Healthesystems™

RxInformer

Topics and issues impacting workers' compensation today

Fall 2011

topics inside:

In the fast moving industry of workers' compensation pharmacy and ancillary benefits management, change comes in many forms ... and with change comes complexity. But change also creates opportunity.

new medications. shifting prescribing patterns. legislative changes. advances in technology. safety issues.

The *Rx Informer* industry journal is published by Healthesystems to address and alert payers of these timely and complex issues and present innovative strategies to successfully manage them.

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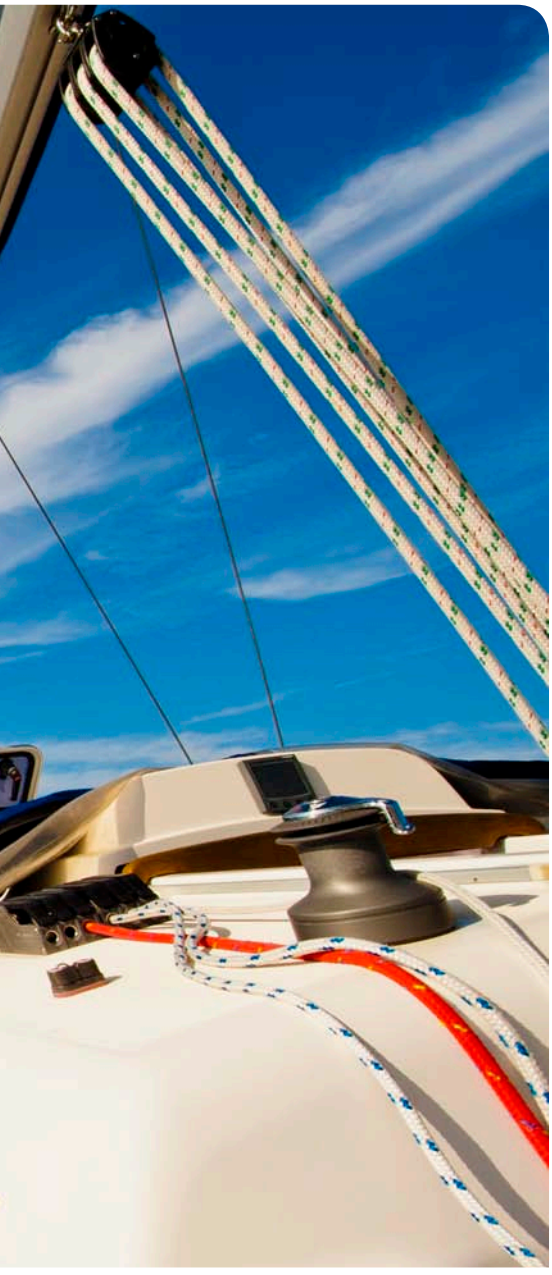


Case Study: A Question of Appropriateness

How a proactive physician outreach strategy produces a successful outcome

A 23 year old male lathe operator sustained a dislocated shoulder while at work in May 2010. Five months later, in October 2010, the Healthesystems clinical database flagged his drug regimen as potentially inappropriate. At the time of this alert, the patient had been prescribed two skeletal muscle relaxants (cyclobenzaprine, carisoprodol), Celebrex®, and hydrocodone/acetaminophen. Issues related to the medications selected and their prolonged use relative to the perceived nature of the injury triggered a recommendation for two Healthesystems clinical program services, a Therapeutic Alert Letter and an Independent Pharmacotherapy Evaluation.

Healthesystems issued a Therapeutic Alert Letter to the prescriber which questioned the appropriateness of Celebrex use in late October 2010. The rationale being most patients in need of an NSAID analgesic can take an older, non-selective NSAID such as ibuprofen or naproxen. A small subset of these patients may require a medication added to prevent stomach ulcers, and an even smaller subset of patients may actually be appropriate candidates to be prescribed Celebrex. Therefore, use of Celebrex in this young patient before attempting to use any other NSAID raised the question of appropriateness.

In addition to concomitant use of two skeletal muscle relaxants, another significant concern was the presence of carisoprodol in the regimen. Carisoprodol (brand name Soma™) is commonly used in the workers' compensation population, however, it is also a frequently abused agent, possibly due to its pronounced sedating effects, which makes it extremely concerning.

Further, chronic use of opioids should be predicated upon objective functional goals, with the ultimate goal being functional restoration and return to work. The claimant's injury of record appeared to be relatively minor (dislocated shoulder) requiring a short recovery time for a 23 year old person. Therefore, not only was the need for opioids in question, but the duration of therapy appeared to be disproportionate to the injury. Opioid "exit strategies" should be incorporated into all such regimens.

Injury Profile

Injury:	Dislocated Shoulder
Patient Profile:	Male, 23 years old

Medications:	
Cyclobenzaprine	Skeletal Muscle Relaxant
Carisoprodol	Skeletal Muscle Relaxant
Celebrex	NSAID
Hydrocodone/ acetaminophen	Opioid

As a result of these concerns, a detailed examination of the patient's recent medication use was conducted by Healthesystems clinicians. The following observations and recommendations for improved therapy were provided to the physician in an Independent Pharmacotherapy Evaluation (IPE): discontinue the use of carisoprodol; wean the opioid dose; incorporate alternatives to Celebrex.

Over the course of four months, the patient was weaned from the use of hydrocodone and carisoprodol. Five months after the outreach to the physician, all medications were discontinued and the claim was closed.

