# Pharmaceutical Fee Schedule Forum Comments

## Jason Schmelzer July 3, 2020

California Coalition on Workers’ Compensation

I write on behalf of the California Coalition on Workers’ Compensation (CCWC) regarding the proposed revisions to the Pharmaceutical Fee Schedule, posted on June 15, 2020 and propose the following comments for consideration.

The California Coalition on Workers’ Compensation (CCWC) is an association of California’s public and private sector employers that advocates for a balanced workers’ compensation system that provides injured workers with fair benefits, while keeping costs low for employers. Our members include not only businesses of every size, but also cities, counties, schools and other public entities.

# Two-tier Dispensing Fee

Under **Sections 9789.40.1(a) and (b) and Sections 9789.40.2(d)(1) and (2),** the DWC proposes a two-tier dispensing fee. We believe this will lead to confusion at the pharmacy level, which will lead to a potential increase in fee disputes. Currently as proposed, the determination of the higher dispensing fee is dependent on the volume of pharmacy claims processed as filed by the pharmacy’s individual National Provider Identifier (NPI). This may mean that a large chain drug store could qualify for the higher dispensing fee, since NPI is based on individual store location versus the actual total prescription volume of the entire pharmacy chain store operations at all locations. In addition, if a fee rate is based on the attestation of the provider, as to the level of their prescription business, then what prevents any provider from falsifying their attestation of prior volume in order to recover a higher dispense fee? It will be difficult to audit and control for fraud under a two-tier dispensing model in determining, by prescription, whether the appropriate dispensing fee was applied.

# Recommend:

* **Single Dispense Fee:** By moving to a single dispense fee, it would ease the administrative set up and processes and curtail potential fraudulent activity.
	+ We would support a mid-level fee that is between the two current proposed dispensing fees, which will result in all providers earning the same fee.
	+ An attestation is not needed, thus potential for fraud is alleviated.

# Day Implementation Requirement

In **Sections 9789.40(d) and (e),** the proposed language indicates implementation 60-days after the amendments are filed with the Secretary of State for the regulatory changes to the Pharmaceutical Fee Schedule. We have concerns over a 60-day implementation requirement, given the complexity of programming involved in developing a two-tiered dispensing fee system as well as other proposed updates to the Fee Schedule. Another consideration at this time is that most of our support staff charged with implementation continue to work remotely due to the COVID-19 pandemic; this short timeframe would make implementation a far greater challenge. This may cause an undue hardship on stakeholders, including Pharmacy Benefit Managers (PBMs), payers and claims administrators in timely meeting a 60- day deadline.

# Recommend:

* + **Six (6) Month Implementation:** In a single tier scheduled, as outlined above, implementation should be easier to achieve, although it still may be difficult to do so in 60-days in the current work-from-home environment and with the other required changes. However, we recommend at least six (6) months for implementation and application of the proposed changes. SHOULD the DWC continue to move forward with a two-tiered dispensing fee system, as previously outlined above, additional challenges will arise in programming this system; therefore, a more appropriate timeframe would be **nine (9) months**.

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## Greg M. Gilbert, President July 3, 2020

California Occupational Medicine Physicians

California Occupational Medicine Physicians (COMP) appreciates the opportunity to provide comments on the proposed changes to the pharmaceutical fee schedule.

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, especially for primary care providers treating even before the claim has been accepted.

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**

| **Medication** | **Class** | **Current Fee Schedule** | **Physicians** | **Pharmacies** |
| --- | --- | --- | --- | --- |
| Cephalexin 500mg #30 | Antibiotic | $10.73 | $3.48 | $13.53 - $16.68 |
| Meloxicam 15mg #7 | Anti-inflammatory | $7.43 | $0.18 | $10.23 - $13.38 |

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 as the costs to acquire would be more than the fee schedule rate.

It should be noted that physicians who dispense are required to perform all of the same processes, both clinical and regulatory, that are required of retail pharmacies. These processes include product labeling, patient counseling and regulatory compliance checks including opioid monitoring and state PDMP reporting.

Also, to be considered are the current COVID-19 circumstances and particularly in California where most patients are still under strict "shelter-in-place" requirements. Physician dispensing provides an option for the patient to NOT make a trip to the pharmacy. Physician dispensing allows the patient to go straight home after the appointment.

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 with the current COVID crisis.
	+ 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.

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## Julian Roberts, President July 1, 2020

American Association of Payers, Administrators, and Networks

The American Association of Payers, Administrators, and Networks (AAPAN) appreciates the opportunity to provide comment on the open forum regarding the draft text of the proposed pharmaceutical fee schedule. We would like to express our gratitude with the Division’s willingness to engage with our members over the last couple years regarding the implications of this fee schedule update. While we anticipate a robust rulemaking process ahead, we wanted to express our concerns on this initial draft text.

Since 2004, the pharmacy fee schedule for workers’ compensation has been tied to the Medi-Cal fee schedule. Nevertheless, the needs and delivery of care for an injured employee is substantially different from that of a Medi-Cal recipient. Utilizing Medi-Cal’s reimbursement calculation on a very different patient population with differing needs remains a top concern for our members. We believe that this draft text presents an opportunity to aptly recognize the value that workers compensation pharmacy providers, processers, and PBMs add to the system and therefore properly align reimbursement with market realities.

