A REPORT TO THE INDUSTRY

Opioids in Workers' Compensation Medicare Set-Asides

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EXECUTIVE SUMMARY

In 2001, the Centers for Medicare and Medicaid Services endorsed Workers' Compensation Medicare Set-Aside arrangements[1] (WCMSAs) as a means to protect Medicare's interests when resolving work injury claims that include future medical expenses. In a WCMSA, the claims administrator obtains an assessment of the worker's future medical needs related to the work injury and allocates funds to cover medical expenses that would otherwise be paid by Medicare.

Over the past 16 years there has been limited research on the WCMSA process and related costs, and no comprehensive evaluation of pharmaceutical use within WCMSAs, particularly opioid utilization and cost. To gain a better understanding of the prevalence of opioids in WCMSAs, and the amounts allocated for these drugs, the authors of this study used a special dataset containing pharmaceutical details from nearly 8,000 approved California WCMSA arrangements compiled from four national WCMSA vendors. Among the key findings:

- The distributions of prescription drugs and allocated prescription drug dollars show that the most common therapeutic drug group in WCMSAs was the opioid analgesic group, which accounted for 28 percent of all prescription drugs and 33 percent of all prescription drug allocations, significantly higher proportions than in the general workers' comp population.
- The cumulative morphine milligram equivalents (MMEs, a measure of opioid strength) in approved WCMSAs was 45 times the cumulative MMEs that were used from the date of injury to claim closure in a control group of permanent disability claims with similar injuries. WCMSA opioid levels for the top 5 injury categories ranged from 33 to 78 times those of the control group.
- For WCMSAs with opioids, injured workers were (on average) approved for a daily dose of 54.7 morphine milligram equivalents, for an average of 20.9 years. Over 10 percent of WCMSAs with opioids had an estimated morphine equivalent dose (MED) level of over 90 per day, a marker of elevated risk to the patient. Additionally, 14.5 percent of WCMSAs with opioids had concurrent prescription reserves for sedative-hypnotics, while 4.8 percent of MSAs with opioids included concomitant sedative-hypnotics and muscle relaxant prescriptions.

Federally mandated formulae to financially account for decades of sustained individual opioid use are at direct odds with a growing body of clinical evidence -- and a widespread recognition -- that opioids are often over-prescribed for the management of chronic, non-cancer pain. While the authors recognize that a WCMSA is a financial (rather than a clinical) extrapolation in which estimates of future need are based on current treatment regimens, it is difficult to avoid the conclusion that current WCMSA policy presumes the long-term use of opioids at extremely high levels for some patients, placing them at extreme risk of harm.

1. Additional details on WCMSAs are available on the CMS website: www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Workers-Compensation-Medicare-Set-Aside-Arrangements/WCMSA-Memorandums/Memorandums.html

BACKGROUND

Workers' Compensation Medicare Set-Aside arrangements protect Medicare's interests under the 1980 Medicare Secondary Payer Act (MSPA)[2] by allocating funds from workers' compensation settlements to cover future medical expenses arising from a work-related injury or illness. Typically, these funds are placed as a lump sum into a trust account that is self-administered by the injured worker from which medical payments associated with the settled workers' compensation injury are made, though they also can be dispersed as structured payments in which the trust account is refilled annually for a period of years based on the worker's life expectancy.

The WCMSA allocation amount is a projection of all future medical expenses that would otherwise be covered by Medicare. At the time of claim settlement, the claims administrator also must reimburse Medicare for any conditional payments that may have been made prior to the settlement date.[3] In addition, Medicare will not pay for any services furnished prior to the date of the settlement unless they were appropriately denied by the workers' compensation payer.[4] Medicare does not mandate that a WCMSA be submitted for approval, but obtaining such an approval may provide a level of reassurance to the payer regarding their future liability. If submitted for approval, the amount of the set-aside is determined by CMS on a case-by-case basis. Following approval, the funds are delivered by the payer to the trust account or to the injured worker for self-administration, as described. After the CMS–approved WCMSA amount is exhausted and accurately accounted for to CMS, Medicare will assume the role of primary payer for future Medicare-covered medical services related to the workers' compensation injury or illness.

CMS will review proposed WCMSA amounts only if defined thresholds are met:

- The injured worker is currently a Medicare beneficiary and the total settlement amount is greater than $25,000; or
- The injured worker has a "reasonable expectation" of Medicare enrollment within 30 months of the settlement date and the anticipated total settlement amount for future medical expenses and disability/lost wages over the life or duration of the settlement agreement is expected to be greater than $250,000.

If these thresholds are not met, the WCMSA is not reviewable by CMS for approval; nevertheless, the set-aside amount must still protect Medicare's interests to ensure that Medicare pays as secondary to workers' compensation.

Most workers' compensation claims with settlements that include future medical provisions involve injuries which have become chronic, requiring ongoing medical care. WCMSAs are usually, but not always, submitted to CMS for approval only after the injured worker has reached maximum medical improvement (MMI). Effective June 1, 2009, CMS introduced methodology to be used to review the adequacy of the prescription drug component of WCMSAs. On July 10, 2017, CMS issued an updated WCMSA Reference Guide (Version 2.6),

2. Medicare Secondary Payer (MSP) applies when Medicare does not have primary payment responsibility for a Medicare beneficiary, as is the beneficiary has medical services covered under workers' compensation. https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/Medicare-Secondary-Payer/Medicare-Secondary-Payer.html
3. A "conditional payment" is a payment that Medicare makes for which another payer may be responsible. https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Beneficiary-Services/Medicares-Recovery-Process/Medicares-Recovery-Process.html
4. For example, a service not covered under workers' compensation, or self-procured by the injured worker and provided by a practitioner outside of the payer's medical provider network.

after which CMS began requesting an "alternative treatment plan" in cases where treatment was denied by utilization review or independent medical review. CMS has provided the following guidance for calculating future medical expenses related to prescription drugs:[5]

- Validated prescription drugs that were used for direct treatment of the work-related injury during the past two years are to be included.
- Drugs are determined to be subject to payment under Medicare Part D benefits.
- WCMSA proposals should note if the injured worker has been using a brand or generic drug.
- CMS uses Truven Health Analytics' RED BOOK™ database average wholesale price (AWP) to price all drugs, with generic drugs repriced at the lowest non-repackaged AWP.
- Off-label use of drugs is permitted if supported by evidence-based medicine.
- Compounded drugs typically used in workers' compensation are not covered under the Medicare Part D benefit and are therefore properly excluded from WCMSAs.
- If utilization review has denied a treatment plan, an alternative treatment plan must be submitted with the WCMSA proposal. Failure to include an alternative treatment plan will result in pricing at full life expectancy value of the denied treatment plan.
- Tapering of a prescription drug is only allowed if the treating physician has determined it is in the best interest of the injured worker, or if evidence of current tapering is provided.

The calculation for prescription drugs included in a WCMSA, in its simplest terms, is as follows:

Unit price of pharmaceutical (AWP)	**X**	**Daily dose**	**X**	**Number of days per year**	**X**	**Estimated years of medical coverage**	**=**	**Total utilization cost**

While the premise upon which this calculation is based is financial rather than prescriptive, it nonetheless implies that chronic conditions, particularly pain, remain static and that drug regimens and dosages will remain fixed for the remainder of the injured worker's life.

