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Laying a Foundation for a WC Drug Formulary



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- 35+ years in P&C, 20+ years in Work Comp
- Created PRIUM's Medical Intervention Program in 2003, Intervention Triage in 2010, Texas Closed Formulary turnkey in 2011, Centers with Standards in 2012, TaperRx in 2014
- From March 2012 thru December 2015, Mark has presented educational content 306 times to 18,420 people in 39 states, including 9 national webinars
- Published and quoted in CLM Magazine, Risk & Insurance, Business Insurance, WorkCompCentral, WorkCompWire, Insurance Thought Leadership and others
- Member of the IAIABC Medical Issues Committee, SAWCA Medical / Rehab Committee, SIIA Work Comp Committee, CompSense pharmacy group

Why is a Drug Formulary Important?



“Teen Athletes at High Risk of Prescription Painkiller, Heroin Abuse, Reports Sports Illustrated” (7/9/15)

High school athletes are often overlooked victims of the prescription drug abuse epidemic, but it is hitting them hard, reports Sports Illustrated

“Most College Students Misusing Prescription Drugs Begin Non-medical Use in Winter Months” (9/3/15)

Winter is the peak season for full-time college students to start non-medical use of prescription drugs, such as pain relievers and stimulants, indicates a new study by SAMHSA

“Legislation Aimed at Curbing Drug Abuse Among Seniors” (8/20/15)

Seniors who receive Medicare and have a history of opioid abuse would be restricted to one pharmacy and one doctor under proposed legislation intended to help them recover from addiction

“ADHD Stimulant Abuse Growing Among US Workers, The New York Times Reports” (4/30/15)

Though commonly associated with college students, abuse of prescription stimulants intended to treat attention deficit hyperactivity disorder (ADHD) is a growing phenomenon among American workers

“Painkiller Abuse Linked to HIV Outbreak in Southeastern Indiana” (4/2/15)

Prescription drug abuse is suspected of being at the root of an HIV outbreak that has plagued southeastern Indiana, prompting Governor Mike Pence to declare a public health emergency and implement a temporary needle exchange program

More than 175,000 dead from prescription drug overdoses 1999 - 2013



http://www.washingtonpost.com/opinions/the-legal-drug-epidemic/2015/03/11/0448b6be-c826-11e4-b2a1-bed1aeea2816_story.html?wpmk=MK0000200

So who is responsible?

The Seven P's

- Prescribers
- Patients
- Pharmacists
- big Pharma
- Payers
- Politicians
- Plaintiff attorneys

The Drugs

Treating Pain

Opioid (narcotic)

- **Pain Purpose:** Relieve pain by acting directly on the central nervous system (oral, topical). Refills are generally prohibited without new script
- **Possible Side Effects:** Sedation, drowsiness, impairments, constipation, respiratory depression, nausea, headache, stomach pain. Extremely high potential for abuse, dependence, addiction and diversion
- **On-label Uses:** Before/during/immediately after surgery, cancer, AIDS patients, end of life care
- **Red Flags:** Used more than 6 contiguous months, DOI of more than 3 years, no change in levels of pain or function, aggregate dosage exceeds 120mg MED/day
 - ACOEM's April 2014 guidelines establish **50mg MED/day**
 - DWC adopts **80mg MED/day** in new opioid guidelines
- **Examples:** Actiq (Fentanyl lollipop), Exalgo (Hydromorphone ER), Avinza / Kadian (Morphine ER), OxyContin (Oxycodone ER), Nucynta (Tapentadol), Duragesic (Fentanyl transdermal), Ultram (Tramadol)

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least **3** other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and **death** for users.

People who are addicted to...



ALCOHOL

are

2x



MARIJUANA

are

3x



COCAINE

are

15x



Rx OPIOID PAINKILLERS

are

40x

...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.

