

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
9789.40.1(a)(2) (A) and (B)	Commenter notes that the division has proposed a two-tiered dispensing fee structure of either \$10.05 or \$13.20, based upon the pharmacy's volume of claims processed. Commenter questions if this two-tiered dispensing fee structure applies to out of state pharmacies. Clarity is needed to avoid possible disputes over different interpretations regarding applicability of this fee structure and the designated rate for out of state pharmacies.	Andrea Guzman Claims Regulatory Director, State Compensation Insurance Fund (SCIF) April 11, 2024 Written Comment	Disagree. The regulations are clear that the two-tier dispensing fee is based upon the Medi-Cal NPI file. The status of a pharmacy as out of state is not relevant to appearance on the NPI list.	No action necessary.
Sample Medi-Cal National Provider Identifier (NPI) File	Commenter notes that the sample NPI file provided shows data specifying the effective dates for when and which pharmacies are eligible for the higher dispensing fee. The 10-digit NPA number represents the dispensing pharmacy location. Enhancing the data list to provide the pharmacy's name and address helps ease the review of the data and ensure proper dispensing.	Andrea Guzman Claims Regulatory Director, State Compensation Insurance Fund (SCIF) April 11, 2024 Written Comment	Disagree. The Medi-Cal NPI files transmitted to DWC do not contain the pharmacy name and address. The NPI is the identifier which will appear on the bill transmitted to the payer; this is sufficient for determination of entitlement to the higher dispensing fee.	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	Commenter states that it is unclear how frequent updates will be made to the data list because the information is fluid, impacting the dispensing process. Commenter seeks clarification and guidance.		Agree that clarification would be useful.	The proposal is modified to add a new section 9789.40.1 which addresses the frequency of NPI file updates, and provides guidance on effective date of changes to the file and issues of retroactivity.
General Comment	Commenter would like to thank the DWC or the effort made toward the implementation of these proposed regulations.	Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Oral Comment	DWC notes the support.	No action necessary.
9789.40	Commenter notes that this section provides for the reimbursement of pharmaceuticals dispensed prior to the effective date of this proposed new rule. Commenter supports the continued use of the current fee schedule based on the	Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024	DWC notes the support for this provision.	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	3/8/2019 Medi-Cal pharmacy data file until the proposed changes are finalized and adopted.	Written and Oral Comment		
9789.40.1	Commenter has concerns about the use of the updated Medi-Cal reimbursement methodology and states that there is a vast difference in the process for dispensing prescription drugs to a Medi-Cal patient versus the process of dispensing prescription drugs to an injured worker covered under the California workers' compensation system. In Medi-Cal coverage and eligibility are predetermined and there is little to no transactional friction in the process. In the workers' compensation system, during the early stages of a claim, the injured worker seeking medication does not typically know which insurance carrier covers their claim, if their employer is self-insured, or whether or not their injury will be deemed compensable and	Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment	The California State Legislature determined that the Medi-Cal methodology is appropriate for workers' compensation. DWC must implement the statutory directive of Labor Code §5307.1. Also, although there may be additional friction for a workers' compensation patient in some cases, commenter overstates the uncertainties and financial risk. Labor Code §4600 requires the employer to provide all reasonable and necessary medical care, including pharmaceuticals, to the	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>therefore covered by the workers' compensation insurance policy. This creates a financial risk that doesn't exist for regular Medi-Cal patients and requires additional work to be done by the pharmacy, a pharmacy benefits manager (PBM), or a pharmacy benefits network (PBN). The proposed two tiered-fee reimbursement is based on the acquisition cost of the prescription medication and doesn't compensate for the additional financial risk, administrative work and clinical evaluation requirements related to a workers' compensation claim.</p> <p>Commenter states that current "in-network" reimbursements for medications in California have already been reduced below the fee schedule amount under existing rule due to competitive pressures and that currently many PBMs will not offer services in California. Commenter opines that</p>		<p>injured worker. Prior to the deadline to accept or reject the case, the employer must authorize medical treatment up to \$10,000 as required by Labor Code §5402, subdivision (c):</p> <p>"(c) Within one working day after an employee files a claim form under Section 5401, the employer shall authorize the provision of all treatment, consistent with Section 5307.27, for the alleged injury and shall continue to provide the treatment until the date that liability for the claim is accepted or rejected. Until the date the claim is accepted or rejected, liability for medical treatment shall be limited to ten</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>this will be aggravated by the new proposed reimbursement regulations.</p> <p>Commenter opines that the low reimbursement may not be enough to incentivize pharmacies to accept workers' compensation claims, creating an access to care issue. Commenter states that there will be a need for some type of administrative or service fee created by the proposed change, and because of this payers will not realize lower net costs.</p>		<p>thousand dollars (\$10,000).”</p> <p>In regard to the assertion that “current “in-network”” reimbursements for medications in California have already been reduced below the fee schedule amount under existing rule due to competitive pressures,” commenter has not presented data to support the assertion. Moreover, Labor Code §5307.1 sets “maximum rates” and does not prohibit reimbursement below fee schedule for “in-network” providers. In particular, Labor Code §5307.1, subdivision (h), and Labor Code §5307.11 both allow parties to contract for</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			"reimbursement rates different from those" in the fee schedule.	
Sample Medi-Cal National Provider Identifier (NPI) File	Commenter is concerned about the timing of the data exchange between Medi-Cal and DWC - will changes be made in real-time or will there be a delay? Commenter would like to know if they will need to go back and reprice payments if there is a delay in updating the information. Commenter suggests adding clarifying language regarding how this will work.	Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment	Agree that clarification would be useful.	The proposal is modified to add a new section 9789.40.1 which addresses the frequency of NPI file updates, and provides guidance on effective date of changes to the file and issues of retroactivity.
9789.40.2	Commenter opines that the additional administrative and clinical services, formulary adherence and other costs associated with a workers' compensation claim are not reflected in the Medi-Cal reimbursement structure and questions if the low reimbursement will cause pharmacies to stop preparing compounds for injured	Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment	The Labor Code specifies that Medi-Cal is the benchmark for compounded drugs. For pharmacies, Labor Code §5307.1 states in part: "The ingredient-level reimbursement shall be equal to 100 percent of the reimbursement allowed by the Medi-Cal	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	workers creating an access to care problem.		payment system and payment shall be based on the sum of the allowable fee for each ingredient plus a dispensing fee equal to the dispensing fee allowed by the Medi-Cal payment systems.”	
9789.40.2 (g)	<p>Commenter supports the inclusion of subsection (g) that would disallow reimbursement for a compound that is a copy of a commercially available product. Commenter notes that this is an area prone to fraud and abuse and that this will help to minimize that risk.</p> <p>In order to reinforce the drug formulary rule requiring compound to be prior authorized, commenter recommends the addition of the following language as subsection (h):</p>	<p>Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment</p>	<p>DWC notes the support for subdivision (g). This provision is proposed in light of the U.S. Food and Drug Administration restrictions on making drugs that are essentially copies of a commercially available drug product. See the Initial Statement of Reasons, page 14.</p> <p>Disagree. The Pharmaceutical Fee Schedule sets the maximum fees for pharmaceuticals pursuant to the Labor</p>	<p>No action necessary.</p> <p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>“Compounded medications that did not receive prior authorization in compliance with 9792.27.9 will not be reimbursed.”</p>		<p>Code §5307.1, but the effect of not obtaining prospective authorization are impacted by non-fee schedule statutes and regulations. Labor Code §4600, subdivision (a) provides that medical treatment “that is reasonably required to cure or relieve the injured worker from the effects of the worker’s injury shall be provided by the employer.” The process for obtaining prospective authorization and the permissibility of retrospective review are governed by the utilization review statute (Labor Code §4610) and implementing regulations.</p>	
9789.40.4	Regarding the miscellaneous provisions related to mail-order	Brian Allen	Labor Code §5307.1 specifies that Medi-Cal	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	pharmacy and drugs not in the data file, commenter states they have the same concerns about the low reimbursement as he outlined in his comments regarding section 9789.40.1.	Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment	be used to benchmark drug prices. Following Medi-Cal rules there is no distinction between fees to a mail order pharmacy and a “brick and mortar pharmacy.”	
9789.40.5	In order to reinforce the prospective review requirement in the formulary rule, commenter recommends the addition of a new subsection (j) to state: “Pharmaceuticals dispensed by a physician that did not receive prior authorization in compliance with 9792.27.8 will not be reimbursed.”	Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment	Disagree. Labor Code §4600, subdivision (a) provides that medical treatment “that is reasonably required to cure or relieve the injured worker from the effects of the worker’s injury shall be provided by the employer.” The process for obtaining prior authorization is governed by the utilization review statute (Labor Code §4610) and implementing regulations. The medical necessity of a	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			medication that did not receive prospective authorization can be reviewed on retrospective review.	
