Lisa Anne Bickford Director, Workers' Comp Government Relations Coventry October 8, 2018

Thank you for the opportunity to provide feedback on the aforementioned proposed rules. After a review of the proposal in light of Coventry's current operational framework, we would like to offer the following comments:

1. 4-Tiered Pharmaceutical Pricing Evaluation is Burdensome and Would Require Extensive Programmatic Lead Time

ISSUE: The rules as proposed define a 4-level comparison for determinations of pharmaceutical pricing for dates of service on/after 1-1-2019, involving evaluation of the Medi-Cal database, the NADAC (Nat'l Average Drug Acquisition Cost), or if no NADAC is available, 0% of the WAC (Wholesale Acquisition Cost), the Federal Upper Limit (FUL), AND the Maximum Allowable Ingredient Cost (or "MAIC").

To date, no jurisdiction has implemented such a complex pricing schema for Workers' Compensation, nor has any jurisdiction relied upon any of the aforementioned data sources. Extensive programming (and commensurate lead time) would be required to implement this proposal. Similarly, extensive processing resources would be required to perform this multitiered pricing evaluation for every prescription written in California. Furthermore, it is unclear what the source is for each of these data files, and for those data files that we were able to locate, each had a different timetable for updating, with some updating as frequently as weekly, further complicating implementation. Lead time of at least six (6) to nine (9) months would be required to implement the rules as suggested, which is incongruent with the proposed effective date of 1-1-2019.

SOLUTION: The proposal should be modified to specify a single-source database for pharmaceutical pricing methodology, such as the MediCal database pricing file. In the event that a medication is not contained in that database, the payer should be able to default to its standard processing for nearly all other WorkComp jurisdictions for pharmaceutical pricing, *i.e.*, obtain the drug pricing through a nationally-recognized, commonly-used data source such as MediSpan or RedBook.

In the alternative, should the Division decide to move forward with this proposal, the effective date for this altered pricing schema should be moved back to 1-1-2020, to ensure that payers have appropriate lead time to build the necessary interfaces and conduct the extensive testing required. Furthermore, the Division should make the necessary data files available on its website, and dictate timeframes for data source updates on a coordinated, predictably-timed schedule, or at least provide specifics as to the locations of the data files being relied upon (such as for the "MAIC" pricing), along with the update timeframes.

2. Repackaged Medications Should Have Specified Billing Instructions for Providers, and Non-Clean Bills Should be Denied

ISSUE: In order to facilitate appropriate (and consistent) pricing of repackaged medications tied to the pricing of the underlying ingredients, companion billing rules should be adopted.

SOLUTION: Modify the proposed rules to require use of the NCPDP standardized paper billing form for repackaged medications, requiring use of Box 61 for designation of the original (manufacturer's) NDC, as dictated in the NCPDD's Workers' Compensation Guidelines:

http://www.ncpdp.org/NCPDP/media/pdf/NCPDP-WorkersCompensationGuidanceForPharmacy-201307.pdf

The NCPDP also outlines companion guidelines for e-billing of pharmaceuticals using the electronic version of the NCPDP, which should also be incorporated into these proposed rules by reference. The rules should be modified to provide for denial of a bill in violation of these rules, and require resubmission of the bill as a "clean bill".

In the alternative, should the Division decide to continue to permit submission of the CMS-1500 for physician dispensed, repackaged medications, the proposed rules should be expanded to include specifications for where specifically on the form the provider is to include the original (manufacturer's) NDC, along with the revised (repackaged) NDC. As mentioned above, the rules should be modified to provide for denial of a bill in violation of these rules, and require resubmission of the bill as a "clean bill".

3. Multi-Tiered Pricing Schema Would Complicate Dispute Resolution

ISSUE: As mentioned above, the pricing schema suggested in the proposed rules is onerous and would require the electronic evaluation of multiple, disparate data sources, each of which provides updates on differing schedules. Furthermore, updates occur very frequently, resulting in potentially hundreds of data files in the aggregate for any given calendar year. As a practical matter, this would make evaluation of a later Second Bill Review (SBR) and/or an IBR for a pharmaceutical pricing dispute nearly impossible, as it would require revisiting an earlier version of four different data sources. As it would be extremely burdensome to store multiple versions of multiple data files historically, this would make this proposal as written extremely problematic operationally.

SOLUTION: As suggested above, modify the proposed rules to specify a single-source database for pharmaceutical pricing, allowing the payer to rely upon already-existing data sources in the event that the single-source pricing database does not have a value for the medication dispensed.

4. Multi-Tiered Dispensing Fee is Unduly Complicated, and Would Require Longer Lead Time

ISSUE: Similar to the multi-tiered pricing schema outlined above, the proposed rules provide for a 2-tier evaluation of the provider's NPI to determine whether the provider meets the

specifications for the \$13.20 higher-level dispensing fee, as dictated by the Medi-Cal Dispensing Fee File. Inclusion of this provision will require additional programming time and the maintenance of multiple data files, in a similar manner to that outlined for the multiple drug pricing data sources. Furthermore, issues will also exist (albeit to a lesser extent) with retrospective determinations on disputes, as the Dispensing File changes over time.

SOLUTION: Modify the proposed rules to specify one single dispensing fee of \$13.20 for all eligible providers.

5. Declining Reimbursement Levels for Pharmaceuticals Undermine PBM's Effectiveness

ISSUE: Coventry's PBM, FirstScriptTM, has been adversely impacted by the changes that have already been implemented by the Division, tying pharmaceutical reimbursement to the Federal Upper Limit (or "FUL's"), and will correspondingly continue to be negatively impacted by the proposed reimbursement schema, putting continuing operations in the state at risk. In this post-SB863-reform era, the role of the PBM's has continued to expand, with the PBM's assuming more and more responsibility for assisting our client payers with services ranging from implementation of the newly-enacted formulary, to changing UR guidelines, to assisting with determinations of first-30-days-of-claim treatment.

Furthermore, in Workers' Compensation, the PBM's often assume the financial risk for advancing payment for medications associated with a claim that is ultimately deemed to be non-compensable (for a myriad of reasons such as work-relatedness, coverage issues, etc.) and/or medications that, at a later point, may retrospectively be determined to fall outside the medical treatment guidelines and/or be deemed medically inappropriate for the industrial injury. In either case, reimbursement will not be forthcoming.

Combining declining revenues with increasing levels of responsibility, along with the potential for financial loss associated with non-reimbursable medications, provides for an unsustainable long-term business model for PBM's operating in California.

SOLUTION: In order to mitigate the exposure to the PBM's associated with the proposed reimbursement methodology changes, a suggested 10% surplus over MediCal's base pricing is recommended. This small differential would make a large difference to PBM's and provide some level of confidence that they will be able to continue providing needed support to their payers/clients for appropriate processing of medications going forward.

Don Schinske, Legislative Advocate October 8, 2018 Western Occupational and Environmental Medical Assn (WOEMA)

The Western Occupational and Environmental Medical Association (WOEMA) appreciates the opportunity to comment on the proposed amendments to the pharmaceutical fee scheduled posted on the DWC Forum. WOEMA is a non-profit professional association representing more

than 500 Occupational Medicine physicians and other health care professionals in five Western states including California, who champion workplace and environmental safety and health.

WOEMA understands that under the California Labor Code, the fee schedule for pharmaceuticals is being updated with the new payment methodology approved by the Centers for Medicare and Medicaid Services (CMS) for pharmaceuticals dispensed on or after January 1, 2019. However, WOEMA has significant concerns with the proposed regulation to eliminate the physician dispensing fee, which would result in the decrease of physician dispensing medications in accordance with the recently established Workers' Compensation formulary in California.

