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CWCI RESEARCH UPDATE - May 2014

Part 1: Schedule II & Schedule III Opioids: Prescription and Payment Trends in California Workers' Compensation

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EXECUTIVE SUMMARY

Over the past decade, the widespread use of Schedule II and Schedule III opioid analgesics to manage both acute and chronic pain has become a hotly debated issue as the volume of prescriptions for these drugs has grown despite a growing body of evidence linking their long-term use to adverse outcomes, including delayed recoveries, functional impairment, increased sensitivity to pain, addiction, overdoses, and death.

This study updates earlier analyses that examined utilization and reimbursement trends for Schedule II and Schedule III opioids in California workers' compensation by reviewing data on prescription drugs dispensed to injured workers through June 2013. The findings show that in the first half of 2013, Schedule II opioids, which include powerful narcotics such as oxycontin, fentanyl and morphine, have grown to 7.3 percent of California workers' compensation prescriptions – nearly 6 times the proportion noted in 2002. Over the same period, payments for these drugs have increased from 4.7 percent to 19.6 percent of California workers' compensation prescription dollars. The data also suggest that the use of Schedule II drugs in workers' compensation may have stabilized near this record level, as over the most recent 3-1/2 years these drugs have accounted for between 6.5 and 7.3 percent of all prescriptions dispensed to injured workers, while over the most recent 4-1/2 years Schedule II drug payments have represented about 1 out of every 5 dollars paid for workers' compensation prescriptions in California.

The findings also show that since 2002, less powerful Schedule III opioids – primarily Vicodin or other forms of hydrocodone compounded with a non-steroidal drugs such as acetaminophen – have accounted for a much more consistent share of workers' compensation prescription drugs, generally representing around 20 percent of all prescriptions dispensed to injured workers and 10 to 11 percent of the overall drug spend. The only exception was a brief dip in both Schedule II and Schedule III prescriptions following the implementation of the 2002-2004 reforms and the adoption of the pharmacy fee schedule, which took effect in January 2004.

The analysis of the prescribing patterns for Schedule II opioid prescriptions reveals that a relatively small percentage of providers continue to account for the vast majority of these prescriptions in California workers' compensation. In 2010, the top 10 percent of doctors who prescribed Schedule II opioids to California injured workers accounted for 79 percent of all workers' compensation prescriptions for these drugs and 88 percent of the associated payments. The more recent data from 2012/13 show similar results, as the top 10 percent of the doctors who wrote these prescriptions accounted for 82 percent of the prescriptions and 86 percent of the payments. The prescribing patterns data also found that more than 8 out of 10 physicians who ranked among the top 3 percent of Schedule II opioid prescribers in 2012/13 were also in the top 3 percent in 2010. In addition, as in the earlier study, almost half of all Schedule II prescriptions dispensed to injured workers in the 2012/13 sample were for relatively minor injuries for which the use of these drugs is not supported by evidence-based medicine.

These findings suggest that the widespread publicity about the dangers associated with opioid medications, the public policy efforts to curb the utilization and cost of these drugs through the adoption of chronic pain medical treatment guidelines and the pharmacy fee schedule, and the attempts to tighten controls over the use of Schedule II and III drugs through utilization review have thus far had limited success in reducing system-wide use.

BACKGROUND

Opioid pain relievers are powerful narcotics that can be natural (morphine or codeine, which are derived from opium), semi-synthetic (hydromorphone, oxymorphone, or oxycodone) or wholly synthetic (fentanyl, methadone, tapentadol). Recognizing the extreme potency and potential dangers associated with these medications, in 1970, Congress enacted the Controlled Substances Act (CSA), which governs the manufacturing, distribution and dispensing of these types of drugs. The Federal Drug Enforcement Administration and the Food and Drug Administration categorized these drugs based on their potential for abuse or addiction or historical factors. For example:

- Drugs such as morphine and fentanyl, which have a high potential for abuse or addiction, but which also have accepted medical uses, were classified as Schedule II drugs; and

- Drugs such as intermediate-acting barbiturates, anabolic steroids, and hydrocodone/codeine compounded with a non-steroidal drug such as acetaminophen, which have less potential for abuse or addiction than Schedule II drugs, and which also have accepted medical purposes, were classified as Schedule III drugs.[1]

Initially opioid painkillers were used primarily in inpatient settings for patients with end-stage cancer or for the treatment of short-term, acute pain – such as that experienced during surgical recovery. In the mid-1980s, however, pharmaceutical manufacturers began aggressively marketing them to physicians as viable long-term options for the treatment of non-cancer pain. To bolster their position, those promoting the expanded use of opioids cited a brief letter to the editor that appeared in 1980 in the New England Journal of Medicine which had noted that less than 1 percent of Boston University Medical Center emergency room patients who had been prescribed narcotics became addicted[2]; and a study that appeared in the journal Pain in 1986 which, while recommending caution and citing the need for long-term studies on the use of narcotics, also concluded that these drugs could be used as an "alternative therapy" for selected patients with relatively little risk of the problems associated with opioid abuse.[3] To help market these drugs, the manufacturers also funded educational programs to introduce their drugs to doctors and hospitals, and set up nonprofit groups that produced and distributed narcotic prescribing guidelines.

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[1] As a point for comparison, heroin, which is highly addictive and has no accepted medical use, was classified as a Schedule I drug.