Treating Pain

Opioid (narcotic)

Morphine Equivalent Dosage (MED)

- A method developed to adjust for the various potency of opioids into a common measurement (morphine, which would be a 1:1 ratio)
- Per ODG, the Factor to be used when calculating MED
 - Codeine - 0.15
 - Fentanyl (Actiq) oral transmucosal - 10-100
 - Hydrocodone - 1
 - Hydromorphone (Exalgo) - 4
 - Methadone, 41 to 60mg per day - 10, > 60mg per day - 12
 - Oxycodone (OxyContin) - 1.5
 - Oxymorphone (Opana) - 3
- **(Quantity / Day Supply) = Daily Pill Count * Dosage * MED Factor = MED**

Treating Pain Opioid (narcotic)

Common Adverse Effects to Opioid Use

sedation

constipation

sense of euphoria

cough suppression

nausea

vomiting

drowsiness

itching

dry mouth

miosis (excessive constriction of the pupil of the eye)

opioid dependence

withdrawal syndrome (with a dependency)

Infrequent Adverse Effects to Opioids

respiratory depression

confusion

hallucinations

delirium

urticaria (chronic hives)

hypothermia

bradycardia/tachycardia (heart rhythm disorders)

orthostatic hypotension (low blood pressure)

dizziness

headache

urinary retention

ureteric or biliary spasm

muscle rigidity

myoclonus (involuntary jerking of a muscle or group of muscles)

flushing

www.oicisdifferent.com
(opioid-induced constipation)
AstraZeneca's MOVANTIK™,
FDA approved 9/16/14

