Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment	The proposed regulation fails to recognize the costs to physicians in obtaining drugs packaged for patient distribution. The proposed regulation will pay less than the costs of acquiring and distributing needed medications. There has been no credible rebuttal, or proof to the contrary. NOTE: When physicians dispense medications, at least 35% of the patients given a prescription fail to fill the prescription at a retail pharmacy.	R. Douglas Chiappetta, M.A. Chief Legislative Representative UAPD/AFSCME September 12, 2006 Written comment	The Division disagrees. The Division anticipates that current purchase costs to physicians of some drugs will decrease under the regulation.	No action to be taken.
	The proposed regulation seeks to close the loophole in S.B. 228 (Speier). This is an extreme approach, one which pays physicians less than the costs of distribution. Such an approach prevents physicians from dispensing in their offices.		The Division disagrees that the regulation will reimburse at less than the cost of distribution.	No action to be taken.
	The proposal is contrary to Business and Professions Code 4170, and 5703.1 of the Labor Code, which authorizes and permits physician dispensing.		The Division disagrees.	No action to be taken.
	The proposed regulation does not reimburse physicians for dispensing. In fact, it is a disguised effort to prohibit physician dispensing by paying physicians reimbursement less than the cost of the drug and dispensing cost. It is disingenuous to say a physician may dispense, but reimburse less than the costs incurred by the physician. Accordingly, the proposal also violates the mandate of the California Supreme Court that a rate regulation system must not be confiscatory, and must pay the regulated entity its costs and a fair return. (CalFarm Insurance Company v. Duekmejian~ 48 Cal.		The Division disagrees. The pricing in the regulation is authorized by Labor Code §5307.1.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	3rd 805, at pages 815 — 821, hereafter "CalFarm Case") The WCRIB analysis of SB 228 demonstrates that the legislative intent was to reduce pharmacy expense using a Medi-Cal based formula. The WCRIB estimated the savings to be approximately $400 million per year. This savings was to be achieved using AWP minus Medi-Cal's then current discount, which is now 17%.		The analysis of the WCIRB has not been adopted as the analysis by the Division. The opinion of WCIRB on how a savings was to be achieved is not relevant to the regulation.	No action to be taken.
	The supporters of the proposed regulation point to instances of abuse. Any abuse is unfortunate, but should not result in the passage of a punitive and harmful regulation. ("Profits of the past cannot be used to sustain confiscatory rates for the future". CalFarm Case, at page 819). Reimbursing at AWP-17% will prevent future abuses, and is in the interest of injured workers. It allows physicians to dispense, and injured workers to obtain their medications directly and immediately.		The Division disagrees – the regulation does not propose a confiscatory pricing scheme, and the scheme proposed is not intended as punishment of anyone.	No action to be taken.
	Under the current pharmacy system (with the loophole), carrier rates are dropping! Therefore, while pharmacy reimbursement in physician offices is in need of reform, there is no rational basis for the approach inherent in the proposed regulation. It imposes burdens on physicians disproportionate to the problem sought to be corrected, harms injured workers by denying them ready access to their medications, is contrary to well-established law on rate regulation by setting confiscatory rates, and is contrary to the legislative intent		The Division disagrees that the regulation will reduce patient access, that the regulation is irrational, or that the regulation will impose significant burdens on physicians.	No action to be taken.

	of S.B. 228, by reducing reimbursement well below the levels intended by the Legislature. Accordingly, our organization strongly opposes the proposal, and asks that you factor these concerns into your final regulation on this matter.			
General Comment	Commenter has been practicing orthopedic surgery for more than 30 years in the Los Angeles and caring for injured workers' for the 25 years. Commenter has been dispensing medication out of his office for the last four-five years and has noticed that since this time his patients have been following his directions and renewing the medication as prescribed. Additionally, since commenter has been dispensing medication directly in his office his patients have a much more clear idea of what the medication is intended to treat and possible complications and reactions that they should anticipate. His patients are very appreciative of the additional information that they obtain from his office that they do not get from their local pharmacist. Commenter states that the cost of providing the medication directly for his office is quite high. He has hired additional personnel to distribute and keep accurate records of dispensing of medication. Commenter also provides consultation with the patient regarding the medication. Reimbursement for the medication is frequently delayed and/or denied by the insurance company.	Elliot Gross, M.D. Diplomate, American Board of Orthopedic Surgery – AME/QME September 12, 2006 Written Comment	The time and manner of payment to physicians is not the subject of this regulation.	No action to be taken.