9789.40.6	<p>In order to reinforce the prospective review requirement in the formulary rule, commenter recommends the addition of a new subsection (j) to state:</p> <p>“Compounded pharmaceuticals dispensed by a physician that did not receive prior authorization in compliance with 9792.27.8 will not be reimbursed.”</p>	<p>Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment</p>	<p>Disagree. Labor Code §4600, subdivision (a) provides that medical treatment “that is reasonably required to cure or relieve the injured worker from the effects of the worker’s injury shall be provided by the employer.” The process for obtaining prior authorization is governed by the utilization review statute (Labor Code §4610) and implementing regulations. The medical necessity of a medication that did not receive prospective</p>	<p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			authorization can be reviewed on retrospective review.	
9789.111	<p>Commenter recommends changing the proposed effective date of this new fee schedule from 90 days to 180 days after the amendments are filed by the Secretary of State.</p> <p>Commenter states that the proposed fee schedule is a significant departure from the way reimbursement is being done today and that 90 days is not a commercially reasonable amount of time to adequately program and test systems to adjust to the various changes, including the newly introduced tiered dispensing fee. PBMs and PBNs will need to work with their customers to develop an administrative or servicing fee to cover services currently being provided to payers in California related to formulary</p>	<p>Brian Allen Vice President Government Affairs, Enlyte Pharmacy Solutions April 11, 2024 Written and Oral Comment</p>	<p>Agree in part. DWC agrees insofar as it would be appropriate to allow 180 days for implementation in light of the system changes that will be needed.</p>	<p>Modify proposal to provide an effective date of the first day of the month following 180 days after the regulation is filed with the Secretary of State, rather than 90 days after the regulations are filed with the Secretary of State.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	adherence management, clinical services, billing and reporting, and other tools.			
9789.40.5(f)	<p>Commenter recommends that the Division continue to allow physicians to bill the existing in-office dispensing fee.</p> <p>If DWC concerned about potential for over-prescribing when a physician is dispensing in-office medication as noted in the Mercer Study, would support limiting the number of in-office medications that could be dispensed on any one visit to 3 prescriptions.</p> <p>Concerns: 1) The AMA CPT rules on billing Evaluation & Management codes published in the CPT Book, have no reference to the inclusion of the cost of dispensing medication in an E&M service. Professional service of evaluating the patient and deciding that a medication is</p>	<p>Diane Przepiorski Executive Director California Orthopaedic Association (COA) April 11, 2024 Written Comment</p>	<p>Agree in part. DWC has considered the contention that physician dispensed medications warrant a dispensing fee. Medi-Cal does not pay a physician to dispense medications, and therefore also does not pay physicians a dispensing fee. Similarly, Business and Professions Code §§ 4183 and 4193 provide that the specified clinics are not eligible for a dispensing fee under the Medi-Cal program. Changes made to Labor Code section 5307.1 (and the enacting bill's legislative intent section) indicate that the</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>medically needed is included in E&M service, but not the cost to dispense the medication.</p> <p>2) Eliminating in-office dispensing may lead to access problems. DWC should recall problems that injured workers had in obtaining needed medications in the past. Pharmacies required injured workers to pay upfront for the medications and wait to get reimbursed. Injured workers would come to their physician follow-up visits, not yet being able to obtain their prescriptions either because of the upfront costs or their inability to travel or to even find a pharmacy who would dispense medications to injured workers with the upfront payment. Should diverge from the Medi-Cal dispensing rules.</p> <p>3) Commenter states that if the injured worker can get their medications from their physician,</p>		<p>legislature was concerned about inappropriate dispensing by physicians and created additional rules to govern reimbursement for physician dispensed medication, such as the caps set forth in subdivision (e). Research studies cited in the ISOR Indicate that financial incentives may sometimes skew drug selection and physician dispensing patterns. DWC is aware that physician dispensing may provide a convenience to injured workers and facilitate the early initiation of treatment. Although the employer is required by Labor Code section 5402, subdivision (c), to authorize treatment</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>these barriers for injured workers are minimized. However, there is a cost for a physician to maintain records on medication in their drug closets and dispense the medications, just like there is a cost for a pharmacy or other entities to dispense medications.</p>		<p>within one working day of the filing of a claim form, and pay up to \$10,000 in treatment prior to determination of liability, these steps may cause delay in obtaining needed pharmaceuticals in some cases. DWC has considered the advantages and disadvantages of providing a dispensing fee to physicians in light of the Business and Professions Code §4170 that allows a physician to dispense to their own patient for a condition they are treating if the specified requirements are met. Labor Code section 5307.1, subdivisions (e)(7) and (e)(8) provide the DWC Administrative Director with additional authority</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			to adopt fee schedule rules specific to physician dispensing. Given this authority, and controls on inappropriate prescribing that address potential abuse (e.g. utilization review, prospective authorization formulary rule, etc.) the DWC has determined that on balance the considerations favor a dispensing fee for physician dispensed drugs. For clarity the maximum allowable dispensing fee of \$10.05 is set forth in the regulation; this is the default dispensing fee except where the entity dispensing is a pharmacy whose NPI is listed on the Medi-Cal	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			NPI file applicable to the date of service.	
9789.40.5(f)	<p>Commenter opines that by removing the dispensing fee, it will effectively eliminate physician dispensing in California. Commenter notes that California's fee schedule is already based upon the acquisition cost only of the medication being dispensed. The dispensing fee covers the additional costs incurred in the dispensing process. Without this fee, the cost to acquire and dispense will exceed the fee scheduled reimbursement. This is true for both medications dispensed by a physician or a pharmacy; however, while the physician fee is being eliminated, the pharmacy fee is being increased.</p> <p>In the ISOR, the Administrative Director has determined that the professional dispensing fee paid</p>	<p>Frank Juliano PharmD Vice President, St. Mary's Managed Pharmacy Programs April 11, 2024 Written and Oral Comment</p>	<p>Agree in part, insofar as DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies listed on the Medi-Cal NPI file</i>. See response above to the written comment submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>by Medi-Cal is not warranted when a physician dispenses a drug to their work comp patient. The reasoning is that the fee for doing so is included in the physician's office visit fee and is covered by the E&M code for the office visit. This is incorrect -- the E&M fee that is paid to a physician is a reimbursement for making the decision to prescribe the medication and is not a reimbursement for the actual process of dispensing.</p> <p>Commenter provides a chart illustrating the cost for the dispensing process for both a pharmacy and for a physician [available by request].</p> <p>The process to obtain medications for both a pharmacy or a clinic is essentially the same.</p> <p>Late last year, CA signed into law Assembly Bill 1286 aimed at promoting patient safety when</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>filling their scripts at a retail pharmacy. In part, this bill arose from a survey by the CA Board of Pharmacy showing that 91% of retail pharmacists reported insufficient staffing to ensure safe patient care and 83% reported a lack of sufficient time to provide safe patient consultation. By eliminating the dispensing fee for physicians, workers' comp clinics, instead of dispensing, will send injured workers to these understaffed retail pharmacies. Commenter does not understand the driving reason for doing this when the Division has controlled all the possible variables surrounding prescription management.</p> <p>Commenter notes that in the ISOR, the Administrative Director suggests that physician dispensing may be influenced by financial incentives. There have been studies that support this</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>suggestion; however, the influence is not the dispensing fee (currently \$7.25 per prescription – proposed to increase to \$10.05/\$13.20) but the influence is business and providers finding loopholes in the reimbursement methodology, choosing medications not listed on the Medi-Cal schedule with exorbitant AWP's. The proposed regulations, and the updating of the Medi-Cal database will close those loopholes and he supports those changes.</p> <p>Eliminating the physician dispensing fee will do nothing to reduce costs as these prescriptions will instead:</p> <ul style="list-style-type: none"> • Be filled at a retail pharmacy, which WCRI data has shown is more expensive and will be more expensive with the proposed rates for pharmacy dispensing. • Not be filled at all. Studies have consistently shown 20- 			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>30% of prescriptions written for retail dispensing are not filled. Not filling a prescription can be directly related to prolonging claim duration and increasing claim cost.</p> <p>Commenter recommends that the Division allow for the lower of the two proposed dispensing fees be allowed for physician dispensed pharmaceuticals.</p>			