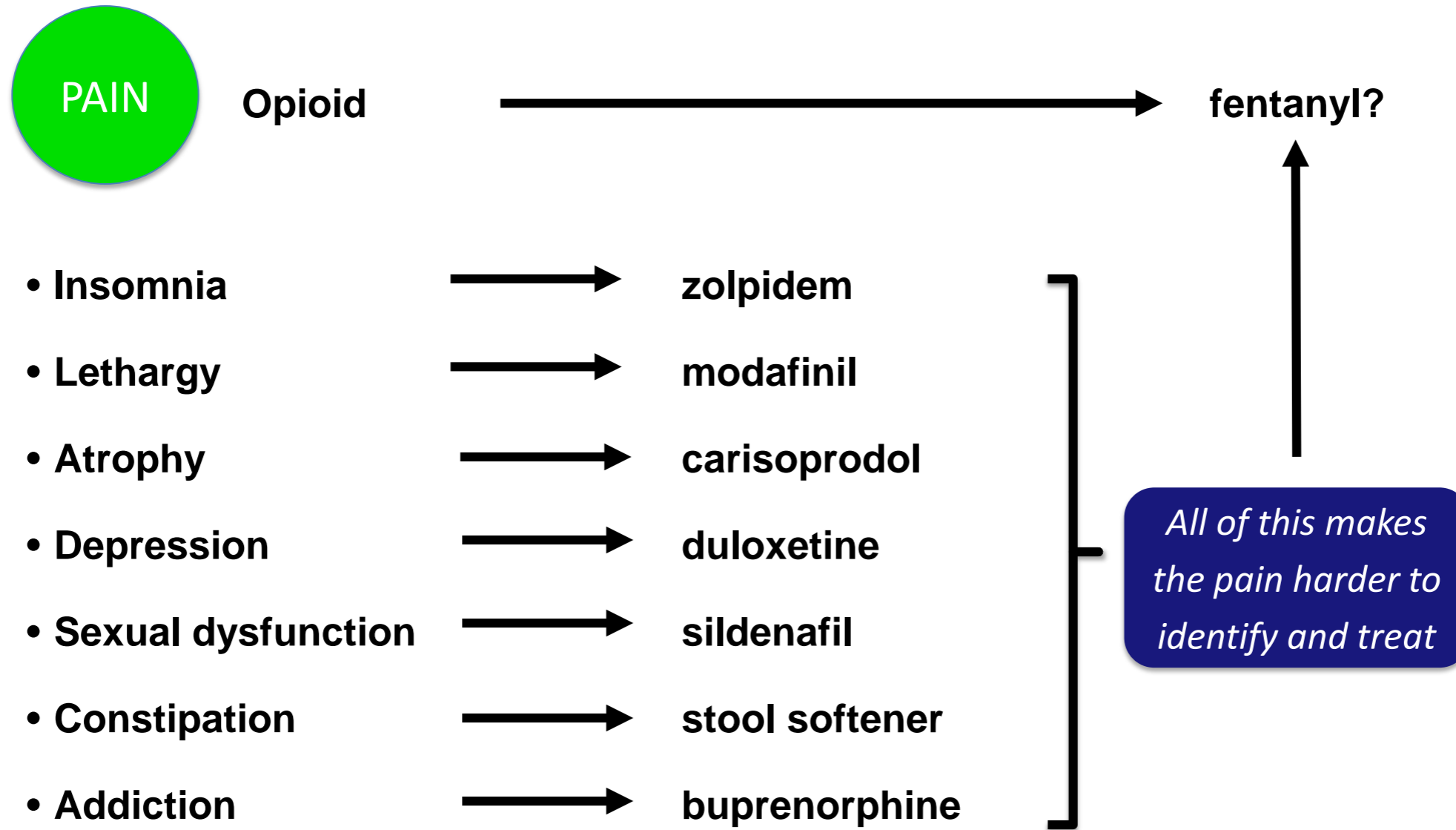
Treating Pain

Opioid (narcotic)

- **OxyContin** (oxycodone) - 1.5 MED
 - 77 major drug interactions, 696 moderate, 3 minor
 - Be sure you check if they're also taking ...
 - Ambien (zolpidem)
 - baclofen
 - Celebrex (celecoxib)
 - clonazepam
 - Cymbalta (duloxetine)
 - furosemide
 - lisinopril
 - Lyrica (pregablin)
 - Neurontin (gabapentin)
 - trazodone
 - Xanax (alprazolam)
 - **DO NOT** use **alcohol** or medications that contain alcohol while receiving treatment with oxycodone!

Polypharmacy

The Enemy of Function



Treating Pain

NSAID (non-steroidal anti-inflammatory drug)

- **Pain Purpose:** Relieve pain and inflammation by reducing enzymes and hormones that cause inflammation and pain in the body (oral, topical)
- **Possible Side Effects:** Nausea, vomiting, diarrhea, constipation, decreased appetite, rash, dizziness, headache, and drowsiness, fluid retention. The most serious side effects are kidney failure, liver failure, ulcers and prolonged bleeding after an injury or surgery
- **On-label Uses:** Acute musculoskeletal pain conditions, rheumatoid and osteoarthritis
- **Red Flags:** Used more than 6 contiguous months, aggregate dosage exceeds 3200mg/day, DOI of more than 3 years, prescriptions when OTC would suffice
- **Examples:** Flector patches, Voltaren (Diclofenac Sodium), Celebrex (Celecoxib), Ketoprofen, Mobic (Meloxicam), Relafen (Nabumetone)

Treating Pain

Skeletal Muscle Relaxant

- **Pain Purpose:** Relax muscles that control the skeleton
- **Possible Side Effects:** Sedation, drowsiness, dizziness. Others include central nervous system depression (Baclofen), hepatotoxicity (Dantrolene), dependence and withdrawal symptoms (Carisoprodol), toxicity in overdose and in combination with other substances (Cyclobenzaprine), low blood pressure (Tizanidine)
- **On-label Uses:** For spasticity (multiple sclerosis, spinal cord injury, traumatic brain injury, cerebral palsy, and post-stroke syndrome). For muscle spasms (fibromyalgia, tension headaches, myofascial pain syndrome, and mechanical low back pain or neck pain)
- **Red Flags:** Used more than 2 contiguous months, DOI of more than 3 years, no rehab program with active treatment
- **Examples:** Soma (Carisoprodol), Amrix (Cyclobenzaprine), Valium (Diazepam), Lioresal (Baclofen), Skelaxin (Metaxalone), Zanaflex (Tizanidine)

