Webinar Logistics

- The Q&A session will occur at the end. Please submit your questions via the ‘questions’ function.

- This webinar is being recorded and will be available on the C-Changetogether.org website on Monday.

@CChangetogether facebook.com/cchangetogether
Thank you to Purdue Pharma, L. P. who generously provided an unrestricted educational grant to C-Change that helped to fund this webinar.
Coalitions Tackling Pain Policy

• State rankings

• Burning issues

• Examples of coalition success in improving policies

• Resources to assist your advocacy efforts
The Facts


• 26% of unscheduled hospital admissions are due to uncontrolled pain (Fortner BV, Okon TA, Portenoy RK: A survey of pain-related hospitalizations, emergency department visits, and physician office visits reported by cancer patients with and without history of breakthrough pain. *J Pain* 3:38-44, 2002)
Today’s Presenters

David Woodmansee
Associate Director, Access to Care
American Cancer Society Cancer Action Network, Inc.

Bob Twillman, PhD, FAPM
Director of Policy and Advocacy
American Academy of Pain Management

Amy Goldstein, MSW
Director
State Pain Policy Advocacy Network (SPPAN)
How does your state rank?

David Woodmansee
Associate Director, Access to Care
American Cancer Society Cancer Action Network, Inc.
ACHIEVING BALANCE in State Pain Policy

- Five Report Cards to date
- Pain Policy Studies Group
- University of Wisconsin
Progress Report Card (CY 2013)

- 16 Evaluation Criteria
- 8 positive and 8 negative measures
15 States with an A Grade

- Arizona
- Georgia
- Idaho
- Iowa
- Kansas
- Maine
- Massachusetts
- Michigan
- Montana
- Oregon
- Rhode Island
- Vermont
- Virginia
- Washington
- Wisconsin
16 States with an B+ Grade

- Arizona
- California
- Connecticut
- Delaware
- Kentucky
- Maryland
- Minnesota
- Nebraska
- New Hampshire
- New Mexico
- Ohio
- South Carolina
- South Dakota
- Utah
- West Virginia
- Wyoming
12 States with a B Grade

- Arkansas
- Colorado
- District of Columbia
- Florida
- Hawaii
- Indiana
- Mississippi

- New Jersey
- New York
- North Carolina
- North Dakota
- Pennsylvania
8 States with a C or C+ Grade

- Alaska
- Louisiana
- Missouri
- Nevada
- Oklahoma
- Texas
- Illinois
- Tennessee
PAIN MANAGEMENT: BURNING ISSUES AND MODEL POLICIES

Bob Twillman, Ph.D., FAPM
Deputy Executive Director
Director of Policy and Advocacy
American Academy of Pain Management
Current Major Pain Policy Issues: What Are the Hot Topics?

• Rescheduling of hydrocodone-containing combination products
• Preventing misuse/abuse/diversion of prescription pain medications
  • Prescribing guidelines and regulations issued by states
  • Restrictions on Zohydro ER™
• Prescription monitoring programs
Hydrocodone Rescheduling

- DEA requested that FDA evaluate rescheduling hydrocodone-containing combination products (e.g., Vicodin®, Lortab®, Norco®, and others) into Schedule II
- Initial request in 2004 was rejected in 2008; DEA repeated its request in 2009
- Moving from Schedule III to Schedule II would mean:
  - No ability to routinely call in prescriptions
  - No automatic refills
  - Written prescription required for each (monthly) supply
  - Greater security throughout the pharmaceutical distribution chain
Hydrocodone Rescheduling

- Advisory committee convened January 2013; voted 19-10 to recommend rescheduling. Several panel members expressed:
  - Skepticism that this would work to reduce hydrocodone abuse
  - Fear that it would lead to increased abuse of heroin
  - A desire for a “third option”
- In October 2013 FDA announced that it was recommending rescheduling
- DEA final rule was approved August 22, 2014; rule will be effective as of October 6, 2014
Hydrocodone Rescheduling: Potential Unintended Consequences

• Some non-physician prescribers are barred by state law from prescribing C-II medications (e.g., nurse practitioners in Texas)

• May see increased oxycodone prescribing (preliminary New York data)

• May see increased codeine and tramadol prescribing

• Patients will need to be seen more frequently by providers
  • No more call-ins; existing refills will be canceled
  • 26 million refills will need to be accounted for (2011 numbers)
  • Disrupts patients’ and caregivers’ lives, reducing productivity and quality of life
Hydrocodone Rescheduling: Policy Needs