9789.40.5(f) and Initial Statement of Reasons	<p>Commenter opines that the Medi-Cal professional dispensing fee should be maintained for physician dispensed drugs and should follow the same requirements as for pharmacy dispensed drugs as defined in Section 9789.40.1 of the proposed amendment.</p> <p>Commenter does not agree with the statement on page 22 of the Initial Statement of Reasons that “Many of the tasks involved in dispensing a drug to a patient are already included in the physician’s</p>	<p>Greg M. Gilbert Executive Vice President – Concentra March 11, 2024 Written Comment</p> <p>Tim Madden Concentra March 11, 2024 Oral Comment</p>	<p>Agree in part, insofar as DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies listed on the Medi-Cal NPI file</i>. See response above to the written comment submitted by Diane</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.40.1.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>reimbursement". This is not accurate. The Evaluation and Management (E&M) fee for a patient encounter (codes 99202-99215) only includes the work value associated with the management of the medication regarding the decision to prescribe. It does not address the cost and value of actual medication dispensing.</p> <p>Commenter states that the value of the dispensing itself is not part of Prescription Drug Management, the industry standard is that the E&M MDM component is strictly intended for the physician to assess the patient's medication needs and determine the action to take, nothing more. The MGMA Guidance for Prescription Drug Management states:</p> <p>Prescription drug management is based on documented evidence that the provider has evaluated the patient's medications as part of a</p>		Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>service. This may be a prescription being written or discontinued or the decision to maintain a current medication/dosage.</p> <ul style="list-style-type: none"> • Simply listing current medications is not considered prescription drug management. • Prescription drug management differs from "drug therapy requiring intensive monitoring for toxicity." <p>The American Medical Association (AMA) Guidance for Prescription Drug Management on their website states:</p> <p>"Appropriate documentation of prescription drug management continues to be an opportunity for many physicians. Doctors need to know that simply adding the current medication list to the progress note is not adequate.</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Prescription drug management is based on documented evidence that the physician has evaluated medications as part of a service that is provided. Physicians should make a direct connection between the medication that is prescribed to the patient and the work that was performed on the day of the clinic visit. Simply stating that the medication list was reviewed will not meet the definition of prescription management. The American Academy of Professional Coders (AAPC) as well as the American Health Information Management Association (AHIMA) also apply this same guideline to the Medical Decision Making component of the E&M service.”</p> <p>Commenter states that it is clear that the cost and work value of in office physician dispensing is not included in the Evaluation and Management medical decision making for Prescription Drug</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Management and should therefore be continued to be paid to a Physician dispensing in the same manner as a pharmacist dispensing.</p> <p>The Medi-Cal professional dispensing fee is defined in Section 14105.45 (a)(12) of the California Welfare and Institutions code to have the same meaning as defined in 42 CFR 447.502 of the Code of Federal Regulations. This meaning includes the overhead associated with dispensing (procurement and inventory management), preferred drug formulary (MTUS) review, patient drug utilization review, patient counseling on how to take the medication and any side effects. None of these tasks are included as part of the E&M fee. All of these tasks are performed by his organization's physicians when dispensing a prescription medication.</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Commenter states that the steps that need to be taken to dispense a prescription medication to a patient largely follow the same path and work value, regardless of whether it is done in a clinic by a physician or a pharmacy by the pharmacist. Furthermore, CA Labor Code Section 5307.1, which is the authority for establishing the workers comp pharmacy fee schedule, does not differentiate between pharmacies and physician dispensing. It states that "Pharmacy services and drugs shall be subject to the requirements of this section, whether furnished through a pharmacy or dispensed directly by the practitioner pursuant to subdivision (b) of Section 4024 of the Business and Professions Code." In addition to the reimbursement issue, eliminating the dispensing fee for physician dispensed medications is contrary to the requirements of California</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Labor Code Section 5307.1(f) which states that “Within the limits provided by this section, the rates or fees established shall be adequate to ensure a reasonable standard of services and care for injured employees.”</p> <p>In 2023, commenter’s organization dispensed almost 200,000 medications from its California clinics, charging payors the same amount as if these same medications were dispensed and billed from a retail pharmacy. The following shows two commonly prescribed medications for occupational injuries and the different reimbursement rates for physicians and pharmacies, as proposed by these regulations.</p> <p>[Chart available upon request.] Commenter shows examples of two drugs that would have higher total costs when dispensed at a</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>pharmacy due to the dispensing fee differential.</p> <p>Physician clinics would have to cease dispensing due to the financial losses created by the proposed fee schedule.</p> <p>If clinics stop dispensing, the standard of services and care for injured employees will be negatively impacted for the following reasons:</p> <ul style="list-style-type: none"> • Medication adherence is essential to lowering the overall cost of care and returning the injured worker to work. An 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. • The proposed regulations would shift his organization's in-office dispensing, along with 			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>most other workers' compensation physician dispensing, to retail pharmacies which are already understaffed and overworked. Commenter cites to a survey by the CA Board of Pharmacy.</p> <ul style="list-style-type: none"> • Patient adherence has been shown to be better when a physician dispenses medications. In a 2014 report by CVS Pharmacy on medication adherence, they cite a statistic that up to a third of all prescriptions are never filled and furthermore, they report that the relative influence of prescribers on medication adherence is 34% vs. pharmacists at 26%. • Pharmacies require payment for medications up front. Injured workers, particularly those newly injured without an approved workers' comp claim, may not be able to afford to pay for the medications. Our 			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>clinics will dispense the medications assuming risk that the claim may not be accepted.</p> <ul style="list-style-type: none"> • If the injured worker cannot afford to pay for medications out of pocket, they will simply go to the emergency rooms which are already overcrowded. • There can be significant language barriers at pharmacies. • Many injured workers will need to coordinate transportation to the pharmacy which can result in delay in filling a prescription. <p>For the reasons outlined above, this will lead to injured workers either delaying taking their medications or not filling their prescription at all, prolonging the workers' injuries and further delaying their return to work, increasing costs which will exceed any cost savings from the currently proposed regulations.</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>California has implemented significant controls on workers' compensation medications over the last several years such as the MTUS medication formulary, RFA requirements and treatment guidelines that control for medical necessity and overutilization of medications. In addition, the proposed regulation closes the loophole related to pricing of medications not in the current fee schedule, which he supports. With these controls, coupled with the lowest medication fee schedule in the nation, we question the need to make additional changes that will hamper the ability for California injured workers to receive timely and appropriate medications at the time of treatment.</p> <p>There is no reasonable and defensible argument to remove the dispensing fee only for physician dispensed medications. The proposed regulations will only</p>			

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	amplify the already existing issues with proper and timely patient care without providing any cost savings to California employers.			
9789.40.5(f)	<p>Commenter is concerned regarding the Division’s proposal to cut the physician dispensing fees for each patient. Commenter opines that creating further cuts to an already laborious and labyrinthian workers’ compensation system will force clinics to stop dispensing and create further hurdles for injured workers, including:</p> <ul style="list-style-type: none"> • Making it more challenging for physicians to ensure adherence to prescriptions by filling prescriptions at the practice • Overburdening already-overburdened retail pharmacies facing staff shortages • Forcing injured workers to pay for medications upfront; clinics 	<p>Ian Stine, MD President Tri-Valley Orthopedic Specialists, Inc. April 9, 2024 Written Comment</p>	<p>Agree in part, insofar as DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies listed on the Medi-Cal NPI file</i>. See response above to the written comment submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>dispense without payment and assume the risk of claim denial</p> <ul style="list-style-type: none"> • Overburdening emergency rooms, where injured workers who cannot afford medications may go to receive medications • Subjecting injured workers to language barriers, which is a more common problem for pharmacies than clinics • Imposing extra transportation needs on injured workers who must visit a pharmacy <p>Commenter requests that the DWC reconsider this decision.</p>			
9789.40.5(f)	<p>Commenter requests that DWC reconsider its proposal to cut the fee for dispensing medications at clinics such as his own. Commenter states that his fee is crucial for ensuring injured workers have timely and easy access to the medication that they need to make a safe and speedy recovery.</p>	<p>James Petros, MD CEO, Allied Pain & Spine Institute April 10, 2024 Written Comment</p>	<p>Agree in part, insofar as DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies</i></p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Eliminating this fee would effectively eliminate medication dispensing services at clinics altogether which would create significant and unnecessary hardships for injured workers, already navigating the complexities of the workers' compensation system. Potential consequences:</p> <ul style="list-style-type: none"> • Reduced Medication Adherence. • Strained Pharmacies: Filling prescriptions for injured workers would further burden already strained retail pharmacies facing staff shortages. • Financial Burden: Injured workers may be forced to pay for medications upfront, a significant burden they often cannot afford. Clinics currently absorb this cost. • Emergency room Overload: Workers unable to afford medications may turn to emergency rooms. 		<p><i>listed on the Medi-Cal NPI file.</i> See response above to the written comment submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<ul style="list-style-type: none"> • Language Barriers: Injured workers with language barriers may face greater difficulty navigating pharmacies compared to clinics with on-site interpreters. • Increased Transportation Needs: Workers would need to visit both clinic and pharmacy. <p>Maintaining the current dispensing fee is vital for injured workers' well-being and a streamlined workers' compensation system and he urges the DWC to reconsider this proposal.</p>			
General Comment	Commenter is not supportive of the overall proposed changes because he opines that a Medi-Cal based reimbursement formula and process do not fit the patient profile or processes of providing pharmacy services to injured workers. However, he does recognize that DWC is forced by	Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum Workers' Compensation April 11, 2024 Written Comment	DWC notes commenter's acknowledgment of the statutory directive for the use of Medi-Cal in the workers' compensation pharmaceutical fee system.	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	statute to implement these changes.			