Treating Pain Anti-Depressant

- **Pain Purpose:** Relieve symptoms of depressive disorders that can negatively affect the healing process
- **Possible Side Effects:** Upset stomach, dry mouth/eyes, increase in skin sensitivity, insomnia, drowsiness, changes in sex drive, changes in appetite and confusion. Serious side effects that require medical attention include constipation, difficulty in speaking, irregular heartbeat, trembling, stiffness of limbs, hallucinations and thoughts of suicide
- **On-label Uses:** Diagnosis of depression or anxiety
- **Red Flags:** Lack of objective findings supporting continued use, psych not accepted as compensable or pre-existing
- **Examples:** Wellbutrin (Bupropion), Lexapro (Escitalopram), Zoloft (Sertraline), Elavil (Amitriptyline), Effexor (Venlafaxine)

Treating Pain

Benzodiazepine

- **Pain Purpose:** Do not have any pain-relieving properties themselves, and are generally recommended to avoid in individuals with pain
- **Possible Side Effects:** Sedation, dizziness, weakness, unsteadiness, feeling of depression, loss of orientation, headache, sleep disturbance, physical dependence, withdrawal symptoms upon disuse
- **On-label Uses:** Anxiety and seizure disorders, insomnia, anesthesia, muscle relaxation, alcohol withdrawal
- **Red Flags:** Use for more than 2-4 weeks, excessive sedation, combination with opioids and/or Soma, alcohol consumption, **weaning can take up to 18 months**
- **Examples:** Xanax (Alprazolam), Valium (Diazepam), Ativan (Lorazepam), Klonopin (Clonazepam), Restoril (Temazepam)

Drug Formulary 101

Drug Formulary 101

Primary Questions for a Drug

- Is it safe?
 - Risk vs. Benefit
 - Compare to alternatives
- Is it effective?
 - Studies demonstrating results
- What is the cost?
 - Not just acquisition but total cost of therapy (pharmacy & medical)

Drug Formulary 101

What is a Drug Formulary?

- A list of drugs that are either included or excluded from coverage / reimbursement
 - PA – Requires prior authorization
 - NPA – Does not require prior authorization
- Used extensively outside of Work Comp
 - A new process for Work Comp but not a new concept
- Types include Closed, Open, Cost-Based, Retail, Preferred Drug List
 - Open – All FDA-approved prescription/non-prescription drugs
 - Closed – “Open” with restrictions
 - Retail – Unique to a PBM
 - PDL – Preferred but no real restrictions

Drug Formulary 101

Guiding Principles

- About better clinical outcomes, not cost savings
- Define how to measure success
- Utilize Evidence Based Medicine
- Design through consensus
- Educate all stakeholders before, during, after
- Easy to implement and enforce
- Include a dispute resolution process with expedited appeal
- Handle new and legacy claims differently

Drug Formulary 101

Benefits / Goals

- Facilitates timely provision of medical treatment
 - Require a clinical rationale for others
- Add evidence-based practices to prescription choices
 - Clarify the difference between a specific drug, alternative drug options, alternatives to drugs
 - Reduce drug-to-drug interactions
- Drives evidence-based prescribing practices
 - Prompts reflection
- Improve treatment outcomes for patients
 - Trends towards more conservative options

Drug Formulary 101

Potential Impacts

- Patient safety
 - Talk about return to function
 - Focus on life
 - Promote (and approve) more conservative options
 - NSAID's, exercise, Yoga, CBT
 - Biopsychosocial
 - Deal with their attitude about pain