[2] Porter, J., & Jick, H. (1980). Addiction is rare in patients treated with narcotics. *New England Journal of Medicine, 302, 2*, 123.

[3] Portenoy, R., & Foley, K. Chronic use of opioid analgesics in non-malignant pain: Report of 38 cases. Pain. Volume 25, Issue 2, May 1986, Pages 171–186

Such efforts did bear fruit, and from the mid-1980s through the 1990s, the growing acceptance of opioids for the treatment of chronic pain became evident in the Medicare, Medicaid, group health systems, as well as in workers' compensation. At the same time, California workers' compensation prescription drug costs began to escalate rapidly, with total prescription drug payments ballooning from $114 million in 1996 to $212 million in 2000, making pharmaceuticals one of the fastest growing cost components in the workers' compensation system during this period.[4] Recognizing this trend, in 2000, the California Commission on Health and Safety and Workers' Compensation (CHSWC) and the California Department of Industrial Relations, working in cooperation with CWCI and other researchers, conducted a study to examine the magnitude and escalation of drug costs – including the cost of opioids -- and to estimate potential savings from modifications to California's current approach to regulating workers' compensation pharmaceutical costs.[5]

That analysis yielded a number of public policy recommendations, and within the next two years, the state had adopted reforms that included the following mandates:

- Create a pharmacy fee schedule by July 1, 2003;
- Channel injured employees to contracted pharmacy networks;
- Require pharmacies to substitute generic drugs for brand drugs unless the physician specified in writing that no substitution should be made;
- Cap maximum reimbursement for pharmacy services and drugs at 100 percent of the Medi-Cal allowance; and
- Establish maximum fees for drugs not covered by Medi-Cal – with fees not to exceed the Medi-Cal fees for comparable drugs.

At the same time, additional reforms such as mandatory utilization review, the adoption of the medical treatment utilization schedule, and the introduction of medical provider networks also impacted the delivery of workers' compensation medical benefits, including prescription drugs.

The pharmacy fee schedule adopted by the Division of Workers' Compensation following public hearings was embedded in regulation,[6] which took effect January 1, 2004. The schedule set maximum reasonable allowances for pharmacy services and drugs at the Medi-Cal rates, which in 2004 were at least 10 percent below the Average Wholesale Price (AWP) of the drug. However,

[4] Commission on Health and Safety and Workers' Compensation, Fact Sheet Number 2, Workers' Compensation Medical Care in California: Costs, August 2003
[5] Neuhauser F, Swedlow A, Gardner L, Edelstein E. *Study of the Cost of Pharmaceuticals in Workers' Compensation*. Report prepared for the California Commission on Health and Safety and Workers' Compensation. 2000.
[6] Title 8, California Code of Regulations Section 9789.40

for drugs or pharmaceutical services not covered by Medi-Cal (most notably, repackaged drugs dispensed in a physician's office) maximum reasonable fees were still governed by the Official Medical Fee Schedule that was in effect in 2003, which at 140 percent of the AWP for generic drugs, and 110 percent of the AWP for brand name drugs, allowed significantly higher fees than the Medi-Cal rates.

In the wake of these changes, which affected both the delivery and reimbursement of prescription drugs in workers' compensation, CWCI and other research organizations conducted multiple studies that focused on issues related to the use of opioids in workers' compensation. For example, Institute research included studies that:

- quantified the growth in the use and reimbursement of Schedule II drugs in California workers' compensation;[7]
- identified prescribing patterns associated with medical providers who write Schedule II prescriptions for injured workers;[8] and
- measured various injured worker outcomes related to the elevated use of these drugs.[9]

The California experience is hardly unique as studies by other research organizations noted similar patterns in other state systems, as well as significant variation across jurisdictions, [10] [11] which verified that the growing use of Schedule II opioids in workers' compensation was a nationwide phenomenon.

As opioids have become more prevalent in workers' compensation, and efforts to rein in their use have increased, other ancillary issues have surfaced. For example, CWCI research from August 2010[12] noted that following the closure of the repackaged drug loophole in 2007, there was an independent sharp spike in the use of largely unregulated compounded drugs – primarily topical creams mixed with various pain management medications – in California workers' compensation. In addition, a 2012 Institute study found that drug testing was becoming a significant cost driver

[7] Swedlow, A., Ireland, J., Gardner, L. Analysis of Medical and Indemnity Benefit Payments, Medical Treatment and Pharmaceutical Cost Trends in the California Workers' Compensation System. CWCI, August 2011
[8] Swedlow, A., Ireland, J., Johnson, G. Prescribing Patterns of Schedule II Opioids in California Workers' Compensation. Research Update, CWCI. March 2011
[9] Swedlow, A., Gardner, L., Ireland, J., Genovese, E. Pain Management and the Use of Opioids in the Treatment of Back Conditions in the California Workers' Compensation System. Report to the Industry. CWCI. June 2008
[10] Wang, D., Mueller, K., Hashimoto D., Chen, J. Interstate Variations in Use of Narcotics. WC-11-01 WCRI, July 2011.
[11] Laws, C. Narcotics in Workers' Compensation. NCCI Research Brief. May 2012
[12] Swedlow, A., Auen, E. "Current Trends in Compound Drug Utilization and Cost." CWCI Research Note, Feb 2013.

in workers' compensation.[13] Beyond that, as the number of injured workers who have become addicted to prescription opioids or died from overdoses of these drugs has increased, there has been growing concern among employers and other workers' compensation stakeholders about the long-term effects, costs and liabilities associated with these medications. All of these issues have added fuel to the debate surrounding the appropriate use of opioids in the treatment of workplace injuries – including the efficacy and appropriateness of these drugs for the treatment of chronic pain, the long-term repercussions for injured workers who take them, the need for tighter controls, and the importance of physician education and monitoring programs by payors, pharmacy benefit managers, and utilization review personnel.

