OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 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) June 27, 2024 Written Comment	Noted.	No action necessary.
General Comment	Commenter supports the Division's changes that add clarity to the provisions and specifically supports the modification to the effective date and new section on the Pharmaceutical Fee Data and NPI Files.	Tracy Euler, Manager Advocacy & Compliance HealtheSystems June 24, 2024 Written Comment	Commenter's support noted.	No action necessary.
Effective date extension from 90 to 180 days	Commenter supports the Division's decision to extend the effective date from 90 to 180 days after the proposed rule amendments are filed and adopted by the Secretary of State. The extra time will give stakeholders ample time to implement the necessary modifications, facilitating a smoother transition, and easing compliance with the new rules.	Tracy Euler, Manager Advocacy & Compliance HealtheSystems June 24, 2024 Written Comment	Commenter's support noted.	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
9789.40.1	Commenter supports the addition of this new section which consolidates and adds clarity to all pertinent information relating to Pharmaceutical and NPI data files into a single, comprehensive section. Commenter states that integrating details about the timing of file updates, implementation requirements, and any retroactive changes, mitigates any confusion on the management of these data files.	Tracy Euler, Manager Advocacy & Compliance HealtheSystems June 24, 2024 Written Comment	Commenter's support noted.	No action necessary.
Effective date extension from 90 to 180 days	Commenter supports the proposed change to the implementation period from 90 days to the first day of the month 180 days after the amendments throughout this rulemaking are filed with the Secretary of State to allow adequate time for necessary system changes, including integrating new data files and data file formats.	Sara Widener- Brightwell, SVP Claims and General Counsel California Workers' Compensation Institute (CWCI) June 26, 2024 Written Comment	Commenter's support noted.	No action necessary.

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9789.40.1(a)	Commenter supports the proposed change to clarify that the calculations of "lowest cost" and "no substitution cost" are performed by the Division of Workers' Compensation (DWC), not by the public.	Sara Widener- Brightwell, SVP Claims and General Counsel California Workers' Compensation Institute (CWCI) June 26, 2024 Written Comment	Commenter's support noted.	No action necessary.
9789.40.5(a)	Commenter supports the proposed clarification that the maximum fee for pharmaceuticals dispensed through a mail order pharmacy includes the ingredient cost, dispensing, compounding and sterility fees whether dispensed within or outside California.	Sara Widener- Brightwell, SVP Claims and General Counsel California Workers' Compensation Institute (CWCI) June 26, 2024 Written Comment	Commenter's support noted.	No action necessary.
General Comment	Commenter appreciates the transparent and open process and for the many opportunities that he has had to express his thoughts and recommendations as this proposal advances through the rulemaking process.	Brian Allen, Vice President Government Affairs – Enlyte June 28, 2024 Written Comment	Commenter's appreciation noted.	No action necessary.
Effective date extension from 90 to 180 days	Commenter supports the change to a 180 day implementation period prior to the regulations	Brian Allen, Vice President Government Affairs – Enlyte	Commenter's support noted.	No action necessary.