Yet, the current draft text falls short of this understanding by further lowering pharmacy reimbursement that has already been repeatedly reduced throughout the years. Therefore, our members ask the Division to adopt the single dispensing fee of $13.20. Not only will adopting a single dispensing fee help encourage pharmacies to participate in our system, a single, rather than a tiered fee, will also lessen the number of disputed claims. If the tiered fee is adopted, California would become the first state to do so.

Furthermore, we seek clarification regarding documentation around paid costs for compounds. How are these documents to be transmitted? Attachments are not standard practice for electronic point-of-sale retail pharmacy transactions submitted utilizing NCPDP standards, this could result in the submittal of additional paper bills.

In closing, we ask the Division for adequate time to comply with these novel requirements. APPAN believes that six months would provide our members with the proper time to build and develop software for this new process

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## Wendy Cloe, Senior Manager July 1, 2020

Workers’ Compensation Regulatory Complaince

myMatrixx, an Express Scripts company

myMatrixx, an Express Scripts Company, appreciates the opportunity to submit comments regarding the proposed regulations for the Medical Treatment Utilization Schedule (MTUS) drug formulary. Our goal is to ensure clear and concise rules to avoid any confusion or misunderstanding for all participants within the workers’ compensation system.

myMatrixx dba Express Scripts  is 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.  We take a strategic approach to workers' compensation, structuring customized client solutions around best-in-class core services, supported by advanced trend-management and clinical-review programs, to ensure safety for injured workers, while aggressively controlling costs.

The adjudication process in the Workers Compensation market is very intricate. The proposed the two tiered pharmacy dispensing fee is very difficult for the industry to implement and is not done in other states. Complex systems will have to be recoded which involves systems analysist time and resources dedicated to reengineer and test. This will not only add complexity to the system but increased administrative cost to the process.

In an effort to compromise we suggest that the following sections proposed be stricken and a single dispensing fee be used. Please consider raising the dispensing fee to a level that would satisfy the Division of Workers Compensation in California, we propose the fee be set at a range between $10.05 and $13. 20.

*Strike:*

*§9789.40.1(C) (2) (a)*

*(A) $10.05 for all pharmacies except those that meet the requirements of subdivision (a)(2)(B);*

*(B) $13.20 for a pharmacy that is designated by the National Provider Identifier to receive this fee in the Medi-Cal dispensing fee file applicable to the date the drug is dispensed.*

*Insert:*

*§9789.40.1(C)(2) The professional dispensing fee is $11.60.*

*Strike:*

*§9789.40.2(c)(3)(d)*

*(1) $10.05 for all pharmacies except those that meet the requirements of subdivision (d)(2);*

*(2) $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.*

*Insert:*

*§9789.40.2(c)(3)(d) The professional dispensing fee is $11.60.*

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## Don Schniske, Legislative Advocate July 1, 2020

Western Occupational & Environmental Medical Assn (WOEMA)

The Western Occupational and Environmental Medical Association (WOEMA) supports the continued dispensing of medication in physician offices, which the proposal would eliminate (Section 9789.40.4 (e)). Studies consistently show that many injured workers do not or cannot travel to other locations to pick up prescriptions. Eliminating the modest office dispensing fee will reduce the use the appropriate medications, which will aggravate many conditions which will then require more expensive and more complicated care. This provision would erect a barrier to appropriate care.

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## Brain Allen, Vice President Government Affairs July 1, 2020

Mitchell International, Inc.

Mitchell International, Inc. (“Mitchell”), headquartered in San Diego, CA, is one of the nation’s leading providers of workers’ compensation services, providing a solution for every aspect of a workers’ compensation claim starting with the first report of injury through to a settlement. Mitchell’s Pharmacy Solutions division provides managed pharmacy care to injured workers in California through our pharmacy benefit manager (PBM) ScriptAdvisor. ScriptAdvisor serves injured workers in all 50 states. We appreciate the opportunity to comment on the proposed revisions to the pharmaceutical fee schedule.

Since 2004, the workers’ compensation pharmaceutical fee schedule has been linked to the Medi-Cal pharmaceutical fee schedule. At that time, reimbursement in the Medi-Cal system was closer to, but slightly less than, the reimbursement for medications in the workers’ compensation system. Over time, as CMS has changed their rules and as budgetary pressures have weighed on the Medi-Cal system, reimbursement for medications in the Medi-Cal system has been reduced significantly. Consequently, reimbursement for prescription medications in the workers’ compensation system has also been reduced. For example, 30 tablets of Tramadol HCL were reimbursed at $20.73 plus the dispensing fee on 01/01/2013 and today would be reimbursed at $0.86 plus the dispensing fee. Another common medication, Naproxen, was reimbursed at $29.69 plus the dispensing fee for 30 tablets on 01/01/2013, but today would be reimbursed at $2.46 plus the dispensing fee. During this same time period, as pharmaceutical reimbursement decreased, other health care providers in the California workers’ compensation system received increases in their reimbursement. Along with the significant reduction in reimbursement, the pharmacy requirements promulgated by the Legislature and Division have added more cost and complexity (i.e. drug formulary, opioid controls) to the management and processing of workers’ compensation pharmacy claims.