Physician-level outreach, through the use of an evidence-based IPE, can be an important impetus in changing prescribing practices, and can also provide necessary educational information for use in future cases. As this case demonstrates, clinical intervention early in the course of the injury can play an essential role in altering the claim's cost trajectory. Payers utilizing specialized clinical services within their pharmacy benefit management program benefit from the clinical professional's expertise and their ability to quickly identify and intervene in these potentially costly and clinically inappropriate cases.

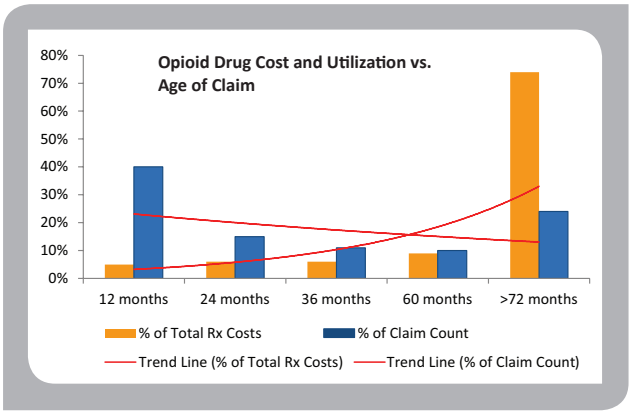
Clinical intervention early in the course of an injury can play an essential role in positively impacting a claim's cost trajectory

“Insidious Incrementalism” of Opioid Use in Workers’ Compensation

The incremental growth in opioid drug therapy costs — excerpts from a Healthesystems published report

In 1991, there were 40 million prescriptions written for opioids. By 2007, that number skyrocketed to 180 million. Upwards of 20 percent of all doctor office visits include an opioid prescription. Along with the increase in prescription volume, the issue of safety has been a significant challenge. In 2009, more than 310,000 Americans were admitted to emergency rooms due to an opioid overdose, and the amount of Oxycontin dispensed in 2009 alone was enough to give every man, woman and child in America 100 mg.

When analyzing the impact opioids have had in workers’ compensation, this single drug class has become the highest utilized of all prescription drugs, accounting for 30% - 45% of most payers total annual drug spend. While the use and application of these drugs cover all claim age demographics, approximately 75 percent of opioid drug costs are generated from claims older than five years, but 75 percent of all claims are less than five years old.

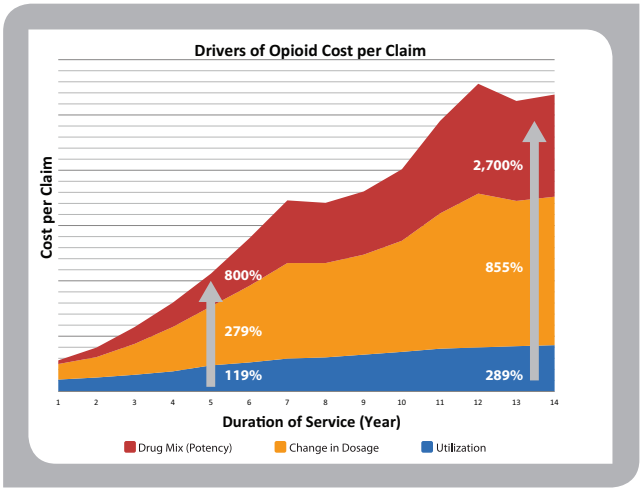


75% of opioid drugs costs are generated from claims older than five years

“Insidious Incrementalism” — the incremental growth in opioid drug therapy costs as a claims ages

Insidious incrementalism is evident when looking at an entire population of claims and seeing the cost and utilization growth of opioids occuring between the initial year of service, after 5 years and then 13 to 15 years.

As illustrated in the “Drivers of Opioid Cost per Claim” graph, when analyzing the drivers of opioid cost over time, the major contributors are the increases in drug mix (potency) and in dosage amounts, while utilization (i.e., the number of pills dispensed per prescription), by comparison, is relatively small. For example, when



comparing the opioid cost per claim for claims in service during their first year versus year 14, utilization makes the cost per claim 289% higher in year 14. Other contributors such as higher dosages and the use of increasingly more potent agents (drug mix) increase the cost per claim by 855% and 2,700% respectively. It’s the “incremental” increase in dosage and drug mix that begin manifesting during years 3 to 5 where the dramatic growth in costs per claim occur.

Other items become very apparent when analyzing the data in more detail. In 2007, opioid costs for claims 10 and 15 years old were heavily influenced by Fentanyl drugs (34.7% and 45.4% of total opioid costs respectively). This was likely due to the increased use of high priced, off label prescribed drugs like Actiq. Conversely Fentanyl represented a fairly small portion of opioid costs in the earlier stages of the claims lifecycle in 2007 at only 1.3% but increased to 9% in 2010.

The other driver impacting the total cost of opioids is the change in drug mix/potency. This can be clinically quantified by comparing the Morphene Equivalent Doses (MEDs) between drugs. For example, when comparing a 10 milligram dose of Morphine to a 10 milligram dose of Oxymorphone (Opana) or Hydromorphone (Dilaudid), both drug forms are 4 times more potent than Morphine. Also, Oxycontin is 1.5 times more potent than morphine. Therefore, the shifting in drug potency can not only be more expensive, but also more powerful.