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	becoming effective and he thanks the Division for considering his prior comments.	June 28, 2024 Written Comment		
9789.40.1	Commenter appreciates the additional clarifying information on the timing and frequency of the data files and when they are effective and states that this information is helpful for the planning of the technical changes required to implement the proposed regulations.	Brian Allen, Vice President Government Affairs – Enlyte June 28, 2024 Written Comment	Commenter's support is noted.	No action necessary.
	Commenter is concerned about the frequency of the updates and the two-day lag to begin the use of the updated files regarding potential disputes and reconsiderations. Such a lag could create an administrative burden if dispensing providers are caught in the lag and decide to file a request for second review. Commenter recommends that after implementation of these regulations, that the DWC monitor		DWC has proposed weekly updates to keep in sync with weekly Medi-Cal updates as envisioned by Labor Code §5307.1. Payers may minimize any "lag" by implementing each new file immediately upon issuance/posting by DWC. Beginning in 2004, DWC posted weekly Medi-Cal fee schedule updates to	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	second review requests to determine if the frequency and timing of updates are spawning an increase in these requests.		govern maximum pharmaceutical fees, which continued until the Dept. of Health Care Services ceased issuing files utilizing the old methodology in early 2019. The posting of weekly file updates did not appear to create issues or disputes. If DWC becomes aware in the future of problems created by allowing a 2- day "lag" period to implement the file, DWC will determine what action may be needed to address the situation.	
9789.40.3(c)	Commenter states that he is sympathetic to the plight of physician dispensers and the lack of profit margin on drugs under the new Medi-Cal pharmacy fee schedule; however, he states that	Brian Allen, Vice President Government Affairs – Enlyte June 28, 2024 Written Comment	Agree that Medi-Cal does not pay a dispensing fee to physicians, and moreover does not pay for physician-dispensed	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	the Medi-Cal fee schedule does		drug ingredient costs.	
	not authorize a dispensing fee for		Disagree that Medi-Cal's	
	physicians.		rule against payment to	
	Commenter states that over the		physicians for dispensed	
	last decade he has consistently been informed that the DWC is		drugs/dispensing fee is binding on workers'	
	statutorily bound to follow the		compensation because	
	Medi-Cal pharmacy fee schedule		Labor Code §5307.1,	
	and that the DWC could not		subdivision (e)(6) and	
	deviate from that to create a		(e)(7) provide additional	
	workers' compensation specific		authority to the DWC	
	pharmacy fee schedule.		administrative director to	
	Commenter requests clarification		craft rules for physician-	
	on how this deviation is allowed		dispensed drugs.	
	while disallowing the creation of a			
	pharmacy fee schedule that better		The DWC has	
	reflects the economics of the		determined that injured	
	workers' compensation system.		workers' medical access	
			will be improved by	
			allowing a dispensing fee	
			for a physician. It should be noted that Business	
			and Professions Code	
			§4170 allows physicians	
			to dispense drugs to	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			their patient if specified	
			conditions are met.	
			Commenter apparently questions the DWC's obligation to "follow the Medi-Cal pharmacy fee schedule" and suggests that DWC could create "a pharmacy fee schedule that better reflects the economics of the workers' compensation system." This comment does not reference any statutory provision directing the DWC to create a fee schedule that is untied to Medi-Cal. The provisions of Labor Code §5307.1 reflect the legislative directive to benchmark maximum workers' compensation pharmaceutical fees to Medi-Cal rates.	

Labor Code §5307.1 (a)(1) states that DWC	OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
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 maximum fees for "a pharmacy service or drug [that] 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				(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 maximum fees for "a pharmacy service or drug [that] 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	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			drugs that require comparable resources."	
9789.40.3(e)	Commenter states that the reference to section 9789.40.3 should actually be 9789.40.4.	Brian Allen, Vice President Government Affairs – Enlyte June 28, 2024 Written Comment	Agreed. DWC agrees that the cross-reference to 9789.40.3 is in error.	The proposal is modified. The cross-reference in §9789.40.3, subdivision (e) is changed to §9789.40.4.
Effective date extension from 90 to 180 days	Commenter supports and thanks the DWC for adding an additional 90 days to the effective date for these regulations. Commenter states that technology automation takes expertise and effort to build a compliant process and, therefore, requests that the DWC assign an internal technology partner, and provide contact information to help guide the industry with any issues that may occur during the implementation and testing phases.	Wendy Cloe Workers' Compensation Regulatory Compliance MyMatrixx by Evernorth June 28, 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.	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			However, DWC anticipates providing some sequential sample Pharmaceutical Fee Data Files and Medi-Cal National Provider Identifier files for use by the public while programming systems.	
9789.40.1	Commenter requests clarification for pricing to be used when neither NADAC (National Average Drug Acquisition Cost) or WAC (Wholesale Acquisition Cost) are available. Commenter asks if the Average Wholesale Price (AWP) should be used when neither NADAC or WAC pricing are available for a drug NDC.	Wendy Cloe Workers' Compensation Regulatory Compliance MyMatrixx by Evernorth June 28, 2024 Written Comment	DWC disagrees that clarification is needed. The "lowest cost" and "no substitution cost" are calculated by DWC based upon the Medi-Cal methodology and data. "Lowest cost" and "no substitution cost" govern the maximum reasonable fee as set out in the regulation text. "Average Wholesale Price" (AWP) is not used in Medi-Cal pharmaceutical reimbursement and is	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			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 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	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
ree Schedule			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 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.	
			in the <u>CMS-approved</u> <u>California State Plan</u> <u>Amendment 17-0002</u> .	

