OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 2nd 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
General Comment	Commenter has reviewed the proposed changes and has no comment at this time.	Andrea Guzman Claims Regulatory Director State Compensation Insurance Fund (SCIF) October 22, 2024 Written Comment	Noted.	No action necessary.
Effective date extension from 90 to 180 days	Commenter supports and thanks the DWC for extending the proposed 90-day timeline to 180-days as this added time will allow the industry to develop the necessary automation to build a compliant process. Commenter recommends that the DWC assign an internal technology partner to help guide the industry through the implementation and testing phases to help ensure the state builds a successful process.	Wendy Cloe, Senior Manager, MyMatrixx October 23, 2024 Written Comment	Commenter's support for the additional time for implementation is noted. DWC is aware that the regulations will require some adjustments to payment and billing systems. DWC is not a trading partner for the fee schedule; it cannot assign "an internal technology partner" to help with implementation and testing within external entities' myriad technological systems. However, DWC anticipates providing some sequential sample	No action necessary.

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			Pharmaceutical Fee Data Files and Medi-Cal National Provider Identifier files for use by the public while programming systems.	
9789.40.3(c)	Commenter supports the DWC's decision to remove the distinction between finished and unfinished drug products used in compound medications, and the more complicated "documented paid cost…plus 10% standard for reimbursing pharmacies for those unfinished ingredients. Commenter opines that this will streamline billing and payment by reducing confusion among industry stakeholders and pharmacies participating in the process.	Wendy Cloe, Senior Manager, MyMatrixx October 23, 2024 Written Comment	DWC notes the support for the modified provision.	No action necessary.
9789.40(a)(1)	Commenter opines that guidance is needed regarding drugs that do not have NADAC, WAC, FUL or MAIC reimbursement values. Commenter questions if the DWC	Wendy Cloe, Senior Manager, MyMatrixx October 23, 2024 Written Comment	DWC disagrees that further guidance is needed. Commenter has not set forth an example of an NDC that would	No action necessary.

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	intends to establish a "backup" reimbursement benchmark to use in instances where none of the four outlined benchmarks is applicable to an NDC. Commenter states that AWP is an established benchmark in the industry, including in most other states' workers' compensation schedules. Commenter states that in rare circumstances the use of AWP or a discount of AWP makes sense. Commenter seeks guidance on how the industry should handle those rare situations.		lack one of the four benchmark prices used by Medi-Cal. The lack of one of these price types for an NDC would be extremely rare and would not warrant a regulatory standard. The "lowest cost" and "no substitution cost" are calculated by DWC based upon the Medi-Cal methodology and data. "Average Wholesale Price" (AWP) is not used in Medi-Cal pharmaceutical reimbursement and is NOT adopted into the workers' compensation regulations. The revised Medi-Cal methodology was specifically designed to move away from AWP, which the Centers for Medicaid and Medicare Services	

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			determined was a flawed methodology. Dept. of Health Care Services specifies the replacement of AWP in its public notice of 3/30/2017, Proposed Changes to Pharmacy Reimbursement for Covered Outpatient Drugs: "Adopt CMS's National Average Drug Acquisition Cost (NADAC) as the basis for ingredient cost reimbursement. Wholesale Acquisition Cost (WAC) + 0% will be used as the basis for reimbursement when a NADAC is not available. The NADAC and WAC benchmarks will replace Average Wholesale Price (AWP) minus 17% in the existing drug	

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			ingredient cost reimbursement methodology, which currently reimburses the lowest of AWP minus 17%, the Federal Upper Limit (FUL), Maximum Allowable Ingredient Cost (MAIC), or the pharmacy's usual and customary (U&C) charge." The proposed methodology was adopted and is set forth in the CMS-approved California State Plan Amendment 17-0002. Welfare & Institutions Code §141.05.451 sets forth the legislative intent to eliminate Average Wholesale Price from the Medi-Cal pricing formula.	
9789.40.4(c), 9789.40.6,	Commenter states that the injured worker's recovery is a priority for	Wendy Cloe, Senior Manager, MyMatrixx	DWC agrees with commenter insofar as	No action necessary.

