Federal and State Policy Efforts to Prevent Prescription Opioid Diversion

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Conflict of Interest Disclosure

- **Authors Conflicts of Interest:**
  - C. Carlson, No Conflict of Interest
  - A. Gilson, No Conflict of Interest
True Disclosure:

- **WE ARE ONLY RESPONSIBLE FOR WHAT WE SAY……..**

- **NOT WHAT THE GOVERNMENT DOES!!!**
Participants should:

- Understand the current epidemiological evidence about the medical use and non-medical use of prescription opioid medications in the U.S., as well as some limitations and their implications.
- Understand the U.S. drug regulatory system and its interface with the medical use and non-medical use of prescription opioid medications.
- Recognize the international principle of Balance and how it relates to prescription medication abuse and diversion.
- Identify a variety of Federal policy efforts to mitigate prescription opioid medications abuse and diversion, and their implications for dental professionals.
- Identify a number of state policy activities designed to reduce prescription opioid medications abuse and diversion, and their implications for dental professionals.
 Deaths involving prescription opioid analgesics now outnumber deaths from heroin and cocaine combined

Death involving prescription drug abuse is one of the most prevalent public health epidemics, outpacing deaths from traffic fatalities.

<table>
<thead>
<tr>
<th>2014: Statistics on Death in the U.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death Determinations</td>
</tr>
<tr>
<td>Drug Overdoses</td>
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<td>Prescription Drug Overdoses</td>
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<tr>
<td>Overdoses involving Opioids</td>
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<tr>
<td>Overdoses involving Benzodiazapines</td>
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<tr>
<td>MVA (2013 )</td>
</tr>
</tbody>
</table>

Past Month Non-Medical Use of Psychotherapeutic Drugs Aged 12 or Older, 2002-2014

The Problem...

- **Nonmedical users of pain relievers most often get the drug from family and friends**

![Diagram showing how different nonmedical users of pain relievers get their drugs.](chart)

**How Different Nonmedical Users of Pain Relievers Get Their Drugs**

- **Methods and sources for obtaining pain relievers**
  - **Recent Initiates**
    - Bought from friend/relative, dealer, or internet: 9%
    - Prescribed from 1 or more doctors: 17%
    - Obtained from friend/relative for free or w/o asking: 68%
  - **Occasional Users**
    - Bought from friend/relative, dealer, or internet: 13%
    - Prescribed from 1 or more doctors: 17%
    - Obtained from friend/relative for free or w/o asking: 66%
  - **Frequent or Chronic Users**
    - Bought from friend/relative, dealer, or internet: 28%
    - Prescribed from 1 or more doctors: 26%
    - Obtained from friend/relative for free or w/o asking: 41%

Source: SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2009-2010
1. **DRUG CONTROL SYSTEM**  
    (lawful distribution)

   - Manufacturers and Distributors
     (Common Carriers)
     - Pharmacies
     - Hospitals/Clinics
     - Internet w/Rx
     - Practitioners
       - Prescribers
       - Dispensers
     - Nursing homes
     - Hospices
   - Patients
     (Lawful medical use)
     ("Prescribed")

2. **PRIMARY DIVERSION**  
    (unlawful; supplies some abusers and re-distribution)

   - Theft from manufacturers and distributors* 
   - Theft in transit*
   - Theft from hospitals*
   - Pharmacies/robbery*
   - Employee/customer Pilferage*
   - Theft of Rx/forgery
   - Script docs/pill mills
   - Inappropriate prescribing
   - Doctor shopping
   - Patient sells or gives
   - Theft from home
   - Theft from patient
   - Improper disposal
   - International smuggling
   - Internet sales without Rx

---

Non-medical use
• Misuse
  - Unintentional
    (sharing with others)
  - Intentional
    (suicide attempt)

• Aberrant behaviors
  (forging/altering Rx)

• “Substance Use Disorders”
  (abuse & addiction)

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PPSG, 2007
* = Amounts reported by law on DEA Form 106

SUBCHAPTER I
DEFINITIONS

961.01 Definitions. As used in this chapter:

(10m) “Diversion” means the transfer of any controlled substance from a licit to an illicit channel of distribution or use.
“Prescription medication” ≠ Prescribed medication

Essential to determine whether valid prescription was involved
Senate Testimony:

“Over the past several years... hundreds of millions of dosage units of controlled substances were diverted into the illicit marketplace across the United States.”