This data is more thoroughly explained and illustrated in a recently published Healthesystems report titled “Insidious Incrementalism of Opioid Use.” Visit the Healthesystems website to request a copy.

Dr. Ralph Kendall, PharmD

A Case for an Independent Pharmacotherapy Evaluation of Complex Patients

An editorial from the perspective of Dr. Ralph Kendall, PharmD, VP of Clinical Services

Have you ever had a claim that you just didn't know what to do with? These are the ones that keep you up at night. The case seems to go around in circles with multiple prescribers, all chasing the claimant with more and more medications.

It helps to remember that most often, the first thing someone does when seeing their doctor about a physical complaint is ask the treating physician for a prescription to fix it. Almost 65% of the time, the patient's complaint involves pain, and almost always, the physician complies with the request.

What tools are available to sort out what is truly an injury-related problem worthy of treatment, and which of these complaints may be brought on by the treatment itself? We sometimes call these iatrogenic problems. As medically defined, an iatrogenic problem could be a side effect, an interaction, or almost any symptom or physical expression caused by the latest drug we've added. It could even be an emotional disturbance. The unintended consequences of drug therapy are many and are rarely considered as contributing to poor treatment outcomes.

Additionally, such complaints may be the result of a diagnosis that was missed or a treatment may be masking a symptom rather than correcting the root cause.

One answer to this perplexing problem might be a thorough evaluation of the drug therapy itself. In recent years, the Clinical Services Department of Healthesystems has conducted nearly 7,000 such evaluations. These are called Independent Pharmacotherapy Evaluations (IPEs) and they are tailored for just such claimants. Its important when doing an IPE to use evidence-based guidelines from the peer-reviewed medical literature to compare treatment of the various injury related diagnoses. A strategy can then be suggested to minimize or reduce the impact of a multiple drug regimen. A clinical pharmacist might then prepare a written communication to the prescriber or prescribers for such a case identifying the likely therapeutic problems and offering possible solutions to the often complex issues that are discovered.

The primary question most payers would like answered when doing these reviews is the **relationship to injury** for each drug in the regimen. When so many medications are used off-label in today's health care systems, this is sometimes a daunting task. It is imperative to consider both FDA approved uses as well as those indications that are off-label but accepted as good medical practice because of their appearance in official guidelines. But, both sides of the treatment issue must be examined. Which medical problems have been accepted as related and compensable as well as which problems are likely to be present, but are untreated. In the return-to-work strategy, neither is neglected.

As mentioned above, **"off-label" use** can be a confusing issue. Payers are very reluctant to provide coverage for investigational uses of medication. These, however, can be helpful when everything else has been attempted and met with treatment failure. Off-label use is usually contrary to guidelines. This means that a thorough review of the current medical literature is necessary. Sometimes a discussion with the treating physician can explain the evidence supporting such use. Payers are usually dis-inclined to support such uses when they lack appropriate evidence.

If a little is good, then more must be better ... An **excessive dose** of medication can do more harm than good. Prescribers sometimes encounter patients who have escalated doses beyond the intended safe treatment range. Some prescribers may have not cautioned the patient concerning the problems of side effect expression and even toxicity. This is common with medications that are available as both an over-the-counter (OTC) medication and a prescription strength drug. *This must be safe, its available without a prescription* — Acetaminophen, Ibuprofen, and many others are examples. This can result in expression of unwanted side effects and the addition of yet another drug being prescribed.

While we realize that each patient has his or her own sensitivity to medication, a less than therapeutic dose is often worse than no drug at all. In these drug regimen evaluations, it is important to look for subtherapeutic or inadequate doses to help correct a poor clinical outcome. Some medications must be slowly titrated upward to therapeutic levels in order to provide adequate control. This may be done to control expression of an unwanted side effect. But the therapeutic range must still be achieved.

The expression of drug-drug **interaction risk** is also a commonly missed problem. It most frequently is seen as another reason to prescribe more medication. An example might be the patient who is taking an opioid analgesic plus an antidepressant that modifies one of the metabolizing enzymes. The antidepressant may inhibit the enzyme preventing the opioid analgesic from being metabolized to its active form. This, in turn, prevents the patient from gaining any pain relief. The more drugs a regimen contains the greater the probability that an interaction will be encountered. This is more likely if several drugs are metabolized and excreted through the same pathway (liver or kidney). Likewise, an increased risk will be experienced if the patient has a diminished function through one of these organ systems.

All drugs have **side effects**. These are more likely to be expressed as doses are increased. We have also observed that if two or more drugs cause the same side effect, that side effect has a greater likelihood of being expressed, even at therapeutic doses. If three drugs in your regimen cause drowsiness, then it is highly likely that you will have drowsiness as a side effect. One reaction that we have observed is the tendency to prescribe a stimulant for these patients. The proper solution may involve simply backing down the dose of one or more of these drugs or changing the timing as well as the dose of medication, rather than adding a stimulant medication. The addition of a stimulant may then cause insomnia resulting in the need for a medication to help sleep.

One of the most critical elements of evaluating a drug regimen is the need to adequately **monitor** the patient's response to each drug. It is very helpful to provide the prescriber with a summary of the lab tests and frequency of monitoring each drug that requires monitoring. This alerts the prescriber to the possibility of developing toxicities or the potential of side effects.

