



## Rx *Informer*

Topics and issues impacting  
workers' compensation  
pharmacy costs



### inside:

Clinical Research: Impact of Prescriber Outreach on Oral Fentanyl Products

Pharmacy Trends: REMS and NSAIDs

Compliance Digest: State Updates



## Compliance Digest

### State of Texas Updates

#### Texas Takes the Reign on Future Pharmacy Reimbursement

In February the Texas Division of Workers' Compensation (DWC) encouraged open dialogue on the future of pharmacy reimbursement during a well attended stakeholder meeting in Austin, TX. Historical data and trends from State Reporting and other data sources relative to pharmacy reimbursement were presented by Texas Department of Insurance representatives.

Public comments focused on the following areas:

- A fair and equitable reimbursement rate promoting patient access to care
- Delays in billing and reimbursement due to challenges in identifying the responsible party
- Burdensome dispensing and handling of workers' compensation medications
- Closed formulary adoption, and whether it may increase administrative burden on payers and providers, and delay the delivery of medications to injured workers
- Future benchmark considerations with the upcoming elimination of AWP

Informal rulemaking is tentatively planned for May 2010. The Healthsystems Compliance & Government Affairs department continues to participate and provide the state with relevant data where appropriate.

#### Other State Updates

##### California

CA Air Ambulance Amendment

On March 10, 2010 the CA DWC proposed regulations to amend Title 8 CCR Section 9789.70, exempting air carriers from the California Official Medical Fee Schedule (OMFS).

##### Oregon

Oregon Posts Changes to Medical Fees, Payment & EDI Rules — OAR 436-009 & OAR 436-160

##### Washington

The state will no longer reimburse for TENs units, Interferential Current Therapy (IFC) and Percutaneous Neuromodulation Therapy (PNT) devices when provided outside of a medically supervised facility.

#### Texas Closed Formulary Nearing Adoption

The third draft of the Closed Formulary Rules was published in February, with a proposed effective date of January 01, 2011. This draft incorporates a tiered implementation, with rules becoming effective on different dates depending upon a claimant's date of injury. For example, injury dates on or after January 1, 2011 will be subject to the closed formulary rules as of January 1, 2011. Claims with injury dates prior to January 01, 2011 will be subject to a two year "grace period" to convert current prescriptions to the closed formulary. This tiered adoption will require a formal notification and pre-authorization process for medications appearing on the Closed Formulary "N" list — currently consisting of 65 drugs.

Concerns for payers and providers relate to the administrative burden of managing a tiered adoption process. In order to prescribe an anti-depressant such as sertraline or floxetine physicians would be required to submit a Statement of Medical Necessity to the pharmacy and the payer.

A formal draft is expected to be published in May 2010. The closed formulary is anticipated to become effective on January 1, 2011.

## Clinical Research Results

### Impact of Prescriber Outreach on Oral Fentanyl Products



HES study results concluded that over 45% of the physicians who received a targeted outreach letter and/or a telephonic consultation discontinued the prescriptions of these drugs while an additional 7% lowered the original dosage.

**Johns Hopkins Study:**  
4% of docs account for  
72% of comp claims

A recent study performed by researchers at the Johns Hopkins School of Medicine revealed 3.7% of physicians in the State of Louisiana accounted for 72% of workers' compensation costs. The article can be found in the January 2010 issue of the Journal of Occupational and Environmental Medicine.

#### Healthsystems presents a study about the impact of prescriber outreach on oral fentanyl products at a recent AMCP meeting

During a presentation at the Academy of Managed Care Pharmacy (AMCP) meeting in April 2010, Healthsystems Clinical Services Department resident Sarah Martinez, PharmD, presented the results of research performed measuring the clinical and financial impact that HES VigilentRx prescriber outreach letters and telephonic consultations have on workers' compensation patients using oral fentanyl products. The findings derived from the controlled study group focused on patients taking fentanyl lozenges and buccal tablets which were prescribed off-label since the indicated usage of these drugs is for breakthrough cancer pain treatment and not for managing chronic pain.

The study results concluded that over 45% of physicians who received a targeted outreach letter and/or a telephonic consultation discontinued the prescriptions of these drugs while an additional 7% lowered the original dosage. Further analysis identified that over 50% of the physicians responded favorably during the teleconsultations to either change or consider changing the prescription treatments. Several cases within the study reported significant prescription cost reductions resulting from the subsequent treatment changes, including one highlighted case that reduced monthly drug costs by 97%.