(July, 2012, p. 5)
Factors to Consider

- Diversion (i.e., no prescription found)
- Doctor-shopping (i.e., diversion)
- Motivations??
- Non-medical routes of administration
- Co-morbidities (e.g., substance use history)
- Poly-pharmacy
- Previous overdose episodes
- Little clinical information
- Not a linear effect
- Not causal

Legitimate Patients?

Methadone

Hall et al. (2008)
Dunn et al. (2010)
Gomes et al. (2011)
Bonhert et al. (2011)
Paulozzi et al. (2012)
Strategies to Reduce Morbidity/Mortality

- Law Enforcement Diversion Control
- Tamper-Resistant Prescription Forms
- Decrease Problematic Medication Combinations
- Treatment Benefit/Risk Evaluations
- Analgesics with No Abuse Potential
- Suspended DEA Registrations
- Public Awareness Campaigns
- Substance Use Disorder Evaluations
- Monitoring Employee Pilferage
- Written Agreements/Contracts
- Hydrocodone Rescheduling
- Safeguarding Prescription Pads
- Abuse-Deterrent Products
- Pharmacy Theft Monitoring
- Clinical Practice Guidelines
- Medication Geotracking
- Medication Drop Boxes
- Continuing Education
- Drug Formularies
- ED Guidelines
- Patient Registration
- Electronic Prescriptions
- PDMPs
- Prescribing Privileges
- Urine Drug Testing
- Prescribing Standards
- Prior Authorization
- Take-Back Programs
- Coordinated Care
- Pill Mill Laws
- Prescription Series
- Step Therapy
- Medication Security
- Practitioner Education
- Disposal Opportunities
- Dosage Limits
- Patient Education
- REMS Training
- Naloxone Access
- Medicaid DURs
Controlled Substances Act (CSA)

- Enacted in 1970
  - Regulates manufacture, importation, possession, use, and distribution of certain substances
- DEA interprets and enforces the CSA
  - DHHS has supporting responsibilities
Controlled Substances Act
TITLE 21 - FOOD AND DRUGS
CHAPTER 13 - DRUG ABUSE PREVENTION AND CONTROL
SUBCHAPTER I - CONTROL AND ENFORCEMENT

PART A - INTRODUCTORY PROVISIONS
§ 801. Congressional findings and declarations: controlled substances.

The Congress makes the following findings and declarations:

(1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people.

(2) The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people.

(7) The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances.
Opioids can be effective, are indispensable
- Must be available

Opioids have an abuse potential
- Must be controlled

“Controlled substance” label does not change medical value

Preventing abuse not to interfere with medication availability

Imperative to Achieve Balance

U.S. Sources

- Department of Health and Human Services (DHHS)
  - Food and Drug Administration (FDA)
  - National Institutes of Health (NIH)
    - National Institute on Drug Abuse (NIDA)
  - Center for Disease Control & Prevention (CDC)
  - National Cancer Institute (NCI)
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
- Drug Enforcement Administration (DEA)
- Office of National Drug Control Policy (ONDCP)
- Institute of Medicine (IOM)
- American Medical Association (AMA)
- American Cancer Society (ACS)
- Federation of State Medical Boards (FSMB)
- National Association of Attorneys General (NAAG)
Still Awake???
Update: What is Happening at the Federal Level...