This new fee schedule is just one more example of added complexity due to the tiered dispensing fee and the changes in reimbursement for repackaged and compounded medications. Added complexity creates added cost while dramatically reducing reimbursement. These changes will require significant programming and operational changes to manage the pharmacy lists and to manage the reimbursement changes required for all medications, but especially the reimbursement for repackaged and compounded medications as noted in our comments below.

We strongly recommend that the Division consider the adoption of a workers’ compensation specific pharmaceutical fee schedule that addresses the unique needs and costs associated with the provision of pharmacy care to injured workers. Medi-Cal is a defined benefit/defined eligibility system, so a formulary medication presented at the pharmacy with a valid Medi-Cal card is guaranteed to be paid, which encourages pharmacies to accept lower reimbursement. In the workers’ compensation system, more information needs to be collected and validated at the pharmacy before a pharmacy bill can be submitted. There is no guarantee of eligibility and even if the injured worker has a valid claim, there is no guarantee that the medication prescribed will be deemed compensable. These additional operating requirements and risk of non-collectability add increased cost to a workers’ compensation pharmacy transaction that are not inherent in managing a Medi-Cal pharmacy transaction.

Additionally, workers’ compensation has a utilization review process for medications that is much more involved than similar processes in the Medi-Cal system. Currently, when changes to reimbursement are considered in Medi-Cal, the workers’ compensation industry, including Mitchell, is not included in any discussion that occurs on how the reimbursement changes might impact the workers’ compensation system. For example, pharmacies reached an agreement on lower reimbursement for drugs in the Medi-Cal system in exchange for a higher dispensing fee. For Medi-Cal drugs, the dispensing fee was retroactively paid. In workers’ compensation, there was no retroactive provision allowed for the dispensing fee so the pharmacies and PBMs were actually paid less during that time period for a prescription for an injured worker as compared to the reimbursement for the same medication in the Medi-Cal system. This proposed rule change is another example of the disconnect and disparity of applying the Medi-Cal system to workers’ compensation.

The Medi-Cal system changed its reimbursement over a year ago. Since that time, reimbursement has been “frozen” in the workers’ compensation system while the DWC worked through the rulemaking process. Many of the drugs had pricing increases in that time period that may not have been reflected in the pricing calculator, again creating a financial disadvantage for workers’ compensation prescriptions. The provision of workers’ compensation pharmacy care has very unique needs that differ substantially from government and commercial health care programs. Those unique needs beg for a fee schedule uniquely designed to meet those needs.

The balance of our comments will be directed to the changes outlined in the proposed fee schedule.

Section 9789.40.1: The transition by Medi-Cal to NADAC pricing is another reduction to the reimbursement for workers’ compensation prescription drugs, further exacerbating the reimbursement issues discussed above. Regarding the tiered dispensing fee, while we understand the logic of its application in the Medi-Cal system, California will be the only state to introduce such a notion into its workers’ compensation system. In the worker’s compensation arena, the work required to process a workers’ compensation prescription and the eligibility risks are the same for any pharmacy, regardless of the volume of medications processed. Additionally, since workers’ compensation prescriptions represent 2% or less of all prescriptions in a pharmacy, there are no real economies of scale in handling workers’ compensation prescriptions at the pharmacy level with increases in total prescription volume.

Another concern is that the tiered dispensing fee will create confusion with pharmacies on how they should be paid and will result in an increase in fee disputes. Since this is a first of its kind proposal, there will also be significant development costs to program the tiered dispensing fee. We recommend the Division adopt a single dispensing fee of $13.20. This dispensing fee would help cover some of the additional costs and risks associated with the dispensing of a workers’ compensation medication, no matter the size of the pharmacy. If a single dispensing fee is not possible, the DWC should consider the programming burden, especially in these times of home- based resources and allow for at least six months after publication before the fee schedule change is effective. The 60 days from date of publication is not sufficient time to make the programming changes necessary to implement the tiered dispensing fee.

We support aligning the reimbursement for repackaged drugs with traditional prescription medications and support the use of the cost of a therapeutically similar drug when the repackaged or original product NDC are not found in the Medi-Cal database.

Section 9789.40.2: Compounded medications continue to be a cost-driver, though the requirement for prior authorization in the drug formulary has helped reduce the impact. We support the proposed changes in reimbursement for compounds, but note two concerns:

* It would be helpful if the rule noted the requirement to comply with 9792.27.9 regarding prospective review of compounded medications, similar to how the requirements were referenced for physician dispensing.
* The definition of “documented paid cost” notes that it is the price the pharmacy paid, net of discounts or rebates. We support ensuring that payers receive the advantage of discounts and rebates. That said, rebates and discounts are often aggregated over a specific time period, based on volume, and may be documented months after the drugs have been dispensed. Rebates are generally received 4-6 months after a transaction. Our pricing to customers includes discounts based on anticipated rebates that we may receive. We have no visibility on rebates received outside our program and would have no way to verify or account for them. Volume discounts aggregated over time may not be shown on an invoice. Once a pharmacy bill has been paid, any discount received and noted by the pharmacy after the fact would require a manual accounting process. We are concerned that this provision will be difficult for payers to enforce and may create a window for abusive pricing practices.

