of non-use of illicit drugs**
- Know limitations of test and your lab
- Know a toxicologist/clinical pathologist
- Consider Medical Review Officer (MRO) training
- Efficacy not well established
- Helpful strategies…
  - What, if anything, do you think we might find today…
  - Your urine was positive, what can you tell me about it?

Starrels JL et al. Ann Intern Med 2010
Heit HA, Gourlay DL. J Pain Symptom Manage 2004
Standridge JB et al. Am Fam Physician 2010

Monitoring: Pill Counts

- **Confirm medication adherence**
- **Minimize diversion**
- **Important: know what the pills look like**
- Helpful strategies…
  - Bring patient back 3-7 days early
  - "Forgot pills", schedule return visit with in a week
  - Unsanctioned dose escalation is unacceptable

Monitoring: Prescription Monitoring Programs

- **"better than a urine drug screen"**
- **Identify patients using multiple providers**
- Share information with patient in a non-judgmental fashion and ask them to explain discrepancies
- Beware limitations: time lag, often will not include information from neighboring states

Consultation with a Friend or Family Member

- Consider including a section in your Controlled Substance Agreement granting permission for you to contact a specific friend or family member if you become concerned about the patient's safety while on opioids
- Consider including this person in overdose prevention education and use of naloxone

Video 2—Pain Management: Opioid Agreement

Observe this physician-patient encounter between a physician whose office uses "universal precautions" including a controlled substance agreement that establish safeguards to increase patient safety when prescribing chronic opioids.
https://www.youtube.com/watch?v=So7rGNUmQqQ

Brief Intervention: Addressing Concerning Behaviors

Concerning (Aberrant) Medication Taking Behaviors- Document These in Your Note

- Illegal activities – forging scripts, selling opioid prescription, buying drugs from illicit sources
- Multiple "lost" or "stolen" opioid prescriptions
- Non-adherence with monitoring requests (e.g. pill counts, urine drug tests)
- Deterioration in function at home and work
- Resistance to change therapy despite adverse effects (e.g. over-sedation)
- Running out early (i.e., unsanctioned dose escalation)
- Requests for specific opioid by name, "brand name only"
- Requests for increase opioid dose
- Non-adherence with other recommended therapies (e.g., PT, behavioral therapy)

Butler et al. Pain. 2007

Note: for most of these, need to track pattern & severity over time

Concerning/Aberrant Medication Taking Behaviors: Differential Diagnosis

- **Inadequate analgesia** – "Pseudoaddiction"[1]
  - Disease progression
  - Opioid resistant pain (or pseudo-resistance)[2]
  - Withdrawal mediated pain
  - Opioid-induced hyperalgesia[3]
- **Addiction**
- **Opioid analgesic tolerance**[3]
- **Self-medication of psychiatric and physical symptoms other than pain**
- **Criminal intent** - diversion

[1] Weissman DE, Haddox JD. 1989; [2] Evers GC. 1997; [3] Chang C et al 2007

Screening: Assess for Opioid Benefit

- PEG scores—lack of improvement may indicate a failure of therapy
- Changes in function: Is opioid therapy achieving the patient's goals?
- Use these findings in your "risk-benefit" decision making

Brief Intervention: Discuss Concerning (Aberrant) Medication-Taking Behavior

- Non-judgmental stance
- Use open-ended questions
- State your concerns about the behavior
- Examine the patient for signs of flexibility
  - Is the patient focused more on **the opioid** or **pain relief?**
- Discuss the need for increased monitoring

Passik SD, Kirsh KL. J Supportive Oncology 2005

Continuation of Opioids

- Assess and document benefits and harms
- To continue opioids:
  - **Does the PEG show evidence of benefit?**
  - **Does the benefit outweigh observed or potential harms?**
- Note: you do not have to prove addiction or diversion to justify tapering opioids—lack of benefit and/or high level of risk is enough

Options for Addressing Concerning (Aberrant) Behaviors & Continuing Pain

1. Increase monitoring—more frequent visits, return for pill counts, call in for UDS
2. Consider non-opioid options to address continuing pain
   - Re-attempt to treat underlying disease & co-morbidities
   - Re-explore possible adjuncts
3. If concerning/aberrant behaviors decrease or disappear, consider escalating dose as a "test."
4. If simply no benefit after several months, begin opioid taper
5. If concerning/aberrant behaviors continue, consider a discontinuation strategy
   - Begin opioid taper
   - Switch to buprenorphine/methadone
   - Refer to treatment