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			Welfare & Institutions Code §141.05.451 sets forth the legislative intent to eliminate Average Wholesale Price from the Medi-Cal pricing formula.	
9789.40.1	Commenter requests clarification of the purpose for a weekly update of the NPI file. Since a pharmacy is required by Medi-Cal to submit this information prior to the annual deadline of March 31st why would there be a weekly update? Would the file ever contain updates that are retrospectively effective?	Wendy Cloe Workers' Compensation Regulatory Compliance MyMatrixx by Evernorth June 28, 2024 Written Comment	Commenter is correct that the annual self-attestation of total pharmacy claim volume deadline is March 31st of each year, which is effective to establish the entitlement to the higher tier fee for pharmacy dispensing in the following state fiscal year period. However, because there can be mid-year changes, the Dept. of Health Care Services sends a weekly Medi-Cal NPI file to DIR/DWC. For example, the DHCS' Pharmacy Provider Dispensing Fee	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			Self-Attestation FAQ	
			explains: "Newly	
			approved fee-for-service	
			pharmacy providers that	
			are notified of their	
			enrollment approval	
			after the attestation	
			period closes will receive	
			the higher dispensing	
			fee. However, those	
			same pharmacy	
			providers will have to	
			attest for subsequent	
			reporting periods in order	
			to continue to be eligible	
			for the higher dispensing	
			fee in subsequent fiscal	
			years." In addition, there	
			may be instances where	
			a provider is disenrolled	
			at some point during the	
			year. DIR/DWC will issue	
			the weekly files to stay aligned with Medi-Cal	
			pharmacy	
			Reimbursement. For the	
			rare instance where	
			Tale instance where	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			there is a retroactive change of a record the regulation allows a 2-day time period for implementation and provides that Request for Second Bill Review can be used to address any change where payment has already issued.	
9789.40.1	Commenter recommends that new pharmacies be designated at the lower volume tier of annual prescriptions during their first year of business. Commenter opines that until sufficient data is available determining claim volume, there is no way to evaluate which of the dispensing fee reimbursements is correct. Commenter opines that this new requirement does not improve the process but adds administrative burden to the administrator without a benefit to the pharmacy.	Wendy Cloe Workers' Compensation Regulatory Compliance MyMatrixx by Evernorth June 28, 2024 Written Comment	DIR/DWC's proposed regulatory approach is intended to stay in alignment with Medi-Cal's method pursuant to the directive of Labor Code §5307.1. As set forth in more detail above, a pharmacy newly enrolled as a Medi-Cal provider will have its NPI on the Medi-Cal NPI file for the first year if they have been notified of their approval after the close	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			of the attestation period. DIR/DWC will utilize the Medi-Cal NPI list to stay in alignment with Medi-Cal; the DIR/DWC will not diverge or alter the Medi-Cal NPI list.	
9789.40.4(c), 9789.40.6, 9789.40.7	Commenter states that the injured worker's recovery should always be considered the priority and that pharmacists play a unique and important role in these patients' treatment. Commenter recommends that when necessary, in case of emergency treatment, it would be reasonable for physicians to provide emergency medication. Commenter opines that the new \$10.05 physician dispensing fee will result in an incentive for a new revenue stream. Commenter states that physician dispensing effectively removes the pharmacist from the equation and raises significant concerns by eliminating safety	Wendy Cloe Workers' Compensation Regulatory Compliance MyMatrixx by Evernorth June 28, 2024 Written Comment	DIR/DWC agrees with commenter insofar as she states that the injured worker's recovery should be the priority. 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	No action necessary.