1. Legislative and Regulatory Mandates
2. Food and Drug Administration (FDA) and Drug Enforcement Agency (DEA) Requests/Rulings
3. Office of National Drug Control Policy (ONDCP) - White House Initiatives
Food and Drug Administration Safety and Innovation Act (FDASIA)

- Signed into law on July 9, 2012, expanded the FDA’s authorities and strengthens the agency’s ability to safeguard and advance public health
- An amendment to the Act: Section 1139 “Scheduling of Hydrocodone”
  - Required FDA to hold a public meeting
  - Solicit advice and recommendations to assist in conducting a scientific and medical evaluation and scheduling recommendation to DEA regarding drug products containing hydrocodone, combined with other analgesics, or as an antitussive

Hydrocodone Rescheduling: Yesterday’s Solutions for Today’s Problem

(Barber, L. DEA Chronicles. (Nov. 19, 2013))

- Hydrocodone combination products were officially rescheduled, 8.22.2014
  - Effective 10.6.2014
New Rule Effect

- Need a new written prescription for each 30 day supply
- May write up to 90 day supply (multiple prescriptions – with instructions indicating earliest date when pharmacy may fill each)
- May fax prescription, but patient must have written prescription to obtain Rx from pharmacy
- May call in for an emergency
  - Only for amount needed to cover emergency
  - Need written prescription within 7 days
Utah post-op patients reported:
- Most received hydrocodone (63%)
- 67% had leftover medication
- 92% received no disposal instructions
- 91% kept the extra medication at home

Will rescheduling change this data?

(Bates et al, 2011; Webster, 2013)
36 months before rescheduling
- Number dispensed hydrocodone combination prescriptions decreased 8.4%
- Number of dispensed tablets decreased 6.0%

After rescheduling (compared to the previous 12 months)
- Number dispensed hydrocodone combination prescriptions decreased 22%
- Number of dispensed tablets decreased 16%

“supply reduction ... in the absence of demand reduction and harm reduction could paradoxically increase overdoses.”

There was a large increase in the number of the opioid prescriptions from 2002-2010

Followed by a slight decrease in the number of opioid prescriptions during 2011-2013

The rates of opioid diversion and abuse and opioid related deaths followed a similar pattern of a large increase during the years of 2002-2010 followed by a slight decrease during 2011-2013

Findings suggest that the U.S. may be making progress in controlling the diversion and abuse of prescription opioids and decreasing opioid related deaths

Abuse of heroin and the number of deaths from heroin has tripled during the years of 2011-2013

Categories of Abuse Deterrent Formulas (ADF)

- Physical/chemical barriers
- Agonist/antagonist combinations
- Aversion
- Delivery System
- New molecular entities and prodrugs
- Combinations
- Novel approaches

Timeline for FDA Approvals for ADFs of Opioids for Pain

FDA Draft Guidance for Industry (1/9/13)

ER oxycodone product (4/10)

FDA Final Guidance for Industry (4/15)

ER oxycodone/naloxone product (7/23/14)

ER morphine sulfate product (10/2/15)

ER morphine sulfate/naltrexone product (10/17/14)

ER hydrocodone bitartrate product (11/20/14)

FDA website.
http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm338566.htm
Accessed January 5, 2016
- Release of multiple extended-release (ER) formulations with abuse deterrent properties.
- Naloxone hydrochloride auto-injection (Evzio) approved 04.03.2014
- Naloxone hydrochloride (Narcan nasal spray). Approved 11.18.2015
- Combination products with greater than 325 mg of acetaminophen per unit were voluntarily withdrawn by the manufacturers at FDA’s request
  - Effective 01.01.2014
Determining when to initiate or continue opioids for chronic pain outside end-of-life care

Opioid selection, dosage, duration, follow-up, and discontinuation

Assessing risk and addressing harms of opioid use
Office of National Drug Control Policy (ONDCP)