- Enhanced prescribing privileges for non-physician prescribers in a number of states
  - Models: AK SB 162; AZ HB 2380; CO HB 1099; IL SB 3109; MN HF 779; RI H 7937; UT HB 98 (pre-emptive, covering optometrists)

- In some states, allowing for the use of the “prescription series”
  - Federal law permits issuance of multiple prescriptions totaling up to a 90-day supply, provided prescriptions are written properly
  - Some states do not permit this, meaning patients receiving regular supplies of hydrocodone products will need to obtain a new prescription at least monthly

- Surveillance for new issues with access to care
Preventing Misuse/Abuse/Diversion: Prescribing Guidelines and Rules

- Some states are passing legislation to require licensing boards to establish rules for opioid prescribing (e.g., Indiana)
- Some are passing legislation to establish task forces to recommend rules for opioid prescribing (e.g., Pennsylvania)
- In other states, health departments are establishing guidelines under existing authority (e.g., Tennessee)
- Themes for these rules/guidelines:
  - Patients must be seen at designated intervals
  - Nature of exam and documentation is specified
  - Informed consent, screening for substance abuse, urine drug testing, treatment agreements all mandated
Preventing Misuse/Abuse/Diversion: Prescribing Guidelines and Rules

- Threshold doses set, beyond which certain things must be done
  - Re-evaluation of patient and treatment plan
  - Consideration of, or mandate for, referral to pain specialist
- Use of threshold doses is problematic
  - Doses are expressed in “morphine equivalents”
  - Equianalgesic conversion tables vary greatly in recommended conversion factors
  - Individuals vary greatly in their pharmacodynamic responses to given doses
  - Co-morbidities and drug-drug interactions can produce varied effects across individuals at a given dose
  - Some treat these as limits, not thresholds
Prescribing Guidelines and Rules: Policy Needs

- Prefer guidelines vs. rules
  - Less restrictive
  - Appears to work (Washington experience)
- Prefer task force (Model: PA HR 659) vs. licensing board
- Prefer that people with cancer NOT be carved out
- Prefer that threshold be based on duration of treatment
- Prefer that post-threshold requirements not include mandatory consultations
- Prefer that prescriber discretion be maximized and that necessary resources be provided
Preventing Misuse/Abuse/Diversion: Restrictions on Zohydro ER™

- Zohydro is a single-entity extended release hydrocodone capsule without abuse-deterrent formulation (ADF)
- FDA Advisory Committee voted 12-2 against approving medication, despite also voting that it was no less effective and no less safe than other drugs already on the market
  - Those voting against it indicated in explaining their votes that they were trying to send FDA a message that no new opioid medication should be approved without ADF
- FDA approved it despite Ad Comm vote
- Drug available for marketing in February 2014
Restrictions on Zohydro ER™

• Several states have sought to ban Zohydro or greatly restrict its use
  • Massachusetts: Banned by Gov. Patrick, but ban overturned in federal court
  • Vermont: Emergency rule implemented restricting prescribing, now converted to permanent rule pending a new rule covering all opioid prescribing
  • Indiana: Pending opioid prescribing rule contains restrictions specific to Zohydro
  • Alabama: Emergency rule effectively banning medication was withdrawn, then medical board decided to establish a consultant group to recommend general opioid prescribing guidelines
  • Maine: New rules being proposed
Currently Marketed Extended Release Opioids

August 2014

Dosage Unit Strength (mg morphine)

Non-ADF
23 dosage forms

ADF
4 dosage forms

22 dosage forms

6 dosage forms
Zohydro ER™ Policy Needs

• It seem illogical and unwise to single out one medication for restrictions and/or bans, when there is no reason to believe it is more dangerous than any other similar medication
• We have opposed these types of policy proposals
• We support proposals that, instead, take a logical approach to establishing appropriate guidelines related to opioid prescribing
• We support replacement of this formulation with an ADF formulation now under development
  • Note the caveat that reimbursement must be adequate
Prescription Monitoring Programs

- Prescription monitoring programs are now authorized in 49 states, DC, and Guam
  - Not yet fully operational in DC, NE, NH
  - Not authorized in MO
- 26 states currently sharing data through NABP PMPInterConnect program
  - 2 additional states with MOUs executed
  - 4 additional states with pending MOUs
  - Unknown number pursuing another interstate data sharing hub
- 44 bills passed this year (so far)
Prescription Monitoring Programs: Trends in Legislation