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	oversight including medication checks, patient medication counseling, and medication management. Commenter requests that the DWC reconsider this new \$10.05 dispensing fee and maintain the \$0 dispense fee for physician dispensed medications.		dispensing, the state law does allow physicians to dispense medications to their patients. (Business and Professions Code §4170.) DWC has 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.	

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9789.40.1	Commenter would like to know if when the Division releases the weekly Pharmaceutical Fee Data File (PFS), if this ongoing release will be a completely new file, or if it will only be corrections to the last file released; need to know this in order to properly implement the feed(s) into their new system(s) and price medication accordingly going forward.  Commenter questions if this is a fully new file for each weekly release, if the changes/corrections from the previous will be highlighted.	Kevin C. Tribout June 28, 2024 Written Comment	The proposed regulation section 9789.40.1, subdivision (a)(3), states: "The Division of Workers' Compensation will post an updated Pharmaceutical Fee Data File on a weekly basis absent extenuating circumstances." This indicates that DWC will post an <i>updated file</i> , not that DWC will post only the updates. The file will be a complete replacement each week. After finalization of the regulations, prior to the effective date of the new fee schedule, DWC anticipates posting sequential files for payers to use in system development and for testing purposes. In keeping with the DWC's prior protocol during the	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			period of posting weekly Medi-Cal updates (From 2004 through February of 2019), the DWC will not post a change report each week.	
9789.40.3 9789.40.7	Commenter states that since Medi-Cal does not pay for unfinished drug products utilized in creating a compounded medication, he questions how stakeholders determine if a drug is an unfinished or finished drug product.  Commenter questions if the PFS feed will include NDCs and drug ingredient costs for both finished and unfinished drug products or just for the finished drug products.  Commenter asks that if the PFS feed only contains NDCs and drug ingredient cost for finished drug products, are the stakeholders to assume products used in a compound not included on the PFS feed are to be calculated	Kevin C. Tribout June 28, 2024 Written Comment	DWC has re-evaluated the approach to setting maximum fees for compounds using bulk ingredients/unfinished drug products.  Medi-Cal does pay for compounded drugs using finished drug products, but does not pay for bulk chemicals that are active pharmaceutical ingredients. They do pay for a small subset of bulk ingredients that are not active pharmaceutical ingredients, for example some excipients (e.g. a product to flavor a drug	Modify section 9789.40.3 and section 9789.40.7 to eliminate the distinction between finished and unfinished drug products and adopt the "Lowest Cost" and "No Substitution Cost" instead of using documented paid cost for unfinished drug products.

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	pursuant to the Division's regulations addressing unfinished drug products.		compounded into liquid dosage form.) Considering comments received, and in order to streamline the process for determining maximum reasonable fee for a compounded drug ingredient, DWC will modify the proposal to eliminate the distinction between finished and unfinished drug ingredients used in a compounded drug. The modified proposal uses the "lowest cost" for drug ingredient part of the formula, except where a brand name drug is prescribed by a physician who has indicated "Do Not Substitute" and has complied with the formulary rules on medical necessity and	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			prospective authorization. By adopting this approach, DWC sets the maximum price under the formula that will most closely align with what Medi-Cal would pay for a drug using comparable resources.	
9789.40(b)(2) Sample NPI Data File	When examining the Division's Medi-Cal status File for Pharmacies (NPI file), commenter found NPIs that have both an "A" indicator as well as an "I" indicator. Some of the dates for the Active (A) status and Inactive (i) overlap which makes determination of the proper dispensing fee difficult. Commenter seeks clarification of the active date and inactive date status overlap, or clarification as to whether this is an error.	Kevin C. Tribout June 28, 2024 Written Comment	Disagree that the regulation needs clarification. The proposed regulation §9789.40.1(b)(2) states that "A pharmacy is eligible for the higher dispensing fee for products dispensed during the effective dates listed, where the effective date period is listed as Active ("A")." Therefore, if a record for a pharmacy NPI is "Active" on the date of	No action necessary.