Specifically, WOEMA has the following concerns:

- According to a study published in April 1, 2014 in the *Annals of Internal Medicine*, 31 percent of all initial drug prescriptions were not filled within nine months.1 Appropriate dispensing of medication consistent with the chosen list of "Preferred" medications based on the evidence-based reviews contained in the Reed Group formulary is an important factor in helping injured workers recover sooner.
- In the same *Annals of Internal Medicine* study, a key finding was that patients who had more visits with the prescribing physician were more likely to fill their prescriptions.1 In the Workers' Compensation patient population, injured workers are referred to medical clinicians within the Medical Provider Networks, and do not have pre-established doctorpatient relationships. As a result, injured workers are more likely to not fill their prescriptions, which can impact their recovery.
- Older patients were less likely than younger individuals to be non-adherent with the odds of non-adherence dropped by 11 percent for each 10-year increase in age.1 As we face an aging work force, this finding will disproportionately impact this population, who is more likely to have longer case duration due to slower recovery time.
- Medication adherence is an important factor in the delivery of quality care.2 The ability
 for physicians to dispense medications at point of care improves the likelihood of
 medication adherence and improves the return to work for injured workers while
 lowering the overall cost of care.
- By eliminating the dispensing fee for physicians while increase the dispensing fees for pharmacies from the current \$7.25 to \$10.05, thereby essentially eliminating the early fill physician dispensing would result in an overall increase in the cost of these fills due to the higher pharmacy dispensing fee.
- Physician dispensing represents a convenience for injured workers allowing the initialization of treatment immediately at point of care. Placing additional obstacles for injured workers to get prescriptions filled at pharmacies may result in unnecessary burden for them as well as potentially delaying treatment.

California Workers' Compensation faces some of the toughest regulations with respect to physician dispensing. The proposed change to eliminate the physician dispensing fee will significantly impact the ability for physicians to deliver quality care to California injured workers while increasing the cost to the Workers' Compensation system and creating undue obstacles for injured workers.

Ron Crowell, MD President, COMP October 8, 2018

California Occupational Medicine Physicians (COMP) appreciates the opportunity to provide comments on the proposed changes to the pharmaceutical fee schedule. For the reasons explained below, we oppose the proposed elimination of the physician dispensing fee and encourage the Division to maintain the current dispensing fee structure.

COMP is comprised of more than 90 occupational clinics throughout California. Our clinics treat over 150,000 injured workers each year. We focus on delivering end to end care that ensures the injured worker receives immediate and thorough treatment that will allow them to return to work as quickly as possible. An integral part of this complete care is dispensing medications to the injured worker at the clinic.

The proposed regulations, that would reduce the reimbursement for medications dispensed by physicians including the elimination of the dispensing fee is extremely worrisome to COMP. California has already implemented some of the strictest regulations for workers compensation pharmacy, including a controlled formulary, quantity limitations and a fee schedule tied to Medi-Cal.

Currently, physicians and pharmacies are equally subject to the same regulations. However, the proposed regulations specifically target dispensing physicians by eliminating any dispensing fee while increasing the dispensing fee allowed for pharmacies. The table below shows two commonly prescribed medications for occupational injuries and the impact of these proposed regulations on the reimbursement rates.

		Proposed Fee Schedule	
Class	Current Fee	Physicians	Pharmacies
	Schedule	-	
Antibiotic	\$10.73	\$3.48	\$13.53 -
			\$16.68
Anti-	\$7.43	\$0.18	\$10.23 -
inflammatory			\$13.38
	Antibiotic Anti-	Antibiotic Schedule \$10.73 Anti- \$7.43	Class Current Fee Physicians Schedule Antibiotic \$10.73 \$3.48 Anti- \$7.43 \$0.18

At the proposed fee schedule rates, the pharmacy fee schedule would increase the cost of these medications by as much as 80%. At the same time, our clinics would be forced to stop dispensing due to the financial losses created by the proposed physician rates.

It is our belief that if these regulations were to become effective our clinics would discontinue dispensing medications to injured workers which would have a severe impact on a workers' ability to return to work.

There are a number of reasons for maintaining this benefit for both injured workers and employers including:

- Studies have shown that up to a third of all prescriptions never get filled. In a 2014 report by CVS Pharmacy on medication adherence, they cite this statistic and furthermore, they report that the relative influence of prescribers on medication adherence is 34% vs. pharmacists at 26%.
- When the types of injuries covered by Workers' Compensation are considered, medication adherence is essential to lowering the overall cost of care and return the injured worker to work. A back sprain or a wound injury can develop into a much more complicated case if the injured worker does not adhere to their doctor's orders. Ensuring adherence begins by filling those prescriptions at the clinic.
- Many pharmacies will demand payment for medications up front for Workers'
 Compensation claims. Injured workers may not be able to afford to pay for the
 medications. Our clinics will dispense the medications without receiving approval from
 the carrier.
- If the injured worker can't afford to pay for medications out of pocket they will simply go the emergency room. California emergency rooms are already overcrowded. Adding more patients for this reason is a further stress on a system that is teetering on collapse.
- There are significant language barriers at pharmacies that intimidate many injured workers which results in them not filling their prescriptions.
- Many injured workers will need to coordinate transportation to the pharmacy which can result in needless delays in filling a prescription.

The reasons outlined above will lead to injured workers either delaying in taking their medications or not filling their prescription at all. This will result in the prolonging of the workers' injuries and further delay their return to work. The net effect of this is the increase in costs to the Workers' Compensation system. These costs will exceed any cost savings that might be gained from the currently proposed regulations.

For these reasons, we must respectfully oppose the proposed changes which would eliminate the physicians dispensing fee schedule.

Stacy L. Jones, Senior Research Associate Denise Niber, Claims and Medical Director October 8, 2018

On behalf of its members, California Workers' Compensation Institute offers these comments on the proposed modifications to the Pharmaceutical Fee Schedule regulations. The Institute members include insurers writing 82% of California's workers' compensation premium, and self-insured employers with \$69.8B of annual payroll (31.5% of the state's total annual self-insured payroll).

Insurer members of the Institute include AIG, Alaska National Insurance Company, Allianz Global Corporate and Specialty, AmTrust North America, Berkshire Hathaway, CHUBB, CNA, CompWest Insurance Company, Crum & Forster, EMPLOYERS, Everest National Insurance Company, The Hartford, ICW Group, Liberty Mutual Insurance, Pacific Compensation Insurance Company, Preferred Employers Insurance, Republic Indemnity Company of America, Sentry Insurance, State Compensation Insurance Fund, State Farm Insurance Companies, Travelers, XL America, Zenith Insurance Company, and Zurich North America.

Self-insured employer members include Adventist Health, Albertsons/Safeway, BETA Healthcare Group, California Joint Powers Insurance Authority, California State University Risk Management Authority, Chevron Corporation, City and County of San Francisco, City of Los Angeles, City of Torrance, Contra Costa County Risk Management, Contra Costa County Schools Insurance Group, Costco Wholesale, County of Alameda, County of Los Angeles, County of San Bernardino Risk Management, County of Santa Clara Risk Management, Dignity Health, Foster Farms, Grimmway Farms, Kaiser Permanente, Marriott International, Inc., North Bay Schools Insurance Authority, Pacific Gas & Electric Company, Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Shasta-Trinity Schools Insurance Group, Southern California Edison, Special District Risk Management Authority, Sutter Health, University of California, and The Walt Disney Company.