Clarification of effective dates of data files	<p>Commenter supports the clear demarcation on responsibly managing claims for pharmacy services prior to and after implementation of final rule language. Language in the proposed regulations provide stakeholders with a simple and precise answer as to application of the existing fee schedule for all pharmacy claims with a date of service before rule implementation and the proposed fee schedule for dates of service after rule implementation.</p> <p>Commenter has the following questions specific to date of service and fee schedule application:</p> <p>1. Is DWC's intention to include the current "frozen" calculation feed/file, currently available on the</p>	Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum Workers' Compensation April 11, 2024 Written Comment	<p>DWC notes the support for this provision.</p> <p>DWC responds as follows:</p> <p>1. There is no intention to merge the old file with the new Pharmaceutical Fee Data File. The sample data file provided</p>	<p>No action necessary.</p> <p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>website, within the new <i>Pharmaceutical Fee Data File</i> from Medi-Cal or will there be two separate feeds/files?</p> <p>2. Will the “frozen” fee schedule calculation feed/file, currently available on the DWC website, remain available for proper calculation of prescriptions with dates of service prior to rule implementation?</p> <p>3. How long does the DWC intend to continue providing the existing “frozen” calculation feed/file?</p>		<p>with the Notice of Proposed Rulemaking evidences the structure of the new files.</p> <p>2. The proposed language in section 9789.40 provides that the “frozen” data file will be made available on the DWC OMFS webpage or successor webpage.</p> <p>3. DWC will continue to provide the existing “frozen” calculation feed/file as long as it appears to be in use by the public. In the event that it is moved to an archive, DWC will make it available upon request.</p>	
Implementation Time Frame	<p>Commenter is concerned over the proposed effective date. In numerous segments throughout the proposed regulations, language indicates the effective date shall be “90 days after the</p>	<p>Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum Workers’ Compensation</p>	<p>Agree in part. DWC agrees insofar as it would be appropriate to allow 180 days for implementation in light of</p>	<p>Modify proposal to provide an effective date of the first day of the month following 180 days after the regulation</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p><i>amendments are filed with the Secretary of State.</i>” Given the complexity of these regulatory changes, intricacy of implementing unique feeds from a state agency into point-of-sale pharmacy processing, billing, bill review and reimbursement systems, a 90-day timeline is unattainable for his company and other stakeholders. As presently crafted, the effective date could be as early as 8/26/2024, given 45 days from the public hearing to adoption and publication by the Secretary of State.</p> <p>Commenter opposes adoption of these regulations; however, he desires to fully comply with all regulatory requirements and ensure continued provision of pharmacy care to injured workers. To do so will require system development, adopting the <i>Pharmaceutical Fee Data File</i> and <i>Pharmacy NPI</i> feeds into their</p>	<p>April 11, 2024 Written Comment</p>	<p>the system changes that will be needed.</p>	<p>is filed with the Secretary of State, rather than 90 days after the regulations are filed with the Secretary of State.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>system(s) and adapting their system(s) to accept and properly utilize the data included in these feeds. This requires system development and programming, testing, and compliance verification upon completion of all development. In discussion with their IT department this will require a minimum of six months' time.</p> <p>Commenter respectfully requests the Division to amend the proposed rule language, where applicable, to state: <i>“180 days after the amendments are filed with the Secretary of State; date to be inserted by OAL.”</i></p>			
Pharmaceutical Fee Data File Feed	<p>Commenter is concerned over implementation and regulatorily prescribed utilization of a Medicaid based reimbursement basis. Medi-Cal provides coverage for a specific category of patients who utilize pharmacy therapy vastly different than injured workers. A</p>	<p>Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum Workers' Compensation April 11, 2024 Written Comment</p>	<p>Disagree with commenter's objection to use of Medi-Cal as a benchmark for the workers' compensation Pharmaceutical Fee Schedule. The California State Legislature</p>	<p>The proposal is modified to add a new section 9789.40.1 which:</p> <ul style="list-style-type: none"> • addresses the frequency of the issuance of the Pharmaceutical

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Medicaid patient population does not synchronize with the patient population found within workers' compensation. Additionally, workers' compensation is a multi-faceted program with many layers of system participants, payers, insurers/employer, PBMs and bill review entities. A single-source/single-payer system is not a suitable match for a multi-faceted system. Finally, the proposed fee schedule is another in a series of reimbursement reductions imposed upon workers' compensation providers simply due to statutory language passed in 2003. These continued reductions have been implemented without any true review or study of their impact on injured workers and pharmacy providers or if they support current marketplace realities of the workers' compensation system.</p>		<p>determined that the Medi-Cal methodology is appropriate for workers' compensation. DWC must implement the statutory directive of Labor Code §5307.1.</p> <p>Agree in part with comments requesting clarification of some of the provisions. Responses to commenter's specific questions: 1) The Pharmaceutical Fee Data File and National Provider Identifier File will be updated weekly. It should be noted that, until the fee schedule was frozen due to lack of Medi-Cal files based on the old methodology, DWC posted updated maximum fee files on a</p>	<p>Fee Data File and NPI file updates</p> <ul style="list-style-type: none"> • requires payers to begin calculating the maximum fee based on each new file not later than the second calendar day after posting of the file • provides that for retroactive cost changes within the Pharmaceutical Fee Data File or costs used during the implementation period allowed (i.e. use of file by 2nd calendar day after posting), payers shall re-

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Commenter is particularly concerned with required utilization of the Medi-Cal <i>Pharmaceutical Fee Data File</i>. Utilization of this type of feed will be unique in the workers' compensation marketplace and could be problematic. Therefore, clarification is requested:</p> <p>1. How often will the feed be updated? Specifically, what is the expected frequency of <i>Pharmaceutical Fee Data File</i> (feed) update from Medi-Cal that will be passed through by DWC?</p> <p>a. Will the feed be a full file refresh or just updates at each publication?</p> <p>b. Will the feed contain all possible NDCs (in comparison to more commonly used drug databases like Medi-Span) or just a subset?</p> <p>c. Will the feed OTC indicator differ from more commonly used drug</p>		<p><i>weekly basis</i>. Weekly updates will resume once the modified regulations are adopted.</p> <p>a) Full file refresh. The modified proposal specifies that "an updated" file will be posted weekly, and that the updated file must be used to calculate fees no later than the second calendar day after posting. Thus, the text indicates a complete file is posted, not just changes to the file.</p> <p>b) The data used to create the Pharmaceutical Fee Data File is derived from the data files sent by the Medi-Cal contractor; it is a subset of records needed for workers' compensation to adopt rates based on the Medi-</p>	<p>adjudicate previously paid claims to correct the cost used for the date a drug was dispensed upon submission of provider's request for second review</p> <p>The proposal is modified so that all sections allow 180 days between adoption and the effective date of the new rules.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>databases such as Medi-Span? If so, which is the master source?</p> <p>2. What is the expected time frame from adoption/submittal of an updated Medi-Cal feed to required compliant utilization by system stakeholders?</p> <p>3. Will future feed updates as issued by Medi-Cal be exempt from rule-making provisions or will each new/updated feed require future rulemaking?</p> <p>4. Is there a compliance factor in mind for any gap between publication of the feed and subsequent utilization?</p> <ul style="list-style-type: none"> • Note: We envision actual source pricing (example: NADAC pricing) being available from CMS sooner than it becomes incorporated into the Medi-Cal feed. <p>Commenter remains concerned even if they seamlessly implement the feed into their system(s) without, as the DWC indicated</p>		<p>Cal methodology; it is not a complete set of the source price reference compendium.</p> <p>c) The Pharmaceutical Fee Data File OTC indicator is derived from Medi-Cal's reference source as transmitted to DWC by the Medi-Cal contractor.</p> <p>2) Payers will want to load each weekly update into their payment system as soon as possible after posting on the DWC website. To provide a regulatory timeframe to maximize accurate payments, DWC will modify the regulation to set a timeframe for implementing each new file.</p> <p>3) The weekly updates will be posted by DWC;</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>developing their own proprietary systems, there will still be a gap in time between when the feed is published, and full integration and compliance testing is completed by system stakeholders.</p> <p>As to the sample feed(s) provided as part of the proposed rule, commenter requests clarification on the following: Is the sample data file provided by DWC in the rule-making documentation from the most current and complete Medi-Cal <i>Pharmaceutical Fee Data File</i>? In reviewing the sample data feed(s), he uncovered several examples where a NADAC price existed but was not included in the sample feed. Without the full feed, it will be difficult for them to ascertain the fiscal impact to the system as well as produce a valid implementation time frame to share with the Division.</p>		<p>there is no requirement for a rulemaking to update the feed. Labor Code §5307.1(g)(1)(A) states in relevant part: “Notwithstanding any other law, the official medical fee schedule shall be adjusted to conform to any relevant changes in the Medicare and Medi-Cal payment systems no later than 60 days after the effective date of those changes...”</p> <p>Labor Code §5307.1(g)(2) provides that the updates are exempt from the Administrative Procedure Act and the Labor Code section 5307.3 and 5307.4 rulemaking provisions.</p> <p>4) The “compliance factor ... for any gap between publication of</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			<p>the feed and subsequent utilization” will be set forth in the modified proposal. Payers must begin using the updated Pharmaceutical Fee Data File by the 2nd calendar day after posting by DWC. It is true there may be a gap between when CMS publishes a NADAC price and when Medi-Cal incorporates it into the system. This will not impact the payer; the payer does not need to independently gather or program the NADAC, nor Federal Upper Limit, nor Maximum Allowable Ingredient Cost. DWC compiles the prices into the Pharmaceutical Fee Data File and posts it on the DWC website for all system participants to</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			<p>access. This will ensure consistency of prices for all parties. Regarding programming for the new data feed, it is substantially similar in structure to the weekly data fee files in effect from 2004 through February of 2019. Only two new data elements are incorporated: Generic Name and Legend Indicator. In addition, insofar as commenter is expressing concern re adjusting their system, the proposal is modified to allow 180 days for implementation.</p>	