In light of such concerns, there have been ongoing calls for the state to strengthen its prescription drug monitoring program (PDMP) to better monitor when these drugs are dispensed, and to provide a tool for doctors and pharmacists to readily obtain a patient's prescription drug history so they can identify and stop prescription drug seekers from doctor shopping and abusing prescription drugs. California's PDMP, first introduced in 2009, is an internet-based tracking system known as the Controlled Substance Utilization Review and Evaluation System (CURES). While the goals of the program were laudable, from the start, the CURES program has had its limitations as the state only requires doctors and pharmacies to report to CURES upon dispensing a controlled substance. Despite a 2013 legislative proposal, under current law, medical providers are not required to check CURES before writing prescriptions for controlled substances, and third parties – including workers' compensation payors – are not allowed access to CURES data to better manage the use of these drugs, even though Institute research has shown that third party access could save millions of dollars a year in workers' compensation prescription costs.[14] Beyond the attempts to monitor when and where Schedule II and Schedule III opioids are dispensed, the sources and recipients of the prescriptions for these controlled substances, and the quantities provided, the state also has instituted regulatory controls over the use of Schedule II and III drugs to treat injured workers. In 2009, the Division of Workers' Compensation added chronic pain medical treatment guidelines to the workers' compensation Medical Treatment Utilization Schedule (effective July 19, 2009). Initially, it was hoped that these guidelines would curb the widespread use of opioids to treat chronic pain in workers' compensation – which had even become prevalent in cases involving relatively minor injuries such as sprains and strains where their use is not supported by the clinical evidence. After the chronic pain medical treatment

[13] Swedlow, A., Young, B. Drug Testing Utilization and Cost Trends in California Workers' Compensation. CWCI Research Note, May 2012.

[14] A CWCI analysis, ""Estimated Savings from Enhanced Opioid Management Controls Through Third Party Payer Access to CURES," published in January 2013, estimated that for accident year 2011 claims alone, allowing workers' compensation payors access to CURES data would have reduced paid losses by $57.2 million.

guidelines were finalized, however, there was concern within the workers' compensation community that they had been severely weakened by an ambiguous definition of chronic pain ("any pain that persists beyond the anticipated time of healing"). In addition, because the pain management guidelines lacked explicit recommendations and limits on the use of opioids, and were based on evidence and rating standards that conflicted with – yet superseded – existing guidelines, many claims administrators and pharmacy benefit managers believed that contrary to their intent, these guidelines had lowered the threshold for the use of opioids, and that the number of claims involving these drugs would increase.

In the 5 years since the DWC added the chronic pain medical treatment guidelines to the Medical Treatment Utilization Schedule, the authors and other research organizations have produced several studies on issues related to the use of opioids in workers' compensation and in other health systems. These studies have spotlighted the costs and the dangers related to the overuse and abuse of these medications, and have garnered the attention of the press and state and federal regulators and legislators. At the same time, claims organizations, self-insured employers, utilization review personnel, pharmacy benefit management companies, and workers' compensation medical providers have implemented programs aimed at assuring that these drugs are only used when appropriate and necessary. While some anecdotal reports have suggested that these efforts and the increased awareness of the problems associated with prolonged opioid use have been helpful, there has been limited evidence of any long-term reduction in the use of Schedule II and Schedule III opioids in California workers' compensation.[15]

DATA

To measure the prevalence of Schedule II and Schedule III utilization in workers' compensation, and to assess the latest utilization and cost trends for these medications, the authors undertook this study to determine:

1) the percentage of California workers' compensation prescriptions and prescription payments represented by Schedule II and Schedule III opioids;
2) how those percentages have changed across the 11-1/2 year period ending in the second quarter of 2013; and
3) which types of Schedule II and Schedule III opioids were most heavily prescribed to injured workers in California during that 11-1/2 year span.

[15] Wang, D. Longer-Term Use of Opioids, 2nd Edition. WC-14-19 WCRI, May 2014.

The pharmaceutical data used in this study was drawn from CWCI's Industry Claims Information System[16] database and consisted of nearly 11.1 million California workers' compensation prescriptions filled between January 2002 and June 2013. Aggregate reimbursements for those prescriptions totaled $1.03 billion. Among those 11.1 million prescriptions, the authors identified 463,851 Schedule II prescriptions that were classified as Analgesics – Opioid (4.2 percent of the total). These prescriptions resulted in nearly $136.6 million in payments (13.2 percent of the prescription dollars paid). In addition, another 2.153 million (19.5 percent) of the prescriptions from the sample were for Schedule III opioid analgesics, for which claims administrators paid $105.0 million (10.2 percent of the prescription reimbursements).