Section 9789.40.4: We have the same concern with the definition of “documented paid cost” as noted above.

Section 9789.40.5: We have the same concern with the definition of “documented paid cost” as noted above. Additionally, in this section, it would be helpful if the rule noted the requirement to comply with 9792.27.9 regarding prospective review of compounded medications, similar to how the requirements were referenced for physician dispensing.

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## Kevin Tribout, Executive Director July 1, 2020

Public Policy & Regulatory Affairs

Optum

Optum Workers’ Comp and Auto No-fault (Optum) appreciates the opportunity to provide input related to the forum on the pharmaceutical fee schedule. While we believe that all medical provider, ancillary and pharmacy fee schedules should undergo regular review, we find the latest proposed review and modification another in a long line of cuts to pharmacy providers, processors and PBMs not necessarily aligned to workers’ compensation market realities.

Since the initial linkage of the workers’ compensation pharmacy fee schedule to Medi-Cal rates, reimbursement rates for pharmacy providers have been reduced several times. Reductions have consisted of initially tying the workers’ compensation pharmacy fee schedule to the Medi-Cal reimbursement rate, a seven percent cut in the AWP based reimbursement rate for all drugs, reducing reimbursement for generic/multi-source drugs to the Medi-Cal FUL/MAIC and now this proposal to reduce reimbursement for brand/legend/single-source drugs to either NADAC or WAC. All while pharmacies, pharmacy processors and PBMs have been asked to do more, with less.

Because major workers’ compensation reforms tie medical and ancillary reimbursements to Medicare **plus a percentage markup,** medical and ancillary providers receive annual updates which generally increase reimbursement for their services, while pharmacy reimbursement, tied to Medi-Cal, is repetitively reduced. During this time-frame, pharmacies, pharmacy processors and PBMs have been asked to implement rules related to opioid dispensing, treatment guidelines for chronic pain and opioid usage and the California Workers’ Compensation Drug Formulary. Medi-Cal and worker’s compensation **are not the same**, so utilizing one system’s reimbursement calculation on a very different patient population, mix of medications and treatment system with clearly divergent needs continues to concern pharmacy stakeholders, including Optum. While Optum opposes this **proposed** additional cut to pharmacy reimbursement, we strongly encourage the Division to hold significant public discussions on a viable and appropriate pharmacy fee schedule, one that ensures care for injured workers and provides accurate and sufficient reimbursement for pharmacies, pharmacy processors and PBMs.

One new example of the continued process where pharmacies, processors and PBMs are asked to do more with less is the introduction of the Medi-Cal bifurcated dispensing fee for workers’ compensation claims. In workers’ compensation there is a need to entice and/or reward a pharmacy’s provision of services to injured workers. Handling a workers’ compensation pharmacy claim is full of unique nuances (benefit eligibility, unknown level reimbursement from a payer and possibility of claim denial) making these claims much more high-touch and labor intensive. Additionally the provision of workers’ compensation pharmacy services averages around 3% of a pharmacy’s overall business and unlike Medi-Cal, workers’ compensation is not a single-payer or single process system. Thus, many pharmacies which take workers’ compensation prescriptions often do so by contracting with pharmacy processors or PBMs to handle this unique piece of their business and often deal with numerous system stakeholders compared to the Medi-Cal single payer system.

By adopting the Medi-Cal process, pharmacies, pharmacy processors and PBMs will once again be required to engage in a **manual process** of taking a Medi-Cal NPI identifier (.txt) file and **manually** integrate this file into processing and adjudication systems to ensure proper pharmacy reimbursement. Again, this process – from the early NPI identifier ‘example’ file – appears to provide stakeholders with data including the start and end date for pharmacies that are subject to receiving the higher dispensing fee in a non-importable format. If adopted stakeholders will have to **manually** integrate this file feed and accurately track the start and end dates for those pharmacies to ensure proper payments while avoiding potential payment fines related to failure to pay the appropriate dispensing fee.

With that being noted, Optum must point out the difference in the two proposed dispensing fee(s) is a mere $3.15. While this may not appear to be a large financial figure, it could lead to an increase in pharmacy fee disputes. The mistaken application of an improper dispensing fee(s) will lead to accidental overpayment or underpayment, either of which will lead to an increase in fee disputes. Pharmacies which process workers’ compensation claims do so with the understanding that full and proper reimbursement is justified for handling these high-touch labor intensive claims. A bifurcated dispensing fee incorrectly applied across numerous pharmacy claims is certain to lead to inaccurate reimbursement and unnecessarily increase fee disputes. This issue could be an unintended consequence of the proposed policy which can easily be avoided.

For these reasons we respectfully request the Division to adopt a single dispensing fee for workers’ compensation claims that reflects the added administrative costs and potential financial risks associated with processing a prescription for a workers’ compensation claim. This will simplify and speed the processing of pharmacy bills and remove an additional layer of regulatory stress for stakeholders. In fact, to help encourage pharmacies to participate in the system we urge the Division adopt a single dispensing fee of $13.20.

As we continue with our comments, we offer specific questions for consideration by the Division.