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9789.40.7	her and her organization's client payers and that the pharmacist has an important role in the treatment of injured workers and their recovery. Pharmacists are uniquely trained and equipped for medication management to ensure patient safety. Commenter opines that when necessary, and usually only in the case of emergency treatment, it would be reasonable for physicians to provide emergency medication. Commenter opines that the inclusion of the new $10.05 physician dispensing fee may unfortunately result in an incentive for physicians to over prescribe leaving the patients safety at risk. Commenter requests that the DWC remove the physician dispensing fee.	October 23, 2024 Written Comment	she states that the injured worker's recovery should be the priority. DWC disagrees with the suggestion to disallow a dispensing fee to the physician. As explained in the Notice of Modification of Proposed Regulations for 15-Day Comment period relating to §9789.40.4, 9789.40.6, 9789.40.7, the injured worker's access to care is the basis for the decision to allow the dispensing fee for physicians. Although there are some downsides to physician dispensing, the state law does allow physicians to dispense medications to their patients. (Business and Professions Code §4170.) DWC has	

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			weighed the advantages and disadvantages of allowing a dispensing fee for physicians and has decided that on balance it is warranted. There are controls on inappropriate prescribing that address potential abuse (e.g. utilization review, prospective authorization formulary rule, etc.) that mitigate the risk that allowance of a physician dispensing fee would incentivize inappropriate dispensing for the purpose of generating a revenue stream.	
9789.40.1	Commenter appreciates that the DWC updated the sample files in this latest commenter period. Commenter requests that the DWC establish a consistent plan for weekly updates to the fee schedule and NPI files in order to	Wendy Cloe, Senior Manager, MyMatrixx October 23, 2024 Written Comment	Commenter's appreciation for the updated sample files is noted. DWC intends to provide sufficient sample files to aid in stakeholder	No action necessary.

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	provide a level of certainty for stakeholders and ensure timely compliance.		implementation and compliance.	
General Comment	Commenter supports the changes as proposed in this latest version of the rule prompting the 2nd 15-day comment period. Commenter opines that the clean-up of the reimbursement language for repackaged drugs and documented paid cost [9789.40.6(c)(d) &(e)] for pharmaceutical dispensed by a physician and the simplification and consolidation of definitions throughout the rule adds clarity to the intent of the fee schedule. Commenter still has concerns about the tiered dispensing fee and how that will work as it is a new concept that workers' compensation has not experienced in any other state; however, he looks forward to the support of the	Brian Allen, Vice President Government Affairs, Enlyte Pharmacy Solutions October 23, 2024 Written Comment	DWC notes commenter's support for cleanup, consolidation, and simplification of regulatory language. Regarding the two-tiered 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 *fee-related structure and rules* of the relevant … Medi-Cal payment system…" [Emphasis added.] Also, note that the language regarding compounded drugs	No action necessary.

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	DWC as they work through implementing this new schedule. Commenter states that physician dispensed medication and compounds continue to be cost outliers in the workers' compensation system. Commenter appreciates clarification regarding reimbursement for these medications, but requests that the DWC continue to monitor those costs and consider additional restrictions should it become necessary. Commenter acknowledges that the DWC is statutorily bound to use the Medi-Cal fee schedule for reimbursement; however, he opines that the California workers' compensation system would be better served by a workers' compensation specific pharmaceutical fee schedule that better reflects the additional administrative efforts and clinical		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 *equal to the dispensing fee allowed by the Medi-Cal payment systems*." [Emphasis added.]	

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	controls unique to workers' compensation and not present in the Medi-Cal system.			
9789.40.1	Commenter is disappointed that the 2-tiered dispensing fee is still included in this 2nd 15 Day version of the proposed regulations. Commenter opines that these proposed rules should be amended to contain a single dispensing fee, regardless of the operational volume of the pharmacy in question. Commenters states that a single equitable and cost-neutral dispensing fee can be arrived at by performing a high-level analysis to determine how many pharmacies fall into each tier today and arriving at a single figure that would likely end up somewhere in the middle between the two tiers suggested.	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers, Administrators, and Networks (AAPAN) October 23, 2024 Written Comment	Disagree; the 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 *fee-related structure and rules* of the relevant … Medi-Cal payment system…" [Emphasis added.] Regarding compounded drugs, 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 *equal to the dispensing fee allowed by the Medi-Cal*	No action necessary.