Although research related to WCMSAs has been limited,[6,7] the authors were able to locate one published study on pharmaceutical allocations within WCMSAs. Lipton (2014)[8] published high-level summary information on a national sample of WCMSAs showing that increases in WCMSA settlements were largely due to pharmaceuticals, and that prescription drugs accounted for approximately 40 percent of the set-aside amount. The authors were unable to locate any studies analyzing individual drugs or drug groups within the WCMSA pharmaceutical component. This is of particular interest given the rising awareness of opioid overprescribing and

5. Centers for Medicare and Medicaid Services Memorandum. Workers' Compensation Medicare Set-Aside Arrangement Reference Guide. July 10, 2017.
6. Swedlow, A. "Medicare Set-Aside Arrangements & the California Workers' Compensation System," NCCI Annual Issues Symposium, May 2009.
7. "Workers' Compensation and Medicare Set-Asides: Webinar on Demand," NCCI, October 2013, www.ncci.com/nccimain/education/completelist/pages/wc-medicareset-asides-wod.aspx?s=Workers Compensation and Medicare Set-Asides
8. Lipton, B., Colon, D., Robertson, J., and Stern, D. Medicare Set-Asides and Workers' Compensation. NCCI Research Brief. September 2014.

resulting morbidity and mortality within the nation's workers' compensation, group health, and federal systems. The long-term nature of a WCMSA raises the question of how to accurately project opioid use across an unknown period of time.

STUDY OBJECTIVES

In conducting this study, the authors focused on four questions:

- What is the proportion of pharmaceuticals versus other medical services in the WCMSA study sample?
- What categories of medications are most prevalent in WCMSAs?
- How do CMS rules for calculating future drug allocations vary by injury type?
- How does the CMS calculation for WCMSA opioid allocation align with the scientific literature for safe and efficacious use of opioids?

DATA

The authors compiled a sample dataset of California WCMSA cases from four national WCMSA vendors that represent more than half of the state's WCMSA market. The final sample dataset consisted of 7,926 WCMSAs completed, submitted, and approved by CMS between January 2015 and December 2016. The data variables obtained from WCMSA decisions provided by the WCMSA vendors fell into three categories:

1. Claim Demographics
    1. Date of Injury
    2. Rated Age[9]
    3. Gender
    4. Injured Worker Zip Code
    5. Life Expectancy Used in the WCMSA[10]
2. Submitted Medical Information
    1. Total WCMSA Amount
    2. Medical Portion
    3. Prescription Drug Portion
    4. Primary and Secondary ICD-9/ICD-10 Diagnosis Codes
    5. WCMSA Completion Date
    6. CMS Submission Date
3. CMS Final Approval
    1. Total WCMSA Approved Amount
    2. Medical Approved Amount
    3. Prescription Drug Approved Amount
    4. CMS Approval Date

9. Injured workers may be assigned a "rated age" (or "substandard age") that takes into account an individual's shortened life expectancy in the presence of certain significant medical conditions. The annuity recommendations provided as part of the MSA proposal include annual payments based on calculated life expectancy based on either the actual or rated age of the individual.
10. Life expectancy is the number of years for which the MSA is calculated.

The authors used a proprietary clinical grouping system to classify the primary diagnosis codes from each WCMSA into homogenous injury categories.[11] This system was used to match WCMSA data with data from a control group (Control) of 71,771 closed permanent disability claims from accident years 2006 through 2009 that involved similar injuries but that did not have an associated WCMSA. Data on the Control claims, compiled from CWCI's Industry Research Information System (IRIS[12]), was developed through 2016. The characteristics of opioids used in the Control claims from the date of injury to claim closure were compared to those in CMS-approved WCMSA allocations for future opioid use. The authors categorized the retail prescriptions by drug name and therapeutic group in a summary database and merged the summary information into a master WCMSA data set.

In addition to summary decision data, the authors received supplementary data on each of the associated pharmaceuticals allocated for the WCMSAs in the sample. Summary data variables for each unique drug are listed below:

A. Prescription Details:
    1. National Drug Code (NDC)
    2. Units per Day
    3. Days per Year
    4. Number of Years
    5. Unit Price
    6. Estimated Costs
    7. Annual Cost
    8. Lifetime Costs

B. Additional Prescription Information:[13]
    1. Therapeutic Group
    2. Therapeutic Class
    3. Generic Product Identifier (GPI) Description Drug Name
    4. Sole/Multi-Source Identifier
    5. Federal Drug Enforcement Agency (DEA) Code

The authors derived additional variables pertaining to opioid use, including total morphine milligram equivalents[14] (MMEs) and average daily morphine equivalent daily dose (MED).[15]

The authors defined WCMSA and control claims with values greater than 3 standard deviations from the mean values for the total WCMSA amount and/or the total MME values as outliers and eliminated them from the sample.

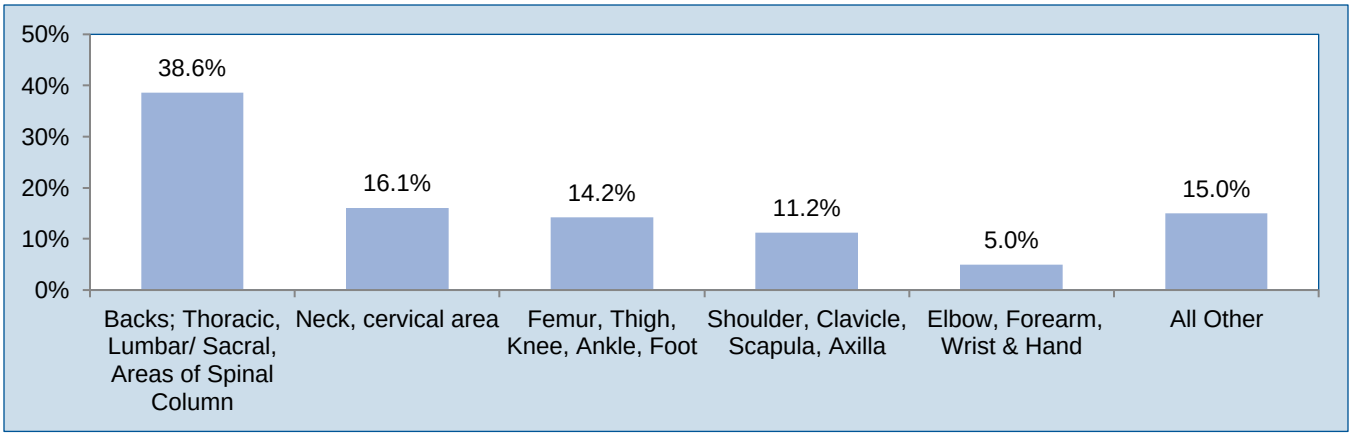
11. The authors used a proprietary algorithm to determine primary, secondary, and tertiary diagnosis and to group each WCMSA and control claim into clinically homogenous injury or illness groups. The algorithm and grouping system have been used in several CWCI studies.
12. IRIS is CWCI's proprietary transactional database of California workers' compensation claims comprised of approximately 65 percent of the insurer market as well as self-insured employers. The database has been used in numerous studies by CWCI and outside research groups and is considered representative of the entire industry.
13. Additional Descriptive Variables were obtained by linking the NDC codes within the WCMSA to a Medi-Span's Master Drug Data Base (MDDB®) Version 2.5 Documentation Manual (Wolters Kluwer Health, Medi-Span).
14. The MME conversion factor represents the relative potency of one milligram of the opioid chemical ingredient, given the formulation of the drug and how it was intended to be used (*e.g.*, swallowed, applied as a patch, or injected). See Appendix C for the MME conversion table.
15. The MED represents the number of morphine equivalents consumed within a 24-hour period. This measure would generally be used when establishing safety standards and/or treatment guidelines.

RESULTS

WCMSA Injury Characteristics

The distribution of WCMSAs by injured body part is noted in Exhibit 1. Back and neck injuries accounted for well over half (54.7 percent) of all WCMSAs. About 1 out of 7 WCMSAs involved injuries to the lower extremities; 1 in 9 involved the shoulder, clavicle, scapula, and axilla; and 1 out of 20 involved upper extremity injuries. The balance of the WCMSAs (15 percent) involved injuries from the "All Other" category, which includes injuries to the abdomen, pelvis, hip, sacroiliac and inguinal areas, head, chest, and intrathoracic areas.