	Commenter states that it would be a great disservice to injured workers on the part of the legislature to stop their office from dispensing generic medication to their patients. Recent studies have revealed that insurance companies have reaped huge profits at the expense of cutting medical services through the inappropriate use of ACOEM guidelines as well as a marked 70% decrease in permanent impairment through the use of the AMA guidelines. The insurance companies have only cut their premiums by about 30% after having raised them by more than 200-300% over the last few years prior to the new laws.		The Division disagrees that the regulation will require physicians to cease dispensing drugs from their offices.	No action to be taken.
General Comment	Commenter opposes proposed regulations 9789.40. The proposed regulation fails to recognize the costs to physicians in obtaining medications packaged for patient distribution. The proposed regulation's attempt to close the loophole in SB 228 (Speier) is an extreme approach that pays physicians less than the cost of distribution and as such, prevents physicians from dispensing in their offices. The proposal also runs afoul of the Business and Professions Code 4170, and 5703.1 of the Labor Code, which authorizes and permits physician dispensing. Although this proposed regulation appears to reimburse physicians for dispensing, it actually is an effort to prohibit physicians from dispensing by paying physicians reimbursement less than the cost of the	William J. Pelote, Sr. Assistant Director of Political Action, International September 13, 2006 Written Comment	This comment is the same as that of Douglas Chiappetta. See the response to that comment.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	medication and the dispensing cost. According the proposal also violates the mandate of the California Supreme Court that a rate regulation system must not be confiscatory, and must pay the regulated entity its costs and a fair return. (CalFarm Insurance Company v. Duekmejian, 48 Cal.3rd 805, at pages 815-821, hereafter "CalFarm Case") The Workers' Compensation Rating Insurance Bureau's (WCIRB) analysis of SB 228 demonstrates that its legislative intent was to reduce pharmacy expenses using a Medi-Cal based formula. The WCIRB estimated that savings to be approximately $400 million per year with savings to be achieved using Average Wholesale Price (AWP) minus Medi-Cal's then current discount, with is now 17%. The supporters of the proposed regulation point to instances of abuse. Any abuse is unfortunate, but should not result in the passage of a punitive and harmful regulation. According to the CalFarm Case at page 819, "[p]rofits of the past cannot be used to sustain confiscatory rates for the future. Reimbursing at AWP upon market price at 17% will prevent future abuses, is legal, and is in the best interest of injured workers. It also allows physicians to dispense and injured workers to obtain their medications directly and immediately. Even under the current pharmacy systems, with the loophole, carrier rate are dropping. Therefore, while pharmacy reimbursement in			

	physician office is in need of reform, there is no rational basis for the extreme approach inherent in the proposed regulation. It imposes burdens on physicians disproportionate to the problem sought to be corrected, harms inured workers by denying them ready access to their medications, runs afoul of well-established law on rate regulation by setting confiscatory rates, and is contrary to the legislative intent of SB 228, by reducing reimbursement well below the levels intended by the legislature.			
General Comment	Commenter would like to share with the division from the medical perspective the advantages of providing prescription medication in the doctor's office. There is no doubt that if this service is reimbursed at the levels currently proposed, his office and most others, will stop dispensing, to the detriment of the injured worker. Commenter states that he simply cannot afford to provide this valuable service at the low proposed reimbursement level. Commenter and his staff spend considerable time educating their patients, making sure that they get and use the medication as prescribed. This improved compliance speeds the return to health and work. Before this service was offered, many patients were refused medications in pharmacies. The patients did not have all the requisite paperwork and pharmacists would not fill the prescription. Transportation is frequently a problem as is language (commenter has interpreters in his office) and there are delays in getting the pills. For example, commenter	Robert Aptekar, M.D. September 15, 2006 Written Comment	Educating the patient on the proper use of a prescribed drug is already compensated under the physician services fee schedule, and is expected to be done whether or not the physician dispenses a drug. Also, in a concurrent regulation, the physician fees for these services are proposed to be increased. The Division expects that some physician dispensing will continue in most offices that now dispense drugs.	No action to be taken. No action to be taken.