**Questions for Clarification and Optum Comments**

Page 5 – 9789.40.1

(a)(1)(A) – NADAC of the drug or when no NADAC is available, WAC

Question: Will the DWC or Medi-Cal provide an official feed for NADAC and/or WAC, or are PBMs and pharmacy processors required to secure (and possible pay for) these feeds from public or private sources? Will a feed from the Division and/or Medi-Cal be all inclusive of the various calculations as proposed in the “ingredient cost” calculation? Has the DWC determined applicability of a feed update to proper drug pricing? Is there a lead time once a feed has changed or is any change in drug cost contained in the feed applicable on date of release?

 (a)(2)(A) & (B) – Bifurcated dispensing fees for pharmacies

Question: Will the DWC provide clarification around the bifurcated dispensing fee or will this come from Medi-Cal? Is this a programmable feed or a manual list feed? At this point it appears to be a .txt file which creates a manual process for PBMs and pharmacy processors.

Is this an ongoing process that will need continual monitoring or will the feed from Medi-Cal be an annual or one-time feed? If it is an annual or one-time feed, which dispensing fee should processors pay to new pharmacies and/or out of state pharmacies in the interim periods?

Question: It appears from the DWC background document that the NPI list of pharmacies will have a start and end date for the indicated pharmacy, is this correct? If so, will this require processors to have multiple start or end dates for paying the varying dispensing fee to each individual pharmacy based upon their indication on the NPI list? Will the NPI feed from Medi-Cal or the DWC be updated in real-time when the list changes or prior to the effective date of such change? Are pharmacy processors, PBM and payers who mistakenly pay the wrong dispensing fee subject to any administrative fines or fee dispute? Is there a process or period by which the payer(s) are required to correct the dispensing fee mistake?

Question: Can the DWC provide greater clarification – other than tying the workers’ comp. pharmacy fee schedule to Medi-Cal – for the nature of a bifurcated dispensing fee in workers’ compensation? Is there a categorization by Medi- Cal and a clarification by the DWC as to which pharmacies receive the higher dispensing fee based on unique workers’ comp. claim experience or is just based on their Medi-Cal claims or overall claims across all insurance/payer types? Does the Division recognize that pharmacy processors PBMs and payers will be required to expend additional resources and costs to comply with this dispensing fee requirement?

Page 6 – 9789.40.2

(c)(2) & (3) – Unfinished drug product

Question: Can the Division provide clarification as to why the language of (c)(2) & (3), which is new language, is being inserted into what appears to be a re-write of existing fee schedule language. Optum does not understand the process or requirements around “unfinished” and “finished” drug products.

1. – Documented paid cost for compounds

Question: Under (f) *the documented paid cost(s) shall consist of invoices, proof of payment, and inventory records where applicable. The pharmacy must submit documentation . . . together with the bill.* Can the DWC provide greater clarification on how these documents are to be transmitted via the current eBilling processes for retail pharmacies? Can the DWC provide greater clarification on both electronic and paper billing transactions? If the documents are not attached or do not accompany a bill, are processors and payers permitted to reject the bill as incomplete? DWC appears to be borrowing this language from Labor Code provisions relating to physician dispensing of compounds. But unlike for physicians, attachments are not standard practice for retail pharmacy electronic point-of-sale transactions submitted utilizing NCPDP standards – which means this requirement may result in the generation and submittal of more paper bills.

1. – Compounds and copy of commercial available products

Question: Can the DWC provide further clarification on their intent here? If a compound is made of two ingredients that are both commercially available, in a different route of administration, would the payer be able to deny the compound? For these ‘compounds’ is the Division looking at compounds which are truly defined as compounds through the act of compounding (found in State/Federal law) or is the division examining pre-packaged, already prepared when provided to the pharmacy, or topical medications?

We believe the intent of the Division was to attack a growing problem within the system which is pre-packaged and/or OTC compounds and topicals. The\_se medications, while containing a mix of medications, are not truly considered compounds in the sense of a pharmacist working or engaging in the act of compounding to manually mix and create a specialty medication. Often these types of pre-packaged compounds and/or topicals are made up of one or maybe two commercially available medications, available via a different route of administration, and come in dispensable tubes.

Some of these medications require a prescription and some can be provided as an OTC. The emerging problem with these medications is not only are they simple combination of already available drugs, they are also truly not compounds and they carry single unique NDCs making their reimbursement rates outside of the norm. Numerous states have uncovered this “loophole” and are undertaking regulatory efforts to control the dispensing and cost of these medications. For those reasons we respectfully suggest the following change to the proposed language.

*Optum suggested language – Newly added language indicated by underline*

(g) A compounded drug, pre-packaged compounded drug or topical medication that is essentially a copy of a commercially available product is not reimbursable. The status of a compounded drug as “essentially a copy of commercially available drug product” is determined pursuant the applicable federal law and regulation.

Page 10 – 9789.40.4

(g) – Documented paid cost

Question: Under (g) the documented paid cost(s) shall consist of invoices, proof of payment, and inventory records where applicable. The physician must submit documentation . . . together with the bill. Can the DWC provide greater clarification on how these documents are to be transmitted via the current eBilling processes? Can the DWC provide greater clarification on paper billing transactions? If the documents are not attached or do not accompany a bill, are processors and payers permitted to reject the bill as incomplete?