Drug Formulary 101

Potential Impacts

- Prescribing behavior
 - Choose the best options
 - Require clinical rationale for exceptions
 - Educate on options
 - No longer “that’s how it’s always been done”
 - Inspire prescriber-patient conversations
 - Office visits no longer just about refills
 - Change one, change all
 - Future patients reap the benefits

Drug Formulary 101

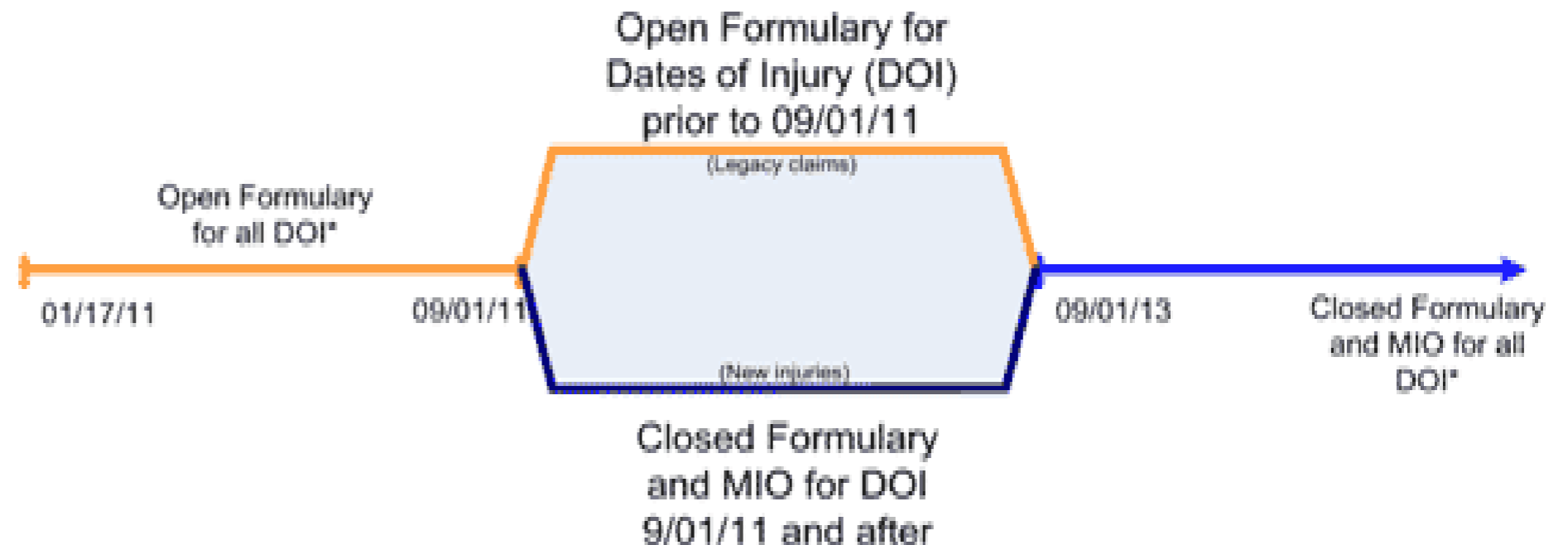
Potential Impacts

- Claims / pharmacy cost
 - Reduce drug utilization
 - Number of drugs / classifications, dosage, quantity
 - Reduce non-mainstream use
 - Compounds
 - Physician dispensing
 - Reduce health/financial impacts
 - Disability, co-morbidities, indemnity
 - Impact friction costs
 - Reduce litigation, delays in treatment
 - Increase possibility of settlement

Texas

Example Formulary Texas

- Private marketplace
- Closed formulary
- New claims – 9/1/11
- Remediation period
- Legacy claims – 9/1/13



Example Formulary

Texas

- Treatment guidelines = Official Disability Guidelines
 - Guidelines are presumed correct, not clinicians