9789.40.1 – Bifurcated Dispensing Fee	<p>Commenter opines that the bifurcated dispensing fees for pharmacies based upon pharmacy transaction volume with Medi-Cal is another hollow and unnecessary</p>	<p>Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum</p>	<p>Agree with commenter in regard to the benefit of providing additional clarification on the frequency of the posting</p>	<p>The proposal is modified to add a new section 9789.40.1 which, <i>inter alia</i>,</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>application of single-payer Medi-Cal program requirements into a multi-payer commercial workers' compensation system. Commenter states that the bifurcated dispensing fee(s) may increase system costs as they will be among the highest dispensing fees for workers' compensation in the nation. Outside of the concern over an increase in system cost(s), commenter seeks clarification of the following two questions:</p> <ol style="list-style-type: none"> 1. How often will the NPI file be published by DWC or available to workers' compensation system stakeholders? 2. Is there a compliance factor in mind for any gap between the publication of the feed and subsequent utilization? <p>Commenter is concerned that even after his organization seamlessly implements the NPI feed into their system(s) without, as the DWC indicated developing their own</p>	<p>Workers' Compensation April 11, 2024 Written Comment</p>	<p>of updated Medi-Cal NPI Files, timeframe to implement each, and issue of retroactivity.</p> <p>Disagree with the contention that DWC should not adopt the Medi-Cal two-tier dispensing fee. The fee schedule statute requires the regulation to follow the Medi-Cal structure. Labor Code § 5307.1 states in pertinent part that for drugs and pharmacy services "...all fees shall be in accordance with the <i>fee-related structure and rules</i> of the relevant ... Medi-Cal payment system..." [Emphasis added.] Also, note that the language regarding compounded drugs indicates the use of the</p>	<p>addresses the frequency of NPI file updates (weekly absent extenuating circumstances) and provides guidance on timeframe to implement changes to the file (by the 2nd calendar day after posting on DWC website) and issues of retroactivity (payer will re-adjudicate upon submission of a request for second review by the provider.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>proprietary systems, there will still be a gap in time between when the feed is published, and full integration and compliance testing is completed by system stakeholders.</p> <p>Commenter recommends that the Division modify the language of Section 9789.40.1, and elsewhere within the proposed regulations to remove any reference of a bifurcated dispensing fee based upon Medi-Cal pharmacy volume and insert language implementing a single dispensing fee for all pharmacies more in line with current workers' compensation dispensing fees found in other states.</p>		<p>Medi-Cal dispensing fee; section 5307.1(e)(2) states the maximum fee is "based on the sum of the allowable fee for each ingredient plus a dispensing fee <i>equal to the dispensing fee allowed by the Medi-Cal payment systems.</i>" [Emphasis added.]</p> <p>Regarding the commenter's opposition based on cost increase, it should be noted that the dispensing fee has been unchanged from \$7.25 since 2004. In addition, the Medi-Cal dispensing fee levels were set chosen by Medi-Cal in light of the Mercer report which analyzed costs in relation to number of prescriptions filled per year.</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			<p>Regarding commenter's assertion of the complexity of a two-tier dispensing fee, it should be noted that beginning in 2004, DWC followed the Medi-Cal system in place at that time which provided an additional \$.75 where the patient is in a nursing home, thus allowing \$7.25, or \$8.00 where the patient is in a nursing home. Thus, the concept of two different dispensing fees is not a novel concept for California workers' compensation.</p> <p>In response to the specific questions: 1) The Medi-Cal NPI file is received from the Medi-Cal vendor on a weekly basis and will be posted weekly on the</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			DWC website for system participants to utilize. 2) Payers will want to load each weekly update into their payment system as soon as possible after posting on the DWC website. To provide a regulatory timeframe to maximize accurate payments, DWC will modify the regulation to set a timeframe for implementing each new Medi-Cal NPI file.	
9789.40.2(c)(2) 9789.40.6(c)(2)	Commenter opines that the language regarding special reimbursement for “ <i>unfinished</i> ” products used in a compound should be simplified. Commenter understands the goal to set reimbursement for these products, which may not be reimbursable by Medi-Cal but could be under workers’ compensation. However,	Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum Workers’ Compensation April 11, 2024 Written Comment	Disagree that the fee schedule should be set at WAC for all unfinished drug products. Since Medi-Cal does not pay for the bulk active pharmaceutical ingredients, they do not have a surveyed price such as NADAC. In	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>since NDCs are required for each compound ingredient, defaulting to WAC as a reimbursement benchmark for these ingredients rather than a percentage of <i>“documented paid cost”</i> may be sufficient and should still have an associated WAC reimbursement rate which should be utilized for standardized reimbursement. Most pharmacies will find providing documentation of their paid costs cumbersome.</p> <p>As the DWC noted in its initial statement of reasons, the NCPDP electronic billing standard(s), used by system stakeholders and adopted by the DWC’s billing regulations, do not include a method to submit documentation, so it is not feasible to require documentation of <i>‘paid cost’</i> at time of bill submittal. Using a standard benchmark may also reduce friction in the system in terms of independent bill review.</p>		<p>order to avoid the possibility of inflated pricing, DWC has determined that documented paid cost plus 10% would provide a reasonable approach. It is true that the standard NCPDP electronic billing standard does not have a mechanism for submitting documentation. However, for pharmacies, the proposed section 9789.40.2 (which will be renumbered 9789.40.3), subdivision (f), does not require submission of documentation with every bill, but rather states: “The pharmacy must submit documentation of paid costs upon request</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Commenter recommends the following amended language:</p> <p>“Where the compounded drug is composed of unfinished drug product(s), the “drug ingredient cost” shall be the WAC of the drug ingredient.”</p> <p>This would also be consistent with proposed Section 9789.40.4(c), which already contains a ‘catch all’ provision defaulting reimbursement for not otherwise specified drugs to the WAC for the drugs NDC.</p>		<p>by the claims administrator.”</p> <p>In contrast, for physicians, documentation must be submitted with the bill as indicated by proposed section 9789.40.6(b) (to be renumbered 9789.40.7(b)), which states in relevant part: “The physician must submit documentation of paid costs and prospective authorization to support a bill for a compounded drug at the time of billing.” For physicians submitting a paper CMS Healthcare Claim Form 1500, documentation is easily transmitted together with the bill. If the physician is submitting an electronic bill using the standard X12 837 Healthcare</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			Claim transaction, there is a mechanism to send the documentation to support the bill electronically.	
9789.40.3	Commenter states that the language in this section, specifically regarding application of a compounding sterility fee(s) and route of administration fee(s), including utilization of the <i>Fee Table</i> , is unnecessary and overly complicated. Commenter opines that these newly proposed fees and utilization of fee table(s) again highlights the dangers of artificially applying Medi-Cal requirements onto the workers' compensation system. Calculation of these additional fees will prove to be cumbersome for the 100's of workers' compensation system stakeholders versus one single payer in the Medi-Cal system. Commenter is concerned that these more complex calculations	Keven C. Tribout Vice President, Public Policy & Regulatory Affairs, Optum Workers' Compensation April 11, 2024 Written Comment	Disagree. The statute requires the regulation to follow the Medi-Cal structure. Labor Code section 5307.1(a) states in pertinent part that for drugs and pharmacy services "...all fees shall be in accordance with the <i>fee-related structure and rules</i> of the relevant ... Medi-Cal payment system..." [Emphasis added.] Commenter expresses concern that "...application of a compounding sterility fee(s) and route of administration fee(s), including utilization of the	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>may also be a future issue of contention between parties in IBR and fee related disputes.</p>		<p><i>Fee Table</i>, is unnecessary and overly complicated” and opposes “[t]hese newly proposed fees and utilization of fee table(s)...” Commenter appears to be unaware of the fact that the compounding fees and sterility fee are currently in effect, based on Medi-Cal Compound Dosage Form, and Route of Administration Table 2024 which has been posted on the DWC website since the year 2004 when the workers’ compensation pharmaceutical fee schedule became tied to Medi-Cal. For clarity the table has been broken into two parts in the current regulatory proposal. However, the</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			compounding and sterility Medi-Cal fees in the proposal are the same fees and structure as applicable in California workers' compensation for over 20 years, since workers' compensation began to be benchmarked to Medi-Cal in the year 2004. Therefore, this is not a new burden on the workers' compensation payers; they should have been paying according to the Medi-Cal system and table as posted by DWC in 2004.	
Multiple sections	Commenter opines that given the complexity and scope of the proposed rule changes, a minimum of six months (or 180 days) is necessary to implement the extensive system changes needed to accommodate these new rules. Typically their members	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs AAPAN April 11, 2024 Written and Oral comment	Agree in part. DWC agrees insofar as it would be appropriate to allow 180 days for implementation in light of the system changes that will be needed.	Modify proposal to provide an effective date of the first day of the month following 180 days after the regulation is filed with the Secretary of State,

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	have been able to implement most changes proposed by DWC within a 90-day timeframe; however, this proposal involves a complete departure from the historical methodology for pricing and paying pharmaceutical bills, so additional lead time is required.			rather than 90 days after the regulations are filed with the Secretary of State.