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			dispensing, the pharmacy is entitled to the higher dispensing fee. Medi-Cal designates a record as "Inactive" on rare occasion, for example to correct an error in the date range. On the sample Medi-Cal NPI file, there are only two NPIs that have any record that is "Inactive." For those two NPIs, the records that are "Active" are used for determining maximum dispensing fee; there is no ambiguity regarding which records are applicable. Subdivision (b)(2) requires each new file to be used to calculate fees not later than second calendar day after posting of the file, and subdivision (4) requires a payer to re-adjudicate	

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			claims for retroactive change in Active/Inactive status upon request for review submitted by provider. Therefore, the payer will pay the higher dispensing fee where the NPI is listed as active on the date of dispensing. If there is a retroactive change to Inactive for a period already paid, the payer will re-adjudicate the claim upon request.	
Effective date extension from 90 to 180 days	Commenter is grateful that the Division has provided a 180-day implementation period from the date OAL approves these regulations in order to implement the extensive system changes required to implement these new rules.	Lisa Anne Hurt- Forsythe, Vice President – Government Affairs AAPAN June 28, 2024 Written Comment	Commenter's support is noted.	No action necessary.
9789.40.1	Commenter is disappointed that a 2-tiered dispensing fee is still included. Commenter opines that the proposed rules should be	Lisa Anne Hurt- Forsythe, Vice President – Government Affairs	Disagree; the statute requires the regulation to follow the Medi-Cal structure. Labor Code	No action necessary.

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	amended to contain a single dispensing fee, regardless of the operational volume of the pharmacy in question. Commenter states that a single equitable and cost-neutral dispensing fee can be arrived at by performing a highlevel analysis to determine how many pharmacies fall into each tier today and arrive at a single figure that would likely end up somewhere in the middle of the two tiers suggested.	AAPAN June 28, 2024 Written Comment	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 payment systems." [Emphasis added.] (Note that for physician-dispensed compounds there is an additional limitation that the reimbursement is limited to 300% of documented	

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			paid costs, but in no case more than\$20 above documented paid costs.")	
9789.40.3 9789.40.7	Commenter states that the revised proposed rules still contain a complex solution for "unfinished" compound ingredients. Commenter states that "drug ingredient cost" should be tied to an established benchmark such as the WAC of the drug ingredient. This would eliminate difficulties associated with obtaining "document paid cost" and would also be consistent with the 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.	Lisa Anne Hurt- Forsythe, Vice President – Government Affairs AAPAN June 28, 2024 Written Comment	Agree in part. DWC agrees that there is a better approach to maximum compound drug ingredient prices than utilizing a distinction between finished and unfinished drug products. The approach that will be included in a modified proposal is more streamlined and more closely models what Medi-Cal pays for drug ingredients. See the response above to the comment submitted by Kevin C. Tribout, dated June 28, 2024 for more detailed explanation.	Modify section 9789.40.3 and section 9789.40.7 to eliminate the distinction between finished and unfinished drug products and adopt the "Lowest Cost" and "No Substitution Cost" instead of using documented paid cost for unfinished drug products.
General Comment	Commenter states that the proposed rules need to be	Lisa Anne Hurt- Forsythe, Vice	Disagree.	No action necessary.