Y = Yes

N = Prior Authorization
required

appendixa.xls [Compatibility Mode] - Microsoft Excel

File Home Insert Page Layout Formulas Data Review View Add-Ins

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Ready

January 2015

December 2014

November 2014

October 2014

100%

Drug Class	Generic Name (FDA-approved name for the chemical entity)	Brand Name	Generic Equivalency	Status (Y status does not require preauthorization. N Status requires preauthorization)
272 Opioids	Morphine	Morphine	Yes	Y
273 Opioids	Morphine ER	Avinza®	Yes	N
274 Opioids	Morphine ER	Kadian®	Yes	N
275 Opioids	Morphine ER	MS-Conti	Yes	Y
276 Opioids	Morphine ER / Naltrexone	Embeda	No	Y
277 Opioids	Oxycodone	Oxecta	No	N
278 Opioids	Oxycodone	OxyIR®	Yes	Y
279 Opioids	Oxycodone ER	OxyContin®	No	N
280 Opioids	Oxycodone ER/acetamin.	Xartemis XR	No	N
281 Opioids	Oxycodone ER/Naloxone	Targiniq ER®	No	N
282 Opioids	Oxycodone/acetaminophen	Percocet®	Yes	Y
283 Opioids	Oxycodone/aspirin	Percodan®	Yes	N

Example Formulary Texas

- A common misperception ...
 - A 'N' drug is not always No
 - *Prospective Review needed by Prescriber*
 - A 'Y' is not always Yes
 - *Retrospective Review needed by Payer*
- The prescriber should validate the medical appropriateness based on EBM
- A formulary requires that to happen

Example Formulary Texas

- New claims:
 - Comparison between 2010-2011
 - 'N' drug costs ▼ 82%
 - 'N' drug # scripts ▼ 74%
 - Claims with a 'N' drug ▼ 67%
- Legacy claims:
 - Data call for 29 carriers (March-July-Aug 2013)
 - 7,520 total legacy claims
 - Peer review conducted ● 22%
 - Agreement to change secured ● 76%
 - Claims with no more 'N' drugs ● 47%

Example Formulary

Texas

- What is not currently known:
 - Switching to less dangerous / no drugs?
 - Switching to more conservative therapy?
 - Switching to interventional methods?
 - Cost shifting to the injured worker's group health policy or Medicare/Medicaid?
 - Injured worker paying for the drugs themselves?
 - Is it a permanent change?
 - Better RTW / clinical outcomes?

Addressing Legacy Claims

Legacy Claims

The Process

- How to address legacy claims:
 - Epiphany
 - Education, Peer Review, Utilization Review
 - Accountability
 - Ongoing engagement, flexibility, connecting the dots
 - Enforcement
 - Customized patient formulary as the regimen changes

Legacy Claims

Weaning – Patient

- The patient **MUST** be motivated and engaged in the process
- The patient must make a life change
 - Proper sleep (7-8 hours each night)
 - Proper nutrition
 - Proper levels of activity
 - Proper attitudes about their pain
- Identify how patient will manage pain with less/no dosage
- Establish coping skills

Legacy Claims

Weaning – Prescriber

- Is the current drug regimen appropriate?
- Can the treating prescriber facilitate the weaning?
- In-patient / out-patient?
- Is CBT / MI required first?
- Is the goal reduction in dosage or removal of drugs?
- Manage the withdrawal symptoms
- Assess co-morbidities and complicating factors

Legacy Claims

The Reason

Per the AMA Guides March/April 2011 Newsletter ...

**“21 of 23 patients in the study reported a
significant decrease in pain
after detoxification”**

Functional Restoration is a natural consequence of Weaning!