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			payment systems." [Emphasis added.] (Note that for physician-dispensed compounds there is an additional limitation that the reimbursement is limited to 300% of documented paid costs, but in no case more than …$20… above documented paid costs.")	
9789.40.3 9789.40.7	Commenter appreciates the removal of the "finished" versus "unfinished distinction for reimbursing compound ingredients. Commenter states that removing the need to separately identify "unfinished" compound ingredients to reimburse them at a "document paid cost…plus 10%, the DWC has curbed potential complications to the billing and reimbursement process. Commenter opines that if this standard had been included in the	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers, Administrators, and Networks (AAPAN) October 23, 2024 Written Comment	Commenter's support is noted.	No action necessary.

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	maximum fee methodology for unfinished products, if would have complicated the process, burdened pharmacies with additional documentation requirements, and may have led to more disputes between parties.			
9789.40.1(a)(2)(A) and (B)	Commenter is disappointed that the DWC retained the $10.05 dispensing fee allowance for physicians that was added to the prior draft version to the regulations. This provision could create financial incentives to utilize comparatively high-cost pharmaceuticals in the absence of proportional improvements to patient care. Commenter notes that in the ISOR it was noted that a Workers' Compensation Research Institute study found that CA physicians tend to prescribe higher-priced drug formulations more often than pharmacies. The WCRI concluded that financial incentives were	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers, Administrators, and Networks (AAPAN) October 23, 2024 Written Comment	Disagree with the suggestion to disallow the dispensing fee to physicians. DWC has considered the contention that physician dispensed medications warrant a dispensing fee and has weighed the advantages and disadvantages of allowing the fee. Changes made to Labor Code section 5307.1 indicate that the legislature was concerned about inappropriate dispensing by physicians and	No action necessary.

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	driving this increase in high-cost physician dispensing with no added therapeutic benefits. Physician dispensing circumvents important safety checks conducted by pharmacists which increase the chances of prescribing errors. Commenter states that this topic was also discussed at the 10/16/2024 meeting of the P&T Committee, wherein Mr. Kevin Gorospe Pharm D (DWC Consultant) provided preliminary data reflecting the disproportionate impact on overall reimbursements paid for "NO"-status drugs dispensed by physicians. Commenter references a table, distributed at this meeting, that depicts aggregated data for drugs dispensed by physicians **[copy of excerpt from table provided upon request.]** Commenter states that even though "Yes" status drugs accounted for 87% of billed lines, the remaining 13% ("NO"		created additional rules to govern reimbursement for physician dispensed medication. And some research studies cited ISOR do suggest that financial incentives may sometimes skew drug selection and physician dispensing patterns. However, DWC is aware that physician dispensing may facilitate the early initiation of treatment and improve access to medications for injured workers, improving health outcomes. DWC has considered the advantages and disadvantages of providing a dispensing fee to physicians in light of the Business and Professions Code section 4170 that allows a physician to dispense	

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	status) accounted for 45% of overall costs. Commenter references a table, also presented at the P&T committee meeting, that depicts aggregated data for drugs dispensed by pharmacies **[copy of excerpt from table provided upon request.]** In this table the "YES" dispensing rate for pharmacies was 96%, reflecting 80% of total amounts paid. The "NO" dispensing rate was only 4%, versus the 13% for physicians. Commenter opines that the financial incentives to physicians to dispense "No"-status drugs warrants closer investigation, and that this should be considered when including a dispensing fee for these medications. Commenter notes that during the June 2024 public hearing for these proposed regulations that proponents in favor if physician dispensing were physicians that 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 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.) DWC has determined that on balance the considerations favor a dispensing fee for physician dispensed drugs. DWC disagrees with Commenter's contention	