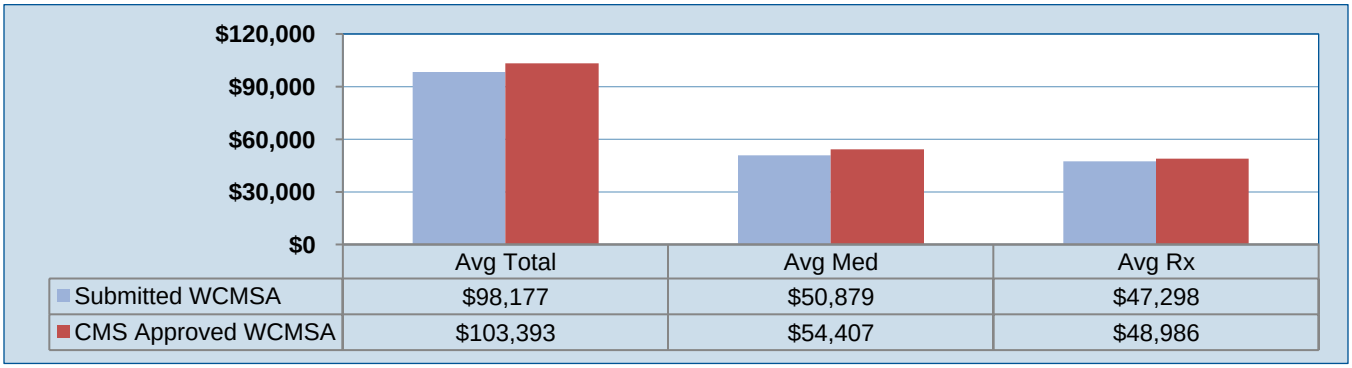
Exhibit 1: Distribution of WCMSAs by Injured Body Part



Average Submitted and Approved WCMSA Medical and Pharmaceutical Amounts

After a claims organization or its vendor submits a WCMSA, CMS reviews and adjusts the estimated medical and pharmaceutical allotments as needed.[16] Exhibit 2 shows that for the 2015 and 2016 WCMSAs included in the study sample, CMS increased the total WCMSA amounts submitted by claims administrators by an average of 6.1 percent prior to approval, while the average medical allotments were increased an average of 6.9 percent and the average pharmaceutical allotments were increased 3.6 percent. The average WCMSA amounts shown in Exhibit 2 for the 2015 and 2016 submissions are in line with those published in Lipton (2014).

Exhibit 2: Average Submitted and Approved WCMSA Medical and Pharmaceutical Amounts



	Avg Total	Avg Med	Avg Rx
Submitted WCMSA	$98,177	$50,879	$47,298
CMS Approved WCMSA	$103,393	$54,407	$48,986

16. A 2011 CWCI analysis showed that 29.1 percent of all submitted WCMSAs were increased in value by CMS prior to approval, 69.9 percent were accepted by CMS without modification, and 1 percent was reduced by CMS. Swedlow, A. Research presentation at the 2011 National Council of Compensation Insurance Annual Issues Symposium.

Top 20 Therapeutic Drug Groups in CMS-Approved WCMSAs

All FDA-approved pharmaceuticals are classified by Therapeutic Group based on their chemical characteristics and how they are used to treat specific conditions. Exhibit 3 displays the top 20 Therapeutic Drug Groups found in CMS-approved WCMSAs based on their percent of total volume. Together, these 20 therapeutic drug groups account for 97 percent of all WCMSA prescribed drugs. Analgesic Opioids are the most common therapeutic group included in CMS-approved WCMSAs, accounting for 28 percent of the prescription drugs and 33 percent of the payment allocations. These levels are higher than found in the general workers' compensation population. Hayes (2017)[17] found that opioids made up 23 percent of all California workers' compensation pharmaceutical prescriptions and 20 percent of the total drug spend in the system. Anti-Inflammatory Agents, were the second most common therapeutic group, representing 13 percent of the prescriptions and 8 percent of the payment allocations, which were significantly below the percentages noted in the general workers' compensation population (21 and 15 percent). Appendix A displays the top five drug names in each of the therapeutic groups.

Exhibit 3: Top 20 Therapeutic Drug Groups in Approved WCMSAs – by Volume

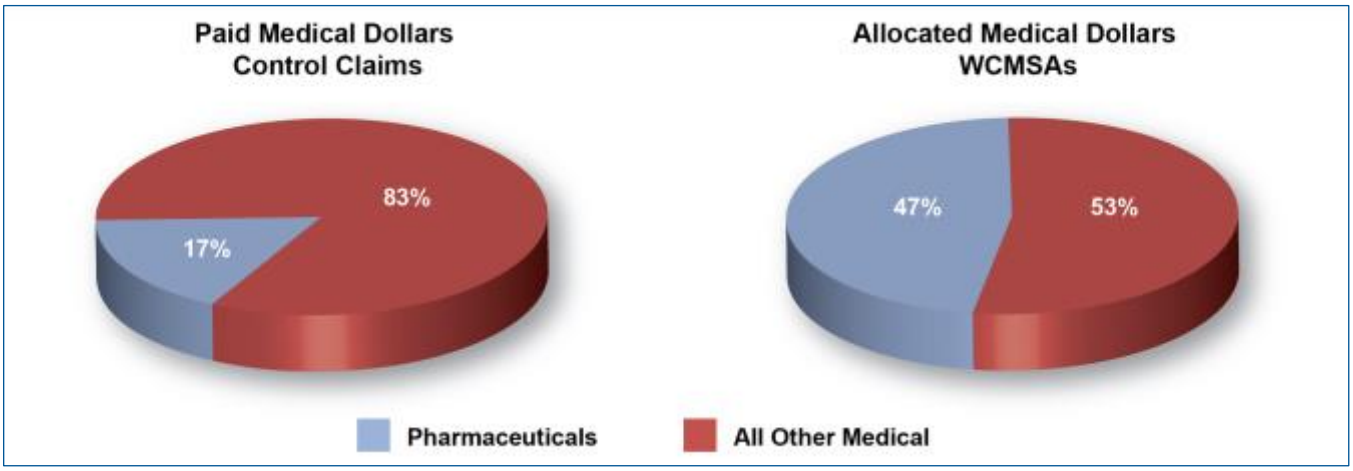
Top 20 Drug Groups	% of Drug Groups	% of Drug Payment Allocations	Avg WCMSA Allocation
Analgesics - Opioid	27.7%	32.7%	$33,113
Analgesics - Anti-Inflammatory	13.2%	7.8%	$16,599
Antidepressants	11.2%	11.0%	$27,412
Musculoskeletal Therapy Agents	9.6%	6.5%	$18,803
Ulcer Drugs	8.8%	4.3%	$13,602
Anticonvulsants	8.5%	8.2%	$26,803
Hypnotics/Sedatives/Sleep Disorder Agents	4.0%	6.1%	$42,465
Antianxiety Agents	3.9%	1.7%	$12,364
Antihypertensives	1.9%	0.6%	$9,188
Antidiabetics	1.1%	2.4%	$58,833
Antipsychotics/Antimanic Agents	1.0%	4.7%	$134,971
Beta Blockers	0.9%	0.2%	$7,319
Antiasthmatic and Bronchodilator Agents	0.7%	1.3%	$47,231
Dermatologicals	0.7%	2.5%	$97,301
Antihyperlipidemics	0.7%	0.3%	$12,558
Calcium Channel Blockers	0.7%	0.1%	$3,817
Diuretics	0.6%	0.1%	$3,754
Gastrointestinal Agents - Misc.	0.6%	1.5%	$71,068
Migraine Products	0.5%	1.9%	$103,390
Antiemetics	0.3%	1.1%	$108,807
Top 20 Drug Group Sub-Total	**96.7%**	**95.0%**	**$37,057**

17. CWCI Industry Research Information System, 2017.

Pharmaceutical Dollars As a Percent of Total Medical Dollars: Control Claims vs. WCMSAs

In addition to higher opioid use, the authors also found that pharmaceuticals accounted for a higher proportion of the total medical dollars in the WCMSA group than in the Control group of workers' compensation permanent disability claims. Exhibit 4 shows pharmaceuticals as a proportion of total medical dollars for the Control claims and for CMS-approved WCMSAs.