Recommended revisions to the proposed regulation are indicated by <u>underscore</u> and <u>strikeout</u>. Comments and discussion by the Institute are identified by *italicized text*.

The Institute recommends reconciliation with the Official Medical Fee Schedule for Physician and Non-Physician Practitioner Services. The following sections of the Physician Fee Schedule Regulations require revision to address changes in the Medicare payment calculation methodology and to include reference to the proposed subsections under §9789.40:

- \$9789.13.2
- §9789.13.4
- §9789.14

Discussion:

In addition to the "Medicare rate" currently defined under § 9789.13.2 for services occurring on or after January 1, 2014, new language must be added describing the revised Medicare payment calculation for services that occur after implementation of the proposed Pharmaceutical Fee Schedule amendments.

Additionally, references to §9789.40 under §9789.13.4 and §9789.14 must be revised to include new sections and subdivisions, since amended language under subsection (d) states that §9789.40 only applies to pharmaceutical services rendered prior to January 1, 2019.

Recommendation:

Section 9789.40.1 Pharmaceuticals Dispensed and Pharmaceutical Services Rendered by a Pharmacy on or after January 1, 2019.

(a) The maximum reasonable fee payable for pharmaceuticals dispensed by a pharmacy on or after January 1, 2019 will be is the rate that is 100% of the payment allowed pursuant to the Medi-Cal pharmacy payment methodology. Payment for legend and non-legend drugs dispensed by a pharmacy is the lower of the drug's ingredient cost plus the professional dispensing fee, or the pharmacy's usual and customary charge to the public.

Discussion:

The Institute recommends changing "will be" to "is" for clarity.

Recommendation:

Section 9789.40.2 Pharmaceuticals Dispensed by a Physician on or after January 1, 2019.

- (a) The maximum reasonable fee payable for legend and non-legend drugs pharmaceuticals dispensed by a physician on or after January 1, 2019 will be is the lower of the rate that is 100% of the payment allowed pursuant to the Medi-Cal pharmacy payment methodology. Payment for legend and non-legend drugs dispensed by a physician is the lower of for the drug ingredient cost or the physician's usual and customary charge to patients under the physician's care.
- (1) The "drug" ingredient cost" means the lowest of:
- (A) The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
- (B) The Federal Upper Limit (FUL), or
- (C) The Maximum Allowable Ingredient Cost (MAIC).
- (b) A dispensing fee is not payable for a drug that is dispensed by a physician.
- (c) The Medi-Cal pharmacy drug ingredient rates will be made available on the Division of Workers' Compensation's Official Medical Fee Schedule web page.

Discussion:

The Institute recommends maintaining language that is similar to §9789.40.1 for ease of reading and clarity.

Recommendation:

Section 9789.40.3 Compounded Pharmaceuticals Dispensed on or after January 1, 2019 by a Pharmacy.

(a) The maximum reasonable fees for compounded drugs dispensed by a pharmacy shall be is the rate that is 100% of the fees payment allowed pursuant to the payable by Medi-Cal pharmacy payment methodology for compounded drugs, including drug ingredient costs, professional dispensing fee, and compounding fees if applicable.

Each ingredient shall be identified using the applicable National Drug Code (NDC) of the ingredient and the corresponding quantity.

- (1) The "drug's ingredient cost" means the lowest of:
- (A) The National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
- (B) The Federal Upper Limit (FUL), or
- (C) The Maximum Allowable Ingredient Cost (MAIC); or
- (2) Where the compound is composed of bulk chemicals, the drug ingredient cost is the Wholesale Acquisition Cost of each active pharmaceutical ingredient.
- (23) The professional dispensing fee is:
- (A) \$10.05 for all pharmacies except those that meet the requirements of (a)(2)(B);
- (B) \$13.20 for a pharmacy that is designated by National Provider Identifier to receive this fee in the Medi-Cal dispensing fee file applicable to the date the drug is dispensed.
- (34) The compounding fees are set forth on the Medi-Cal Compound Dosage Fee Table which is adopted and incorporated by reference.

Discussion:

The Institute recommends maintaining language that is similar to §9789.40.1 for ease of reading and clarity.

The numbering in subdivision (a) requires correction.

The Medi-Cal payment methodology is currently not limited only to "active pharmaceutical" ingredients. If the intent is to limit payment to active ingredients, then a definition of "active pharmaceutical ingredient" should be provided.

Recommendation:

Section 9789.40.4 Compounded Pharmaceuticals Dispensed on or after January 1, 2019 by a Physician.

- (a) The maximum reasonable fees for compounded drugs dispensed by a physician shall be is the lower of:
- (1) Three hundred percent (300%) of documented paid costs for the drug ingredients; or
- (2) Documented paid costs plus twenty dollars; or
- (3) The drug ingredient cost and compounding fees if applicable. The "drug ingredient cost" has the meaning set forth in section 9789.40.3 subdivision (a)(1). "Compounding fees" has the meaning set forth in section 9789.40.3, subdivision (a)(3).
- (b) <u>"Documented paid costs"</u> means the price paid by the physician for the drug <u>ingredients</u>, net of discounts <u>and rebates</u>, evidenced by documentation of the price actually paid by the physician for the drug <u>ingredients</u>. <u>Documentation shall consist of invoices, proof of payment, and inventory records as applicable</u>. The physician must submit documentation <u>of paid costs</u> and prior authorization to support a bill for a compounded drug at the time of billing.

(c) A dispensing fee is not payable for a compounded drug that is dispensed by a physician.

Discussion:

The Institute recommends changing "shall be" to "is" for consistency.

The Institute recommends additional language in 9789.40(b) to clarify and define the type of documentation necessary for payment of a physician-dispensed compounded drug, with language reflective of Section 5307.1(e)(5)(E).

For consideration:

<u>Section 9789.40.5 Miscellaneous Provisions - Pharmaceuticals Dispensed on or after January 1, 2019.</u>

(f) Unless otherwise specified in this Article, for a pharmacy service or drug that is not covered by a Medi-Cal payment system, the maximum reasonable drug ingredient fee shall not exceed the Wholesale Acquisition Cost applicable to the National Drug Code NADAC rate for a pharmaceutically equivalent drug as defined by the standardized nomenclature for clinical drugs (RxNorm) produced by the National Library of Medicine.

Discussion:

NADAC rates are calculated based on paid costs to more accurately reflect prices paid by retail community pharmacies acquiring prescription and over-the-counter outpatient drugs. If a particular NDC is not included in NADAC reporting, it will not be included in the NADAC database. Payment rates associated with a shared RxNorm Concept Unique Identifier (RXCUI) would enable payments for pharmaceuticals produced and sold, using comparable resources to be paid in an equitable manner.

The following tables provide examples of NDC payment rates for the same drug with NADAC records, and examples of WAC values for NDCs that are not found in the current NADAC database.

NADAC price as of 10/03/18					
NDC	NDC Description	NDC Price	RXCUI		
00378628001	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
00378628010	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
61442010201	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
61442010210	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
61442010260	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
68001028000	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
68001028006	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
68001028008	DICLOFENAC SOD DR 50 MG TAB	0.12635	855906		
NDCs not found in NADAC database					
NDC	NDC Description	WAC	RXCUI		
00440639500	DICLOFENAC SOD DR 50 MG TAB	0.1434	855906		

60429042110	DICLOFENAC SOD DR 50 MG TAB	0.10354	855906
60429042118	DICLOFENAC SOD DR 50 MG TAB	0.13228	855906
42291023018	DICLOFENAC SOD DR 50 MG TAB	0.15667	855906

Jose Ruiz, Claims Operations Manager State Compensation Insurance Fund October 8, 2018

§9789.40.1 Pharmaceuticals Dispensed and Pharmaceutical Services Rendered by a Pharmacy on or after January 1, 2019.