• Increased interest in:
  • Mandatory registration and use
  • Allowing interstate data sharing
  • Allowing delegates to obtain reports
  • Expanding access to other relevant professionals
  • Shortening reporting intervals
  • Establishing secure ongoing funding

• Integration with EHRs and HIEs is viewed as a major priority in many states and in the PMP community
Prescription Monitoring Programs: Policy Needs

- We have positions on a number of policy issues related to PMPs
- We favor:
  - Delegate authority
  - Unsolicited reporting
  - Interstate data sharing—bidirectional and universal
  - Mandatory registration to use PMP
  - Secure ongoing funding
  - Use of advisory committees
  - Reporting at least daily
  - Limited expansion of access to data
  - Efforts to integrate with EHRs and HIEs
  - Establishing a PMP in Missouri!
What can coalitions do to support state advocacy?

State Pain Policy Advocacy Network (SPPAN)

Amy Goldstein, Director
What can you do?

• Utilize SPPAN as a resource (updates, website)
• Help gather stories from patients or professionals about relevant topics
• Familiarize yourself with your state’s new laws, other relevant issues
• Know that C-Change, ACSCAN and SPPAN are involved with new CPATF
SPPAN as a resource

- Launching new website 10/2014 with 50 new state pages
- Sign up for legislative updates sent Jan.-June
- Complete survey to identify SPPAN’s Policy and Advocacy Priorities for 2015
- Coordinating connections on the state level (e.g., CA, TN, FL calls)
- End of Session Report (PDF attached)
Patient/professional stories

Need stories that paint an accurate picture of the short-comings of the prior authorization (PA) process.

- **Administrative burden on medical staff**
- **Lack of transparency**
- **Unreasonable timelines for accepting/denying a PA request**

**Some states needed:** IN, FL, KS, LA...

Other topics: Access to integrative care, rescheduling HCCP, ADFs, step therapy/specialty tier
Example of new PMP laws

- 24 states and D.C. passed a total of 44 laws related to prescription monitoring programs
- 7 dealt with delegate authority
- 11 dealt with access to the PMP
- 7 states passed laws that require mandatory PMP checks (AZ, IN, LA, MN, OH, VA, WV)
- D.C. passed law establishing PMP; MO is the last PMP-free locale in the nation
Sneak Peek of Website
Alabama

The SPPAN team is working hard to bring you relevant policy information about your state so that you — an important pain policy advocate — can quickly find:

Legislature Quick Facts

<table>
<thead>
<tr>
<th>Convene Date</th>
<th>3/2/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjourn Date</td>
<td>Varies; regular session is</td>
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Alabama

The SPPAN team is working hard to bring you relevant policy information about your state so that you — an important pain policy advocate — can quickly find:

- current legislation and regulations
- news
- analysis
- opportunities for action

Help us stay current! If you have updates or information about pain policy issues in your state, please email SPPAN’s Director, Amy Goldstein.

Legislature Quick Facts

<table>
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</thead>
<tbody>
<tr>
<td>Adjourn Date:</td>
<td>Varies; regular session is limited to 30 meeting days within a period of 105 calendar days.</td>
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<tr>
<td>Carry-over:</td>
<td>No</td>
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<td>Prefiling:</td>
<td>Yes</td>
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<td>Introduction Deadline:</td>
<td>None in House; 26th Legislative Day in Senate.</td>
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State Pain Policy Finder: Legislation & Regulation

September 08, 2014

Please select a link to view a report or click the ▶ to limit the report to specific states.

▶ All Pain-related Legislation by State
  ▶ Abuse Deterrent Formulations
  ▶ Awareness Bills, Resolutions, and Proclamations
  ▶ Medical Marijuana
  ▶ Overdose Prevention / Safe Disposal
  ▶ Pain Clinic Regulation / Pill Mill Eradication
  ▶ Pain Management Practice Guidelines
  ▶ Palliative Care / Quality of Life
  ▶ Practitioner Education
  ▶ Prescription Monitoring Programs (PMP)
Consumer Pain Advocacy Task Force (CPATF)

**CPATF** is comprised of leaders from 16 consumer-nonprofit organizations who are dedicated to the well-being of people living with pain.

**Collective goal:** To support, influence, and monitor the implementation of the HHS’ National Pain Strategy.
Thank you for your time!

Questions, comments, or to sign up for e-updates, contact Amy Goldstein, SPPAN Director
agoldstein@aapainmanage.org
Questions?

Please submit your questions via the ‘questions’ function.
Thank you!

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