By evaluating drug possession rates, we identify how well the patient is able to comply with or adhere to the prescribed directions. This may not assure that the patient is taking the medication according to directions, but it at least suggests that the patient can be compliant because they have the drug in their possession. This can also identify "refill creep" or an "insidious incrementalism" as well. These are situations where the patient has incremented, or self-escalated, the dose without being so directed by the prescriber.

Observing the use of multiple prescribers and even multiple pharmacies can identify those patients who may be using the system to obtain additional supplies of medication for the intent of abuse, or for illicit purposes. Of significant importance is the inclusion of a sample pain management agreement with most IPEs. This provides suggestions to the prescriber about many of the tools available to assess, monitor, and manage patients taking opioid therapies. The agreement provided is suitable for copying and inserting into the patient chart or use elsewhere in the physician's practice.

Every IPE also includes a feedback form to help evaluate the utility of the information presented. Feedback is used to help structure future IPEs to be of greater educational value to those who help return our injured workers to productive and functional life.

The IPE can be a roadmap towards simplifying the drug regimen. But we must realize that physicians don't follow such roadmaps all at once. Our intent is that the complex drug regimen is simplified one step at a time, taking first one step – observing the patient's response – taking the next step, and so forth. Over time, we can arrive at a much simpler solution to the return-to-work issues confronting our patients.

As a clinician, I strongly believe that we have an obligation to interact with all those who play a role in caring for our injured workers. We must use the various systems available to us to identify patients who are at-risk for drug misadventure, analyze the nature of their therapeutic problems, thus leading to meaningful and cost effective suggestions for resolutions to these problems. By providing support in this manner we can enhance the clinical outcomes of our patients, and insure restoration of function and hasten return-to-work.

Electrotherapy: Identifying the drivers to better manage costs

An analysis of the real savings opportunities

Electrotherapy products and services comprise one of the largest portions of total DME spend for workers' compensation claims, typically falling within the top five most costly items. For many payers, upwards of one third of all claims receiving DME services include electro-therapy equipment. Although, the individual charges and paid amounts can be relatively small for most electro-therapy equipment and supplies, the total financial impact driven from the utilization and number of claims necessitates developing better strategies manage costs. Healthesystems has compiled the following information from our innovative Ancillary Benefits Management (ABM) program. Based upon our analysis, better management and cost savings for electrotherapy can be achieved by focusing on these three primary areas:

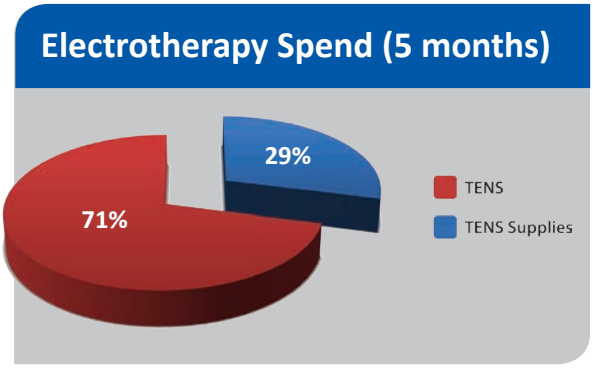
- **Price and quantity** - What services are you paying for?
- **Duration of services and supplies** - How long is the injured worker using a TENS unit and receiving supplies?
- **Identification of the total cost of electro-therapy** - What equipment and supplies are billed using miscellaneous codes?

The data analyzed was for home usage of electrotherapy, not equipment and supplies billed by physical therapy clinic visits.

Price and Quantity

The prices for electrotherapy products usually are relatively small. A TENS unit can be rented for approximately $40-$60 per month and the associated supplies such as electrodes, batteries, lead wires, etc. will add another $75-$100 per month. As a result, over a five month period, electrode supplies comprise as much as 71% of the total electrotherapy costs (depending on the types of electrodes and duration of electro-therapy, i.e. the longer the duration, the greater the need for replacement batteries and additional lead wires).

The significant challenges most payers encounter when evaluating the price of these products is being able to determine the individual services (the correct code), the quantity dispensed (appropriate billing quantity) and whether the equipment is purchased or rented.



Note: the use of combination stimulators instead of TENS units reverses the cost allocation illustrated in the chart due to the high purchase cost of these products

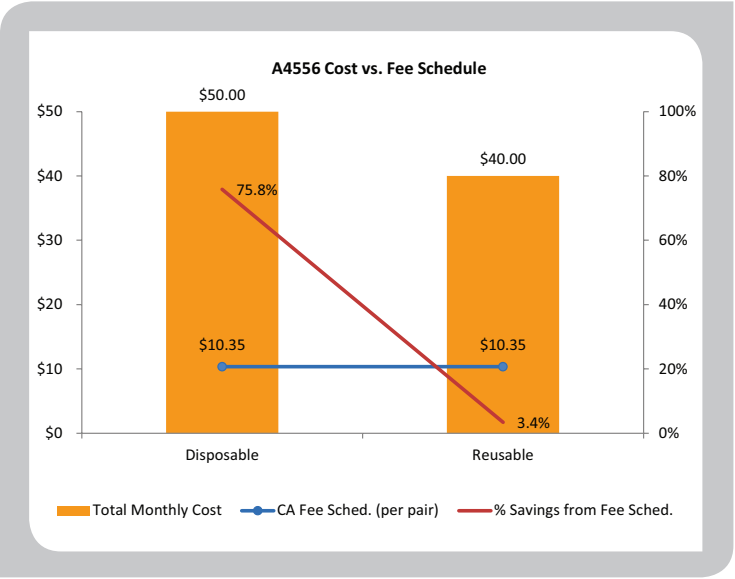
Prices vary significantly by HCPCS code. For example, the most commonly billed electrotherapy code is A4556, for electrodes. Prices for these products range from a few cents to over $100. Other price variables include whether the electrodes are reusable or disposable, the size and quantity. The price of disposable electrodes is approximately $2-$3 per pair and the price of reusable electrodes can be around $9-$10 per pair. While, the prices of disposable electrodes are significantly less than reusable ones, the actual monthly spend is less for the reusable based upon the lower total monthly quantity of units. The net result could result in a savings of $10 per month per claim (monthly disposable electrode cost = $50, monthly reusable electrode cost is $40. See chart on next page).