9789.40.1	<p>Commenter appreciates the efforts that DWC has made to reduce overall system costs but opines that the technological and operational changes necessary to implement a two-tiered dispensing fee are larger than the cost savings recognized.</p> <p>Commenter recommends that the proposed rules should be amended to contain a single dispensing fee, regardless of the operational volume of the pharmacy in question. A single equitable and cost-neutral dispensing fee can be arrived at by performing a high-level analysis to determine how many pharmacies</p>	<p>Lisa Anne Hurt-Forsythe, Vice President, Government Affairs AAPAN April 11, 2024 Written and Oral comment</p>	<p>Disagree with the contention that DWC should adopt a single dispensing fee. The fee schedule statute requires the regulation to follow the Medi-Cal structure. Labor Code section 5307.1 states in pertinent part that for drugs and pharmacy services "...all fees shall be in accordance with the <i>fee-related structure and rules</i> of the relevant ... Medi-Cal payment system..." [Emphasis added.] Also, note that</p>	<p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	fall into each tier today to arrive at a single figure that would likely end up somewhere in the middle between the two tiers suggested.		the language regarding compounded drugs indicates the use of the Medi-Cal dispensing fee; section 5307.1(e)(2) states the maximum fee is “based on the sum of the allowable fee for each ingredient plus a dispensing fee <i>equal to the dispensing fee allowed by the Medi-Cal payment systems.</i> ” [Emphasis added.]	
9789.40.2	Commenter states that the proposed rules provide a complex solution for “unfinished” compound ingredients. Commenter recommends that “drug ingredient cost” should be tied to an established benchmark such as the WAC of the drug ingredient. This would eliminate the difficulties associated with obtaining “documented paid cost”. This would also be consistent with	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs AAPAN April 11, 2024 Written and Oral comment	Disagree. See response above to comment regarding §9789.40.2(c)(2), and §9789.40.6(c)(2) submitted by Keven C. Tribout, Vice President, Public Policy & Regulatory Affairs, Optum Workers’ Compensation, on April 11, 2024	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	proposed Section 9789.40.4(c), which contains a provision allowing use of WAC for a drug's NDC in a situation where the rules do not already have an existing reimbursement methodology.			
9789.40.3	<p>Commenter opines that a single, uniform compounding fee would suffice and would eliminate unnecessary complication in the proposed rules.</p> <p>Commenter appreciates the DWC's efforts of ensure the safety of compounded medications by including consideration of sterilization and routes of administration but commenter states that incorporating these considerations into the compounding fee greatly increases the administrative burden associated with implementing and operationalizing the fee.</p>	<p>Lisa Anne Hurt-Forsythe, Vice President, Government Affairs AAPAN April 11, 2024 Written and Oral comment</p>	<p>Disagree. The statute requires the regulation to follow the Medi-Cal structure. Labor Code section 5307.1(a) states in pertinent part that for drugs and pharmacy services "...all fees shall be in accordance with the <i>fee-related structure and rules</i> of the relevant ... Medi-Cal payment system..." [Emphasis added.] Commenter expresses concern that consideration of sterilization and routes of administration in the compounding fee</p>	<p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			<p>“greatly increases the administrative burden associated with implementing and operationalizing the fee...” However, the compounding fees and sterility fee based on Medi-Cal Compound Dosage Form, and Route of Administration Table 2024 have been in effect and posted on the DWC website since the year 2004 when the workers’ compensation pharmaceutical fee schedule became tied to Medi-Cal. For clarity the table has been broken into two parts; and the Medi-Cal fees are currently the same as when workers’ compensation began to be benchmarked to Medi-Cal. Therefore, this</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			is not a new burden on the workers' compensation payers; they should have been paying according to the Medi-Cal system and table as posted by DWC in 2004.	
9789.40.5(f)	<p>Commenter supports the elimination of the physician dispensing fee. Many states have eliminated the practice of physician dispensing entirely; others have greatly curtailed the practice. Workers' compensation pharmacy benefit managers, working in tandem with contracted traditional pharmacies, provide an invaluable role in assuring that injured workers are receiving appropriate medications using clinical tools that:</p> <ol style="list-style-type: none"> 1. provide verification of potential drug interactions, 2. assess appropriateness of dispensed medications <i>vis 'a</i> 	<p>Lisa Anne Hurt-Forsythe, Vice President, Government Affairs AAPAN April 11, 2024 Written and Oral comment</p>	<p>Disagree that the proposal to discontinue the physician dispensing fee should go forward. DWC has reevaluated the proposal to discontinue the physician dispensing fee and will modify the proposal to allow the physician a maximum fee of \$10.05, which is the Medi-Cal lower tier fee. For explanation of DWC rationale for the modification, see the response to the comment regarding</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p><i>vis</i> body parts and conditions claimed,</p> <p>3. provide immediate information related to the compensability of the claim, <i>etc. etc.</i></p> <p>Bypassing these safeguards with physician dispensing practices has been an on-going challenge within the Worker's Compensation system. Commenter supports the division's efforts to curtail this practice and remove incentives for the dispensing of often-higher-cost and clinically unnecessary/inappropriate medications that may have limited or potentially negative implications for the injured worker.</p>		<p>§9789.40.5(f) submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024</p>	
General Comment	<p>Commenter recommends that the proposed rules be amended to specifically allow a payor to deny payment for medications that have not obtained proper pre-authorization, such as any of the following scenarios:</p>	<p>Lisa Anne Hurt-Forsythe, Vice President, Government Affairs AAPAN April 11, 2024 Written and Oral comment</p>	<p>Disagree. Labor Code §4600, subdivision (a) provides that medical treatment "that is reasonably required to cure or relieve the injured worker from the effects of the</p>	<p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<ul style="list-style-type: none"> • Compounded medications with no pre-authorization • Physician-dispensed medications with no pre-authorization, and • Compounded, physician-dispensed medications with no pre-authorization. 		worker's injury shall be provided by the employer." The process for obtaining prior authorization is governed by the utilization review statute (Labor Code §4610) and implementing regulations. The medical necessity of a medication that did not receive prospective authorization can be reviewed on retrospective review.	
9789.111 9789.40 9789.40.1 9789.40.2 9789.40.3 9789.40.4 9789.40.5 9789.40.6	Commenter recommends an implementation period of at least 180 days rather than the 90 days proposed throughout this rulemaking to allow adequate time for necessary system changes, including integrating new data files and data file formats and programming for multiple dispensing fees.	Sara Widener-Brightwell, SVP Claims & General Counsel California Workers' Compensation Institute (CWCI) Written Comment April 11, 2024	Agree that it would be appropriate to allow 180 days for implementation in light of the system changes that will be needed.	Modify proposal to provide an effective date of the first day of the month following 180 days after the regulation is filed with the Secretary of State, rather than 90 days after the

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
				regulations are filed with the Secretary of State.
9789.111	<p>Commenter recommends extending the timeframe for the effective date of these regulations from the currently proposed 90 days to six months from the date of adoption. Commenter opines that six months is a more suitable time frame given that most IT development work is planned on a quarterly basis. Commenter states that it is not viable for any organization to begin development work prior to the release of the finalized regulatory language; and opines that if they were to do so, it could potentially necessitate re-work, which is costly and wasteful. Commenter states that a 6 month timeframe from the date of adoption to the effective date would facilitate the required system modifications, and ensure</p>	<p>Tracy Euler, Manager Advocacy & Compliance HealthSystems April 8, 2024 Written Comment April 11,2024 Oral Comment</p>	<p>Agree that it would be appropriate to allow 180 days for implementation in light of the system changes that will be needed.</p>	<p>Modify proposal to provide an effective date of the first day of the month following 180 days after the regulation is filed with the Secretary of State, rather than 90 days after the regulations are filed with the Secretary of State.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	stakeholder are able to easily comply with the new rules.			
9789.40.1	<p>Commenter states that the proposed two-tiered dispensing fee contingent upon the volume of prescriptions filled by the pharmacy in the previous calendar year is a novel approach for workers' compensation claims and necessitates system development and opines that this requirement adds a layer of complexity without providing any benefit to patient care.</p> <p>Commenter recommends that the DWC consider a singular, uniform dispensing fee. Commenter opines that this approach would sufficiently compensate pharmacist for their professional services, irrespective of a pharmacy's size or prescription volume and would simplify the adjudication process for the pharmacy benefit managers</p>	<p>Tracy Euler, Manager Advocacy & Compliance HealthSystems April 8, 2024 Written Comment April 11, 2024 Oral Comment</p>	<p>Disagree with the contention that DWC should adopt a single dispensing fee. The fee schedule statute requires the regulation to follow the Medi-Cal structure. Labor Code section 5307.1 states in pertinent part that for drugs and pharmacy services "...all fees shall be in accordance with the <i>fee-related structure and rules</i> of the relevant ... Medi-Cal payment system..." [Emphasis added.] Also, note that the language regarding compounded drugs indicates the use of the Medi-Cal dispensing fee; section 5307.1(e)(2) states the maximum fee</p>	<p>No action necessary.</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	and payers who are required to implement this change.		is “based on the sum of the allowable fee for each ingredient plus a dispensing fee <i>equal to the dispensing fee allowed by the Medi-Cal payment systems.</i> ” [Emphasis added.]	