On the Horizon States Considering

- Arizona – Rules being finalized
- Arkansas – On hold
- **California** – Rules being developed
- Georgia – Initial discussions
- Louisiana – Rules being developed
- Maine – Initial discussions
- Montana – Initial discussions
- Nebraska – Initial discussions
- North Carolina – Study underway
- Oklahoma – Implemented in 2014
- South Carolina – Initial discussions
- Tennessee – Effective February 2016

California

On the Horizon

California History

- **First Major Milestone**
 - October 2014 – CWCI published a whitepaper “*Are Formularies a Viable Solution to Controlling Prescription Drug Utilization and Cost in California WC*”
- **Second Major Milestone**
 - 3/5/15 – Assemblyman Henry Perea (D-Fresno) introduced AB 1124 to direct the DWC’s Administrative Director to adopt a formulary
- **Third Major Milestone**
 - 7/23/15 – At the CCWC conference, David Lanier stated “*Based on the work to date and the urgent need I have instructed Christine [Baker, Director of the Division of Industrial Relations] to move forward with creating a formulary as expeditiously as possible*”

On the Horizon

California History

- Final Milestone
 - 9/12/15 – Legislature approves AB 1124
 - 10/6/15 – Governor Brown signs into law
- Next Step on the Journey
 - The rules and regulations process, including public forums and comment periods along with an advisory committee

On the Horizon

California History

- The process
 - Three months of discussion, debate, disagreement, negotiation and compromise
 - Stakeholders during this process included:
 - Labor (Cal Labor Fed)
 - Management (Cal Chamber, CCWC Small Business CA)
 - Providers (CMA, COA, CSIMS, CompPharma)
 - Insurers (Zenith, Liberty Mutual, ACIC)
 - CAAA
 - DIR Director, DWC AD and Med Director
- “Kudo’s to California!” ... <http://bit.ly/1JXn4Hr>

On the Horizon

California History

- The contents
 - “On or before July 1, 2017, the medical treatment utilization schedule adopted by the administrative director shall include a drug formulary using evidence-based medicine”
 - Includes a TBD phased-in implementation for transition of injured workers to medications on the formulary
 - Plan for no less than quarterly updates to the drug list
 - Establishes a Pharmacy and Therapeutics (P&T) committee
 - Interim reports starting on July 1, 2016

On the Horizon

California History

- The goals
 - Improve appropriate care through the dispensing of evidenced-based medicine
 - Expedite pharmaceutical treatment for ill and injured workers
 - Reduce delays, including reducing the need for elevated utilization review and independent medical review
 - Improve efficient delivery of medical benefits and reduce administrative costs

On the Horizon

California Questions

- **How will the drug list be defined and maintained?**
 - Creating a drug list from scratch is difficult
 - *Build vs. Buy?*
 - Maintaining a drug list is even more difficult
 - *California P&T Committee*
 - Creating a cross-walk from drugs to ICD / treatment guidelines
 - *Easy to understand and use*

- **What will be the arbiter for disputes?**
 - Opinion vs. Opinion is just opinion
 - *The UR / IMR process*
 - Evidence Based Medicine includes the best science available so prescribers can make the best decisions possible
 - *MTUS, including the new chronic pain and opioid guidelines*

On the Horizon

California Questions

- **What is the “carrot”?**
 - Speedier delivery of appropriate care – NPA drugs
 - *But these can be non-related or medically inappropriate*
- **What is the “stick”?**
 - Second opinion on questionable care – PA drugs
 - *No state-mandated UR plan ... Currently*
- **How will a formulary be enforced?**
 - Nothing precludes a prescriber from writing any script
 - Nothing precludes a pharmacy from dispensing any script
 - *Third-party billing? Physician dispensing? Compounding?*