Savings calculations compared to state fee schedules can be quite substantial for electrotherapy, however, they can also be misleading depending on the actual product being used. The following is an example of savings calculations in California. The fee schedule for all HCPCS code A4556 products is $10.35 per pair.

Using the price per pair for a reusable electrode of $10, the savings below fee schedule is $.35 (3.3%). Compared to a disposable electrode price per pair of $2.50, the savings below fee schedule is $7.85 (75.8%). However, the total monthly cost is still lower for the $10 reusable electrode. Therefore solely using the savings from fee schedule will not identify the most cost advantageous approach.

Disposable vs. Resuable Electrodes (A4556)

Electrode (A4556)	Cost $ Per Pair	Weekly Qty.	Monthly Qty.	CA Fee Schedule	Savings/ pair vs. Fee Schedule	Monthly Fee Schedule Cost	Monthly Savings from Fee Schedule	Savings % from Fee Schedule	Actual Monthly Cost
Disposable	$2.50	5	20	$10.35	$7.85	$207	$157	75.8%	$50
Resuable	$10	1	4	$10.35	$0.35	$41.40	$1.40	3.4%	$40



Another factor to consider is quantity — how many electrodes, replacements or lead wires are being billed and paid? Electrodes are dispensed in many different quantities. The most common quantities are per each, per pair, and packages of 4, 20 and 48. In order to better manage the pricing of electrodes, identifying the translation of dispensed quantities compared to billed quantity is crucial. Using the previous example, the HCPCS code A4556 expects a per pair scenario. However, if a supplier bills for two electrodes, does it equate to two pairs or one pair? Frequently, the supplier bill is for two electrodes and not two pairs and the likelihood is that payers are charged too much.

The higher quantity packages of 20 and 48 are also very challenging to validate correct billing and payment. Often a quantity of 20 pairs is used to provide a monthly supply of disposable electrodes. However, the package of 20 should be priced as 10 pairs and yet it is billed as 20. Validating the correct quantities is an important step in the adjudication process, especially since the quantities billed are highly variable and the specific item and package size frequently aren't included on the bill within the A4556 HCPCS code.

Another challenge with validating quantities occurs with rentals and purchasing of TENS units and other combination stimulator units. There are different billing scenarios associated with TENS units and combo-stimulator units. These include:

- Billing quantity of 1 for a 1 *month* rental ($50 rental for basic TENS unit for one month)
- Billing quantity of 1 for a 1 *day* rental ($50 rental of an expensive TENS unit for one day)
- Billing quantity of 1 for a *purchase* ($125 purchase of a basic TENS unit)

Typically the process of distinguishing and validating appropriate quantities for TENS and combo-stimulator units requires matching each bill to the authorization without knowing what was ordered. As a result, it becomes impossible to validate what price the provider used to arrive at the billed amount due to the various quantities and prices used within a single HCPCS code. Implementing a prospective authorization process is the necessary solution for managing costs associated with TENS units.

Duration of Electrotherapy

Duration of electrotherapy treatment has two components, the duration of the rental and the number of times supplies are to be delivered. A TENS unit may be rented for three months and then converted to purchase with intent of using it for two more months resulting in a total of five months of therapy and five months of supplies.

Reducing the duration of electro-therapy treatment by 60 days can lead to a 15% reduction in the cost of electrotherapy services for a claim.

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HIPAA Standards in Workers' Compensation

Health information data exchange presents unique challenges for workers' comp

On November 18, 2011 the National Committee of Vital and Health Statistics (NCVHS) will conduct hearings on Section 10109 of the Affordable Care Act (ACA). The hearings will focus on health information data exchange and standards — an emerging area of attention for many workers' compensation payers, their vendors, clearing-houses and state agency policymakers. The upcoming hearings have already generated significant discussion and preparation amongst industry groups who are slated to testify about the impact of the ACA and associated HIPAA regulations on workers' compensation payers and providers.

Today, electronic data exchange is becoming more the norm in a workers' compensation system which was at one time primarily driven by paper processes. The technology to provide real time claim adjudication adds significant efficiency to the system, but also presents unique challenges for system participants. For example, nationally adopted electronic health exchange standards allow providers to check on patients' eligibility and coverage in group health or government sponsored health insurance programs. But the terms "eligibility" and "coverage" have different meanings in the world of workers' compensation, and this presents an obstacle for allowing medical providers to conduct "real time" eligibility checks, as they can for other types of insurance programs. State workers' compensation policymakers understand this nuance, and are working to educate federal and state agencies on the differences between workers' compensation programs and other types of insurance programs.