Each prescription contained information on pharmaceutical sources, packaging, formula, class, pricing and other characteristics of the drug sample. The authors grouped the Schedule II and Schedule III opioid analgesic prescriptions from the sample by year of the fill date, and after identifying the active ingredient, classified them into major categories (those that accounted for at least 1 percent of the scripts). This produced seven major categories of Schedule II drugs:

- Oxycodone (e.g., OxyContin, Endocet, Percocet)
- Morphine (e.g., Avinza, Morphine Sulfate, Oramorph)
- Fentanyl (e.g.,Actiq, Duragesic, Fentora)
- Hydromorphone (e.g., Dilaudid, Hydromorphone)
- Tapentadol (e.g., Nucynta)
- Methadone (e.g., Methadone, Methadose)
- Oxymorphone (e.g., Opana)

As in CWCI's earlier analysis, Hydrocodone with Acetaminophen, available in various forms (e.g., Vicodin, Lortab, Norco) was the predominant Schedule III drug category in the study sample, accounting for more than 92 percent of Schedule III opioid prescriptions dispensed to injured workers during the 11-1/2 year study period. Various forms of Codeine (e.g., Acetaminophen/Codeine, Tylenol with Codeine) comprised the second most common category of Schedule III drugs used in workers' compensation (6.5 percent of the Schedule III prescriptions), while Buprenorphine, which like methadone, is used to treat addictions to other prescription opioids and heroin, ranked third, accounting for 1 percent of the Schedule III drugs dispensed to injured workers.

[16] ICIS is a proprietary database maintained by the California Workers' Compensation Institute that contains detailed information, including employer and employee characteristics, medical service information, and benefit and other administrative cost information on more than 4 million workplace injury claims with dates of injury between 1993 and 2013(ICIS V15A).

RESULTS

To measure the percentage of California workers' compensation prescriptions and prescription payments represented by Schedule II and Schedule III opioids, and the utilization and payment trends for these drugs, the authors calculated the total number of Schedule II and III prescriptions, as well as other types of prescription medications dispensed to injured workers, with the results broken out by the year in which the prescriptions were filled. They then used the payment records to determine the total amount reimbursed by claims administrators for these prescriptions.

Exhibit 1. Schedule II & III Opioids as a % of Calif WC Prescriptions and Prescription Payments: Calendar Year 2002 – Q2 2013 Fill Dates

	Schedule II Opioids		Schedule III Opioids		Schedule II & III Opioids	
Fill Date	% of Scripts	% of Payments	% of Scripts	% of Payments	% of Scripts	% of Payments
2002	1.3%	4.7%	20.0%	11.1%	21.3%	15.8%
2003	1.6%	5.2%	20.4%	10.4%	22.0%	15.6%
2004	2.0%	6.8%	18.6%	8.3%	20.6%	15.1%
2005	1.4%	4.1%	17.7%	9.5%	19.1%	13.6%
2006	1.8%	4.2%	18.7%	9.9%	20.5%	14.1%
2007	3.2%	9.7%	19.6%	11.3%	22.8%	21.0%
2008	5.4%	17.3%	19.9%	9.9%	25.3%	27.2%
2009	5.8%	20.0%	18.8%	10.4%	24.6%	30.4%
2010	6.5%	19.8%	20.5%	10.3%	27.0%	30.1%
2011	7.0%	20.1%	20.9%	10.5%	27.9%	30.6%
2012	7.2%	19.1%	19.0%	10.4%	26.2%	29.5%
2Q 2013	7.3%	19.6%	19.3%	10.3%	26.6%	29.9%

Exhibit 1 shows that Schedule II opioids accounted for just 1.3 percent of all prescription medications dispensed to California injured workers in 2002, and only 4.7 percent of workers' compensation prescription drug payments. Those percentages grew through 2004, at which point the 2002 – 2004 workers' compensation medical reforms, including the pharmacy fee schedule, were implemented, leading to a short-term decline in the use of opioids. By 2006, however, the use of Schedule II opioids to treat injured workers began to accelerate rapidly, consuming a growing proportion of the workers' compensation prescriptions and prescription dollars. Results from the first half of 2013 show Schedule II opioids accounted for a record 7.3 percent of all prescription drugs in California workers' compensation, though the growth rate for these drugs may be leveling off near this level, as Schedule II prescriptions have remained between 7.0 and 7.3 percent of California workers' compensation prescriptions over the last 2-1/2 years.

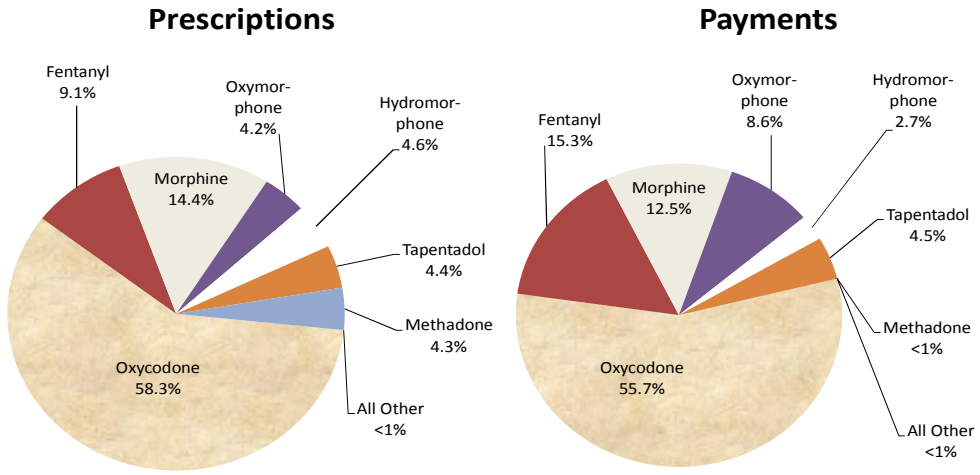
In contrast to the 11-1/2 year trend in Schedule II opioid use, Schedule III opioids (primarily various forms of hydrocodone with acetaminophen) have accounted for a much more consistent share of workers' compensation prescriptions and prescription payments. Other than the post-reform year of 2005, when they dipped to less than 18 percent of California workers' compensation prescriptions, since 2002 Schedule III opioids have continued to account for about one out of five prescriptions dispensed to injured workers, and about 10 to 11 percent of the prescription dollars. The latest measurements (prescriptions filled in the 2nd quarter of 2013) show Schedule III opioids remain within those historical ranges, accounting for 19.3 percent of all prescriptions dispensed to injured, with payments for these drugs representing 10.3 percent of the workers' compensation drug expenditures in that quarter.