Comment:

State Fund recommends the DWC to post relevant source pricing material on the National Average Drug Acquisition Cost (NADAC), the Wholesale Acquisition Cost (WAC), the Federal Upper Limit (FUL), and the Maximum Allowable Ingredient Cost (MAIC) on its website for access and review.

§9789.40.3 Compounded and Pharmaceuticals Dispensed on or after January 1, 2019 by a Pharmacy

Comment:

State Fund recommends the inclusion of the definition for "bulk chemicals" to avoid any potential ambiguity.

Jessica Rubenstein, Associate Director Center for Health Policy American Medical Association

October 8, 2018

On behalf of more than 43,000 physician members and medical students of the California Medical Association (CMA), we appreciate the opportunity to provide comments on the proposed changes to the Pharmaceutical Fee Schedule, currently codified at Cal. Code of Regs, tit. 8, § 9789.40. Through a comprehensive program of legislative, legal, regulatory, economic and social advocacy, CMA promotes the science and art of medicine, the care and well-being of patients, the protection of the public health, and the betterment of the medical profession.

We write to express our concern about the elimination of the physician dispensing fee in section 9789.40.2(b) which states: "A dispensing fee is not payable for a drug that is dispensed by a physician." Though the other changes proposed by the Division of Workers' Compensation are necessary to align the fee schedule with the Medi-Cal pharmacy payment methodology, the new Medi-Cal rules do not address dispensing fees for physicians.

CMA policy supports the right of physicians to dispense prescription and nonprescription medications from their clinics or offices as a way of providing more efficient and economic care to the patient, thereby increasing patient compliance with the treatment plan prescribed by the physician and increasing access to care, improving individual health outcomes and reducing system costs. The American Medical Association (AMA) Code of Medical Ethics also allows physicians to dispense drugs in their office practices when such dispensing primary benefits the patient.¹

Allowing injured workers to receive needed medications at their physicians' office will improve health outcomes for these patients. Studies have found high rates of medication non-adherence, with many patients failing to fill prescriptions, leading to greater disease morbidity and increases in health care costs². In-office dispensing eliminates the need for patients to travel to a pharmacy and to further navigate the complexities of the worker's compensation system. If injured workers cannot receive drugs from their treating physicians, they will face unnecessary barriers to obtaining their prescriptions, potentially forcing them to wait days before receiving medication from a pharmacy.

Eliminating the dispensing fee for physicians will make it cost-prohibitive for physicians to continue in-office dispensing. Physicians incur costs when storing, ordering, and furnishing medication. With the proposed changes to the reimbursement allowance for many medications, the total reimbursement to physicians may not even cover the actual cost of the medication and the repackaging fee. We urge the Division to delete the proposed amendment to Section 9789.40.2, such that physicians can continue to bill a dispensing fee when they are dispensing medication from their office.

Brian Allen Vice President Government Affairs Mitchell International October 8, 2018

Thank you for the opportunity to comment on the proposed changes to the workers' compensation pharmacy fee schedule. Mitchell International is one of the leading providers of managed pharmacy services in workers' compensation systems across the country. We employ innovative solutions to help employers and insurers provide efficient and appropriate care to injured workers, including special focus on opioids and other potentially problematic medications. Our services also help ensure easy and convenient access to pharmacy care for injured workers.

¹ AMA, Code of Medical Ethics Opinion 9.6.6, available at https://www.ama-assn.org/delivering-care/prescribing-dispensing-drugs-devices

² See, e.g., Fischer et al., Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions., J. OF GENERAL INTERNAL MED., 25(4) 284-290 (2010);

Since tying the workers' compensation pharmacy fee schedule to the Medi-Cal pharmacy fee schedule in 2004, reimbursement for pharmacy services has continued to erode. PBMs doing business in California have been expressing concern about the continued erosion of reimbursement for pharmacy services. The Medi-Cal budget is a constant topic of discussion in the California Legislature. The Medi-Cal system is also impacted by the whims of Congress and CMS. Significant policy and reimbursement decisions are made in the context of Medi-Cal and never is any thought given to how a change in pharmacy reimbursement in Medi-Cal might affect the California workers' compensation system. The Division of Workers' Compensation (DWC) is likely rarely, if ever, consulted on how a change in pharmacy reimbursement might impact their stakeholders. Pharmacy stakeholders in the workers' compensation system have been forced to live with reimbursement changes without our input as there is seemingly no place our voice matters since we are the proverbial "tail on a much bigger dog." This rulemaking by the DWC is the first time we have had a formal forum to voice our concerns.

Different Patient Sets, Different Outcome Expectations

The typical patient populations in workers' compensation and Medi-Cal differ greatly, as do the types of injuries and illnesses treated in each system. In the Medi-Cal system, half of the eligible participants are either younger than 21 or older than 65. In workers' compensation, 95% of injured workers fall between the ages of 20-65. The types of injuries between the two populations also vary significantly. The Medi- Cal system predominantly deals with sicknesses and chronic conditions such as hypertension, diabetes, and high cholesterol. The workers' compensation system deals primarily with trauma induced injuries that cause sprains, tears, cuts, punctures, bruises, fractures and pain. The outcome expectations are also very different. Since Medi-Cal spends a lot of time and money on chronic diseases, their outcome goals are focused on better management of the illness or disease. The underlying goal is to reach a point in disease management resulting in less utilization of Medi-Cal services. Workers' compensation, on the other hand, has an obligation to return the injured worker to the highest functional state possible, with the underlying goal of returning the individual to work. There is no disability component in Medi-Cal so the productivity of the enrollee is less important than the utilization of services. In workers' compensation, utilizing the best services to achieve the highest level of productivity is an integral part of the "Grand Bargain" and critical in the process of returning the injured worker to their job. How that care is managed is also very different.

Different Worlds of Pharmacy Care

When comparing a Medi-Cal pharmacy transaction to a workers' compensation pharmacy transaction, the only real similarity is how a Medi-Cal enrollee and an injured worker access care at the pharmacy. But, that is where the similarity ends. Medi-Cal has a pre-defined benefit and has pre-determined eligibility. Consequently, when a Medi-Cal enrollee needs to access pharmacy care, they need only to present a valid prescription and their Medi-Cal card at the pharmacy. As long as the medication is allowed under the Medi-Cal formulary and the enrollee is still eligible for Medi-Cal benefits, the pharmacy knows where to submit the claim and they know with certainty that they will be paid for the medication. A Medi-Cal pharmacy transaction is relatively simple and streamlined.

Conversely, when an injured worker presents a prescription at a pharmacy, there can be a host of unknowns. If it is a new claim and the injured worker has not yet been given a pharmacy benefit card, the pharmacist will likely have no idea where to submit the claim and will have even less certainty about being paid for the medication they are being asked to dispense. The pharmacy is faced with three choices; turn the customer away, dispense the medications then do the research to figure out where to send the claim along with assuming the financial risk, or demand a cash payment from the injured worker. Demanding a cash payment is difficult since many injured workers don't have the funds necessary and most are concerned about spending extra money if they are facing time away from work, especially for medical care that should be covered by their employer. The pharmacy wants to serve its customers, so rather than turn a customer away or assume the financial risk themselves, most pharmacies have transferred the risk for these "uncarded" claims to a third-party billing processor. The third-party billing processor guarantees payment to the pharmacy and assumes the financial risk for the claim. The third-party biller also verifies the prescription against the MTUS drug formulary and does all of the back shop work to determine which insurer or third-party administrator is responsible for handling the claim.