Video 3: Follow-up Interview

Observe this clinician-patient encounter between a patient who is requesting increased medication and a clinician who discovers behaviors that concern him.

https://www.youtube.com/watch?v=ur_PxJ8QPCM

Discontinuing Opioids

Opioids may be discontinued when the physician's assessment indicates:

1. Lack of benefit (monitor using PEG scores)
2. Risk outweighs benefit

Discontinuation of Opioids: Discussing Lack of Benefit

- Stress how much you believe / empathize with patient's pain severity and impact.
- Express frustration re: lack of good pill to fix it.
- Focus on patient's strengths.
- Encourage therapies for "coping with" pain.
- Show commitment to continue caring about patient and pain but without opioids

Discontinuation of Opioids: Discussing Lack of Benefit

- Stress that some patients experience improvement in function and pain control when chronic opioids are stopped
- Make it clear that you are **not** discharging the patient but discontinuing an ineffective treatment
- Taper patient slowly to prevent opioid withdrawal

How To Taper Opioids

- Decrease by 10–50% percent each week
  - Rate of decrease determined by reason for taper
  - More rapid tapers (2-3 weeks) with severe adverse events like overdose
- Allow supply of short-acting medications to treat "breakthrough" symptoms
  - Build up alternative pain treatment modalities
  - Comfort medications
- Schedule close follow-ups

Treatment: Clonidine

Oral Dosing

- Initial dosing: 0.1 mg po Watch BP carefully
- Titrate up to 0.1 to 0.3 mg po q4-6 hours, then taper
- Risk: HYPOTENSION
- Effective adjuvant to other meds listed

Transdermal (Patch)

- More steady levels of med; avoid cyclic hypotension and rebound.
- Dosed one patch per week ($10/patch).
- Dose range: 0.1-0.4 mg
- 24-48 hours to start to work -- can use oral clonidine initially while waiting for effect.

"Comfort" Meds

- Ibuprofen 600 QID
- Dicyclomine 20 mg QID for stomach cramping
- Antiemetics: Trimethobenzamide 250 mg po/ 200 mg IM q6-8 hours or promethazine
- Muscle relaxants: Methacarbamol 500-750 mg up to QID

- Antidiarrheals:
  - Kaolin with Pectin
  - Bismuth subsalicylate
  - Loperamide (less effective)

Sleep aids

Trazodone	50-100 mg
Doxepin	25-50 mg
Amitriptyline	50mg

Referral to Treatment:
Helping Patients with Signs of Addiction

Stopping Opioids in Patients with Possible Addiction: Talking Points

- **Give specific feedback** on what previous behaviors raise your concern for possible addiction/loss of control
  - You may have to agree to disagree on your diagnosis
- **Explain that benefits no longer outweigh risks**.
  - "I cannot responsibly continue prescribing opioids as I feel it would cause you more harm than good."
- **Offer a menu of treatment options:** refer for opioid free treatment, buprenorphine, or methadone.
  - Stay 100% in "Benefit/Risk of Med" mindset.

Video 4: Discontinuing Opioids

Observe this physician-patient encounter between a physician and a patient who is documented in his state's Prescription Monitoring Database to be receiving opioids from multiple prescribers.
https://www.youtube.com/watch?v=GhPoWgLAvfU

Additional Materials

- Visit PCSS-O.org & sbirtonline.org for additional materials including:
  - CME & mentoring opportunities
  - Videos demonstrating interview techniques
  - Model Controlled Substances Agreement
  - Model Pain Assessment Form
  - Practice Role Plays (scripts for patient, clinician and observer scripts)
  - Pocket Card on Pain and Addiction

Thanks!

- Questions? Comments? Suggestions?
- Contact info: seale.paul@navicenthealth.org

PCSS-O Colleague Support Program

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Mentors comprise a national network of trained providers with expertise in **addiction medicine/psychiatry and pain management.**
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.

For more information on requesting or becoming a mentor visit:
www.pcss-o.org/colleague-support

- **Listserv:** A resource that provides an "Expert of the Month" who will answer questions about educational content that has been presented through PCSS-O project. To join email: pcss-o@aaap.org.

PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American College of Physicians (ACP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org
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