Right now, there are only a handful of state workers' compensation programs which have adopted the electronic data exchange standards which are already widely implemented outside of the Property and Casualty lines of insurance. Texas' workers' compensation agency was the first to adopt electronic requirements for billing, and several other states including Minnesota and California have followed suit by adopting e-billing standards. Many other states currently have advisory committees which are in the process of exploring e-billing rules for future consideration. Healthesystems staff continues to serve on several of these advisory committees to educate state policymakers about the benefits and challenges of adopting national standards in workers' compensation. For more information on the hearings, or for information on HIPAA standards, visit http://www.ncvhs.hhs.gov/.

Wound V.A.C. Therapy: Patent Expiration Promotes Competition

Competitive pressure changes the NPWT landscape

Wound V.A.C. (Vacuum Assisted Closure®) therapy, also known as Negative Pressure Wound Therapy (NPWT), is commonly used to treat wound injuries for workers' compensation claimants. This type of therapy assists in wound care, and helps to promote the healing process by working deep inside the wound. The current leading manufacturer of wound V.A.C. devices is KCI.

For years, KCI has held a patent on this device and in turn, has become well established in the hospital industry, where the onset of use for this device typically begins. Recently KCI's patent on wound V.A.C. technology has expired, leading to increased competitive pressure in the market. KCI remains well entrenched in the hospital industry, with a market share of 83% according to Business Wire, however Healthesystems does forecast a trend towards price decrease for these devices, as companies such as Smith & Nephew begin to gain market share.

There are currently 16 manufacturers who have applied for and received coding assignment from Noridian Administrative Services Pricing, Data Analysis and Coding (PDAC) for Medicare billing. Manufacturers include Smith and Nephew, Medela, Prospera and Genadyne Biotechnologies.

It is interesting to note that wound V.A.C. therapy often does not take a wound to full closure, although it does assist in the healing process and minimizes the size of the wound while drawing wound edges closer together, removing infectious materials and actively promoting granulation at the cellular level.

Alternative treatment options are now available for wound care and include medication regimens as well as oxygen therapy. Oxygen therapy, in which oxygen is pulsed into the wound, does result in full closure of a wound. Therefore, it remains important to consider all options for wound care therapy in the treatment of injured workers.

Electrotherapy

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TENS & Supply Cost by Duration of Treatment

	Day Delivered	30 days	60 days	90 days	180 days	365 days
Program Average	$90.68	$190.56	$290.44	$350.32	$479.28	$889.24

The following are some questions to ask about your program:

What is your average duration of electro-therapy treatment? Is it more or less than 180 days? How are your DME suppliers managing electrotherapy supplies on your behalf? Do they automatically ship another month's supply to an injured worker? Do they send $75 worth of supplies without validating that all the supplies were needed?

The savings opportunity is real — for example, 1000 claims accumulating two months of unused electrotherapy supplies equates to $150,000 of cost to those claims.

Proactively monitoring DME suppliers and ensuring they are verifying electro-therapy supplies are being provided only when needed is another critical step in managing DME costs.

Evaluating Electrotherapy Spend

For most payers, monitoring and evaluating their electro therapy costs is not an easy task. The starting point is compiling a limited set of HCPCS codes. The 11 HCPCS codes listed to the right represent the vast majority of costs for electrotherapy equipment and supplies, while the remainder is billed using miscellaneous codes, particularly E1399.

Controlling the use of E1399's is another critical element in managing electrotherapy costs. Based upon the analysis Healthesystems has performed, we have found the use of E1399 is only appropriate for certain types of electrotherapy equipment such as combination units where there is no defined HCPCS code. However, these are frequently expensive items, with the most commonly used units ranging from $330 to $3,500. In order to ensure the appropriate contracted rates and fee schedule structures are being applied, these products require more stringent prospective oversight to effectively manage them.

Incorporating a tool such as the Healthesystems ABM Catalog, provides a process to identify and map the specific equipment and supply items to categories and sub-categories independent of billing codes, thus allowing a greater degree of management over price and utilization. Maintaining visibility into the details of the miscellaneous code activity is critical. The list below contains some of the most frequently dispensed and more expensive of the electrotherapy unit items billed with the E1399 HCPCS code.

Common HCPCS

HCPC	Description
E0720	Tens two lead
E0730	Tens four lead
E0745	Neuromuscular stim for shock
E0762	Trans elec jt stim dev sys
E0770	Functional electric stim NOS
A4556	Electrodes, pair
A4557	Lead wires, pair
A4558	Conductive gel or paste
A4595	TENS suppl 2 lead per month
A4630	Repl bat t.e.n.s. own by pt
E0731	Conductive garment for tens

Frequently Dispensed (E1399)

RS Medical RS-4I Combination Interferential/ Neuromuscular Stimulator

H-Wave Stimulator (Combination Muscle Stim and TENS device)

VQ Vector, Neuromuscular/Interferential Stimulator

SurgiStim Interferential Unit

Orthostim 4

IF 8000 Interferential Stimulator

Ultimate Ortho TENS combo stimulator

Medications to Watch

Every year, new medications are approved and introduced into the marketplace with the potential to impact costs for workers' compensation payers

In 2010 alone the Food and Drug Administration (FDA) approved four new generics formulations and 13 new drugs that are likely to be seen as players in workers' compensation drug spend. Notably, there were three new opioid products including Exalgo™ (hydromorphone extended-release), the reformulated, abuse-deterrent Oxycontin® (oxycodone extended-release), and a generic version of Opana IR® (oxymorphone immediate-release) that warrant close monitoring.