## Pharmacy Trends

### REMS:

### Reducing the Risk of Opioid Use?

While opioids are widely accepted to have a role in the treatment of moderate to severe pain, their use is associated with potentially serious risks. Abuse of opioids in the United States, and deaths caused by overdose has risen dramatically in the last 15 years.<sup>1</sup> The abuse of prescription opioids exceeds the combined abuse of cocaine, hallucinogens, inhalants and heroin; an estimated three hundred billion dollars (\$300,000,000,000 US) of healthcare costs is attributable to substance abuse and addiction. Efforts to curb this trend have included crackdowns on opioid "pill mills" in several states, requiring warning labels for opioids, and state-level prescription drug monitoring programs.<sup>2</sup>

Despite these efforts, the rates of misuse and accidental overdose continue to rise. The Food and Drug Administration Amendments Act of 2007 (FDAAA) provides the FDA with the authority to require pharmaceutical manufacturers to develop a Risk Evaluation and Mitigation Strategy (REMS) to ensure the benefits of each product outweigh the risks inherent in consuming them. This new effort is initially being applied to combat the dangers posed by use of long-acting opioid medications.<sup>3</sup>

The opioid drugs affected by this requirement include long-acting and extended-release brand and generic products formulated with the active ingredients fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone.

The scope of the REMS is unprecedented, affecting a significant number of patients and prescribers; these requirements could potentially have a large effect on the prescribing of these medications. However, in the near term, very little is expected to change. The FDA is currently in an extended REMS comment period, and is gathering information and input from the various stakeholder groups (i.e. patients, prescribers, pharmacists, payers, manufacturers, etc.) that will be affected.

Expect more information on the Opioid REMS programs in the months to come.

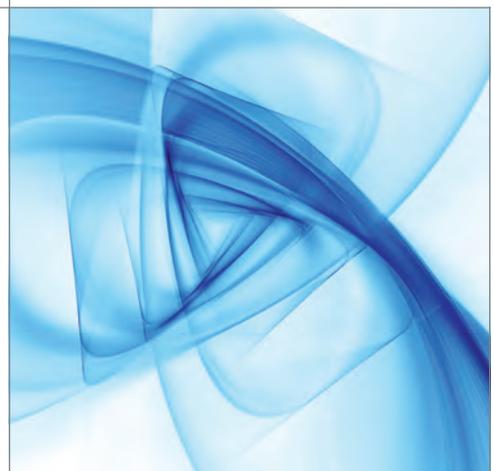
The REMS program, depending on the drug, could consist of one or more of the following\*:

**Medication guide** (patient education tool provided each time the drug is prescribed or dispensed);

**Communication plan** (letters to healthcare providers, professional education, etc.), which will assist in recognition of misuse, abuse, or overdose, or;

**Elements to ensure safe use** (special requirements or restrictions to optimize safe use of the medication), which may include prescriber and pharmacist training, and certification before the medication is allowed to be dispensed.

Healthsystems was recently awarded full accreditation for Workers' Compensation and Property and Casualty Pharmacy Benefits Management from URAC, a Washington, DC-based health care accrediting organization that establishes quality standards for the health care industry. URAC accreditation sets industry-wide clinical and operational standards and brings a recognizable seal of quality to accredited organizations.



## NSAIDs: Non-Steroidal Anti-Inflammatory Drugs

NSAIDs are used for the treatment of mild-to-moderate pain and inflammation and, accordingly, are commonly used within the workers' compensation population. In fact, NSAIDs represented the fourth largest therapeutic class of workers' compensation drugs in terms of total spend, according to Healthsystems data in 2008. Based on most treatment guidelines, NSAIDs are the first-line of treatment for acute pain, and can provide additive pain relief when combined with an opioid analgesic. There are continuing concerns among physician groups and regulatory agencies in regard to the safety of these agents when used for an extended period.

### A Clinical Explanation of How they Work

NSAIDs exert their effect by blocking or inhibiting a group of enzymes called cyclooxygenase (COX). These enzymes are critical in the body's production of prostaglandins, a family of substances which play different and important roles in the body. One form of cyclooxygenase (COX-1) is responsible for producing a prostaglandin necessary for maintaining the lining of the stomach; another form (COX-2) is responsible for the production of the prostaglandins involved in pain and inflammation. While NSAIDs decrease pain and alleviate inflammation by inhibiting COX-2, most NSAIDs also block COX-1. This can lead to an upset stomach in the short term. When taken long term, this can lead to stomach ulceration and bleeding. Studies have shown that 71% of those who were exposed to NSAIDs for more than 90 days have visible injury to their stomach or small intestine.<sup>2</sup> Each member of the NSAID class appears to exert a greater or lesser tendency to cause COX-1 related side effects while decreasing pain.

The benefits of selecting a COX-2- inhibitor versus a traditional NSAID are generally more pronounced in patients with risk factors for a gastrointestinal (GI) bleed. The American College of Gastroenterology (ACG) recommends that only high risk patients be considered for prevention of NSAID induced gastritis.