	was advised by State Fund that all their insureds were sent a card to have their prescriptions filled in a local pharmacy. Commenter asked 10 patients in a row about his claim and not a single one knew what he was speaking about. Many have limited education and communication skills. There are many reasons why physicians have increased expense in providing this service as compared to the corner drugstore. Physician's have: ▪ Extra cost of staff that handles the medications. Nurses and physicians do not staff pharmacies. ▪ Extra cost of a fixed, prepackaged inventory vs. a pharmacist's bulk storage and packaging flexibility. ▪ Extra cost of professional liability insurance greater than that for a pharmacist. ▪ Extra cost of MPN discounts 10-20% discount. ▪ Extra cost of the prolonged billing and collection cycle within workers' compensation – different from other insurance. This will be true even after electronic billing comes in. ▪ Extra cost of unpaid medications due to UR or other issues affecting liability for a claim. ▪ Extra cost of physician's time for counseling of the injured worker compared with that of a pharmacist. ▪ Cost of disposal of expired medications – (factor in the cost of		The Division is aware that some physicians claim that their dispensing costs are greater than some pharmacies'.	No action to be taken.

	regulatory compliance) – a cost that pharmacists do not have. ▪ The lack of opportunity to sell other merchandise to walk-in clientele such as pharmacies can. In conclusion, this valuable option for patients (and benefit to insurers) should be retained through realistic reimbursement rates, reflecting the actual cost of dispensing in the office. The proposed calculation will result in an end to this service as physicians will be forced to stop providing it.		The Division is not proposing that physician dispensing cease. The Division disagrees that the regulation will cause it to cease.	No action to be taken.
General Comment	The recent CHSWC study simply confirms the anecdotal evidence that I and other involved in workers compensation have learned, specifically that the only party to benefit form physician-dispensing of repackaged drugs is the physician. Employers, including numerous self-insured public entities, have paid exorbitant fees for far too long, as confirmed by the study. Additionally, there is no evidence to confirm significant detriment to injured workers who obtain their medications at a location other than form the prescribing physician. For this reasons, commenter echo's his support for the Commission's findings and the proposed administrative rules.	Jeff J. Rush, WCCP, ARM Tuolumne JPA September 15, 2006 Written Comment	No change is suggested.	No action to be taken.
General Comment	Commenter is states that he began to dispense medication out of his office two years ago. The reason he started was because that on average, it would take 10-20 days for workers comp insurance companies to authorize mediation for his patients. In many cases, they never authorized the medication forcing the patient to pay out of pocket or use their	Vinay M. Reddy, M.D. Neurodiagnostic & Spine Rehabilitation Consultants September 17, 2006 Written Comment	The Division does not disagree that timely acquisition of prescribed drugs is a desired objective.	No action to be taken.

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	private insurance (which he believe is the ultimate goal of the delay). Oftentimes patients would be suffering for 2 weeks or more with debilitating pain because they could not get their medications. Workers' compensation has been a nightmare for physician offices. Their office has to appeal everything just to get the standard of care. HMOs are a breeze compared to workers compensation. Dispensing medication allows the patient to obtain the medications quickly. Commenter has to fight to get paid, but at least the patients get the medications and when he does get paid, it usually covers the cost of dispensing. Dispensing medications has its costs. Commenter has a dedicated medical assistant who monitors inventory and files a DEA CURES report regarding the medication. Commenter spends approximately $6,000 on medication per month and an additional 10-15 per patient with dispensing of the medication and proper documentation. Commenter makes about a 15% return on his cost which allows him to pay his employees and comply with DEA rules. If the fee schedule is changed to Medi-Cal rules, there is no way he can continue to dispense medication. Commenter suggests the following options: • Do not go to a Medi-Cal reimbursement system. There is a		The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them. The Division does not disagree that that many physicians regard Medi-	No action to be taken. No action to be taken.