Exhibit 4: Pharmaceutical Dollars as a Percent of Total Medical: Control Claims vs. WCMSAs

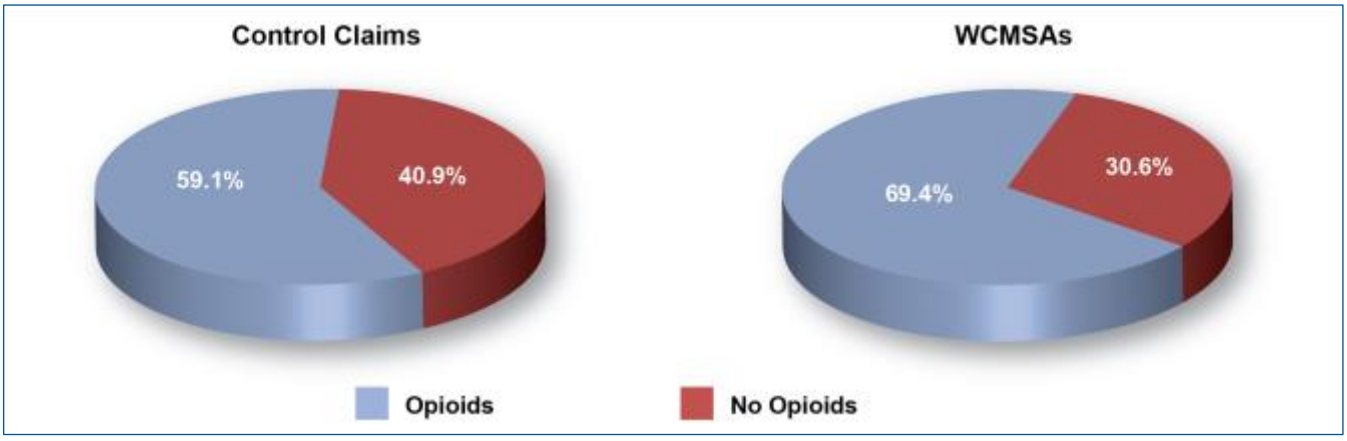


The dollars allocated for pharmaceutical payments within MSAs represent just under half (47 percent) of the total projected medical payments in these agreements. In comparison, pharmaceutical payments accounted for only 17 percent of the cumulative paid medical losses for the Control group of permanent disability claims from the date of injury to claim closure.[18]

Prevalence of Opioids: Control Claims vs. WCMSAs

Exhibit 5 shows the percentage of claims in the Control group and in the WCMSAs that involved opioids. Opioids were very common in both samples, but were significantly more prevalent in the WCMSAs, where they were present in 69.4 percent of the agreements, compared to 59.1 percent of the PD claims in the Control group.

Exhibit 5: Prevalence of Opioids: Control Claims vs. WCMSAs



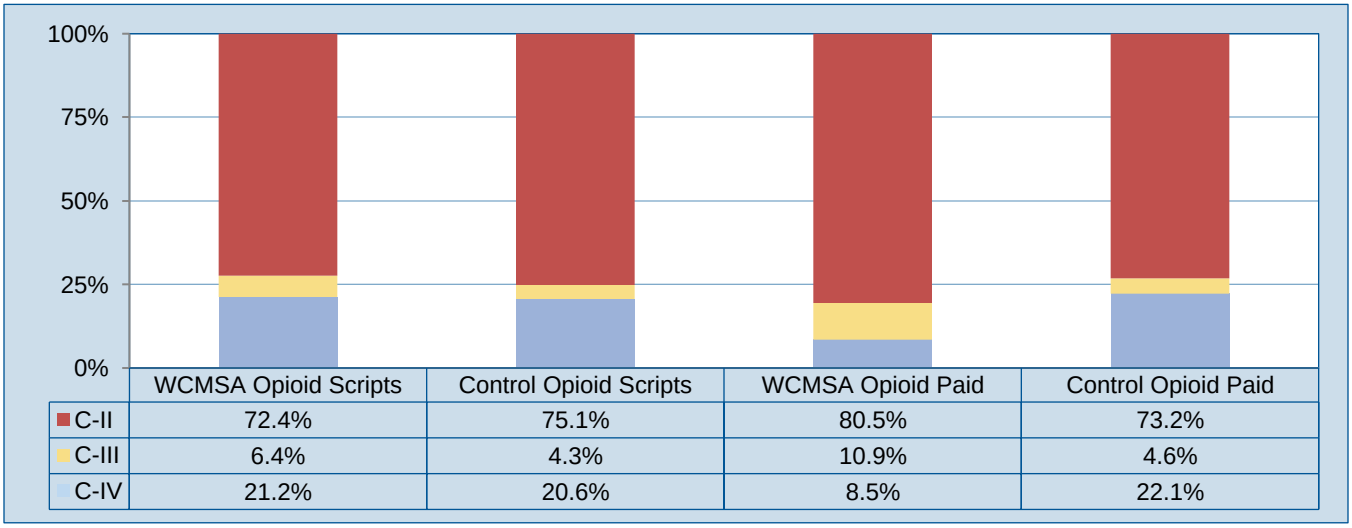
18. The Control group's percentage of pharmaceuticals to all medical benefits was based on actual payments during the course of treatment and did not include any end-of-claim "lump-sum" medical settlements, as such payments do not apportion for subsets of medical or pharmaceutical service.

Distribution of Opioid Prescriptions by Schedule Class: WCMSAs vs. Control Claims

The Federal Drug Enforcement Agency classifies pharmaceuticals based on risk of abuse or harm. Drugs banned from medical practice, such as heroin, are Schedule I drugs. Schedule II opioids have a high potential for abuse which may lead to severe psychological or physical dependence, while Schedule III and IV opioids are considered to have a lower abuse potential.

Exhibit 6 compares the distribution of opioid prescriptions and the distribution of the associated dollars over the life of the claim by schedule class for WCMSA opioid allotments and the Control group of workers' compensation permanent disability claims.

Exhibit 6: Associated Schedule Class of Opioid Prescriptions: Approved WCMSAs vs. Control Group of Workers' Comp Permanent Disability Claims



	WCMSA Opioid Scripts	Control Opioid Scripts	WCMSA Opioid Paid	Control Opioid Paid
C-II	72.4%	75.1%	80.5%	73.2%
C-III	6.4%	4.3%	10.9%	4.6%
C-IV	21.2%	20.6%	8.5%	22.1%

Within WCMSAs, Schedule II drugs (the highest abuse potential) account for 72.4 percent of the opioid prescriptions, and 80.5 percent of the lifetime opioid payment allocations. The distributions of WCMSA and Control opioids prescriptions by schedule class are similar, but comparing the distributions of opioid dollars by schedule classes show WCMSAs had a much lower percentage of opioid dollars for Schedule IV opioids (8.5 percent vs. 22 percent, or a 159 percent relative difference), but a higher percentage of the WCMSA opioid dollars were for Schedule II and Schedule III opioids.