Page 10 – 9789.40.5

(b) – Documented paid cost

Question: Under (g) the documented paid cost(s) shall consist of invoices, proof of payment, and inventory records where applicable. The physician must submit documentation . . . together with the bill. Can the DWC provide greater clarification on how these documents are to be transmitted via the current eBilling processes? Can the DWC provide greater clarification on paper billing transactions? If the documents are not attached or do not accompany a bill, are processors and payers permitted to reject the bill as incomplete?

Page 12 – 9789.111

(d) – Effective date

Optum respectfully requests, at this time, a minimum of six months from adoption of the rule to application of the rule change on all pharmaceutical transactions. We believe this six-month time period **should** permit stakeholders to engage in system modification and IT development required to utilize the adopted ingredient cost and comply with integrating the bifurcated dispensing fee. However, this time frame is subject to change as DWC clarifies the exact nature of the file formats to be provided and their availability as updated.

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## Tracy Euler, Manager, Advocacy & Compliance July 1, 2020

Healthesystems

Please accept these comments on behalf of Healthesystems as it relates to the draft pharmaceutical fee schedule changes that were posted for comment on June 15, 2020. We have reviewed the updated draft and the focus of our feedback will be the two-tiered dispense fee, unfinished compound documentation requirement, and implementation timeframe.

# Section 9789.40.1 | Pharmaceuticals Dispensed and Pharmaceutical Services Rendered By a Pharmacy Professional Dispensing Fee

The Division proposes to incorporate a dual tiered dispense fee which is determined based on the volume of prescriptions dispensed by the pharmacy in the prior calendar year. The Division has not yet shared the full data which demonstrates how many pharmacies may be eligible for which fee, so it is difficult to analyze how this would impact the pharmacy payment system, if at all.

What we do know is that having a dual tiered dispensing fee based on prescription volume has never before been proposed or implemented in any state workers’ compensation system, and as such, would require system development to implement. It is unclear what the goals of this payment methodology might be or how that relates to providing care to injured workers. What is clear, is that the application of different dispensing fees to pharmacies based on volume would add a layer of complexity without any improvement to patient care.

In light of these concerns, Healthesystems would like to recommend that DWC consider a single, uniform dispense fee that will adequately compensate pharmacists for their professional services, without consideration to the size or volume of that pharmacy.

# Section 9789.40.2 & 9789.40.5 | Compounded Pharmaceuticals Dispensed By a Pharmacy and Physician Unfinished Drug Product Reimbursement

As proposed, this section proposes that the “drug ingredient cost” means the *documented paid cost* of each unfinished drug product, calculated based on units used in the compound, plus 10%. Again, this is the first time language of this kind has been proposed in a workers’ compensation system, adding complexity to an already streamlined and efficient process. Today most pharmacies connect to the insurer’s PBM to confirm patient eligibility, the status of the prescribed drug as compared to the state formulary rule and to transmit their billing in real time. It would be highly unusual for a pharmacist who is dispensing a compounded drug to have cost documentation on hand and, considering the manual review which would be required for these types of services, would circumvent the value of transmitting electronically to the payer or their PBM. If a bill were to be received on paper that met these parameters, each of those bills would require manual review on the part of the PBM, medical bill review agent, and/or the claims professional.

We are highly concerned that requiring documentation of paid costs along with the bill for an “unfinished drug product” will not only slow down what is today, a highly efficient automated process, but will create an additional administrative manual process for the pharmacy and the payer, slowing down their ability to serve the injured workers. These provisions are unnecessary given the existing cost and utilization controls that are already in place for managing these drug products through:

1. California Labor Code §4600.2 which allows payers to utilize a network of pharmacies, and hold those pharmacies accountable for cost effective dispensing through their contracts with a pharmacy benefit network and,
2. the MTUS drug formulary, which has an established pre-authorization requirement for any compounded drug.

To simplify the process, we recommend utilizing an established benchmark for reimbursement of these drug products. Adopting the same payment allowance as would be allowed by the Medi-Cal for the components within the compounded drug product would be an effective strategy. If the NDC for an ingredient within a compounded drug does not appear in the Medi-Cal data base and is absent in National Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC), then the maximum drug ingredient fee shall not exceed the drug ingredient cost of the lowest priced therapeutically equivalent drug. This payment cap methodology currently exists in section 9789.40.4 |Pharmaceuticals Dispensed By a Physician of the pharmacy fee schedule for drug products not found in the Medi-Cal data base.

# Timing of Effective Date

We appreciate the Division has the difficult task of incorporating these rules into the pharmacy payment guidelines, however considering the two concerns we have raised above, if the state does elect to move forward with a dual dispense fee and/or requires proof of cost documentation for unfinished drug products within a compound, we must ask for ample time to implement these changes. The draft proposal indicates that the changes will become effective 60 days following the filing of the amendments with the Secretary of State. Due to the level of effort in programming and testing, and number of entities impacted, we would recommend extending the 60 days following the filing of the amendments with the Secretary of State to, at minimum, a 6-month timeframe from the date of adoption, to allow for adequate development and testing.