In the first three months of 2011, five new medications were approved that will likely be used for treating workers' compensation patients. Three of these, Gralise™ (gabapentin extended-release), Viibryd™ (vilazodone), and Abstral® (fentanyl sublingual tablet) are certainly drugs to watch as they emerge in the marketplace.

Healthesystems clinical professionals actively monitor the pharmaceutical pipeline and alert clients to the potential impact of newly released medications. One such product, slated for a release in fall 2011, is LAZANDA.

>>LAZANDA™ (fentanyl nasal spray) Lazanda is the next in the line of rapid-release fentanyl products, similar to Actiq®, Fentora®, and Onsolis™. Like these other products, Lazanda is indicated only for the management of breakthrough pain in adult cancer patients who are already receiving, and are tolerant to opioid therapy. It is not indicated for the treatment of acute pain, or for chronic, non-cancer pain.

Unlike other orally-administered fentanyl products, Lazanda is a nasal spray, and can reach maximum blood concentration in as little as 15 minutes. The maximum dose is two sprays (1 spray in each nostril) up to 4 times in 24 hours. Patients must wait at least 2 hours before treating another breakthrough pain episode. Lazanda should not be substituted for other fentanyl products, as they are not equivalent.

Because of the risk of abuse, addiction, and overdose, Lazanda is available only through a restricted Risk Evaluation and Mitigation Strategy (REMS) program and can only be dispensed from a pharmacy that is enrolled in the REMS program.

While pricing information is currently unavailable, the off-label use of Lazanda in treating chronic pain conditions will have likely but unknown cost implications in the workers' compensation patient population. This impact, however, may be mitigated by the presence of similar rapid-release fentanyl products on the market.

Healthesystems strongly discourages expensive off-label use of rapid-acting oral fentanyl products, including Lazanda. Proactive drug plan management of our clients' drug plans avoids potentially inappropriate use of these extremely potent opioids in the workers' compensation patient population.

Physician Dispensing of Repackaged Medications: A Legislative Challenge

Physician dispensing of medications has become a major cost driver of workers' compensation medical costs

At the close of the 2010 Florida legislative session, lawmakers unanimously passed House Bill 5603, which would have controlled the high cost of physician dispensed repackaged medications provided to workers' compensation claimants. The bill required repackaged drugs to be reimbursed using the National Drug Code (NDC) of the "original manufacturer."

The passage of House Bill 5603 by the two houses of the legislature was not the end of this story. Governor Charlie Crist vetoed the bill, a move which received a significant amount of press throughout the insurance industry. Some stakeholders publicly questioned whether the veto was motivated by political contributions. Just months later, similar legislation was filed; again intending to control costs associated with repackaged drugs. Despite support from payers throughout the state, the 2011 legislative session closed without passing a single bill addressing the reimbursement of repackaged drugs. For Florida employers, change could not come sooner. During the week of October 24, 2011, Insurance Journal reported that Florida rate increases have been directly tied to repackaged drug costs.[1]

There is plenty of research published on the topic — reputable industry organizations such as the Workers' Compensation Research Institute, the National Council on Compensation Insurance, and the California Workers' Compensation Institute have all highlighted physician dispensed drugs as a major cost driver of medical costs. Physician dispensing, and specifically the lack of regulation around the reimbursement of these medications, has resulted in per pill charges that are sometimes several hundred percent more than the identical medications when dispensed by a pharmacy. In addition, physician dispensing can also contribute to over utilization of many types of medications, including opioids. Because these drugs are often billed on paper, they are not subject to prospective DUR and adjudication processes which are standard for point of sale prescription transactions.

Many states are challenged with finding a legislative solution to the costs associated with physician dispensing. In fact, of the relatively few states that have already adopted language addressing physician dispensed repackaged drugs, nearly all have done so through regulatory fee schedule changes — not legislation. Regulatory change may become more difficult in the future, as is evidenced by recent hearings in Maryland, Colorado and Tennessee. The repackaging industry has organized physicians to testify about the supposed benefits of physician dispensing, citing patient compliance, convenience and in some cases, improved patient outcomes, as ways to lower costs to payers.

When addressing the costs associated with physician dispensing, legislators must understand and focus on two of the main challenges: 1) excessive overcharging can definitely be considered price gouging; and 2) over utilization can place patients' health and safety at risk. While the cost issue should not be ignored, especially when the cost differences between physician and pharmacy dispensed medications can be hundreds of percents higher, it is important to also understand the health risks associated with utilization patterns resulting from physician dispensing.

Due to the wide group of competing stakeholder's business and financial interests involved, it is a difficult task for lawmakers to draft legislative language for physician dispensing that can be easily implemented and enforced. History has shown us that loopholes can be easily exploited but some states, such as Oklahoma, have done a good job adopting laws which leave very little room for loopholes. Either way, it is necessary for states to proactively address this growing trend, and Healthesystems will continue to be involved in educating and communicating with legislators in regards to this practice.

State-by-State Compliance & Regulatory Updates

Compound drugs, physician dispensing, pricing benchmarks and e-billing are major legislative topics to stay on top of for the remainder of 2011 and 2012

Florida

The Florida Division of Workers' Compensation has issued the "final draft" of its update to the *Provider Reimbursement Manual*. The latest draft incorporates changes based on comments received at a July hearing. Healthesystems provided information about electronic authorization for DME, home health and home medical supplies. No changes were made to previously proposed language regarding physician dispensing. The manual will be submitted to the legislature for review prior to it becoming effective, and will not become effective before the spring of 2012.