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	<ul> <li>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:</li> <li>Compounded medication with no pre-authorization</li> </ul>	President – Government Affairs AAPAN June 28, 2024 Written Comment	See response to the same comment submitted on April 11, 2024, in the 45-day comment period.	
	<ul> <li>Physician-dispensed medications with no pre- authorization, and</li> <li>Compounded, physician-</li> </ul>			
	dispensed medications with no pre-authorization.			
9789.40.3 9789.40.7	Commenter opines that a single, uniform compounding fee would suffice and would eliminate unnecessary complication in the rules. Commenter appreciates the Division's efforts to ensure the safety of compounded medications by including consideration of sterilization and routes of administration; however, she opines that incorporating these	Lisa Anne Hurt- Forsythe, Vice President – Government Affairs AAPAN June 28, 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 servicesin accordance with the feerelated structure and	No action necessary.

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	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.		rules of the relevant Medicare and Medi-Cal payments systems" The various provisions of §5307.1 make it clear 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	

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			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" 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."	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
			Commenter also states that the compounding fee and sterility fee structure "greatly increases the administrative burden." It 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.	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
General Comment	Commenter supported the removing of the physician dispensing fee during the 45 day comment period. Commenter notes that this 15 day version restored the physician dispensing fee after feedback from various stakeholders during the public hearing. Commenter notes that the restoration of the dispensing fee was made to ensure fundamental fairness in the system and to recognize the expenses incurred by physicians in providing this service to injured workers – a targeted variance from the standard MediCal reimbursement rules.  Commenter's organization represents the vast majority of pharmacy benefit managers operating the in workers' compensation space. Commenter has been concerned regarding the	Lisa Anne Hurt- Forsythe, Vice President – Government Affairs AAPAN June 28, 2024 Written Comment	Disagree with the suggestion to adopt a 1.4 multiplier for pharmaceuticals. There is no statutory provision authorizing the DWC to create a fee 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	No action necessary.
	drastic reduction in pharmacy reimbursement rates associated		and rules of the relevant Medi-Cal payment	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	with the shift to a MediCal-based reimbursement system. Commenter requests that recompense be given to recognize the value of the services provided not only by pharmacies serving WC patients, but also the value that WC PBM's provide to injured workers, in analogous fashion to		systems"; directs pharmacy services and drug fees to be 100% of Medi-Cal pending adoption of the fee schedule; directs the DWC to establish maximum fees for "a pharmacy service or	
	that provided by the physicians in dispensing medications. Commenter has suggested 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. Clear precedent for such a move already exists with the CA Workers' Compensation system, such as the multiplier for		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	
	physician services in California added to the Medicare reimbursement base. After the WC add-on, reimbursement rates for physicians in the state sit at approximately 145.72% of		to conform to any relevant Medi-Cal payment system changes no later than 60 days after the effective date of those changes.	

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	standard Medicare rates, as of April 1, 2024.  Commenter recommends using a targeted variance from standard MediCal pharmacy rates using the physician service 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 shift to MediCal and ensure fundamental fairness to all stakeholders in the system.			
9789.40.1	Commenter thanks the Division for its clarification with respect to the posting of the PFS and NPI feeds on a weekly basis. Commenter requests that the file releases be scheduled to occur on a specified recurring day and time – e.g., every Thursday at 10:00pm Pacific time. Commenter states that if	Lisa Anne Hurt- Forsythe, Vice President – Government Affairs AAPAN June 28, 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	No action necessary.

OMFS Physician - Pharmaceutical Fee Schedule	RULEMAKING COMMENTS 15 DAY COMMENT PERIOD	NAME OF PERSON AND AFFILIATION	RESPONSE	ACTION
	stakeholders know that the file release(s) will take place at a published day/time on a consistent basis, it will make the process of uploading the file and implementing it into our systems much easier and less time consuming.		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 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.	