If the injured worker does present a pharmacy benefit card, prior to dispensing, the pharmacy will send the claim to the PBM for eligibility. The PBM will verify that the claim is active, the medication is allowed under the MTUS drug formulary and that it aligns with treatment guidelines. There can be a significant amount of administrative work involved in prospectively approving a non-exempt or unlisted medication. Once the medication is approved, the PBM guarantees payment to the pharmacy.

If the prescribed medication is listed as exempt on the MTUS drug formulary and is indicated as appropriate in the treatment guidelines, the PBM will allow those to process and will guarantee payment to the pharmacy. However, the medication could still be denied upon retrospective review, leaving the PBM at financial risk for the prescription that was processed.

There are also several additional items of information that a pharmacy must collect related to injury, employer, etc. they are not required to collect on other pharmacy transactions. This adds additional time and complexity to a workers' compensation pharmacy claim.

Different Care Management Expectations

The differences in care management begin with how the formularies are developed at the state level. Both the workers' compensation and Medi-Cal systems have pharmacy and therapeutics committees but how they evaluate medications and place them on the approved list is very different. In the Medi-Cal system, significant consideration is given to the cost of the medication, potential for rebates from manufacturers, etc. to help manage the overall cost of the Medi-Cal pharmacy program. The DUR committee does also provide input on safety and efficacy issues related to specific medications. The MTUS Drug Formulary is based solely on prevailing medical evidence as outlined in the MTUS treatment guidelines. The Pharmacy and Therapeutics committee advises the Administrative Director on potential changes to the MTUS Drug Formulary based on emerging clinical evidence for new drugs or for drugs currently on the formulary. Very little consideration is given to the cost of the drugs or the availability of rebates or other pricing concessions. This, of course, is completely appropriate since the DWC is not the

ultimate payer of the medications and the primary responsibility of the DWC is to ensure that injured workers receive the best care and the benefits entitled to them under the workers' compensation act. However, for PBMs and payers, a state-mandated and state-derived formulary limits their ability to negotiate pricing or any potential rebate revenue since they have no real way to influence the prescribing volume of any particular drug. Conversely, in the Medi-Cal system, as the ultimate payer and developer of the Medi-Cal formulary, the Department of Health Services is well positioned to negotiate pricing and rebates by ensuring volume to drug manufacturers by inclusion of a drug on the Medi-Cal formulary.

Another difference in care relates to the involvement of the employer/payer related to the care of the injured worker. The employer has a vested interest in making sure their injured employee is treated well and is able, where possible, to return to work. Managing or monitoring that care often involves using the clinical services of a PBM to help manage pharmacy care, especially as it relates to recommending "exempt" drug options and managing the use of opioids. This level of care management and PBM involvement is not present in the Medi-Cal system, and there are costs associated with this care management that are not anticipated or accounted for in the Medi-Cal reimbursement rate.

It is also important to point out that most workers' compensation PBMs take great pride in their ability to drive utilization of generic drugs. Contrary to popular belief, the vast majority of generic drugs used in the workers' compensation system are not eligible for rebates so the reimbursement established by the DWC is, for most drugs, the only reimbursement available.

Impact Over Time

The impact, since the legislative action in 2004, has been a significant erosion of profitability for pharmacies and PBMs providing pharmacy care to injured workers. At the same time, more is being asked of PBMs to help manage the pharmacy care of injured workers. The largest negative impact on profitability came with the adoption of the CMS federal upper limit (FUL) reimbursement methodology in 2015 and 2016. In many cases, the FUL reimbursement allowed by Medi-Cal is less than our acquisition price for the same medication. For the balance of the medications, the reimbursement has been reduced to a point that the profits from those transactions no longer offset the losses for the under-reimbursed drugs and the general costs of doing business.

The current Medi-Cal reiumbursement for most of the medications dispensed in the workers' compensation system ranges from AWP-70% to AWP-90%. It is important to note that prior to the changes to Medi-Cal reimbursement imposed by CMS in 2015 and 2016, reimbursement allowed for prescriptions was approximately the average wholesale price (AWP) minus 17%. Today's extremely low reimbursement rates and the volatility of those rates make it extremely difficult to offset potential losses and to adequately provide the extra work involved in handling a workers' compensation pharmacy claim.

Add to that the introduction of the MTUS Drug Formulary, the technology costs to implement the formulary and the added ongoing service costs to manage prior authorization requests, opioid restrictions and exceptions for drugs prescribed outside the formulary, and it has become

extremely challenging for workers' compensation PBMs to continue to provide solid clinical services to payers and injured workers in California.

The proposed tiered dispensing fee also creates another significant programming cost that will be shouldered by the PBMs doing workers' compensation business in California. Additionally, the tiered dispensing fee has no real relevance in the workers compensation system to the volume of workers' compensation prescriptions dispensed or the extra work involved in handling a workers' compensation prescription.

Based on our reading of California Labor Code 5307.1, we believe the Administrative Director has the power to adopt a fee schedule for pharmacy care that deviates from the Medi-Cal fee schedule. Therefore, we respectfully request the Administrative Director to adopt the following fee schedule for workers' compensation pharmacy care:

110% of the Medi-Cal rate + \$13.20 dispensing fee

We believe this is a fair reimbursement level based on the inherent risk of financial loss and the additional operational costs that are unique to workers' compensation pharmacy transactions. This reimbursement level will allow workers' compensation PBMs to continue to provide appropriate clinical support, manage the MTUS Drug Formulary and continue to keep pharmacies in our networks to provide consistent and broad access to pharmacy care for injured workers in California while still allowing for a significant pharmacy cost savings for payers and employers in California. The adoption of a single dispensing fee will also simplify the process and eliminate the need for extensive re-programming falling on the heels of the costly re-programming the PBMs just had to complete for the MTUS drug formulary.

Kristie Griffin My Matrixx, an Express-Scripts Company Workers' Compensation Regulatory Compliance

October 8, 2018

As one of the largest pharmacy benefit management (PBM) companies in North America providing PBM services to thousands of client groups, including managed-care organizations, insurance carriers, employers, third-party administrators, public sector, workers' compensation, and union-sponsored benefit plans, myMatrixx takes a strategic approach to workers' compensation to ensure safety for injured workers while aggressively controlling costs.

In review of the proposed fee schedule regulations, we are submitting a few comments/requests for clarification or confirmation as follows:

1. Per sections 9789.40.1(b) and 9789.40.2(c): The Medi-Cal pharmacy drug ingredient rates and the dispensing fee files will be made available on the Division of Workers' Compensation's

Official Medical Fee Schedule web page (http://www.dir.ca.gov/dwc/OMFS9904.htm)

Clarification: Can the DWC clarify that the web page (https://www.dir.ca.gov/dwc/pharmfeesched/pfs.asp) will also be updated with the Medi-Cal pharmacy drug ingredient rates and the dispensing fee files? Will the DWC online pharmacy fee schedule calculator (on the same web page) also be updated to use the new price benchmarks (NADAC and WAC) and dispensing fee changes?

Question: Does the DWC plan to share a sample price file with stakeholders prior to implementation to ensure that no additional development and/or logic will be needed with intake of the new file?

2. Per sections 9789.40.1(2)(B) and 9789.40.3(2)(B): \$13.20 for a pharmacy that is designated by National Provider Identifier to receive this fee in the Medi-Cal dispensing fee file applicable to the date the drug is dispensed.