WCMSAs With Opioids: Volume and Lifetime Cost Distributions for Specific Drugs

Exhibit 7 displays all opioids and their associated opioid class found within the WCMSA study group. The last two columns focus on WCMSAs in which opioids were approved, noting the distributions of specific drugs by volume and lifetime cost. Hydrocodone-Acetaminophen, generally known as Norco® or Vicodin®, is the most common opioid found in WCMSAs. It is worth noting that of the WCMSAs in which opioids were approved, 2.2 percent included ongoing Fentanyl use, a drug originally FDA approved for breakthrough cancer pain and linked to more than 20,000 deaths in 2016.[19]

Exhibit 7: WCMSAs With Opioids: Volume and Lifetime Cost Distributions for Specific Drugs

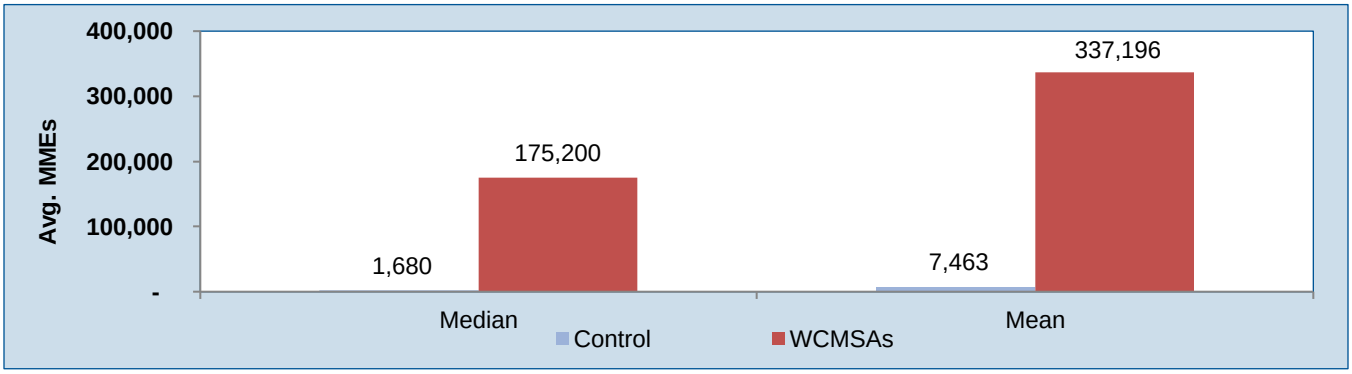
Analgesic Opioid Drug Name	Schedule Class	Opioids w/in WCMSAs	Lifetime Cost
Hydrocodone-Acetaminophen	C-II	44.0%	20.7%
Tramadol HCl	C-IV	19.1%	7.4%
Oxycodone HCl	C-II	7.4%	16.5%
Morphine Sulfate	C-II	5.0%	7.1%
Oxycodone w/ Acetaminophen	C-II	4.8%	13.7%
Acetaminophen w/ Codeine	C-III	4.0%	0.7%
Oxymorphone HCl	C-II	2.2%	2.6%
Fentanyl	C-II	2.2%	6.6%
Buprenorphine	C-III	2.1%	9.0%
Hydromorphone HCl	C-II	2.0%	1.6%
Tramadol-Acetaminophen	C-IV	2.0%	1.1%
Methadone HCl	C-II	1.9%	0.3%
Tapentadol HCl	C-II	1.6%	9.2%
Hydrocodone-Ibuprofen	C-II	0.4%	0.2%
Hydrocodone Bitartrate	C-II	0.3%	1.1%
Oxycodone	C-II	0.3%	0.4%
Acetaminophen-Caff-Dihydrocod	C-III	0.2%	0.4%
Morphine Sulfate Beads	C-II	0.2%	0.5%
Hydrocodone-Acetaminophen	C-III	0.1%	0.8%
Codeine Sulfate	C-II	0.1%	0.1%
Levorphanol Tartrate	C-II	0.0%	0.1%
Meperidine HCl	C-II	0.0%	0.0%
Butorphanol Tartrate	C-IV	0.0%	0.0%
Pentazocine w/ Naloxone	C-IV	0.0%	0.0%
Total		**100%**	**100%**

19. Katz, Josh. *"The First Count of Fentanyl Deaths in 2016 - Up 540% in Three Years"*. (September 2, 2017) The New York Times.

Cumulative Morphine Equivalents: Mean and Median MMEs, Control Claims vs. WCMSAs

Opioids vary in how frequently they are prescribed, route of administration (pill, patch, etc.), and potency. Researchers use MME conversion tables[20] to compare and contrast the cumulative potency of different types of opioids. Appendix C contains the conversion factors for calculating MMEs. Total MMEs used over the life of each case-matched Control claim were compared to the projected MME values for each CMS-approved WCMSA based on the specific opioid, dose, and projected years of use from the WCMSA approved values (Exhibit 8). The median level of opioid MMEs allocated on WCMSAs was 104 times the actual level in the Control claims, and the mean level was 45 times the level in the Control claims.

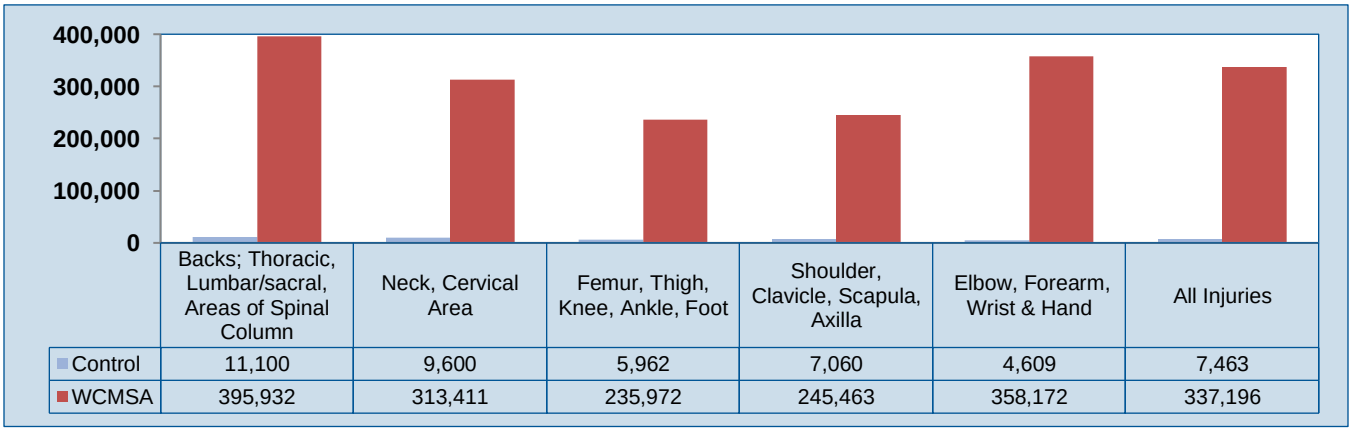
Exhibit 8: Cumulative Morphine Equivalent Levels



Cumulative MMEs for Top Injuries: Control Claims vs. WCMSAs

Exhibit 9 compares MME levels across the top 5 injury categories for the WCMSA and Control groups. WCMSA opioid levels within the top 5 injury categories ranged from 33 to 78 times that of the Control group of PD claims. Back injuries had the highest level of MMEs for both the WCMSA and Control groups, though the MME level for the WCMSA group was 36 times the level of the Control group. WCMSA Lower Extremity injuries had the lowest MME value of 235,972 MMEs, 40 times the level in similar Control injuries. Appendix B shows examples of de-identified injury description extracts from 10 WCMSA back injuries and their lifetime MME allocations.