A recent study showed that the use of the high dose COX-2 agent currently available increased the risk of an adverse event by five times, diclofenac by four times, and ibuprofen by only two times when compared to patients not taking a COX-2 inhibitor or NSAID. There also appears to be a higher risk with increasing doses for all of the agents.<sup>4</sup>

According to the study referenced above, in the workers' compensation health care venue, NSAIDs ranked fourth in terms of drug spend within the therapeutic classes in 2008. The top five medications within this class were celecoxib (Celebrex), ibuprofen, naproxen (Naprosyn, Aleve), meloxicam (Mobic), and nabumetone (Relafen). The primary cost-driver of this trend was Celebrex, due to its high cost relative to other NSAIDs, which are all available in lower-cost generic forms. The total number of prescriptions written for Celebrex and ibuprofen were essentially the same, although the total drug spend on Celebrex was nearly double that of ibuprofen.

Though there have been expanded warnings and cardiac risks associated with Celebrex use, it still remains one of the most frequently prescribed NSAIDs. Physician and pharmacist groups generally agree that all PPIs produce the same level of protection; therefore, OTC versions of Prilosec or Prevacid are recommended by Healthsystems Clinical Pharmacists. It is recommended that NSAIDs be prescribed at the lowest dose for the shortest duration.

According to the American Gastroenterological Association, more than 30 million Americans use NSAIDs to treat headaches, sprains, arthritis symptoms, fever, swelling, and other daily discomforts.<sup>1</sup>

### Vioxx & Bextra

Over the past several years, the COX-2 inhibitors Vioxx (rofecoxib) and Bextra (valdecoxib) have been removed from the market due to cardiovascular risk posed by these products<sup>i, ii</sup>.

### ACG-established Risk Factors

Placing a patient at higher risk for NSAID-induced GI complications include:<sup>3</sup>

- Patients with a prior history of peptic ulcer disease
- Patients over 60 years of age
- Patients receiving high dose NSAIDs
- Patients concurrently using another NSAID (e.g., aspirin)
- Patients concurrently using corticosteroids
- Patients concurrently using anticoagulants
- Patients with a serious systemic disorder

## About Healthesystems

Healthesystems is a specialty provider of innovative medical cost management solutions for the workers' compensation industry. Our comprehensive products include a leading Pharmacy Benefit Management program, expert Clinical Review services and a revolutionary Ancillary Benefit Management solution. By leveraging powerful technology, clinical expertise and enhanced workflow automation tools, we provide clients with flexible programs that reduce the total cost of medical care while increasing the quality of care for injured workers.

## About Our Data

Data referenced in this document was produced using Healthesystems' proprietary pharmacy database information.

## References

### REMS article:

- 1 Jan S. Landscape of opioid dependence. *J Manag Care Pharm.* 2010;16(1b): S4-S8.
- 2 Manchikanti L. National drug control policy and prescription drug abuse: facts and fallacies. *Pain Physician.* 2007;10:399-424.
- 3 US Food and Drug Administration. Background on opioid REMS. Available at: <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm187975.htm>.
- 4 US Food and Drug Administration. Approved Risk Evaluation and Mitigation Strategies (REMS). Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm>. Accessed March 31, 2010.

### NSAIDs article:

- 1 Singh, G., Triadafilopoulos, G. Epidemiology of NSAID induced gastrointestinal complications. *J Rheumatol Suppl.* 1999; 56:18-24.
- 2 American Gastroenterological Association (2005, January 16). Study Shows Long-term Use Of NSAIDs Causes Severe Intestinal Damage. *ScienceDaily.* Retrieved November 10, 2009, from <http://www.sciencedaily.com/releases/2005/01/050111123706.htm>.
- 3 Lanza F, et al. A guideline for the treatment and prevention of NSAID-induced ulcers. *Am.J.Gastroenterol.* 1998; 93:2037-2046.
- 4 Gislason GH, Soren J, Rasmussen JN, et al. Risk of death or reinfarction associated with the use of selective cyclooxygenase-2 inhibitors and nonselective nonsteroidal antiinflammatory drugs after acute myocardial infarction. *Circ.* 2006; 113:24.
- i. FDA Alert 4/7/2005. Voluntary Withdrawal of Valdecoxib. <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm124649.htm>
- ii. FDA Alert 9/30/2004 Voluntary Withdrawal of Rofecoxib. <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108361.htm>

**Healthesystems™**

5100 West Lemon Street, Suite 311, Tampa, FL 33609

800.921.1880 | [www.healthesystems.com](http://www.healthesystems.com)

The contents of this document are for informational purposes only. It is not a substitute for a medical exam, nor does it replace the need for services provided by a medical professional. The information provided in this document is not intended to diagnose, treat, or cure. Every effort has been made to provide accurate, up-to-date and complete information, but no warranty or guarantee is made to that effect. Healthesystems is not liable for any direct, indirect, consequential, special, exemplary, or other damages arising from the use or misuse of any material or information provided in this document.