To some extent, the prevalence of Schedule II and Schedule III opioids in California workers' compensation – and even some of the post-reform growth in Schedule II utilization that began in 2006 and continued through the first half of 2013 -- may indicate their use during post-surgical acute care when these medications may be appropriate for injured workers. On the other hand, these trends may simply be bearing out the earlier concerns that the limitations of the chronic pain medical treatment guidelines added to the Medical Treatment Utilization Schedule in 2007 have weakened the standards for prescribing these drugs for injured workers, making it difficult to limit their use.

PRESCRIPTION & PAYMENT DISTRIBUTIONS BY DRUG TYPE

The distributions of Schedule II and Schedule III opioid prescriptions and payments by drug type noted in the pie charts below reveal which of the opioids have been most heavily utilized over the past 11-1/2 years, and which of these drugs have been the primary cost drivers.

Exhibit 2: Calif WC S-II Prescription & Payment Distributions by Drug Type
CWCI Study Sample: S-II Prescriptions with 2002 – 2Q 2013 Fill Dates

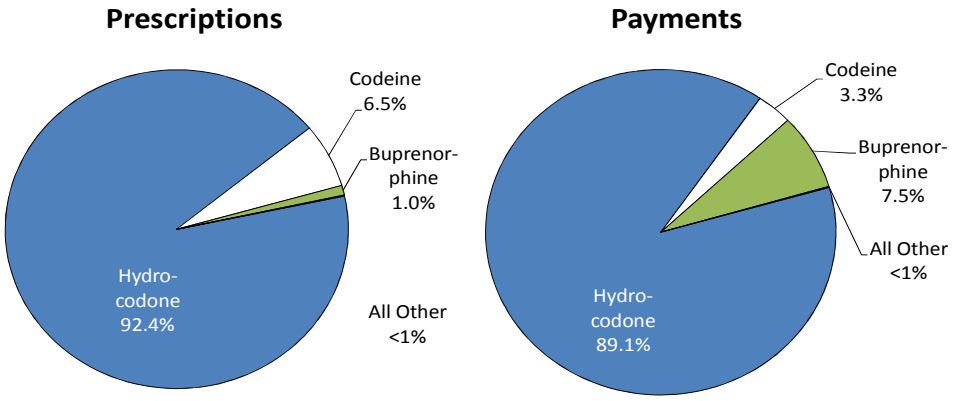


Schedule II Opioids	% of Schedule II Opioid Prescriptions	% of Total Schedule II Opioid Payments
Oxycodone	58. 3%	55.7%
Fentanyl	9.1%	15.3%
Morphine	14.4%	12.5%
Oxymorphone	4.2%	8.5%
Tapentadol	4.4%	4.5%
Hydromorphone	4.6%	2.7%
Methadone	4.3%	< 1%
All Other	<1%	< 1%
Total in Study Sample	100%	100%

There were seven types of drugs that had more than a 4 percent share of the Schedule II opioids identified in the study sample. Any Schedule II drugs that did not fall into one of these categories were placed in the "Other" category, but all together, the seven major categories represented more than 99 percent of all Schedule II opioid prescriptions in the study sample.

Oxycodone comprised more than 58 percent of the Schedule II opioids dispensed to California injured workers in the study sample, and nearly 56 percent of the Schedule II opioid payments. Morphine, which accounted for 14.4 percent of Schedule II opioid prescriptions, ranked second in terms of the volume of Schedule II prescriptions, though Fentanyl, which represented 9.1 percent of the prescriptions, consumed a higher proportion of the payments; indicating a high average cost for Fentanyl prescriptions. Similarly, Oxymorphone accounted for 4.2 percent of the Schedule II prescriptions, but 8.5 percent of the opioid expenditures, also a disproportionate share reflecting a relatively high average cost of per prescription. Exhibit 3 shows the distributions for Schedule III opioids dispensed to California injured workers over the past 11-1/2 years.