Comment: With regard to the tiered dispensing fee language, we request consideration be given to a sole dispensing fee apply to workers' compensation medications to avoid undue administrative burden and alleviate potential confusion among stakeholders. Further, the administration of Medi-Cal and workers' compensation are not aligned today and the reimbursement of a tiered dispense fee based on Medi-Cal eligibility does not apply to workers' compensation participants.

3. Per section 9789.40.5(c)(3): The National Drug Code of the dispensed repackaged drug and the National Drug

Code of the underlying drug product shall be identified on the bill, in accordance with the billing regulations for paper and electronic billing set forth in Section 9792.5.1 et seq.

Question: Does the DWC plan to update the Medical Billing and Payment Guides (paper and electronic) to align with the requirement of billing using both NDCs for repackaged drugs?

Kevin C. Tribout, Executive Director Government Affairs – Optum October 8, 2018

Thank you for the opportunity to provide comments on proposed revisions to the current California workers' compensation pharmaceutical fee schedule. Our comments are mainly limited to requests for clarification or suggestions for better alignment of existing regulatory numbering. We do however respectfully request the Division to better examine the impact of these proposed changes on continued provision of pharmacy care and services and for simplicity suggest enactment of a single dispensing fee for all pharmacy claims.

We look forward to working with the Division and staff during this rule-making process, and offer our assistance and resources at your convenience.

Section 9789.40.1

(a) "... Payment for legend and non-legend drugs dispensed by a pharmacy is the lower of the drug's ingredient cost plus the professional dispensing fee, or the pharmacy's usual and customary."

OWCA Comment: OWCA suggests clarifying or providing a definition of usual and customary. Any pharmacy may have several variants of usual and customary depending on patient population being served. A usual and customary price could be based on Medicaid, Medicare, private pay, group health or even cash pricing for non-insured patients. In the past fee disputes have arisen between payers and providers regarding "\$4 generics or free generics" offered by some pharmacies. These disputes are based on the perception that these free or discounted medications are the billable usual and customary for that particular pharmacy or chain of pharmacies. Optum would suggest potentially adding in the phrase "for the same or similar patient population or claimant type" after usual and customary in 9789.40.1(a).

Section 9789.40.2

(a) "... to the Medi-Cal pharmacy payment methodology for the drug ingredient cost or the physician's usual and customary charge to patients under the physician's care."

OWCA Comment: While the lessor of language should prevent abuse of usual and customary pricing by dispensing physicians, PBMs and payors may find it difficult to fully ascertain the provider's usual and customary price. Unlike payment of pharmacy transactions where a PBM and/or a payor can ascertain a potential usual and customary price by reviewing pharmacy payment and benchmark reimbursement data, this may prove more difficult when processing a payment to a physician where this information and data is not as transparent. We would suggest potentially adding language which would require the physician to disclose the basis of their usual and customary price with their billing for pharmaceuticals.

Section 9789.40.3

<u>OWCA Comment</u>: There appears to be a slight misnumbering in this section. We suggest the Division look at numbering of the subsections after (a)(1)(C).

- (a) "... including drug ingredient costs, professional dispensing fee, and compounding fees if applicable."...
 - (3) "The compound fees are set forth in the Medi-Cal Compound Dosage Fee Table which is adopted and incorporated by reference

OWCA Comment: We are confused by language in the proposed rules as stated above. It appears the Division is now including in this proposed fee schedule – something not included in the current fee schedule – a compounding fee for pharmacists on top of a dispensing fee. Not only is this a change requiring additional programming by PBMs, payers and other stakeholders, it could lead to a cost increase for the system. Additionally, as a PBM and a stakeholder we remain concerned with the additional burden placed on our operational systems to not only incorporate the Medi-Cal feed but now the Medi-Cal Compound Dosage Fee Table information/data, all at a time when reimbursement for workers' compensation pharmacy reimbursement rates continue to decrease. Finally, the proposed language does not indicate if this element of the Medi-Cal feed/database will be made available to stakeholders. Will it be published on the DWC website for access and will it require continual updating as changes are made by Medi-Cal? We request the Division provide greater guidance and clarification on these newly proposed requirements around calculating and reimbursing a compounding fee.

Section 9789.40.4

OWCA Comment: There appears to be a slight misnumbering in this section. We suggest the Division look at the numbering in subsection (a)(3).

OWCA Comment: Optum is confused by the language found in this section related to a dispensing and compounding fee and seeks clarification. While we support the position that physicians should not receive a dispensing fee – due to the types of pre-prepared compounds most commonly dispensed by physicians – we are uncertain of the language in (a)(3). It appears to refer to Section 9789.40.4 which includes a compounding fee. We do not believe it is the Division's intent to allow physicians to receive a compounding fee for dispense of a compounded drug where the physician does not engage in the activity of compounding, so we respectfully request clarification.

Section 9789.40.5

OWCA Comment: There appears to be a slight misnumbering in this section. We suggest the Division look at the numbering of subsections (4)(A) and (4)(b) as well as (f).

Fee Schedule and Reimbursement Calculation

OWCA Comment: Implementation of the new fee schedule requirements and reimbursement levels will require system changes, programming and IT development for many pharmacies and other pharmacy processors, such as PBMs and third-party billers. Specifically integration of the Medi-Cal feed and data base for ingredient cost and NPI-based dispensing fee requirements, changes to processing reimbursement for physician dispensed medications and addition of what

appears to be a new requirement for payment of a compounding fee are clear regulatory requirements which will require time, effort and resources. These regulatory changes will need to be prioritized amongst other regulatory requirements and non-regulatory requirements by pharmacies, PBMs, pharmacy processors and payors who have a nationwide business footprint. For these reasons we strongly urge the Division to provide as much lead time as possible for implementation and provide stakeholders no less than the 60-days allotted by statute for the Division to incorporate any changes made by Medi-Cal.

OWCA Comment: We would be remiss in not continuing to express concern with the continuing link of workers' compensation pharmacy reimbursement to Medi-Cal. This link was joined due to last-minute legislative action taking place over a decade ago, well before any of the recent requirements (such as treatment guidelines and drug formularies) were ever considered for application to workers' compensation claims. In the years since original linkage, pharmacy reimbursement has decreased due to various policy developments outside of the control of pharmacists, PBMs and the Division, while other medical reimbursement benchmarks have increased or have been sensibly adjusted. Now, pharmacists, pharmacies, PBMs and other pharmacy service providers are again asked to integrate additional regulatory requirements required by these proposed rules at an ever decreasing reimbursement rate.

While debate continues on the merits of workers' compensation reforms over the years and if the link to Medi-Cal is a reasonable reimbursement rate for workers' compensation claims, a solid argument can be made that the link to Medi-Cal is not rationale. So far in 2018 pharmacies, PBMs and other pharmacy service providers have had to integrate the MTUS Drug Formulary and now will be required to integrate additional elements of the Medi-Cal feed to ensure proper reimbursement is rendered for a workers' compensation claim. This process will not be automatic, will require system development and will include manual processes for extraction of data. We are aware statute requires reimbursement to be tied to Medi-Cal, but we are also aware the Division has regulatory authority to make determinations on medical reimbursement rates, which is granted to the Division by the Labor code. We respectfully urge the Division to engage in discussion with all impacted stakeholders regarding the continued link of workers' compensation pharmacy reimbursement to the Medi-Cal rate during the coming year.