9789.40.2 9789.40.5	Commenter notes that the proposed regulation defines the compound “drug ingredient cost” for unfinished drug products as the “documented paid cost of each unfinished drug product, calculated based on units used in the compound, plus 10%, not to exceed the unfinished drug product’s WAC as published by the manufacturer.” This is the first language of this kind proposed in any workers’ compensation system, adding complexity to what is currently a streamlined and efficient process for processing compounded drug bills, in real time via point-of-sale systems.	Tracy Euler, Manager Advocacy & Compliance HealthSystems April 8, 2024 Written Comment	Disagree. See response above to comment regarding 9789.40.2 and 9789.40.6 submitted by Keven C. Tribout, Vice President, Public Policy & Regulatory Affairs, Optum Workers’ Compensation April 11, 2024 In addition, commenter’s suggestion to use the “lowest-priced therapeutically equivalent drug” for an NDC if a compound drug ingredient is absent from	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>Because most pharmacy transactions are transmitted to the payer through their PBM in real time, it is highly unlikely any pharmacist who is dispensing a compounded drug would have the pharmacy's purchase invoices on hand to transmit along with their electronic billing. Therefore, a manual (paper) bill and paper documentation would be required after the fact for these types of services, and each bill would require manual review by the PBM, medical bill review agent and/or the claims professional.</p> <p>Commenter opines that these provisions are unnecessary given the existing cost and utilization controls that are already in place for managing these drug products through:</p> <p>(a) California Labor Code 4600.2 which allows payers to utilize a network of pharmacies, and hold those pharmacies</p>		<p>the Medi-Cal database would not provide a methodology for bulk drug ingredients, only for finished drug products. The preface to the FDA's Orange Book states as follows: "FDA classifies as therapeutically equivalent those drug products that meet the following general criteria: (1) they are approved as safe and effective; (2) they are pharmaceutical equivalents in that they (a) contain identical amounts of the identical active drug ingredient in the identical dosage form and route of administration, and (b) meet compendial or other applicable standards of strength, quality, purity, and</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>accountable for cost effective dispensing through their contracts with a pharmacy benefit network and,</p> <p>(b) the MTUS drug formulary, which has an established pre-authorization requirement for any compounded drug.</p> <p>To streamline this process, commenter proposes adopting an established benchmark for reimbursement of these drug products. Employing the same payment allowance permissible under Medi-Cal for compounded drug components could be effective. If an NDC for a compounded drug component is absent from the Medi-Cal database and unavailable in National Drug Acquisition Cost (NADAC) or Wholesale Acquisition Cost (WAC), then the maximum drug ingredient fee should not surpass the cost of the lowest-priced therapeutically equivalent</p>		<p>identity; (3) they are bioequivalent in that (a) they do not present a known or potential bioequivalence problem, and they meet an acceptable in vitro standard, or (b) if they do present such a known or potential problem, they are shown to meet an appropriate bioequivalence standard; (4) they are adequately labeled; and (5) they are manufactured in compliance with Current Good Manufacturing Practice regulations.”</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	drug. This payment cap methodology mirrors the existing framework in section 9789.40, 9789.40.1, and 9789.40.5 of the Fee Schedule for drugs not listed in the Medi-Cal database.			
9789.40.1	<p>Commenter states that the workers' compensation market is intricate and she has concerns regarding the proposed two tiered pharmacy dispensing fee based on a pharmacy's higher or lower Medi-Cal volume. Commenter opines that, as proposed, it will be problematic to implement necessary code changes, testing, QA and deployment within the 90-day implementation timeframe, increasing error probabilities and administrative cost to all parties.</p> <p>Commenter requests that the DWC partner with the industry to provide a complete and accurate data file with NPI production data prior to the adoption of this proposed rule and extend the</p>	Wendy Cloe MyMatrixx April 11, 2024 Written Comment	Agree in part insofar as the DWC recognizes that 90 days appears to be an inadequate time period for implementation. In light of the many comments received suggesting that 180 days is an adequate period for implementation, DWC will issue a modified proposal making the changes effective on the first day of the month following 180 days after the regulations are filed with the Secretary of State. DWC has balanced the time	Modify proposal to provide an effective date of the first day of the month following 180 days after the regulation is filed with the Secretary of State, rather than 90 days after the regulations are filed with the Secretary of State.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>effective date to one year after adoption.</p> <p>Commenter recommends that the NPI file be updated no more frequently than annually and that changes not be effective retrospectively. To avoid claims processing and pharmacy confusion, her recommendation would be to assign any new pharmacies to the lower volume dispensing fee tier their first year. This would benefit both the pharmacies and pharmacy benefit administrators by eliminating claims processing confusion associated with operationalizing the state's unique NPI list multiple times per year. Commenter also recommends that any NPI updates in the NPI file be effective 30 days after file publication to eliminate claims reconciliation, payment and billing issues. This will avoid unnecessary disruption to current</p>		<p>needed for implementation with the need to update the fee schedule as soon as possible.</p> <p>DWC disagrees with the suggestion to update the NPI file no more frequently than annually. Labor Code §5307.1, subdivision (g)(1)(A), states in relevant part: "Notwithstanding any other law, the official medical fee schedule shall be adjusted to conform to any relevant changes in the Medicare and Medi-Cal payment systems no later than 60 days after the effective date of those changes..."</p> <p>In regard to the suggestion to assign any new pharmacies to the lower volume tier for</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	PBM processes supporting pharmacies and payers.		<p>their first year, this is basically the methodology followed by Medi-Cal. Note that DWC will not be assigning a pharmacy to a tier; DWC is adopting the NPI Medi-Cal list, which will include pharmacies enrolled with Medi-Cal who are qualified for the higher tier by virtue of the annual attestation, or whose enrollment is effective after the attestation cutoff date. The use of the Medi-Cal NPI list by workers' compensation is very straightforward; on the date of dispensing, does the pharmacy NPI fall within the eligibility dates listed on the Medi-Cal NPI file?</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
General Comment	<p>Commenter notes that the state Labor Code requires the California Division of Workers Compensation to use the Medi-Cal fee schedule. Considering an increase of up to 53% for dispensing fees, commenter opines that this rule is financially unreasonable and creates considerable burden to carriers and employers operating in the state of California.</p> <p>Commenter recommends that the Division of Workers Compensation deviate from the Medi-Cal fee schedule, as was done through the legislative process by amending the Labor Code section 5307 in 2011. This effectively altered the fee schedule related to physician dispensing fee schedules for workers compensation programs, and recognized the injured workers population as unique and differing from Medi-Cal members and the Medicaid program.</p>	Wendy Cloe MyMatrixx April 11, 2024 Written Comment	<p>Agree that the Labor Code requires the DWC to use the Medi-Cal fee schedule for pharmaceuticals.</p> <p>Disagree with the suggestion to deviate from the Medi-Cal fee schedule for dispensing fees. Labor Code §5307.1(a) requires the fees to be “in accordance with the fee-related structure and rules of the relevant ... Medi-Cal payment systems.”</p> <p>Legislation passed in 2011, effective 2012, added additional caps on physician dispensed drugs. However, this was done by the legislature, not by DWC. As an administrative agency DWC issues regulations</p>	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			to implement, interpret, and make specific legislative enactments. DWC does not have authority to alter the statutory mandate to adopt a pharmaceutical fee schedule based upon the fee-related structure and rules of Medi-Cal, which includes the dispensing fee.	
9789.40.5(f)	<p>Commenter recommends that the Medi-Cal professional dispensing fee be applied for physician dispensed drugs.</p> <p>Commenter 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</p>	<p>Lucas Evensen Associate Director California Medical Association (CMA) April 11, 2024 Written Comment</p>	<p>Agree in part, insofar as DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies listed on the Medi-Cal NPI file</i>. See response above to the written comment</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>increasing access to care, improving individual health outcomes and reducing system costs.</p> <p>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 costs. In-office dispensing eliminates the need for patients to travel to a pharmacy and navigate the complexities of the worker's compensation system. If physicians cease dispensing, patients will face new, unnecessary barriers to accessing their medications, potentially increasing medication non-adherence.</p> <p>Eliminating the physician dispensing fee will make it cost-prohibitive for physicians to continue in-office dispensing. Physicians incur costs that are not</p>		<p>submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	covered by the E&M reimbursement rates. With the proposed changes to the allowance for many medications, the total reimbursement to physicians will not cover the actual cost of the medication and dispensing it to the patient.			