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	proportionately more “YES” status drugs. Low cost antibiotics dispensed during a first visit where cited as a common example. This is not the problematic prescribing practices that she is referring to. Commenter states that the DWC should consider drawing a distinction between physician dispensing of “YES” vs. “NO” drugs when determining whether a dispensing fee should be added. Commenter opines that adding a dispensing fee to an expensive “NO” status drug adds even more to the comparatively high costs and creates a perverse incentive to prescribe these medications. Commenter supports a physician dispensing fee for “YES” drugs but not for the dispensing of high-cost “NO” drugs.		that the allowance of a dispensing fee should be based upon whether the drug is listed on the Medical Treatment Utilization Schedule Drug List. Drugs on the list are those that have been addressed by the treatment guidelines; other drugs not on the list may very well be medically necessary and appropriate and warrant a dispensing fee. The drug utilization data presented at the 10/16/2024 Pharmacy & Therapeutics Committee meeting does NOT provide a basis for action on the physician dispensing fees. It is high level aggregate data that is wholly inadequate to discern whether financial	

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			incentives are motivating improper physician dispensing or dispensing of inordinately higher priced drugs. Notably, the utilization statistics presented at the meeting are the opposite of what commenter sets forth. The table excerpt she states is for physicians was actually the table for pharmacies. And the table excerpt she presents as the physician table is the pharmacy table. She states that "the "YES" dispensing rate for pharmacies was 96%, reflecting 80% of total amount paid. The "NO" dispensing rate was only 4% **versus 13% for physicians**." However, she has cited the *wrong*	

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			tables, mixing them up and presenting the opposite of what they say. The physician utilization table showed 96% of billed prescriptions were MTUS drugs, representing 80% of the total paid, contrary to her contention that this is the pharmacy statistic.	
General Comment	Commenter continues to recommend that these proposed regulations need to 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: a. Compounded medications with no pre-authorization b. Physician-dispensed medications with no pre-authorization	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers, Administrators, and Networks (AAPAN) October 23, 2024 Written 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	No action necessary.

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	c. Compounded, physician-dispensed medications with no pre-authorization		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.	
9789.40.3 9789.40.7	Commenter appreciates the DWC's efforts to ensure the safety of compounded medications by including consideration of sterilization and routes of administration; however, she opines that incorporating these considerations into the compounding fee greatly increases the administrative burden associated with implementing and operationalizing the fee, and creates an analogous situation to the 2-tiered dispensing fee.	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers, Administrators, and Networks (AAPAN) October 23, 2024 Written Comment	The proposed compounding fees are in conformity with Medi-Cal. Labor Code §5307.1(a)(1) directs the DWC to adopt a fee schedule for "…medical services…, drugs and pharmacy services…in accordance with the fee-related structure and rules of the relevant Medicare and Medi-Cal payments systems…" The various provisions of §5307.1 make it clear	No action necessary.

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			that drugs and pharmacy services are capped at no more than 100% of Medi-Cal. Subdivision (a)(1) additionally states that prior to adoption of the fee schedule, "for pharmacy services and drugs that are not otherwise covered by a Medicare fee schedule payment for facility services, the maximum reasonable fees shall be 100 percent of fees prescribed in the relevant Medi-Cal payment system." Subd. (g)(1)(A) states in 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	

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			days after the effective date of those changes…" Subdivision (d) states in part: "If the administrative director determines that a pharmacy service or drug is not covered by a Medi-Cal payment system, the administrative director shall establish maximum fees for that item. However, the maximum fee paid shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources." Commenter also states that the compounding fee and sterility fee structure "greatly increases the administrative burden." It	

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			should be noted that this structure is not new; it has been in use for California workers' compensation since 2004 when the Medi-Cal methodology was adopted in section 9789.40. The Route of Administration / Sterility Fee Table and the Dosage Form Compounding Fee have been in effect, and posted on the DWC website, since 2004, and are now adopted with minor formatting change, but substantively unmodified.	
General Comment	Commenter notes that the inclusion of a physician dispensing fee allows for a variance from MediCal payment policies. Commenter opines that a variance from MediCal should also be	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers,	Disagree with the suggestion to adopt a 1.4 multiplier for pharmaceuticals. There is no statutory provision authorizing the DWC to create a fee	No action necessary.