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## Andrea Guzman, Claims Regulatory Director July 1, 2020

State Compensation Insurance Fund

State Compensation Insurance Fund appreciates the opportunity to provide input regarding the Division of Workers’ Compensation’s (DWC) proposed amendments to the Pharmaceutical Fee Schedule. State Fund respectfully submits the following comments for your consideration.

# Section 9789.13.2 Physician-Administered Drugs, Biologicals, Vaccines, Blood Products.

In section (a) (2), the pharmacy drug ingredient cost is modified to follow the current Medi-Cal State Plan Amendment 17-002, as “*…defined as the lower of (1) National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) if a NADAC price does not exist, (2) Federal Upper Limit (FUL), or (3) the Maximum Allowable Ingredient Cost (MAIC). The modified drug ingredient cost will be implemented for workers’ compensation prospectively as set forth in sections 9789.40.4 and 9789.40.5 for pharmaceutical products dispensed on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].*”

Here, four different sources for drug pricing are referenced:

* + National Average Drug Acquisition Cost (NADAC)
	+ Wholesale Acquisition Cost (WAC)
	+ Federal Upper Limit (FUL)
	+ Maximum Allowable Ingredient Cost (MAIC)

The drug ingredient cost will vary depending on which drug pricing method is used. For this reason, it would benefit users to have the ability to access the relevant pricing source material directly within this section and/or post the relevant source pricing material to a centralized location for users to access and review.

# Recommendation:

State Fund recommends links within this section to 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) and/or the posting of material on these four pricing sources onto the DWC’s website for access and review.

# Section 9789.40.1 Pharmaceuticals Dispensed and Pharmaceutical Services Rendered By a Pharmacy on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

**Discussion:**

In this section, the pharmacy dispensing fee value and structure is revised to a two-tiered dispensing fee structure.

Section (a)(2)(A)(B) states:

1. $10.05 for all pharmacies except those that meet the requirements of subdivision (a)(2)(B);
2. $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.

The professional dispensing fee was a flat rate of $7.25. Here, the proposed new dispensing fee is either $10.05 or $13.20, determined by the number of claims that a pharmacy processes. It is noted that the volume of claims is set at 90,000. Each local pharmacy has its own NPI number. With pharmacy chains, it is not clear if the number of claims processed is determined at the national level or local level. Thus, the amount the chain pharmacy is entitled to may either be $10.05 or $13.20, depending on if the number of claims processed is less than/more than 90,000.

There is an added concern that the pharmacies on the list may continually change, thereby creating a burden to consistently confirm the correct dispensing fee is being billed.

# Recommendation:

State Fund recommends use of a flat rate for the dispensing fee instead of a tiered structure for the dispensing fee that is based upon the volume of claims a pharmacy processes.

If a tiered dispensing fee is used, State Fund seeks clarification as to how the tiered dispensing fee is determined with pharmacy chains. The proposed regulation does not specify if the dispensing fee is determined by pharmacy location or the combined/aggregate locations within the pharmacy chains. In addition, clarity is needed as to how often the list of pharmacies showing less than or more than 90,000 prescriptions processed annually will be updated and how this information will be shared. As such, State Fund recommends the provision of a link to the Medi-Cal dispensing fee that is applicable to the date the drug is dispensed.

# Section 9789.40.2 Compounded Pharmaceuticals Dispensed By a Pharmacy on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL

**Discussion:**

In this section, the professional dispensing fee has also changed to a two-tiered dispensing fee structure. Please refer to our comments made above under Section 9789.40.1.

# Recommendation:

Please refer to our comments made above under Section 9789.40.1 whereby State Fund recommends a flat rate be used, provision of a link to the Medi-Cal dispensing fee be provided, and clarification be provided as to how the tiered dispensing fee is determined with pharmacy chains.

# Section 9789.40.3 Miscellaneous Provisions - Pharmaceuticals Dispensed By a Pharmacy on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].

**Discussion:**

Here, this section applies the regulations to pharmaceuticals dispensed through mail order pharmacies. It is not clear if California’s fee schedule applies to mail order pharmacies located out of state when medications are dispensed to injured workers residing outside of California.

# Recommendation:

State Fund requests clarification as to whether California’s fee schedule will apply to mail order pharmacies located out of state when medications are provided to injured workers residing outside of California.

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## Alexso Inc. June 30, 2020

Thank you for notifying our industry that you have created a forum to comment and give feedback to the DWC with regards to Formulary and the Pharmaceutical Schedule Fee. Our company Alexso, Inc. is a manufacturer of specialty products designed to help patients with pain management concerns without having to resort to opiate based therapies.

Alexso Inc. has several products which we feel should be listed on the DWC formulary. This will allow physicians to have more options as well as an alternate path to pain management without resorting to opiate based therapies. We offer many unique products and three of them are detailed in the addendum; these products are listed on DailyMed and with the pricing companies such as First Data Bank and MediSpan.

**Addendum I.** Lidocaine and Tetracaine 7%/7% Cream.

*NDC No. 69420-3077-1*

**Addendum II.** Terocin™ Patch (Lidocaine 4% and Menthol 4% Topical Patch)

*NDC No. 50488-1001-1*

**Addendum III.** Zingo™ 0.5 mg (Lidocaine HCl Monohydrate) Powder Intradermal Injection System

*NDC No. 70645-123-12*

**[Note: Addendums I through III available upon request.]**

Alexso, prides itself on finding alternative choices for conventional opioid therapies. Our products have a proven success with our customer base and the challenges for dispensing these products has been finding available coverage options.