Epidemic: Responding to America’s Prescription Drug Abuse Crisis 2011

1. Education – parents, youth, patients, & HCP
2. Tracking & Monitoring
3. Proper medication disposal
4. Enforcement
What Can We Do?
Promote Government and Society Actions

- Require comprehensive prescriber education on opioid pharmacology and management—including risks, benefits, and alternatives
- Advocate for increased access and funding for mental health treatment services, including substance use disorder treatment
- Advocate for increased research funding for pain management and substance use disorder treatment
- Develop safe, convenient and environmentally friendly medication disposal programs
- Expand Prescription Drug Monitoring Program features
  - Support expanded access for all health professionals to PDMP websites
  - Support interstate/national sharing of information
  - Simplify and standardize state requirements for account registration

Conduct a thorough history and physical exam including the patient’s medical, psychiatric, and social history that also ascertains any substance use disorder.

Obtain records from other providers treating the patient with pain.

Facilitate interdisciplinary management (including specialist referrals) of comorbid conditions, including psychiatric and substance use disorders/conditions that may affect risk with opioid use (i.e., OSA, obesity, depression, PTSD, anxiety).

Utilize multimodal pharmacologic treatment, combining non-opioids with opioids.

Initiate opioid therapy as a trial with the understanding if it decreases pain and increases function it may be maintained.

Start opioid therapy on lowest effective dose. Recommend pain specialist referral with higher doses of opioids (Some guidelines cite 90-100 mg morphine sulfate equivalents [Nuckols, et al., 2014])

Use Pain Management Universal Precautions regularly to monitor and manage potential risks with chronic opioid use (Gourlay, Heit, & Almahrezi, 2005):

- Employ regular risk evaluations for all patients on opioids
- Implement written Pain/Opioid treatment agreements
- Determine opioid adjustments on outcomes of the 5 ‘A’s: Analgesia, activity, adverse effects, aberrant behavior, and affect
- Employ intermittent adherence monitoring measures as indicated, including:
  - Urine drug testing
  - Pill counts
  - State prescription monitoring program (PMP) websites
- Plan for safe opioid tapering when discontinuing therapy


Let’s Change from Federal to State
American Association of Dental Examiners

2008 Policy:

The Report of the AADE Committee to Develop Guidelines on Comprehensive Pharmaceutical Drug Evaluation

Approved by the General Assembly at the 125th Annual Meeting, October 15, 2008

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(October 15, pp. 1-58)
Content of Dental Records for Ongoing Pain Management

- Patient evaluation
- Physical examination
- Diagnostic investigation & diagnosis
- Treatment plan with goals
- Consultation or referral results
- Benefit/Risk discussion
- Informed consent
Content of Dental Records for Ongoing Pain Management (continued)

- Documentation of treatment, and medications used (prescribed, dispensed, administered)
- Patient instructions
- Agreement, if needed
- Ongoing evaluation of treatment progress
- Emerging problems
- PDMP queries
Recent State Responses to CSs Abuse and Diversion

- **State Prescribing Laws**
  - Dosage ceilings

- **Reducing Volume of Unused Medications**
  - DEA Take Back
  - DEA Disposal Requirements

- **Prescription Drug Monitoring Programs (PDMPs)**

- **Addressing Pill Mills**
# State Regulatory Policies with Dosage Ceiling

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<td>WA (2012)</td>
<td>120</td>
<td>Requirement</td>
<td>Chronic non-cancer pain</td>
<td>Consultation</td>
<td>Yes</td>
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<tr>
<td>OH (2013)*</td>
<td>80</td>
<td>Guidance</td>
<td>Chronic non-terminal pain</td>
<td>Consider treatment review/referral</td>
<td>--</td>
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<tr>
<td>IN (2014)</td>
<td>15/60</td>
<td>Requirement</td>
<td>Chronic pain</td>
<td>Treatment requirements/Treatment review/Consider referral</td>
<td>No</td>
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<tr>
<td>CO (2014)*</td>
<td>120</td>
<td>Guidance</td>
<td>Acute &amp; Chronic non-cancer pain</td>
<td>Additional safeguards/Consult or refer</td>
<td>--</td>
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<tr>
<td>CA (2014)</td>
<td>80</td>
<td>Guidance</td>
<td>All</td>
<td>Consider referral</td>
<td>--</td>
</tr>
<tr>
<td>RI (2015)</td>
<td>120</td>
<td>Requirement</td>
<td>Chronic pain</td>
<td>Consider consultation</td>
<td>No</td>
</tr>
</tbody>
</table>