9789.40.5(f)	<p>Commenter doesn't see any value in eliminating a point of distribution by eliminating the physicians' dispensing fee.</p> <p>Commenter opines that this will centralize the distribution through MPNs that are entities that provide physician services and are contracted to provide everything through a single portal or single method. Commenter states that this puts MPNs in the position of making more money when the physicians do not dispense because they will go through their in house PBM.</p>	<p>Stephen J Cattolica SC Advocates for California Neurology Society and California Society of Physical Medicine and Rehabilitation April 11, 2024 Oral Comment</p>	<p>Disagree with the assertion that the proposed regulations "eliminate a point of distribution." The proposal does not prohibit physician dispensing. Nevertheless, DWC has considered comments in relating to the physician dispensing fee and will modify the proposal to restore the physician dispensing fee, for the reasons set forth above in the response above to the comment relating to</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.40.1.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			§9789.40.5(f) submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.	
9789.40.5(f)	<p>Commenter acknowledges that the history of physician dispensing in California includes a litany of abuse, but the presence of MPNs (LC 4616), the Drug Formulary, and accompanying regulatory structure developed over the past 10 – 15 years has abated much of what was the wild west of workers compensation within prescription delivery.</p> <p>Commenter opines that there is no data that justifies prohibiting physician dispensing, especially as applied to initial visits by the injured worker. Regardless of any other consideration, the first treater has a duty of care that trumps the administrative concerns of any</p>	<p>Stephen J Cattolica SC Advocates for California Neurology Society and California Society of Physical Medicine and Rehabilitation April 11, 2024 Written Comment</p>	<p>Agree with commenter in part, insofar as the Division has decided to reinstate a dispensing fee for physicians. Disagree with Commenter’s repeated suggestion that the proposed regulation “prohibits” physician dispensing. This contention is erroneous. There is nothing in the proposal that <i>prohibits</i> physician dispensing; the proposal states merely that a <i>dispensing fee</i> is not payable to a physician.</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>health care system – work-related or not. There is no question that providers take advantage of that duty of care. Commenter does not think that the Division, with this recommendation to disallow physician dispensing, means to prevent care, including medicines, from being administered if called for and circumstances do not support an elongated approval process.</p> <p>Commenter recommends that if the Division believes that the MPN “entities,” including those with an in-house Prescription Benefit Manager (PBM), can do a better job of determining the medical necessity, then we suggest the physician dispensing prohibition be limited after the first two or three visits, subject only to the denial of liability if it is determined between the two dates. Keeping in mind that the DWC’s Drug Formulary and all incumbent rules remain in</p>		<p>However, DWC has reconsidered the proposal disallowing a dispensing fee to a physician in light of comments received. DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies listed on the Medi-Cal NPI file</i>. See response above to the written comment submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.</p> <p>The comments referencing Utilization</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>force, this scenario may be much easier to implement and oversee.</p> <p>Commenter states that there is a well-documented, if relatively infrequent UR/MTUS tug-of-war between claims and medical even when the MTUS and Formulary support the treating physician's RFA. Commenter opines that "splitting up the team" by giving the PBM (which is not part of the URAC accredited UR plan) decision making responsibility ignores the professional liability still retained by the treating physician.</p> <p>Commenter requests that the subsequent changes reinstate physician dispensing for the first two or three visits and a fair working relationship between the PTP and MPN/PBM. With respect to professional responsibility, the physician bears it all while those other two partners in the</p>		<p>Review (UR), Medical Treatment Utilization Schedule (MTUS), Medical Provider Networks do not relate to the proposed regulations which would govern the maximum allowable fees for pharmaceuticals.</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	healthcare delivery process bear none.			
9789.40.1 and Initial Statement of Reasons	<p>Commenter alleges the Division’s intention to come into congruence with the “<i>Mercer Report, Professional Dispensing Fee and Actual Acquisition Cost Analysis for Medi-Cal – Pharmacy Survey Report, dated January 4, 2017.</i>” Commenter opines that it is important to note that the Mercer report stated unequivocally that the Report, “<i>set forth options</i>” (not mandates) “<i>for a revised methodology for the drug cost reimbursement and the professional dispensing fee.</i>”</p> <p>The Division’s ISOR continued, “<i>In light of the Mercer study, DHCS selected the actual acquisition cost alternative utilizing the National Average Drug Acquisition Cost (NADAC) (or Wholesale Acquisition Cost (WAC) +0%</i></p>	Stephen J Cattolica SC Advocates for California Neurology Society and California Society of Physical Medicine and Rehabilitation April 11, 2024 Written Comment	<p>Disagree with the comments.</p> <p>Commenter appears to misunderstand the intent of the regulations and the Medi-Cal system upon which they are based. First, commenter states that the DWC’s intent is to “come into congruence with the Mercer report” and states that the report sets forth options, not mandates. Commenter misunderstands the DWC’s intent, which is to carry out the statutory directive to adopt a fee schedule for pharmacy services and drugs “in accordance with the fee-related structure and rules of the relevant ...</p>	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p><i>for drugs lacking a NADAC price) in place of the Average Wholesale Price (AWP) in the drug ingredient formula.” For the professional dispensing fee, DHCS selected the two-tier dispensing fee model: \$10.05 for pharmacies with total annual prescription volume of 90,000 or more, and \$13.20 for pharmacies with total annual prescription volume of less than 90,000. A Medi-Cal-enrolled pharmacy wishing to receive the higher dispensing fee submits a “self-attestation” of total claim volume for the prior calendar year during a prescribed attestation period.”</i></p> <p>Regarding "the professional dispensing fee, DHCS selected the two-tier dispensing fee model: \$10.05 for pharmacies with total annual prescription volume of 90,000 or more, and \$13.20 for pharmacies with total annual</p>		<p>Medi-Cal payment system.” (Labor Code section 5307.1(a).) The intent is to be congruent with the Medi-Cal system, not with the Mercer Report itself. As background, the ISOR discusses the Mercer Report, the recommendations made to the Dept of Health Care Services (who administers Medi-Cal), and the <i>options selected by DHCS</i>: the drug ingredient cost approach using the National Average Drug Acquisition Cost (NADC) and the two-tier dispensing fee. In selecting the dispensing fee, DHCS considered the analysis of Mercer showing different claim volume and its relation to</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p><i>prescription volume of less than 90,000. A Medi-Cal-enrolled pharmacy wishing to receive the higher dispensing fee submits a "self-attestation" of total claim volume for the prior calendar year during a prescribed attestation period."</i></p> <p>Commenter alleges the unworkability of any number of scripts as a threshold, the origin of the data used in an attestation remains undefined. Is it defined by how many scripts an individual has written over the life of his/her practice? A combined number generated by all physicians in a medical group practice? From all claims, both industrial and general health care? Only those for the specific payor (requiring a separate sum for each carrier or employer or TPA)? Only scripts submitted to the specific PBM processing the claim (the provider very likely interfaces with more</p>		<p>costs and selected the two-tier approach among the options suggested. By statute, DWC follows the selected the Medi-Cal structure. (Labor Code section 5307.1(a).)</p> <p>Commenter appears to misunderstand the role of the number of prescriptions filled in relation to the workers' compensation pharmaceutical fee schedule. The questions he poses are all irrelevant, as the qualification for the higher dispensing fee is based on the Medi-Cal classification of the pharmacy (by National Provider Identifier.) The regulations provide that the higher dispensing fee is allowed for</p>	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	than one PBM). If the doctor works at two separately owned clinics plus a hospital, are they combined? Who will keep track?		pharmacies whose National Provider Identifier is indicated as eligible on the Medi-Cal National Provider Identifier file. (Section 9789.40.1(a)); Section 9789.40.2(d).) The regulations state that the file will be posted on the DWC website. (Section 9789.40.1(d).)	
9789.40.5(f)	<p>Commenter requests that the DWC maintain the Physician dispensing fee of \$7.25 per prescription. He opines that disallowing a dispensing fee will not drive doctors out of the workers' compensation system; however, he states that they will stop dispensing medications.</p> <p>Commenter states that this is bad for the injured worker receiving treatment. He provides an example of a person that comes for</p>	Don Schinske Western Occupational & Environmental Medicine and Rehabilitation April 11, 2024 Oral Comment	<p>Agree in part, insofar as DWC has determined that physicians should be allowed the dispensing fee, at a maximum rate of \$10.05, which is the lower Medi-Cal dispensing fee tier which is applicable except for <i>pharmacies listed on the Medi-Cal NPI file</i>.</p> <p>See response above to the written comment</p>	<p>Modify proposal to allow the physician to receive a dispensing fee of \$10.05 in section 9789.40.6(f) (section 9789.40.5 will be renumbered due to the addition of a new §9789.41.)</p>

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	<p>treatment with a cut or needle stick and if they cannot get their first round of antibiotic dispensed by their physician they will have to go to the pharmacy to fill the prescription. The process of filling the prescription would likely be delayed by the lack of information/initiation of coverage. The person may be told to come back the following day and stand in line once again or be delayed even longer obtaining their medication, or never receive it at all.</p> <p>This situation could possibly lead to the person's condition deteriorating and causing higher costs for the workers' compensation system.</p>		<p>submitted by Diane Przepiorski, Executive Director, California Orthopaedic Association (COA), April 11, 2024.</p>	