Exhibit 9: Cumulative Morphine Equivalent Levels for the Top 5 Injury Categories



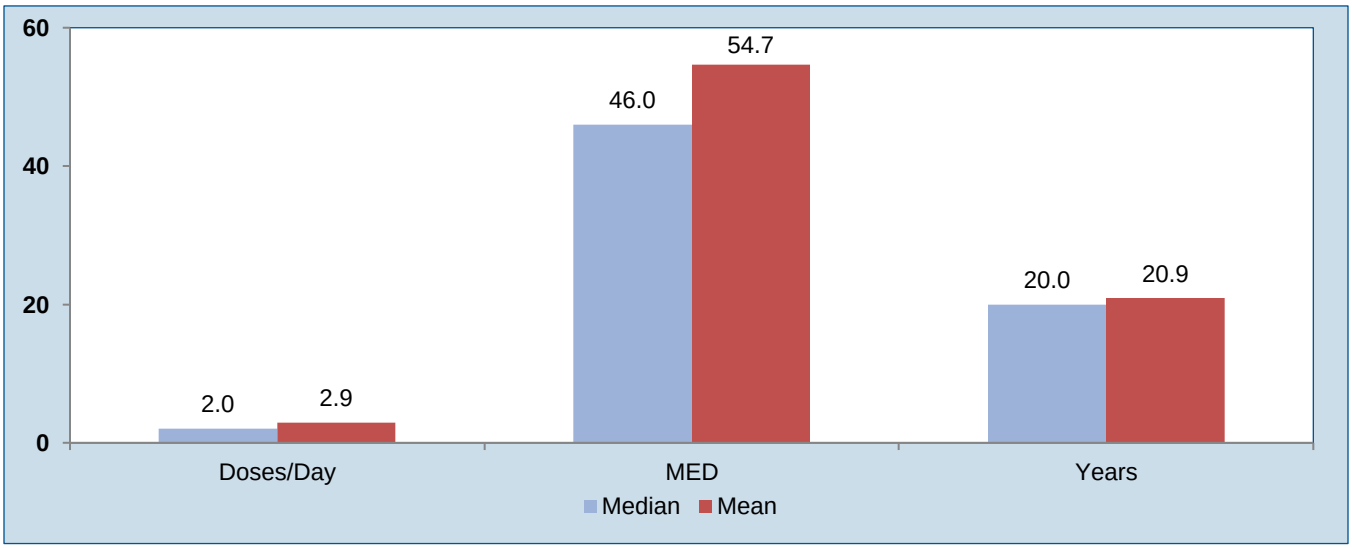
	Backs; Thoracic, Lumbar/sacral, Areas of Spinal Column	Neck, Cervical Area	Femur, Thigh, Knee, Ankle, Foot	Shoulder, Clavicle, Scapula, Axilla	Elbow, Forearm, Wrist & Hand	All Injuries
Control	11,100	9,600	5,962	7,060	4,609	7,463
WCMSA	395,932	313,411	235,972	245,463	358,172	337,196

20. The authors used CDC MME calculations and conversion factors: https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf

Average Daily Rate, Potency and Duration of Opioids in WCMSAs

The authors calculated the mean and median values for the number of doses per day, the potency (MEDs), and the duration of opioid allotments in WCMSAs (Exhibit 10). Among the WCMSAs with opioids, injured workers were approved for an average of nearly 3 doses of opioids per day, comprising 54.7 MEDs per day, for an average of 20.9 years.

Exhibit 10: Opioid Use in WCMSAs: Mean and Median Doses per Day, MEDs, and Years



Presence of Other Drugs in Addition to Opioids in WCMSAs

Opioid allotments within WCMSAs are often included in conjunction with other drugs and in different levels of pharmacological strength. Because other investigators have found increased mortality risk when other therapeutic drugs are taken concurrently with opioids,[21,22,23,24] the authors also examined the percentage of the approved WCMSAs that included drugs such as sedative hypnotics and muscle relaxants along with opioids.

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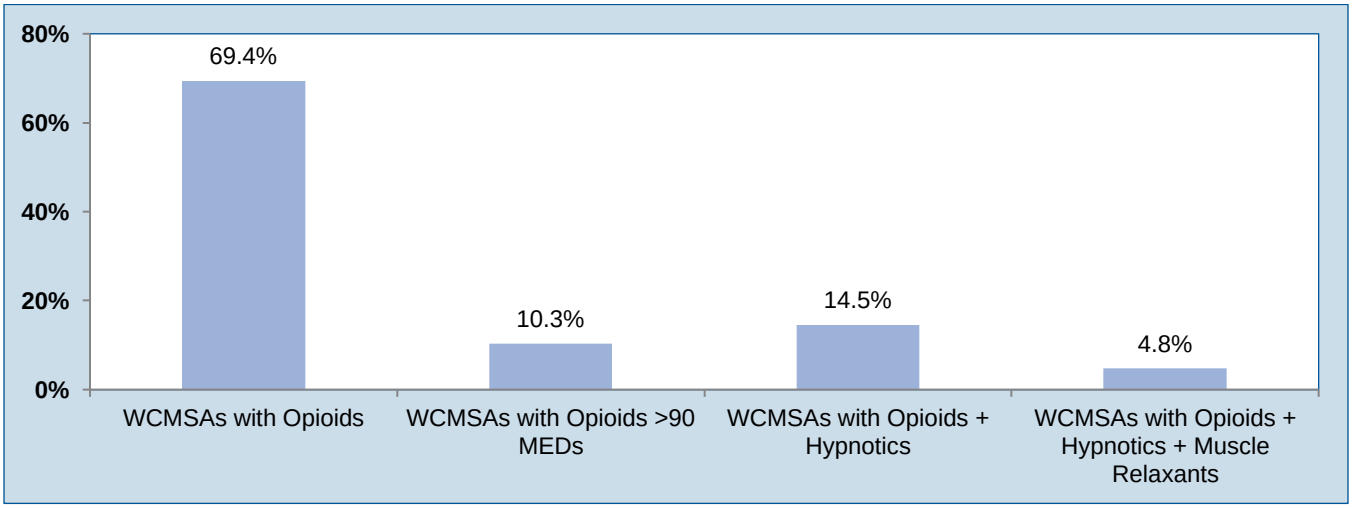
As shown in Exhibit 11, 1 in 10 MSAs with opioids had an estimated MME level of over 90 per day, a marker of elevated risk to the patient. Approximately 1 in 7 MSAs with opioids had concurrent prescription reserves for sedative-hypnotics, while approximately 5 percent of WCMSAs with opioids were approved for both concomitant sedative-hypnotics and muscle relaxants.