	reason why so many specialists will not see Medi-Cal patients. They can't afford to. Reimbursement is less than the overhead of seeing these patients. • Any other system would be preferable. Use an HMO fee schedule. Use a PPO fee schedule. Make a new fee schedule. • If you do insist on a Medi-Cal reimbursement for physicians, use the same reimbursement for pharmacies which have much less overhead than physician's offices. If you really want to cut costs? Why allow pharmacies to make money on workers comp medications but no one else? This only makes sense if there is special interest money from their organizations influencing law makers. • If you do insist on Medi-Cal reimbursement system, why not add a rule that insurances must authorize medication within 24 hours or have $1000 per penalty occurrence. At least his would protect the patient.		Cal rates for treatment to be too low to be profitable. The Division has not determined any advantages to using an HMO or PPO schedule as suggested. This comment does not suggest change. The Administrative Director does not have authority to make the suggested change.	 No action to be taken. No action to be taken. No action to be taken.
	Commenter is an orthopedic surgeon who has been dispensing medications out of his office to injured workers for well over ten years. His patients are very happy (and the insurance companies should be, too) because he dispenses the necessary medications in a timely fashion and at very reasonable prices. Eliminating this system will not only inconvenience the injured worker but also delay the healing process, which, in turn, would add cost to the system.	Hose Kim, M.D. Orthopedic Surgery September 22, 2006 Written comment	The Division disagrees.	No action to be taken.

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	Commenter understands that there are those doctors who may have been abusing the system by prescribing excessive number of drugs at exorbitantly high prices and he thinks that the State government knows who they are. Commenter is tired of the government coming up with ideas to completely overhaul the system instead of going directly after the "bad actors." Commenter proposes a system which would set reasonable fee limits, rather than completely eliminating the physician's ability to dispense medications out of his office, as it would be counter-productive.		The Division finds that the proposed regulation does set reasonable fee limits.	No action to be taken.
General Comment	The major objection to physician dispensing is based on moot points. There is no question that current regulations created a gap in what was intended to be a comprehensive pharmaceutical fee schedule. There is little question that this fee schedule anomaly has been exploited by some. There is no question that this situation should be remedied. Therefore, commenter concludes that recent studies that harp on economics, do not give the Division credit for understanding the totality and nuances of the issue. To the critical aspects of access, comparable resources and value, these same studies offer only anecdotes, fundamentally flawed access studies, references to foreign health care systems and re-emphasis on reimbursement disparities. In contrast, commenter appreciates that the Division has acknowledged these concerns and remains open to an improved public policy decision.	Stephen J. Cattolica AdvoCal September 27, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.
Section 9789.40 (a)	The Division has heard a consistent message	Stephen J. Cattolica		

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and (b)	from providers and injured workers in meetings as well as in oral and written testimony with respect to the value delivered and value received when a physician dispenses prescription medicines within the occupational medicine system. In response, commenter proposes that the Division include a separate dispensing fee applicable to prescription drugs dispensed by a physician as set forth below. Language stricken from the current proposal is indicated with a single-line strikeout and ALL CAPS, indicate additional language. **Proposed revision:** (a) The maximum reasonable fee for pharmaceuticals and pharmacy services rendered after January 1, 2004 is 100% of the ~~fee~~ reimbursement prescribed in the relevant Medi-Cal payment system, including ~~the Medi-Cal professional fee for dispensing:~~ THE APPROPRIATE DISPENSING FEE AS INDICATED IN PARAGRAPH (b)- Medi-Cal rates will be made available on the Division of Workers' Compensation's Internet Website (http//!www.dir.ca.gov/DWC/dwc_home_pape.htm) or upon request to the Administrative Director at: DIVISION OF WORKERS' COMPENSATION (ATTENTION: OMFS - PHARMACY) P.O. BOX 420603 SAN FRANCISCO, CA 94142.	AdvoCal September 27, 2006 Written Comment		

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	(b) For a pharmacy service or drug that is not covered by a Medi-Cal payment system, the maximum reasonable fee paid shall not exceed the fee ~~specified in the OMFS 2003.~~ determined in accordance with this subdivision, plus A $7.25 professional fee for dispensing BY A PHARMACY, A $1 5 PROFESSIONAL FEE FOR DISPENSING BY A PHYSICIAN or A $8.00 FEE if the patient is in a skilled nursing facility or an intermediate care facility. **BASIS FOR RECOMMENDATION** **California Labor Code requirements:** **Labor Code 5307.1(d)** specifically provides that in the situation where a pharmacy service or drug is not covered by a Medi-Cal payment system, "the administrative director shall establish maximum fees for that item provided, however that the maximum fee paid shall not exceed 100 percent of the fees paid by Medi-Cal for pharmacy or drugs that require comparable resources" (emphasis added). **Labor Code 5307.1(f)** requires that rates or fees established (by the Administrative Director) "shall be adequate to ensure a reasonable standard of services and care for injured employees." Under the Administrative Director's current proposal, reimbursement for the drugs themselves is roughly equivalent, regardless of the point of service. Yet, dispensing from a		While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ from those of pharmacies.	No action to be taken.