U.S.

In response to the decision by First Data Bank to stop publishing its AWP "Blue Book," the U.S. Department of Labor, Office of Workers' Compensation Programs — which administers workers' compensation programs for the Division of Longshore and Harbor Workers' and the Division of Coal Mine Workers' Compensation — announced that it would begin using Medi-Span for its pharmacy pricing resource. The agency had previously utilized Blue Book.

Oklahoma

The Oklahoma Workers' Compensation Court announced that it would begin using Medi-Span as its AWP resource. The change became effective September 6, 2011.

Tennessee

The Tennessee Division of Workers' Compensation conducted a hearing on September 28, 2011 on amendments to its medial fee schedule. New provisions included in the amendments could require the pharmaceutical fee schedule to use "lesser of" language incorporating (between?) Average Wholesale Price (AWP) and General Equivalent Average Price (GEAP) . Written and oral testimony during the hearing opposed the addition of the GEAP language. The Division will continue to receive testimony through October 12, 2011 and expects to make a decision on any changes before adopting shortly thereafter. The Division intends to adopt amendments to the medical fee schedule to be effective by the end of January 2011 , due to the scheduled expiration of an emergency rule related to issues in the physician fee schedule.

Illinois

The Illinois General Assembly passed House Bill 1698 to reform workers' compensation legislation and was signed into law by Governor Pat Quinn on June 28, 2011. The bill includes numerous updates to the Medical Fee Schedule such as changes to out-of-state provider reimbursement, days to pay or deny a bill, a 30% reduction in medical fee reimbursement rates, new reimbursement rules for medical implants and prescriptions dispensed outside of a licensed pharmacy, the use of AMA criteria, as well as changes to fee schedule regions. Several of the fee schedule changes became effective when the Governor signed the bill and others will become effective at later dates.

California

AB378 was signed into law by Governor Jerry Brown on October 7, 2011 incorporating disclosure standards for physician owned pharmacies, along with a new fee schedule methodology for reimbursement of compound drugs. These measures are intended to better control pharmacy costs. The legislature made a unilateral 10% cut in all Medi-Cal spending earlier this year due to budget constraints.

Separately, Medi-Cal will implement a new reimbursement methodology based on Actual Acquisition Cost (AAC) for drug product reimbursement in February or March of 2012. AAC rates are determined based on surveys of pharmacy purchasing invoices. In the interim, Medi-Cal and the California Division of Workers' Compensation will both continue using AWP data supplied by First Data Bank under a special arrangement to determine reimbursement rates. First Data Bank had suspended its publication of the AWP "Blue Book," for determining reimbursement rates, but the company has agreed to continue producing the data for Medi-Cal until work is completed on the new ACC benchmark.

It is important to note that The CA Division of Workers' Compensation posted the interim pharmaceutical fee schedule data file on September 28, 2011 and stated it will not be updated for "approximately one month" due to logistical issues delaying Medi-Cal's continued use of the AWP data.

Maryland

The Workers' Compensation Commission has withdrawn its pharmacy fee schedule rule that was heard in April, 2011. The rule would have incorporated the use of Generic Equivalent Average Price (GEAP) into the fee schedule. A new rule is expected to be proposed in November.

Kentucky

The Commissioner of the Division of Workers' Claims is planning to amend current regulations governing pharmacy reimbursement by the end of 2011. The Commissioner indicated he will hold a public stakeholder meeting prior to the regulations being formally proposed. He is considering providing an option in addition to AWP for determining reimbursement, though he acknowledged that difficulty in obtaining necessary data may make it difficult to act on the issue in the short term. Planned amendments will also address physician dispensed medications.

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Oregon

The Workers' Compensation Division has proposed changes that will set reimbursement rates for durable medical equipment, prosthetics, and orthotics at 110% of the CMS rate. Items that do not appear in the fee schedule would be based on a contracted rate with the payer or 80% of usual and customary charges.

South Carolina

A South Carolina pharmacy task group is addressing reimbursement for repackaged drugs. The consensus of the group to date has been to come up with a definition of AWP and to reimburse repacks based on original NDC. There was also discussion of using Medi-Span. No formal proposal has been made yet, and we expect more activity around this in the coming weeks.

Louisiana

A draft of e-billing regulations has been issued by the Office of Workers' Compensation Administration (OWCA). Proposed regulations are not expected to be implemented prior to January 2013. E-billing will not be mandatory for all billing providers, but it will be mandatory for all payers to be able to accept bills electronically.

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 Benefits Management solution for prospectively managing ancillary medical services.

Our Verticē Claims Information Portal delivers real-time pharmacy and ancillary benefit management program information, reports and tools. This intuitive web portal allows claims professionals to access tools for quickly and efficiently processing provider transactions, running reports, retrieving relevant clinical information and many other functions.

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 and manage drug utilization, including the overuse of narcotics and other problematic drugs, all while increasing the quality of care for injured workers.

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

Healthesystems™

5100 West Lemon Street
Suite 311
Tampa, FL 33609
800.921.1880 | Toll Free
800.758.5779 | Customer Service Center
800.964.1681 | Drug Information Line
www.healthesystems.com

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