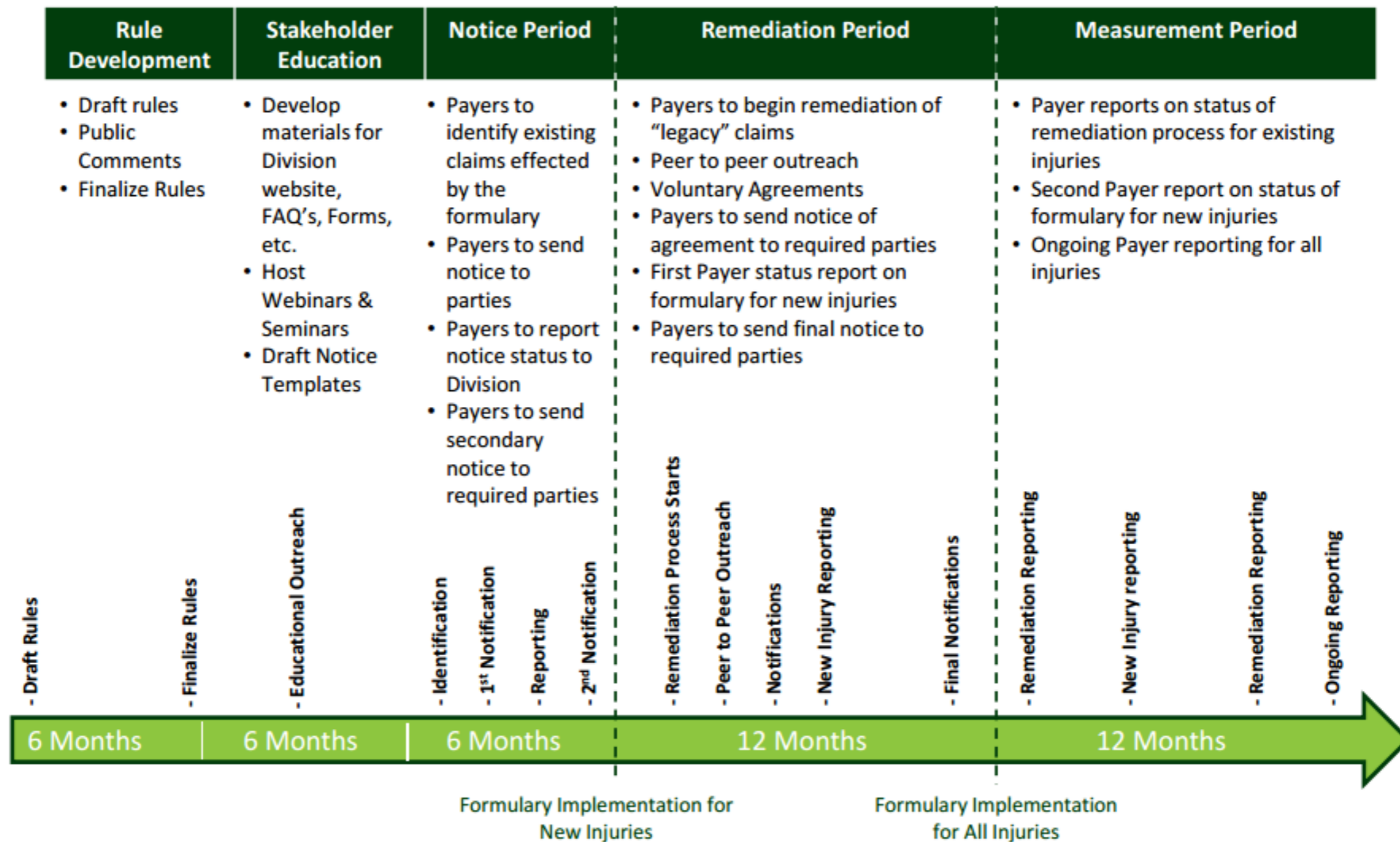
On the Horizon

California Questions

- **How will a formulary be phased in?**
 - Education and consensus before implementation are key
 - Ongoing collaboration after implementation allows adjustments
 - The process must be transparent and understandable
 - Timeline must be identified and unchangeable

- **How will legacy claims be handled?**
 - A new claim is different than a legacy claim
 - There must be a remediation period allowed for legacy claims, to taper towards formulary compliance
 - *Different timelines for new and legacy claims?*

Formulary Development and Implementation Timeline



INSIGHT AND INTERVENTION



PRIUM 



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