Exhibit 3: Calif WC S-III Prescription & Payment Distributions by Drug Type
CWCI Study Sample: S-III Prescriptions with 2002 – 2Q 2013 Fill Dates



Schedule III Opioids	% of Scripts	% of Total Paid
Hydrocodone	92.4%	89.1%
Buprenorphine	1.0%	7.5%
Codeine	6.5%	3.3%
All Other	<.1%	<.1%
Total in Study Sample	100%	100%

Hydrocodone with acetaminophen, available in various forms (e.g., Vicodin, Lortab, Norco) was the overwhelmingly dominant Schedule III drug category in the study sample, accounting for more than 92 percent of the Schedule III opioid prescriptions dispensed to injured workers. The various forms of codeine (e.g., acetaminophen/codeine, Tylenol with codeine) ranked second among Schedule III drugs, accounting for 6.5 percent of the Schedule III opioids and 3.3 percent of the Schedule III drug payments in the study sample. Buprenophine, which is used to treat

opioid addiction, was the only other Schedule III drug category that represented at least 1 percent of the Schedule III opioid prescriptions, accounting for 1 percent of the Schedule III scripts, but because of the relatively high cost per prescription, buprenophine payments consumed more than 7.5 percent of Schedule III opioid payments over the 11-1/2 year study period.

SCHEDULE II OPIOID PRESCRIBING PATTERNS

In addition to overall trends in opioid use and cost in workers' compensation, other studies have shown that the majority Schedule II opioids are prescribed by a small minority of physicians. In 2011, Swedlow found that 54.9 percent of all 2010 Schedule II opioid prescriptions and 64.7 percent of all payments were generated from 3 percent of all physicians who prescribed any such drugs. [17] Since the publication of the 2011 study, many employers, managed care organizations and workers' compensation insurance payors have sought to improve opioid utilization oversight.

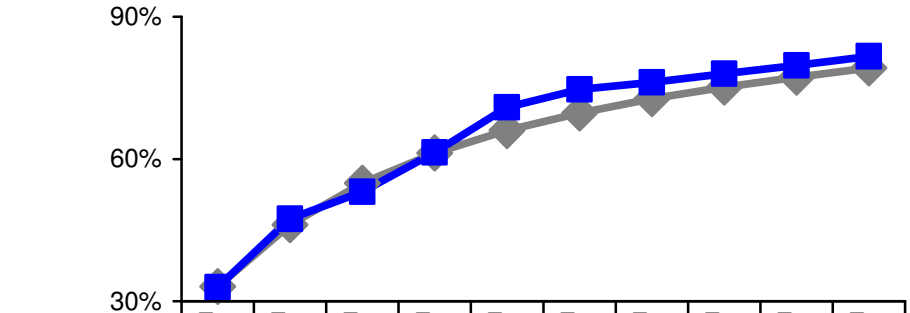
In an effort to replicate the conditions of the prior prescribing patterns analysis, the authors prepared a special dataset of 196,319 California workers' compensation prescriptions for Schedule II opioids that were filled between June 1, 2012 and June 30, 2013. The data included the prescribing physician's Drug Enforcement Agency (DEA) number, the prescribed medication, billed and paid amounts per prescription, the National Drug Code (NDC),[18] and other descriptive details about the drugs. Additional drug classification data included drug therapy class, drug group class, drug source and DEA classification. Detailed information on each prescription included the quantity and dosage of each prescription. The authors also compiled additional data from the ICIS database, including associated diagnosis classifications for the injured workers who were prescribed Schedule II opioids. The primary diagnosis code and diagnostic category were derived for each claim in the study sample by a clinical grouper. The final study dataset contained 9,733 prescribing physicians who were associated with the 25,050 claims in the sample. As in the original study, there were limitations associated with the data. The available data had no pre-injury health care status information and limited non-occupational injury co-morbidity details, so the degree to which such underlying medical conditions may have impacted the course of treatment and medical rationale to prescribe Schedule II therapies is unknown.

[17] Swedlow, A., Ireland, J., Johnson, G. Prescribing Patterns of Schedule II Opioids in California Workers' Compensation. Research Update, CWCI. March 2011.

[18] Drug products are identified and reported using a unique number called the National Drug Code (NDC) which is a universal product identifier for human drugs maintained by the Federal Drug Administration (FDA). These ten-digit numbers identify the labeler (or manufacturer), product, and trade package size.

High-Volume Schedule II Opioid Prescriber Experience, 2010 vs. 2012/13. The authors stratified the individual providers based on the percentage of all workers' compensation Schedule II opioid prescriptions that they had written and the percentage of the total amount paid for those prescriptions. Exhibit 4 shows the cumulative percentage of California workers' compensation Schedule II prescriptions for the top 10 percent of opioid prescribing medical providers from 2010 and compares the results to the more recent data from the 2012/2013 sample.

Exhibit 4: Cumulative Percentage of Schedule II Opioid Prescriptions
(Top 10% of Schedule II Prescribing Physicians, 2010 vs. 2012/13 Fill Dates)

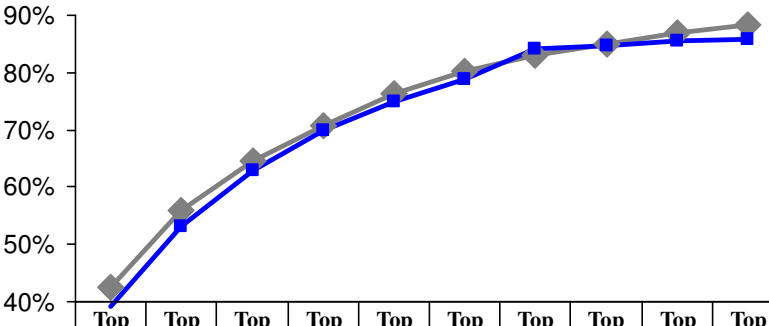


	Top 1%	Top 2%	Top 3%	Top 4%	Top 5%	Top 6%	Top 7%	Top 8%	Top 9%	Top 10%
2010	33.1%	46.2%	54.9%	61.3%	66.0%	69.7%	72.7%	75.2%	77.3%	79.2%
2012/2013	33.0%	47.4%	53.1%	61.4%	70.9%	74.7%	76.2%	78.0%	79.8%	81.7%

