How Restrictive Pain Medication Policies May Reduce Access for Cancer Patients

December 6, 2013
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.

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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

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Director of Policy and Advocacy
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PAIN MANAGEMENT POLICY:
FEDERAL ISSUES

Bob Twillman, Ph.D., FAPM
Deputy Executive Director
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Current Major Policy Themes: What People are Saying

• There is an epidemic of prescription drug abuse and related overdose deaths
  • Over-prescribing is causing this epidemic
  • The solution is to reduce prescribing
  • Pressure is being exerted throughout the pharmaceutical distribution chain to achieve reduced prescribing and dispensing
  • The impact on people with pain is a concern, but secondary

• The federal government needs to increase regulation of opioid analgesics
  • Citizen petition to change opioid label indications partially denied, partially accepted by FDA
  • FDA recommends rescheduling hydrocodone products
  • REMS participation needs to be mandatory
Current Major Policy Themes: What People are Saying

• “Abuse-deterrent” opioid formulations are good; everyone should use them
  • At least an incremental step in the right direction
  • More of these products need to be available
  • Need to balance concerns about cost with need to protect patients, their families and friends, and society as a whole; not everyone needs them
Two Public Health Crises

• According to SAMHSA statistics, about 12.5 million Americans aged 12 and older engaged in non-medical use of opioid pain relievers in 2012.
• It is estimated that prescription drug abuse costs the economy ~$70 billion per year in healthcare costs, perhaps as much as $120 billion per year if including associated costs.
• According to the 2011 IOM report, more than 100 million American adults have chronic pain.
• IOM estimates that chronic pain costs our economy $560-$635 billion per year.
• Chronic pain is more common and costly than cancer, diabetes, and heart disease—COMBINED.
Overdose Deaths Involving Prescription Drugs

- CDC reports that, in 2010, about 16,600 Americans died of overdoses involving prescription drugs.
- Statistics are somewhat “squishy” due to reliance on death certificates.
- Usually called “prescription painkiller overdose deaths”.
- Yet, previous CDC research suggests that about 75-80% of decedents used multiple drugs, not including alcohol, and that as many as 55-60% did not have a prescription for the drugs involved.
Another CDC Observation

- CDC notes an apparent correlation between opioid sales and overdose deaths
- They suggest that this means increasing sales causes the increase in deaths
- Ergo, the way to reduce deaths is to reduce prescribing
- This is an overly simplistic view
- “For every complex problem, there is a solution that is neat, simple, and wrong”—H.L. Mencken
Initiatives to Address Prescription Drug Abuse

- ONDCP: National Drug Control Strategy
- ASTHO: Presidential Challenge
- NGA: State Policy Academy

- Stated goal for both ONDCP and ASTHO: Reduce overdose deaths by 15% by 2015

- Unlike many legislative and regulatory efforts, these initiatives are balanced in their recognition of the need to control prescription drug abuse and still to provide for the needs of people with pain, and all address both supply and demand sides of this equation.
Opioid Label Changes

• Citizen petition from Physicians for Responsible Opioid Prescribing (PROP) requested change in label for opioids

• Old label: Opioid analgesics are indicated for treatment of moderate to severe pain [when a continuous, around-the-clock analgesic is needed for an extended period of time]
  • *[ ] language refers to extended-release and long-acting opioid analgesics

• PROP request:
  • Strike the term “moderate” from indication for non-cancer pain
  • Add a maximum daily dose equivalent to 100 mg of morphine for non-cancer pain
  • Add a maximum duration of 90 days for continuous (daily) use for non-cancer pain
Opioid Label Changes

• We, along with ACS, AAHPM, and others, argued that the evidence supporting these changes was inadequate.

• We also argued that making a distinction between “cancer pain” and “non-cancer pain” would be erroneous; a distinction without a difference.
  - It is the proximal etiology of the pain that matters, not the presence/absence of cancer.
  - How do we define “cancer pain”? Does it include pain caused by cancer treatment? What about long-term survivors with pain that resulted from their treatment—for how long would we call that “cancer pain”?
  - The term “non-cancer pain” covers disparate pain conditions, some of which respond well to opioids, and some of which do not.
Opioid Label Changes

• FDA issued a decision in September; the new label will state that extended-release and long-acting opioids are indicated:
  • For the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate
    • Could lead to increased use of step therapy
• FDA also is requiring post-marketing safety studies
• Also added a boxed warning that maternal use during pregnancy can result in neonatal opioid withdrawal syndrome
Hydrocodone Rescheduling

- DEA requested that FDA evaluate whether hydrocodone-containing combination products (e.g., Vicodin®, Lortab®, Norco®, and others) should be rescheduled 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
- Must be approved by Secretary of HHS and then go to DEA, which must go through rule-making
Potential Unintended Consequences

• Some providers have policies against prescribing C-II medications, so may increasingly rely on codeine and tramadol products, which have higher adverse event rates

• Some mid-level providers are not allowed by state law to prescribe C-II medications (e.g., nurse practitioners in Texas); laws will need to be changed to allow this

• Patients will need to be seen more frequently by providers
  • 26 million refills will need to be accounted for (2011 numbers)
  • If all of them required office visits, capacity would be strained
  • Potential cost to healthcare system could top $500 million per year
  • Disrupts patients’ and caregivers’ lives, reducing productivity and quality of life
Abuse-Deterrent Formulations (ADF)

• We have supported FDA’s development of guidance for these products, and believe they represent an incremental positive step
• We will be working to support state legislation prohibiting automatic substitution of a non-ADF formulation contrary to the prescriber’s specific intent
• We also are concerned about financial consequences of using ADFs, so will work to ensure appropriate reimbursement
• Need to recognize that not every patient needs to use an ADF, so forcing them on everyone will constitute a significant, unnecessary, incremental healthcare expenditure
Thank you for your attention
Pain Management Policy: State Issues

David Woodmansee
Associate Director, Access to Care
American Cancer Society Cancer Action Network, Inc.
Current Barriers to Access at the State Level

- Laws and Regulations
- Uncertainty among Providers
- Media
- Pharmacies
Cancer Pain
vs.
Non-Cancer Pain
Preventing Misuse

• Should not be just provider focused
• Increasing Public Awareness
• Alternatives that work
Learn More & See How Your State is Doing
How Do You Measure Up?

http://www.acscan.org/content/how-do-you-measure-up/
SPPAN Toolkit

• Website tracks active legislation and proposed regulatory changes, organized both by state and by issue

• Explanatory information is provided for the most important issues, including position statements, model legislation, blog posts, etc., where they are available

• In 2014, we will be adding to our Resource page, with a policy brief series and other key pieces for advocates

• www.sppan.aapainmanage.org
Achieving Balance in Pain Policy

Achieving Balance in State Pain Policy: A Progress Report Card


http://www.painpolicy.wisc.edu/
Take Action

• Advocate against restrictive policies and for increased access to pain management therapies
• Groups drafting prescribing and dispensing guidelines must hear about access consequences
• Need advocacy for adequate coverage of non-pharmacological services
• Efforts to eliminate “pill mills” shouldn’t unduly restrict legitimate providers
• Send stories to Kristen Santiago: kcoxsantiago@c-changetogether.org
Questions?

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

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