Application of the Medi-Cal bifurcated dispensing fee is another in a series of burdens placed on workers' compensation pharmacy service providers for which there is little to no financial return. We believe the Division could remove this burden through regulatory action by not requiring application of two separate Medi-Cal dispensing fees as currently proposed under Section 9789.40.1(2) and 9789.40.1(b). The Division should establish a single and reasonable dispensing fee for workers' compensation claims and, given the cost to dispensing and processing a medication for workers' compensation is typically higher than in Medi-Cal, we believe the dispensing fee should be the higher of the two as proposed. Respectfully we suggest the following (deleted text appears as strikethrough and new text appears as underlined):

Section 9789.40.1

- (2) The professional dispensing fee is: shall be: \$13.20
- (A) \$10.05 for all pharmacies except those that meet the requirements of (a)(B)(2);
- (B) \$13.20 for a pharmacy that is designated by

(b) The Medi-Cal pharmacy drug ingredient rates and the dispensing fee files will be made available . . .

We appreciate the continued transparency and openness exhibited by the Division during this and other rule-making efforts. Should the Division have any questions or wish to discuss any of our comments or proposed changes, please feel free to contact me or my staff at any time.

Julian Roberts, President American Association of Payer Administrators and Networks October 8, 2108

American Association of Payers, Administrators and Networks (AAPAN) is the national trade association for provider networks, payers, and other workers' compensation organizations, including pharmacy benefit managers (PBMs). Through our members, we work on behalf of thousands of injured workers throughout the country, including in California. We are submitting comments on the proposed changes to the Pharmaceutical Fee Schedule because we believe that modifications to the proposal are necessary to reflect the realities of the workers' compensation market in California, and to protect access to care for injured workers.

Since 2004, the pharmacy fee schedule for workers' compensation has been tied to the Medi-Cal fee schedule. However, the needs and delivery of care for an injured employee is substantially different from that of a Medi-Cal recipient. The proposed changes in the Medi-Cal fee schedule will not serve the injured worker, regardless of the appropriateness for Medi-Cal recipients. Accordingly, pharmacists should be protected from potential risks associated with providing access to injured employees through workers' compensation benefits. AAPAN's members recommend a higher single dispensing fee of \$13.20, not tied to multiple pharmacy transactions, and requests that the DWC adopt a Medi-Cal rate + 10% for workers' compensation pharmacy care.

Injured Workers' Access to Care

As noted above, there are substantial differences between services provided pursuant to workers' compensation when compared to those same services provided through Medi-Cal. Care for injured workers is administered on a different principle, returning the employee to health and employment, wholly divorced from budgetary concerns. This should be taken into context, especially as reimbursement rates decline. First, from the perspective of the pharmacist, an injured worker will require additional administrative costs and delays in payment, particularly for initial interactions when an injured employee may not yet have a pharmacy benefits card and claims filing is delayed. Even when the appropriate card is applied, pharmacy claims will be subject to additional prior authorization and review pursuant to MTUS requirements. Additionally, when a claim is submitted, a pharmacist's effective reimbursement rate will be still lower than Medi-Cal (already at, or below, cost) because there is no patient cost sharing allowed.

AAPAN is concerned that the long-term trend of these policies will result in a decreased number of pharmacies providing care to injured workers. Unless reimbursement rates and dispensing fees are elevated above the Medi-Cal rate, serving injured workers will make less financial sense for pharmacies. Further, while higher reimbursement rates and dispensing fees will correct for the issues above, AAPAN opposes the use of a tiered dispensing fee. Pharmacies will provide a higher level of service to injured workers, services that will cost substantially the same regardless of the number of transactions

In Conclusion

Again, AAPAN recommends a higher single dispensing fee of \$13.20, not tied to the number of pharmacy transactions, and requests that the DWC adopt a Medi-Cal rate + 10% for workers' compensation pharmacy care. We believe that these changes will maintain access for injured workers and reflect the differences between the workers' compensation market and Medi-Cal.

Sandy Shtab, AVP, Advocacy & Compliance Healthesystems

October 5, 2018

Please accept these comments from the Healthesystems as they relate to the draft proposal dated September 27, 2018 which will incorporate a new Pharmaceutical Fee Schedule for medications dispensed on or after January 1, 2019.

We have reviewed the proposal and have concerns about the impact these reimbursement changes will have on the pharmacies serving California's injured workers, pharmacy benefit managers (PBMs) and most of all, on the injured worker. We will outline our concerns below and ask for consideration from the DWC in exercising its authority to make modifications to the rule to make it more practical for the needs of injured workers and to fairly compensate the parties who serve them.

Impact to Pharmacies and PBMs

Pharmacies who serve injured workers are often connected to the PBMs who are the critical integration point between the pharmacy and the claims administrator. Many stakeholders believe PBMs connect the pharmacy and the claim administrator solely for the purpose of billing and remittance. The truth is, in most cases, the PBM has a major role in serving the injured worker, the pharmacy and the insurer/TPA/employer. PBMs are the single point through which eligibility is electronically verified by the pharmacy; through which all MTUS formulary edits and generic rules are applied, and by which prior authorizations are triggered based upon these rules and edits. These services have a tremendous impact in delivery of care to the injured worker and compliance with the MTUS, and they assist the pharmacist in understanding which drugs are covered under the MTUS and which require additional review.

The new fee schedule methodology which is now being rolled out in the California Medicaid program (Medi-Cal) is driven by budget changes on the federal and state level and does not in any way take into account the differences between Medi-Cal and the workers'

compensation benefit delivery systems, coverage differences, funding sources and overall goals. Medi-Cal's new pharmacy reimbursement structure will require pharmacies to dispense medications at the pharmacy's purchase cost, and in some cases BELOW the purchase cost. Significant feedback from pharmacies has been provided to the Medi-Cal program on this subject by the California Pharmacist Association, the National Community Pharmacist Association and the National Association of Chain Drug Stores. These entities have all commented in similar language that "No business can stay afloat if they are paid less for products than their own purchase price."

There is some relief for pharmacists in that they will continue to be compensated in other ways for their services, beyond the cost of the drug and the dispense fee. Medi-Cal beneficiaries share in the cost of the drug, via a co-pay requirement and pharmacists are also able to now bill Medi-Cal for pharmacists' professional services under Medication Therapy Management (MTM) services at 85% of the allowable physicians' fee for service. These fees are separately reimbursable to pharmacists since 2016 under AB1114.³ As we know, there is no patient cost sharing in workers' compensation and MTM is not recognized or acknowledged in the current Workers' Compensation Fee Schedule. If the proposed changes are adopted as is, pharmacists who serve injured workers will now receive even LESS for serving injured workers than they do when serving a Medi-Cal patient. If this were the case for any other type of medical service in workers' compensation it is unlikely providers would be able to sustain their practices serving other than the occasional workers' compensation patient.

Impact to Injured Workers

As we have noted above, we are highly concerned some pharmacies will refuse workers' compensation patients once these changes are implemented because pharmacy reimbursement would be whittled down to a dispense fee to offset all the costs associated with serving the patient. According to the Mercer report⁴ from January 2017, the proposed changes to Medi-Cal pharmacy pricing would result in additional decreases in overall drug costs for Medi-Cal. However, the survey conducted by Mercer was limited to pharmacy purchase prices serving Medi-Cal beneficiaries only. This is important because the needs and delivery of care for the workers' compensation population are substantially different from that of Medi-Cal. Workers' Compensation medications often fall into three categories: pain medications, anti-depressants, and muscle relaxants. While Medicaid covers all these drug classes, they also cover many medications used to treat diabetes, asthma, cardiovascular, and cancer. Mercer estimates the ingredient cost expenditures for all Medi-Cal covered drugs to be reduced by 4.4%. Our own analysis indicates this new decrease in reimbursement for the workers' compensation drug mix will be almost three times greater than resulting in a 12.8% reimbursement reduction for pharmacy providers in the workers' compensation system. This newest cut is in addition to the massive cuts made to Medi-Cal pricing in 2016 which occurred following the changes to CMS's Outpatient Drug Rules. Those 2016 cuts reduced Medi-Cal rates by over \$500 million, as was reported in California's Department of Health Care Services Annual Medi-Cal Drug Cost Reports, (Comparison of FY 2015-2016 to 2016-2017). They impacted workers' compensation

³ https://leginfo.legislature.ca.gov/faces/billCompareClient.xhtml?bill id=201520160AB1114

⁴ https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/PRP Merc Rpt 170127.pdf

in a significant way, yet they were not reported on publicly and now, the industry is again being asked to accept another cut. Continued cuts are unsustainable, and we are asking the DWC to consider the long-term impact to serving injured workers.