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	physician's office involves vastly different resources, higher fixed costs and delivers greater value. The standard of care within the California Workers' compensation system includes physician dispensing when medically called for. The Federal Trade Commission has gone on written record many times' in support of physician dispensing in California and many other jurisdictions. A plain reading of these Labor Code Sections clearly indicates that the proposed fee schedule must be adequate to ensure the standard of care. Without arguing the adequacy of the basic Medical reimbursement formula for the pharmaceutical product itself, physician dispensing, as a necessary component of the standard of care, must be adequately accommodated in accord with the resources necessary to ensure the availability of this service.			
Supporting Information	Commenter provides a lengthy cost analysis to support his argument which is displayed in its entirety in the 45 day comment section of the rulemaking file.	Stephen J. Cattolica AdvoCal September 27, 2006 Written Comment		
	IMPACT ON PATIENTS The proposed changes will affect patients severely in a variety of manners. Under the old system where doctors did not dispense medications directly to the injured workers out of their private offices, patients would get a prescription and go to a pharmacy that would accept Workers Compensation payments. While the pharmacy called the Claims adjuster for authorization there was a delay of hours to	Daniel Mark Silver, M.D. Qualified Medical Examiner September 30, 2006 Written Comment		

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	days before the response and approval would be given. Frequently the approval would not be given and since there were very few pharmacies that would dispense drug without approval, the patient would never get their medications. This lack of obtaining meds to "cure or relieve symptoms" goes against the spirit of ACOEM and good medical treatment and ethics.			
	If the new amendments to Section 9789.40 go into effect, because of the lack of financial incentive to Workers' Comp physicians to dispense medications directly to their injured workers without delay and hassle, I fear the old system will re-emerge. Patients will not receive the proper care to "cure or relieve" their pain, infection, spasm, depression in a timely manner. They will suffer unnecessarily for days and in some cases weeks. Acute injuries will drag out and become chronic, again violating principles set out in the ACOEM Guidelines Chapter 6. The cost savings on drugs will be offset by prolonged times of disability, more legal actions due to anger and frustration on the patients' parts, and more potential secondary psychiatric claims.		The Division cannot base regulations on speculations of how various actors may act in response. The speculation of the Commenter fails to account for the lack of such complaints arising out of claims treated by the many physicians who do not directly dispense but rely upon pharmacies.	No action to be taken.
	Currently, under the present system that allows physicians treating injured workers to dispense medication at a fair and reasonable profit, there is incentive to give the patients what they need immediately at the end of the office visit, eliminate the involvement of a trip to the pharmacy with the usual hassle and delays. We physicians are willing to wait for		The Division disagrees that the existing system allows only a fair and reasonable profit, but instead it allows many exorbitant profits.	No action to be taken.

	authorized payments so that the patient is not inconvenienced. Occasionally, no payment is received if the overall case is denied and those medications are "written off" as un-collectable. IMPACT ON PHYSICIANS The proposed changes will affect physicians in specific ways that will ultimately cause most of us private experienced honest treating physicians to stop treating injured workers, because financially it makes no sense. There is a basic business principle that was told to me by a very successful entrepreneur years ago. In business and life in general you want a high profit to hassle ratio. What this means to me as a small business owner of a successful orthopedic practice, is that to stay in business and keep my sanity, I try to eliminate the hassles and do things that are good for my business without the hassles. Over the past two years with passage of SB899 and its implementation there have been many hassles that I have adapted to. These include new rules and fee schedules for medical treatment and surgeries, prior authorization for everything, multiple denials and appeal letters that had to be written at my expense, utilization review companies that don't follow proper medical practices, increased overhead in trying to get authorized payments in time specified by the labor codes. All of these hassles are stressful to me and other physicians. These hassles also increase the overhead to run a practice.		The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them. This comment does not suggest a change.	No action to be taken. No action to be taken.