* Includes Board of Dental Examiners as part of Joint Policy
Note: Table does not include workers compensation policies
PhRMA Statement on Support of DEA National Take Back Day

Washington, D.C. (September 23, 2010) — The Pharmaceutical Research and Manufacturers of America (PhRMA) stands behind National Take Back Day, an effort spearheaded by the Drug Enforcement Administration (DEA) that will allow patients to drop off expired, unused, and unwanted prescription drugs — which will be collected and destroyed by local law enforcement officials — at designated sites nationwide.

National Take Back Day takes place on Saturday, September 25, 2010 from 10 a.m. to 2 p.m. local time and is free and anonymous.

"Some take back programs can miss the mark by failing to provide aggressive law enforcement oversight, or by attempting to create programs that don’t work with a community’s existing resources. The DEA’s National Take Back Day takes both of those concerns to heart, building on both the community resources and diversion prevention elements, as well as a strong educational component," said Jeff Bond, Senior Vice President for State Government Affairs at PhRMA.

National Take Back Day combines necessary law enforcement oversight with educational and grassroots community advocacy to create a voluntary program that attempts to prevent prescription medicine diversion. Unlike unsupervised, unregulated take back programs, the DEA’s National Take Back Day offers consumers a voluntary program with guidance on handling unused and expired medications.

PhRMA partners with the Department of Fish and Wildlife and the American Pharmacists Association on the SMARxT Disposal Program. This program informs people how to safely dispose of medicines in the trash, and notes the environmental risk posed by flushing medicines down the toilet. PhRMA recommends that all unused medicines, unless specified otherwise by the Food and Drug Administration, should be mixed with water; sealed in an opaque container safely secure from children, pets, and others; then discarded in household trash to be later incinerated or placed in a government approved solid waste landfill. Consumers may also take part in the DEA’s National Take Back Day as a way to safely dispose of medications in a way that prevents diversion or potential for abuse.
<table>
<thead>
<tr>
<th>Drug name</th>
<th># of prescriptions (%)</th>
<th># of dosage units (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All C-II</td>
<td>229(37.9)</td>
<td>6763.5(46.7)</td>
</tr>
<tr>
<td>fentanyl (trnsdrml)</td>
<td>21(3.5)</td>
<td>133(0.9)</td>
</tr>
<tr>
<td>hydromorphone</td>
<td>1(0.2)</td>
<td>60(0.4)</td>
</tr>
<tr>
<td>meperidine</td>
<td>1(0.2)</td>
<td>4(0.0)</td>
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<tr>
<td>methadone</td>
<td>10(1.7)</td>
<td>422(2.9)</td>
</tr>
<tr>
<td>morphine</td>
<td>12(2.0)</td>
<td>571(3.9)</td>
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<tr>
<td>morphine SR</td>
<td>10(1.7)</td>
<td>273(1.9)</td>
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<tr>
<td>oxycodone</td>
<td>26(4.3)</td>
<td>1254(8.7)</td>
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<td>oxycodone ER</td>
<td>25(4.1)</td>
<td>1117(7.7)</td>
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<td>oxycodone/comb</td>
<td>123(20.3)</td>
<td>2929.5(20.2)</td>
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<tr>
<td>All C-III</td>
<td>376(62.1)</td>
<td>7713.5(53.3)</td>
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<tr>
<td>codeine/APAP</td>
<td>103(17.0)</td>
<td>1978.5(13.7)</td>
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<tr>
<td>hydrocodone/APAP</td>
<td>273(45.1)</td>
<td>5735(39.6)</td>
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<tr>
<td>Total</td>
<td>605(100)</td>
<td>14477</td>
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</tbody>
</table>