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	granted to recognize the value of workers' compensation PBM's. Commenter states that she understands that reinstating the physician dispensing fee was done to ensure fundamental fairness in the system and to recognize the expenses incurred by physicians in providing this service to injured workers, particularly when low-cost, "YES" status drugs (such as antibiotics) are being prescribed. Commenter states that throughout this regulatory process she has expressed her concern regarding the drastic reduction in pharmacy reimbursement rates associated with the shift to a MediCal-based reimbursement system. Commenter opines that recompense be given to recognize the value of the services provided not only by pharmacies service injured workers, but also the value that workers' compensation pharmacy benefit mangers (WC	Administrators, and Networks (AAPAN) October 23, 2024 Written Comment	schedule that is 140% of Medi-Cal. Reading the fee schedule statute it is apparent that the legislative intent is to set the maximum workers' compensation pharmaceutical fees at 100% of Medi-Cal rates. Labor Code §5307.1 (a)(1) states that DWC shall establish an official medical fee schedule that includes drugs and pharmacy services, stating that "all fees shall be in accordance with the fee-related structure and rules of the relevant … Medi-Cal payment systems…"; directs pharmacy services and drug fees to be 100% of Medi-Cal pending adoption of the fee schedule; directs the DWC to establish	

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	PBMs) provide to injured workers, in analogous fashion to that provided by the physicians "YES" status medications. Commenter recommends the use of a multiplier/conversion factor as an add-on above the standard baseline MediCal reimbursement levels, to help offset the drastic price reductions. Commenter states that clear precedent for such a move current exists in the workers' compensation system, such as the multiplier for physician services in California added to the Medicare reimbursement base. Commenter notes that after the workers' compensation add-on, reimbursement rates for physicians in the state sit at approximately 145.72% of standard Medicare rates, as of April 1, 2024. Commenter recommends that the DWC use a targeted variance from standard MediCal pharmacy rates using the physician services		maximum fees for "a pharmacy service or drug is not covered by a Medi-Cal payment system" at a rate that "shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources," and directs the fee schedule to be adjusted to conform to any relevant Medi-Cal payment system changes no later than 60 days after the effective date of those changes.	

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	multiplier as a guide – i.e., a multiplier of 1.4 (or 140%) to be applied to the MediCal base rates for pharmaceutical services. Commenter opines that use of this multiplier will help to off-set the drastic price reductions associated with the full shift to MediCal and ensure fundamental fairness to all stakeholders in the system.			
9789.40.1	Commenter thanks the DWC for its further clarification in the revised proposed rules with respect to the posting of the PFS and NPI feeds on a weekly basis. Commenter is pleased to see that the DWC is planning on-going weekly releases. Commenter requests that these weekly releases be scheduled to occur on a specified recurring day and time – e.g., every Thursday at 10:00 p.m. Pacific time. Commenter opines that if stakeholders know what time and date the file release will take place	Lisa Anne Hurt-Forsythe, Vice President, Government Affairs – American Association of Payers, Administrators, and Networks (AAPAN) October 23, 2024 Written Comment	DWC notes commenter's support for clarification that the PFS Data File and NPI Medi-Cal File will be posted on a weekly basis. DWC acknowledges that it would be useful for stakeholders to know that the posting of updates would occur on a consistent day and time. The DWC will endeavor to provide consistency for the public and will provide	No action necessary.

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	that it will make the process of uploading the file and implementing it into their systems much easier and less time consuming. Commenter recommends that the DWC consider an "opt in" notification process, where stakeholders could sign up for automated notifications that an update to the files has been posted. Commenter also suggests that the DWC consider use of a "Beta" period to allow stakeholder to work with the uploaded files for a period of time in a testing environment prior to "going live."		the public information on the scheduled postings. However, due to potential changes that may occur in the schedule for receiving the Medi-Cal feed, and due to potential technical issues, it would not be appropriate to set a specific day and time in regulation since it would take a rulemaking action to effectuate a change. Commenter's suggestion for an automated notification process for updated files is noted and will be considered for implementation. DWC does intend to provide files before the "go live" date for stakeholder use in development and testing.	