Exhibit 4 shows that that the top 3 percent of the doctors who prescribe Schedule II opioids to California injured workers accounted for more than half of all Schedule II prescriptions dispensed in the workers' compensation system. The comparison of the 2010 and 2012/13 prescribing patterns shows this result has remained consistent in recent years, with only an immaterial change in the proportion of prescriptions filled by the top 3 percent of the prescribers. In 2012/13, the top 3 percent of the Schedule II opioid prescribers (292 physicians) accounted for 53.1 percent of the prescriptions, which nearly matched the 2010 result, when the top 3 percent of the prescribers (276 physicians) wrote 54.9 percent of the prescriptions.

Comparing the 2010 and 2012/13 cumulative payments for Schedule II opioids that were associated with the top 10 percent of the prescribing physicians showed similar results (Exhibit 5).

Exhibit 5: Cumulative Percentage of Schedule II Opioid Payments (Top 10% of S-II Prescribing Physicians, 2010 vs. 2012/13 Fill Dates)

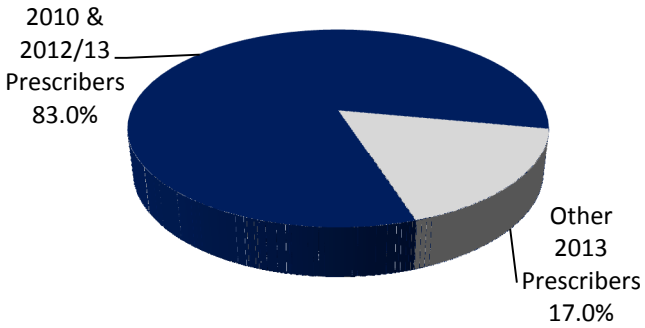


	Top 1%	Top 2%	Top 3%	Top 4%	Top 5%	Top 6%	Top 7%	Top 8%	Top 9%	Top 10%
2010	42.4%	55.8%	64.7%	70.8%	76.3%	80.1%	83.1%	85.1%	86.8%	88.2%
2012/2013	39.1%	53.2%	62.9%	69.8%	74.9%	78.9%	84.0%	84.8%	85.5%	85.9%

In the 2012/13 study sample, the top 3 percent of Schedule II opioid prescribing physicians were associated with 62.9 percent of all Schedule II opioid payments, down only slightly from 64.7 percent in the 2010 sample. Similarly, in the 2012/13 sample, the top 5 percent of the Schedule II opioid prescribers (487 out of 9,733 physicians) were associated with three out of four dollars paid for Schedule II opioids, again nearly matching the result from 2010, when the top 5 percent of the prescribers were linked to 76.3 percent of the Schedule II opioid payments.

To determine if there has been a significant change in the physicians who are the highest volume Schedule II opioid prescribers since 2010, the authors cross-referenced the DEA identification numbers associated with the top 3 percent of Schedule II opioid physicians in 2010 with the top 3 percent of Schedule II prescribing physicians from the 2012/13 sample, then determined the proportion of the physicians who ranked among the top 3 percent in 2012/13 who were also in the top 3 percent in 2010 (Exhibit 6).

Exhibit 6. Proportion of Schedule II Opioid Prescribers Who Ranked in the Top 3 Percent in 2010 and 2012/13



The results show that 83 percent of physicians who were in the top 3 percent of high volume Schedule II opioid prescribers in 2012/13 were also in the top 3 percent of high volume prescribers in 2010.

Types of Injuries Treated with Opioids. CWCI's March 2011 study on Schedule II prescribing patterns found that a high proportion of injured workers who received Schedule II opioids had relatively minor injuries. To determine if that is still the case, the authors sorted the Schedule II opioid claims in the 2012/13 sample by diagnostic category, then determined the top 12 diagnoses categories in California workers' compensation for which Schedule II opioids are prescribed. The resulting distribution for the top 12 injury categories in which Schedule II opioids were dispensed is shown in Exhibit 7, along with the corresponding distribution from 2010.

Exhibit 7. Distribution of Top 12 Injury Categories Receiving Schedule II Opioids

Diagnostic Category (Primary DRG)	2010	2012/2013
Medical Back Problems w/o Spinal Cord Involvement	35.7%	40.0%
Spine Disorders w/ Spinal Cord or Root Involvement	11.3%	13.5%
Degenerative, Infective & Metabolic Joint Disorders	9.3%	10.3%
Sprain of Shoulder, Arm, Knee or Lower Leg	6.8%	4.9%
Wound, FX of Shoulder, Arm, Knee or Lower Leg	6.3%	3.7%
Ruptured Tendon, Tendonitis, Myositis & Bursitis	6.0%	4.6%
Other Injuries, Poisonings & Toxic Effects	5.5%	4.6%
Cranial & Peripheral Nerve Disorders	5.0%	6.4%
Other Diagnoses of Musculoskeletal System	1.5%	1.3%
Other Mental Disturbances	1.2%	1.8%
Head & Spinal Injury w/o Spinal Cord Involvement	1.1%	0.9%
Carpal Tunnel Syndrome	1.1%	1.0%
Subtotal: Top 12 Diagnostic Categories	90.8%	92.9%

As noted in Exhibit 7, the use of Schedule II opioids to treat relatively minor work injuries remains very common in California workers' compensation, with 40 percent of all Schedule II opioids delivered in 2012/13 used to treat injured workers with medical back problems without spinal cord involvement -- typical sprains and strains of the lower back. These drugs are also commonly used to treat other types of injuries such as sprains of the shoulder, arm, knee or lower leg and "other mental disturbances," even though there use is not generally supported by evidence-based medicine guidelines.