Data collected at a 4-hour event in Dane Country in October 2011

MEDDROP
“THE BEST PLACE TO GET RID OF MEDICINES”

A Med Drop box is now available in the lobby at the Middleton Police Department, 7341 Donna Drive. The lobby is open 24 hours a day, every day. Please empty pills into plastic sealed bags and recycle the pill bottles at home. If you are dropping off liquids or creams, they may remain in the original container, but also placed in a sealed plastic bag to avoid spillage. Please see www.ci.middleton.wi.us/police/meddrop/htm for more information about what is accepted.
THURSDAY, DEC. 3

Sauk Prairie police officer [REDACTED] appears in court, facing felony charges for stealing prescription medication from the department’s drug disposal box, the Baraboo News Republic reports. Investigators found nearly 500 pills in the officer’s home.
Permits certain registrants to become “collectors”

“Collection” = receiving CSs for destruction

Effective 10/9/14
Disposal of Controlled Substances
Currently Allowable Methods

Practitioners

- Request assistance from local DEA Agent
  - List the CSs on DEA Form 41
    - Submit 3 copies to the Agent

- Agent authorizes and instructs disposal:
  - Transfer to reverse distributors
  - Deliver to DEA agent/nearest DEA office
  - Destruction in front of DEA agent/authorized person
  - Other means determined by Agent

- Does not change requirements of state law
Prescription Drug Monitoring Programs (PDMPs)

- **Where**
  All states but 2 (1 of the 2 have legislation)

- **When**
  Most PDMPs established since 2005

- **Why**
  Reduce prescription medication abuse and diversion

- **What**
  Statewide electronic databases
  - Collect, monitor, reports dispensing data

- **Who**
  Access by authorized HCPs
  - Physicians (prescribers)
  - Pharmacists (dispensers)
  - Other HCPs
Identify people who may be abusing or diverting prescription drugs

Inform clinical decisions about CSs

The issue is how to make this information more available and used:

- HCP practices
- Emergency departments
- Pharmacies
Insufficient usage due to:

- Awareness and system requirements
- Care team members often are not permitted access
- Using standalone Web portals or unsolicited reports do not support clinical practices and workflows
- No system-level access and standards among PDMPs, EHRs, and pharmacy
- Translating information into clinical decisions
- Work load
State Successes

New York
75% ↓

2012 Action:
New York required prescribers to check the state’s prescription drug monitoring program before prescribing painkillers.

2013 Result:
Saw a 75% drop in patients who were seeing multiple prescribers to obtain the same drugs, which would put them at higher risk of overdose.

Tennessee
36% ↓

2012 Action:
Tennessee required prescribers to check the state’s prescription drug monitoring program before prescribing painkillers.

2013 Result:
Saw a 36% drop in patients who were seeing multiple prescribers to obtain the same drugs, which would put them at higher risk of overdose.

States with “Pill Mill” Activity (n=46)

Last assessed via Internet search, January 6, 2016
Questions???
Providers’ Clinical Support System for Opioid Therapies (PCSS-O) Training

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
For questions email: pcss-o@aaap.org
Twitter: @PCSSProjects

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Webinar Evaluations (Post and 30-Day)

• Each PCSS-O partner organization that provides CE credit to participants is asked to submit a post and 30-day evaluation to participants for completion.

• Participants in today’s webinar can click on the following link to complete their evaluation: http://www.cvent.com/d/zfqqn7

• Participants will also receive the evaluation link by email at the completion of today’s webinar.

• By completing the evaluations, you are helping us improve PCSS-O resources!