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## Stacy L. Jones, June 30, 2020

Senior Research Associate

California Workers’ Compensation Institute

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

**Recommendation:**

# Section 9789.13.2 Physician-Administered Drugs, Biologicals, Vaccines, Blood Products.

(a) Physician-administered drugs, biologicals, vaccines, or blood products are separately payable.

(1) Vaccines shall be reported using the NDC and CPT-codes for the vaccine. Other physician-administered drugs, biological and blood products shall be reported using the NDC and HCPCS Level II code assigned to the product.

(2) The maximum reimbursement shall be determined using the “Basic Rate” for the HCPCS code contained on the Medi-Cal Rates file for the date of service. The Medi-Cal fee schedule reimburses drug products, vaccines and immunizations at the Medicare rate of reimbursement when established and published by the Centers for Medicare & Medicaid Services (CMS) or the ~~Medi-Cal~~ ~~pharmacy~~ Pharmaceutical Fee Schedule rate of reimbursement when the Medicare rate is not available. The Medicare rate is currently defined as average sales price (ASP) plus 6 percent. ~~The Medi-Cal pharmacy rate has been defined as the lower of (1) the average wholesale price (AWP) minus 17 percent; (2) the federal upper limit (FUL); or (3) the maximum allowable ingredient cost (MAIC). Pursuant to the Medi-Cal State Plan Amendment 17-002, the Medi-Cal pharmacy drug ingredient cost is modified to be defined as the lower of (1) National Average Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC) if a NADAC price does not exist, (2) Federal Upper Limit (FUL), or (3) the Maximum Allowable Ingredient Cost (MAIC). The modified drug ingredient cost will be implemented for workers’ compensation prospectively as set forth in sections 9789.40.4 and 9789.40.5 for pharmaceutical products dispensed on or after XXX XX, 2020 [60 days after the amendments are filed with the Secretary of State. Date to be inserted by OAL].~~

(3) The “Basic Rate” price listed on the Medi-Cal rates page of the Medi-Cal website for each physician-administered drug includes an injection administration fee of $4.46. This injection administration fee should be subtracted from the published rate because payment for the injection administration fee will be determined under the physician fee schedule. See section 9789.19 for a link to the Department of Health Care Services’ Medi-Cal rates file.

(4) For a physician-administered drug, biological, vaccine or blood product not contained in the Medi-Cal Rates file referenced in subdivision (a)(2), the maximum reimbursement is the amount prescribed in the Pharmaceutical Fee Schedule applicable to physicians as adopted by the Division of Workers’ Compensation in sections 9789.40, 9789.40.4, or 9789.40.5 and posted on the Division website as the Pharmaceutical Fee Schedule. See section 9789.19 for a link to the Division of Workers’ Compensation Pharmaceutical Fee Schedule.

**Discussion:**

*The proposed language in §9789.13.2 is confusing as written. The Institute recommends removing the date defined explanations of the Medi-Cal reimbursement methodology. Reference to the Pharmaceutical Fee Schedule, which is further clarified under subdivision (4) provides greater clarity for physician-administered drugs that are not included in the Medicare ASP rate files.*

**Recommendation:**

Add a list of definitions to section §9789.40.1 to include unfamiliar terms: Legend and Non-Legend, Unfinished Drug Products.

**Discussion:**

*The Institute recommends the addition of definitions for terms that may be unfamiliar to industry stakeholders who must understand Pharmaceutical Fee Schedule coverage and requirements.*

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## Kim Stone June 29, 2020

I write on behalf of the California Orthopaedic Association (COA) regarding proposed revisions to the Pharmaceutical Fee Schedule, posted June 15, 2020 with comments due before July 3, 2020. COA urges you to delete one sentence at the top of page 10: (e) A dispensing fee is not payable for a drug dispensed by a physician.

Eliminating dispensing fees for physicians who dispense medications to their patients is not justified and is not smart public policy. This change will likely result in injured workers experiencing delays in getting access to needed medications.

The DWC background information provided as justification for the revisions to the Pharmaceutical Fee Schedule Revision states that the changes are consistent with Medi-Cal payment system changes. But we do not see where Medi-Cal has changed their policy of allowing a physician dispensing fee. The document cited by DWC addresses “pharmacy dispensing” and “physician administered medications,” but not “physician dispensed” medications. If we have overlooked some change in the Medi-Cal Pharmacy program to support the elimination of the physician dispensing fee, please send us the documentation.

Since, it seems that the Medi-Cal program continues to allow physicians to bill a dispensing fee, we believe the Division should follow their policy and;also, continue the physician dispensing fee for physician dispensed medications in the Workers’ Compensation program.

There are a host of reasons why it may be in the patient’s best interest for the physician to dispense the medicine – perhaps it needs to be taken immediately, or perhaps there are not pharmacies nearby, or perhaps the patient is injured or infirm and additional appointments are unwise, or perhaps the inconvenience of going to a pharmacy makes taking the needed medicine less likely.

We therefore urge you to remove the prohibition on dispensing fees by physicians.