Exhibit 11: Percent of WCMSAs With Opioid Levels >90 MEDs and Select Drug Combinations



DISCUSSION

This analysis of opioid levels required by CMS within the WCMSA program reveals a new dimension to the opioid epidemic in the United States. These federally mandated formulae to pay for decades of sustained individual opioid use are at direct odds with a growing body of clinical evidence, and the widespread recognition, that opioids are often over-prescribed for the management of chronic, non-cancer pain. This is particularly evident in trends over the last 10 years in the California workers' compensation system.[25,26,27,28] Reviews of available evidence have noted the absence of any high-quality studies on the long-term efficacy of opioids for chronic pain.[29,30,31,32] For injured workers with chronic low back pain, who accounted for 39 percent of the WCMSAs in this study, evidence for long-term efficacy is particularly weak. In their review of treatment efficacy of opioids for low-back pain Abdel Shaheed *et al.* (2016) noted that: 1) treatment effects are small and often no larger than those reported for non-steroidal anti-inflammatory drugs (NSAIDs) compared with placebo; and 2) there is no evidence for improved function with use of opioids.[33]

While data on long-term efficacy of opioids remain scarce, evidence of substantial harm continues to accumulate. Multiple, well-designed studies all indicate that: 1) mortality for opioid users increases with average daily opioid dose; 2) the effect is linear, and begins even at small daily doses; and 3) doses in excess of 50 MME per day are particularly hazardous.[34,35,36,37] Other side effects, such as opioid-induced hyperalgesia and hypogonadism are not well quantified, but also contribute to a poor benefit-risk profile. In consideration of these data, combined with limited evidence for long-term benefit, the American Pain Society, the American College of Physicians, and the American Academy of Neurology all recommend against the use of opioids as first-line therapy for chronic pain, and urge caution with frequent patient monitoring when doses exceed 50 MME.[38,39,40]

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Both national and state public policy guidelines have concurred, including those developed specifically for workers' compensation.[41,42,43,44] Of note, the California Workers' Compensation Medical Treatment Utilization Schedule (MTUS)[45] currently recommends that clinicians should be increasingly vigilant and "conduct semiannual attempts to wean patients whose dose has been 80 mg/day MED or higher for at least six months to lower than 80 mg/day MED."[46] Moreover, proposed updates to the MTUS include adoption of ACOEM's April 2017 Opioids Guideline, and support an even more judicious use of opioids: in the case of subacute or chronic pain, the recommendation is semi-annual attempts (at a minimum) to wean to below 50 MED.[47]

Recent data also indicate that individuals who are taking benzodiazepines concomitantly with opioids are at even higher risk of death. Park, *et al*. (2015) note an almost 4-fold increase in risk in a large study of US veterans,[48] while Garg, *et al*. found an increased risk ratio of 7.5.[49] Both studies noted increases in risk with benzodiazepine use even at the lowest daily doses of opioids (1-19 MED). In the current study, 14 percent of patients treated with long-term opioids were also approved to receive benzodiazepines, and their WCMSA financial calculations were premised on long-term use of both drugs. Furthermore, in 3.3 percent of all WCMSAs, the approved pharmaceutical treatment regimen included approvals for opioids, sedative-hypnotics and muscle relaxants. Clearly, these patients are at extreme risk.

While the authors recognize that a WCMSA is a financial rather than a clinical extrapolation in which estimates of future need are based on current treatment regimens, it is difficult to avoid the conclusion that current WCMSA policy presumes the long-term use of opioids at extremely high levels for some patients, placing them at increased risk of harm. We further recognize that some of these individuals have failed other treatments and are left with opioids as the last, albeit poor, option for chronic pain relief. This illustrates a public policy dilemma, which is well stated in the recent National Academy of Science, Engineering and Medicine (NASEM) report:[50] "How exactly does a regulator….balance, for any particular regulatory action limiting access to opioids, the otherwise avoidable suffering that patients with pain would experience against the harms, not only to those individuals and their families but also to society, that would be prevented by the restriction?"

In discussing the underlying rationale behind many of its public policy recommendations for opioids, NASEM has introduced the concept of "opioid exceptionalism." Simply put, opioid exceptionalism suggests that, given

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46. https://www.dir.ca.gov/dwc/DWCPropRegs/MTUS-Opioids-ChronicPain/MTUS-Opioids-ChronicPain.htm; https://www.dir.ca.gov/dwc/DWCPropRegs/MTUS-Opioids-ChronicPain/Final-Regulations/CleanCopy/Opioids-Guidelines.pdf
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the many potential detrimental impacts of opioid therapy to individual patients, their families, and to society at large, sound public policy requires that opioids must be treated differently than other medications. Mindful of these considerations, there are modifications to the WCMSA approval process that would re-balance the anticipated individual needs of injured workers with sound public policy. These considerations include modifying the basic formula to remove incentives to over-treat and over-medicate, while placing greater emphasis on alternative pain treatment. This would require a patient-specific treatment plan that does not require projected cost allocation for open-ended opioid use. In addition, re-evaluating WCMSA settlements over time would allow the injured worker's future treatment plans to be realigned with changes in their health status.

Recent changes within the CMS Workers' Compensation Medicare Set-Aside Portal (WCMSAP) User Guide[51] included a re-evaluation process for MSA calculations for medical and pharmaceutical treatment that may provide an opportunity to address these issues. The new "Amended Review" option can only occur under certain conditions, including:

- The WCMSA conditional approval date was at least 12 months, but no more than 48 months, prior to the request for review.
- The case has not yet settled as of the date of the request for review.
- Projected care has changed so much that the submitter's new proposed amount would result in a 10 percent or $10,000 change (whichever is greater) in CMS' previously approved amount. Additional documentation would be required to justify a 10 percent or $10,000 change (*e.g.*, if care has already been provided or if care is no longer required). Availability of a new generic drug is not considered a valid reason to request a new review for changes in projected price.

The review conditions could be modified to include all cases where opioids have been approved at doses in excess of 50 MED.

The authors have identified managed care practices and public policy options that have been developed to begin to address the unforeseen consequences of the opioid epidemic. Workers' compensation claims administrators should closely monitor long-term opioid usage to ensure that treatment plans are in accordance with evidence-based medical protocols, and consider appropriate detoxification and weaning programs when they are not. From a policy standpoint, CMS and federal regulators can modify the WCMSA process of accounting for future opioid utilization so that it is fully aligned with evidence-based medicine guidelines that contemplate tapering. Because of the very real threat of harm to individuals affected by these policies, we believe such public policy modifications should be considered an urgent matter.

51. See Section 16 of the User Guide for changes in reevaluation requests: https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Workers-Compensation-Medicare-Set-Aside-Arrangements/Downloads/WCMSA-Reference-Guide-Version-2_6.pdf

Appendix A: Top Drug Names by Therapeutic Group

Therapeutic Group / Top 5 Drug Names	Pcnt of Drug Groups	Pcnt Total Paid
Analgesics - Opioid	**27.7%**	**32.7%**
Hydrocodone-Acetaminophen	12.2%	7.0%
Tramadol HCl	5.3%	2.4%
Oxycodone HCl	2.0%	5.4%
Morphine Sulfate	1.4%	2.3%
Oxycodone w/ Acetaminophen	1.3%	4.5%
Analgesics - Anti-Inflammatory	**13.2%**	**7.8%**
Ibuprofen	3.9%	0.4%
Naproxen	3.6%	1.3%
Celecoxib	1.9%	1.7%
Diclofenac	1.2%	1.1%
Meloxicam	1.1%	1.1%
Antidepressants	**11.2%**	**11.0%**
Duloxetine HCl	2.7%	2.4%
Trazodone HCl	1.7%	0.3%
Bupropion HCl	1.3%	3.9%
Amitriptyline HCl	1.1%	0.2%
Escitalopram Oxalate	0.8%	0.3%
Musculoskeletal Therapy Agents	**9.6%**	**6.5%**
Cyclobenzaprine HCl	3.9%	2.7%
Carisoprodol	1.8%	0.6%
Tizanidine HCl	1.7%	1.6%
Baclofen	1.0%	0.2%
Methocarbamol	0.5%	0.0%
Ulcer Drugs	**8.8%**	**4.3%**
Omeprazole	5.8%	1.8%
Pantoprazole Sodium	1.1%	0.2%
Ranitidine HCl	0.5%	0.1%
Lansoprazole	0.3%	0.3%
Esomeprazole Magnesium	0.3%	0.8%
Anticonvulsants	**8.5%**	**8.2%**
Gabapentin	6.2%	5.5%
Clonazepam	0.8%	0.3%
Topiramate	0.6%	0.3%
Pregabalin	0.2%	0.9%
Lamotrigine	0.2%	0.4%

Appendix A: Top Drug Names by Therapeutic Group (continued)