For this reason, we recommend the DWC consider implementing language which would lessen the blow; by adopting a 10% mark-up over the "lesser of" language which is proposed in the Medi-Cal reimbursement rate. We also recommend implementing a single dispense fee of \$13.20 to adequately compensate the pharmacist. The use of a single dispense fee for all pharmacists in workers' compensation claims would also significantly address our next concerns, laid out below.

Dual Dispense Fees Create Inefficiency Without any Added Value to the Patient

Adopting a two-tiered dispensing fee sets lower value on the professional service provided by the pharmacist in filling the drug and the associated patient counseling on medications for large chain pharmacies. Pharmacies often must provide a higher level of service and time to workers' compensation patients than the typical Medi-Cal or group health beneficiary where coverage is clearer cut and co-payments help offset the pharmacist overhead costs. The labor cost and time for the pharmacist is similar in high volume pharmacies and lower volume pharmacies. The schooling and compliance requirements are the same. How can we support paying the pharmacist less of a fee, simply because their pharmacy processes more claims per year? Accordingly, Healthesystems supports implementing the higher of the two dispense fees as the single uniform dispense fee. We believe injured workers require more service and attention now than ever before with the implementation of the MTUS formulary and the increased focus on appropriate prescribing, yet with reimbursement eroding actual drug costs, pharmacists – and even the PBMs who provide critical support, directly or indirectly to ensure patient safety and ease of access to care – are among those who will be shortchanged.

Timing of these Changes

The timing of the proposal and effective date is January 1, 2019. This equates to roughly 90 days from the time of this initial (informal) draft proposal to effective date. While Medi-Cal has been working on the technology changes that will be needed to comply with the CMS Plan Amendment since at least August 25, 2017⁵, they are a single payer system. There are many more impacted entities in the workers' compensation payer community which includes PBMs, pharmacy processing agents, medical bill review entities, insurers and TPA systems which operate in California today.

Workers' compensation stakeholders have not had access to the actual data (or even a sample data set) to enable them to understand the scope of system changes which would be needed to comply with dispense fees tied to a provider NPI, and this is a major issue. How can system changes be contemplated without access to the data which as of the date of this writing has still not been made available. Programming these changes is difficult without having the details needed to assess the size of work which would be needed.

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⁵ https://www.dhcs.ca.gov/formsandpubs/laws/Documents/17-002ApvOct.pdf

We do know each of the proposed changes within the DWC draft proposal will require some level of effort in programming and testing, and every single entity involved in medical bill review and pharmacy processing will be impacted. If changes are adopted as proposed here with a dual dispensing fee tied to a provider NPI and are expected to become effective on January 1, 2019, it will be a tremendous burden on the PBMs and bill review entities who must make system modifications to implement the changes in such a short timeframe. We would recommend this data be made available ASAP and at least a 90 days implementation window from the date of adoption, to allow for the appropriate planning and development.

Repackaged and Compounded Medications

We support the DWC in its endeavor to adopt language that will serve the needs of the injured workers, medical and pharmacy providers, and employers while also balancing costs. We appreciate the inclusion of new language that clarifies the inclusion of shipping and handling costs in the maximum reimbursement for mail order pharmacies, and the clarifications in the language on repackaged drug reimbursement. To continue the Division's objective to harmonize the regulations, we do recommend including additional reimbursement language for compounds that is contained within Labor Code 5307.1(e)(2), which provides that "Ingredients with no NDC shall not be separately reimbursable."

Recommendations for Preserving Good Access to Care

For all these reasons noted above, we strongly urge the DWC to consider modifying its proposal to incorporate the maximum pharmacy reimbursement rate at the lesser of Medi-Cal rate plus a 10% markup, and a single \$13.20 dispense fee for pharmacists only.

Healthesystems supports the California Division of Workers' Compensation in its mission to ensure a fair and balanced system which serves injured workers, employers and the stakeholders who facilitate the delivery of benefits to injured workers. We appreciate the opportunity to share with you our unique perspective in hopes to facilitate a positive outcome for everyone involved in the system, and most of all for injured workers who deserve the highest level of care as they work towards recovery and return to function.

Lesley Anderson, MD, Chair, WC Committee California Orthopaedic Association

October 4, 2018

First, of all we understand and support that the Medi-Cal Drug Formulary would be moving to using the lowest possible reimbursement for the medication ingredient costs. The maximum reimbursement would be based on the lower of the following:

- National Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) for drugs lacking a NADAC price;
- Federal Upper Limit;

- Maximum Allowable Ingredient Cost (MAIC);
- Usual and Customary Charge

This will likely reduce the current reimbursement allowance for medications and bring down the reimbursement, for some common medications, to just pennies per pill. For example, current reimbursement for Ibuprofen (NDC 67877032105) is \$0.0618 per pill. So, if a physician prescribes 30 pills, the reimbursement would be \$1.85.

Currently, in addition, the prescriber can bill a \$7.25 dispensing fee when the medication is dispensed in a physician's office, so the reimbursement for this medication is \$9.10. See Attachment A.

Under the proposed changes, the cost of the medication may go down and the physician is expressly prohibited from billing the dispensing fee, so the total reimbursement to the prescribing physician would only be \$1.85. This will not even cover the physician's actual costs of the medication and the repackaging fee which can easily run \$1.00-\$3.00 per medication.

In addition, physicians must comply with all dispensing, labeling, and patient disclosure requirements required by Business & Professions Code 4170. See Attachment B.

Since a physician's reimbursement will be so low and not even cover their real costs, the result of this change will be to effectively drive physicians to stop dispensing medications in their office to injured workers.

Some may say that physicians should not be dispensing medications from their offices. We would argue that this overlooks the real problem of injured workers' accessing needed medications. When the physician writes the prescription, often the injured worker gets to the pharmacy and they will not fill the prescription. Injured workers do not receive their pharmacy benefit cards in a timely manner. The confusion around the new Drug Formulary regarding exempt and non-exempt medications and whether they require prior authorization is also adding to the confusion and additional access problems for injured workers.

We believe that the Division is aware of these real day-to-day problems for injured workers. Physicians dispensing medications in their office helps to eliminate some of these access problems.

We urge the Division to amend Section 9789.40.2 to allow the physician to bill a dispensing fee when they are dispensing the medication from their office. The Medi-Cal dispensing fee has not been increased for many years. We believe the dispensing fee for the physician should also be set at \$10.05.

Note: Attachment A is available upon request. You can calculate the results at the following link: https://www.dir.ca.gov/dwc/pharmfeesched/pfs.asp

Attachment B can be found here:

https://codes.findlaw.com/ca/business-and-professions-code/bpc-sect-4170.html