DISCUSSION

Earlier research documented the rapid growth in both the volume and the cost of Schedule II opioids in California workers' compensation, with both utilization and costs trending up rapidly from 2005 through June 2010. This study extends prior trend analysis and finds that Schedule II opioids remain prevalent within California workers' compensation, accounting for a record 7.6 percent of all prescription drugs dispensed to injured workers in the second quarter of2013, and consuming nearly 1 out of every 5 prescription dollars. In contrast, the study finds that the use of Schedule III drugs, which also can be addictive, but which are more widely accepted for the treatment of a broad range of work injuries, has shown little change over the past six years, consistently accounting for about 1 out of 5 California workers' compensation prescriptions, and about 10 percent of the total prescription drug spend. Taken together, the latest data show Schedule II and Schedule III opioids combined account for more than a quarter of all prescription medications dispensed to injured workers in California, and nearly 29 percent of the prescription dollars – with little change in those percentages over the past two and half years.

The comparison of prescribing patterns from 2010 and 2012/13 confirms that the vast majority of Schedule II workers' compensation opioid prescriptions continue to be written by a relatively small number of physicians, with just 3 percent of the physicians who prescribe opioids accounting for nearly 2/3 of the payments. The analysis of prescribing patterns also noted that there has been little change in the make-up of the high-volume opioid prescribers, with more than 8 out of 10 physicians who ranked among the top 3 percent of opioid prescribers in 2012/13 also in the top 3 percent of prescribers in 2010. In addition, the recent results on the types of injuries for which Schedule II opioids have been prescribed raise questions about whether these drugs are being appropriately used, as almost half of the Schedule II prescriptions in the 2012/13 sample were written for injured workers with relatively minor occupational injuries such as sprains and strains.

These findings suggest that despite widespread publicity about the dangers associated with opioid medications, public policy efforts to curb the utilization and cost of these drugs through the adoption of chronic pain medical treatment guidelines and a pharmacy fee schedule, and efforts to tighten controls over the use of Schedule II and III drugs through utilization review have thus far had limited success in reducing their use. Nevertheless, additional efforts are continuing, including:

- Recently enacted California legislation (SB 809) providing permanent funding for the CURES prescription monitoring program;

- Revised labeling requirements adopted by the FDA for long-acting painkillers;
- New federal requirements mandating testing of the long-term effects of opioids;
- The FDA's recommendation to reclassify hydrocodone combination drugs as Schedule II drugs;
- The FDA's announcement that it will not approve any new drug applications for generic versions of Oxycontin that rely upon approval of the original formulation;
- The enactment of a 2013 bill (SB 670) intended to bolster state medical board investigations of doctors suspected of overprescribing in cases where the patient dies
- The California Division of Workers' Compensation's April 2014 release of draft regulations that would implement new guidelines for the use of opioids to treat injured workers.[19]

In some cases, efforts intended to clamp down on Schedule II and III drugs have met with resistance. Recent examples, including proposals to require physicians to check the CURES database before prescribing controlled substances and to allow third party access to CURES data in order to improve the quality of care and strengthen utilization and cost control over opioid prescriptions, were both opposed by lobbyists for the medical community.[20] At the same time, new opioids – including Zohydro, a powerful form of pure, extended release hydrocodone approved by the FDA in November 2013 and now available -- continue to be introduced into the market, presenting new challenges in the efforts to contain the widespread use of these drugs.

As the debate over the opioid controversy continues, legislators, administrators, employers and employees continue to discuss and explore methods to reverse the opioid trend. One of the promising methods, common in group health and federal healthcare programs, involves the use of a closed pharmaceutical formulary. Formularies are lists of approved medicines. In workers' compensation, states like Washington, Texas and Ohio have recently implemented formularies with encouraging results. In Part II of this research series, which will be published later this year, the Institute will analyze the potential effects of implementing a closed formulary on the California workers' compensation system.

[19] "DWC Posts Proposed "Guideline for the Use of Opioids to Treat Work-Related Injuries" to Online Forum for Public Comment." The Department of Industrial Relations, Newsline No.: 2014-29. Date: April 11, 2014

[20] "Doctors' Lobby Guts Patient Safety Reforms As New Evidence Reveals Rampant Narcotics Over-Prescribing by Physicians, Says Consumer Watchdog" ConsumerWatchdog.org, August 13, 2013.

About CWCI

The California Workers' Compensation Institute, incorporated in 1964, is a private, non-profit organization of insurers and self-insured employers conducting and communicating research and analyses to improve the California workers' compensation system. Institute members include insurers that collectively write more than 80 percent of California workers' compensation direct written premium, as well as many of the largest public and private self-insured employers in the state.

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