Therapeutic Group / Top 5 Drug Names	Pcnt of Drug Groups	Pcnt Total Paid
Hypnotics/Sedatives/Sleep Disorder Agents	**4.0%**	**6.1%**
Zolpidem Tartrate	2.5%	3.2%
Eszopiclone	0.7%	2.2%
Temazepam	0.5%	0.2%
Zaleplon	0.1%	0.1%
Estazolam	0.1%	0.0%
Antianxiety Agents	**3.9%**	**1.7%**
Alprazolam	1.3%	0.6%
Lorazepam	0.9%	0.2%
Diazepam	0.8%	0.4%
Buspirone HCl	0.4%	0.4%
Hydroxyzine Pamoate	0.2%	0.0%
Antihypertensives	**1.9%**	**0.6%**
Lisinopril	0.7%	0.0%
Losartan Potassium	0.3%	0.1%
Clonidine HCl	0.1%	0.1%
Benazepril HCl	0.1%	0.0%
Lisinopril & Hydrochlorothiazide	0.1%	0.0%
Antidiabetics	**1.1%**	**2.4%**
Metformin HCl	0.4%	0.0%
Glipizide	0.2%	0.0%
Insulin Glargine	0.1%	0.3%
Insulin Detemir	0.1%	0.3%
Liraglutide	0.0%	0.4%
Antipsychotics/Antimanic Agents	**1.0%**	**4.7%**
Quetiapine Fumarate	0.4%	0.9%
Aripiprazole	0.3%	2.6%
Olanzapine	0.1%	0.4%
Risperidone	0.1%	0.1%
Lurasidone HCl	0.0%	0.6%
Beta Blockers	**0.9%**	**0.2%**
Atenolol	0.2%	0.0%
Metoprolol Tartrate	0.2%	0.0%
Carvedilol	0.2%	0.1%
Metoprolol Succinate	0.1%	0.0%
Propranolol HCl	0.1%	0.0%

Appendix A: Top Drug Names by Therapeutic Group (continued)

Therapeutic Group / Top 5 Drug Names	Pcnt of Drug Groups	Pcnt Total Paid
Antiasthmatic And Bronchodilator Agents	**0.7%**	**1.3%**
Albuterol	0.3%	0.1%
Montelukast Sodium	0.1%	0.0%
Fluticasone-Salmeterol	0.1%	0.4%
Tiotropium Bromide Monohydrate	0.1%	0.3%
Budesonide-Formoterol Fumarate Dihydrate	0.1%	0.1%
Dermatologicals	**0.7%**	**2.5%**
Diclofenac Sodium (Topical)	0.4%	1.8%
Calcipotriene-Betamethasone Dipropionate	0.0%	0.1%
Silver Sulfadiazine	0.0%	0.0%
Lidocaine	0.0%	0.0%
Clobetasol Propionate	0.0%	0.1%
Antihyperlipidemics	**0.7%**	**0.3%**
Atorvastatin Calcium	0.3%	0.0%
Simvastatin	0.1%	0.0%
Pravastatin Sodium	0.1%	0.0%
Rosuvastatin Calcium	0.1%	0.1%
Gemfibrozil	0.1%	0.0%
Calcium Channel Blockers	**0.7%**	**0.1%**
Amlodipine Besylate	0.5%	0.0%
Nifedipine	0.1%	0.0%
Verapamil HCl	0.0%	0.0%
Diltiazem HCl	0.0%	0.0%
Diltiazem HCl Extended Release Beads	0.0%	0.0%
Diuretics	**0.6%**	**0.1%**
Hydrochlorothiazide	0.3%	0.0%
Furosemide	0.1%	0.0%
Triamterene & Hydrochlorothiazide	0.1%	0.0%
Spironolactone	0.0%	0.0%
Spironolactone & Hydrochlorothiazide	0.0%	0.0%
Gastrointestinal Agents	**0.6%**	**1.5%**
Lubiprostone	0.3%	0.8%
Naloxegol Oxalate	0.1%	0.4%
Metoclopramide HCl	0.1%	0.0%
Lactulose (Encephalopathy)	0.0%	0.0%
Linaclotide	0.0%	0.1%

Appendix A: Top Drug Names by Therapeutic Group (continued)

Therapeutic Group / Top 5 Drug Names	Pcnt of Drug Groups	Pcnt Total Paid
Migraine Products	**0.5%**	**1.9%**
Sumatriptan	0.3%	0.8%
Rizatriptan Benzoate	0.1%	0.3%
Eletriptan Hydrobromide	0.1%	0.3%
Zolmitriptan	0.0%	0.3%
Acetaminophen-Isometheptene-Dichloralphenazone	0.0%	0.1%
Antiemetics	**0.3%**	**1.1%**
Ondansetron	0.3%	1.1%
Meclizine HCl	0.0%	0.0%

Appendix B: Examples of Low Back Injuries with WCMSA Opioid Allotments

	Injury Description	Cumulative MMEs	MEDs / Day	Proposed Use (Years)
1	50 year old female with trauma to the ankle	1,051,200	182.5	16
2	63 year old male with a right knee injury	680,400	95.5	20
3	53 year old male with low back and neck pain	745,200	102.1	20
4	65 year old male with a low back injury	518,400	88.8	16
5	62 year old male with right ankle, knee, and low back injuries	397,200	57.3	19
6	51year old male with left knee and low back injuries	194,400	44.4	12
7	30 year old female with neck and low back injuries	371,520	56.5	18
8	66 year old male with low back injury	259,200	59.2	12
9	65 year old female with low back injury	234,500	42.8	15
10	70 year old female with neck and lower back injuries.	294,400	67.2	12

Appendix C: Relative Potency of Common Opioid Medications

Opioid Ingredient	Morphine Milligram Equivalent (MME) Conversion Factor	Common Product Name	Common Individual Doses	Morphine Equivalent Dose (MED)
Hydrocodone	1.00	Generic Vicodin/Norco	5-10 mg tablet 5-10 mg tablet	5-10 5-10
Tramadol	0.10	Generic Generic Ultracet Ultram Ultram ER	37.5-50 mg tablet 100-300 mg 24-hr release capsule 37.5 mg tablet 50 mg tablet 100-300 mg extended release tablet	3.75-5 10-30 3.75 5 10-30
Oxycodone	1.50	Percocet/Endocet OxyContin	5-10 mg tablet 10-80 mg extended release tablet	7.5-15 15-120
Propoxyphene	0.23	Generic Darvon/Darvocet Propoxacet	100 mg tablet 100 mg tablet 100 mg tablet	23 23 23
Codeine	0.15	Tylenol/Codine	15-60 mg tablet	2.25-9
Morphine	1.00	Generic Generic MS Contin Kadian	15-30 mg tablet 15-200 mg extended release tablet 15-200 mg extended release tablet 10-200 mg 24-hr release tablet	15-30 15-200 15-200 10-200
Fentanyl Patch	7.20	Generic Duragesic	12-100 mcg/hr 72-hr patch 12-100 mcg/hr 72-hr patch	86-720 86-720
Fentanyl Lozenge/ Sublingual Tablet	0.13	Generic Actiq Fentora	200-1600 microgram lozenge 200-1600 microgram lozenge 100-800 microgram tablet	26-208 26-208 13-104

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California Workers' Compensation Institute

The California Workers' Compensation Institute (CWCI), incorporated in 1964, is a private, nonprofit membership organization of insurers and self-insured employers. CWCI conducts and communicates research and analyses to improve California's workers' compensation system. CWCI members include insurers that collectively write about 83 percent of California's workers' compensation direct written premium, as well as many of the largest public and private self-insured employers in the state. Additional information about CWCI research and activities is available on the Institute's website, www.cwci.org.