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	A specific example is that for 30 years of Orthopedic practice approximately 50% of my income came from office visits and treatments such as injections, x-rays, and reports. The other 50% came from surgery fees. Now with difficulty in getting prior authorizations for surgery plus a very reduced fee schedule of payments equal to 1974, only 20% of my income comes from surgical fees. Dispensing medication out of my office makes up the 30% difference in my office income that allows me to continue practicing, even though my overhead continues to rise due to the many hassles I listed above. The bottom line for a practicing physician with 30 years experience in the Workers' Compensation System, will I be able to stay in practice and continue to serve injured workers or will I stop seeing these patients. This is a choice many of my colleagues and I will make depending on the passage of the proposed amendments. IMPACT ON WORKERS' COMPENSATION SYSTEM The proposed changes will affect the Work Comp. System by having fewer physicians to treat injured workers. At a conference at La Costa earlier last year, Anne Searcy, M.D. Medical Director of DWC was herself making a plea for more physicians to enter the system rather than less. She already had noted a decline in the participating number of QME's which reflect the overall loss of physicians treating Work Comp. Patients. I am sure Administrative Director Carrie Nevans is also			

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	aware of the shortage and it will get acutely worse if these changes go through without some compromise which allows some reasonable profit for the practicing physicians who are dispensing. If these changes are implemented unmodified, we will see a disparity between the savings to the insurance companies and reduction in premiums to employers. Even after a large savings to insurers by effects of SB899, so far only a fraction of the savings have been passed down to the employers. Only the self insured have directly benefited from the total amount of savings from the changes in SB899. If some reduction in drugs fees is to be implemented, I as a physician and a small business owner and tax paying citizen of California demand a required proportional decrease in insurance premiums for employers. Without this requirement, the insurance companies unfairly win again. CONCLUSION In conclusion, passage and implementation of the amendments to Article 5.3 of Chapter 4.5, Subchapter 1, of Title 8, California Code of Regulations, Section 9789.40 will actually harm injured workers, prolong their disability, increase potential litigation and psychiatric and secondary stress claims. The passage of the amendments will cause a significant drop in the number of available experienced competent treating physicians, who currently are making a reasonable profit on medication dispensing to justify putting up		This comment does not suggest a change. The Division disagrees.	No action to be taken. No action to be taken.

	with all of the new hassles in dealing with the Workers' Compensation System. The passage of the amendment will save money for the insurance companies and self insureds, but less than they think, because disability will be prolonged from delays in pain relief, increased litigation and stress claims. More will be paid out in disability dollars rather than in pharmacy dollars I predict. Lastly, there must be as part of any compromise in the regulations a reduction in premiums to employers by insurance companies that equates to the pharmacy savings to the insurance company.		The Division has no authority to regulate insurance premiums.	No action to be taken.
General Comment	Commenter states that workers' compensation patients represent about 90% of his practice and that he has been dispensing medications out of his office for the last two years. Especially in a surgical specialty such as his, it is very important to be able to dispense medications at the time of the visit for many reasons. Frequently he sees lacerations where infections become a major risk and the ability to dispense antibiotics from our office without delay from workers' compensation approval can make the difference between a serious limb threatening infection. Additionally, patients are frequently seen that require urgent surgery within 24-48 hours and those patients additionally need to be started on both antibiotics and pain medications. Frequently he sees delays up to a weeks' time to get approval for these medications which is totally	J. Phillip Maloney, M.D. October 2, 2006 Written Comment		

	unacceptable medical care. Ultimately these patients will receive their medications, it's just a matter of who is going to be paid for the dispensing of those medications. Commenter has no problem with receiving the same compensation that is paid to a pharmacist as that does not increase the burden to the workers' compensation system at all. The idea that medications for the office are somehow less honorable than medications from the pharmacy is ridiculous. Let's use some common sense here and make it convenient and appropriate medical care for our injured workers. Commenter strongly supports the ability for physicians to dispense medications appropriately from their offices. If there is an abuse of this use, then it should be identified individually and those violators brought to light.		The regulations do not limit existing physician dispensing authority.	No action to be taken.
General Comment	Commenter states that many of his patients are on crutches or in a wheelchair or on medication that makes it difficult for them to travel to a pharmacy to pick up their medication. Besides the added convenience of office distribution of medication, there is tremendous patient benefit in quality control and patient care. Every patient who receives mediation in our office receives a one-on-one consultation about their medications, and a discussion of possible reactions, side effects and proper dosing. In addition, he has the patient's entire medical record available for review, including all previous drug reactions, and current medications, making his consultation with	Jeffrey L. Halbrecht, M.D. October 4, 2006 Written Comment		

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	them much more effective and accurate than would occur in a pharmacy. In order to provide these services, there is a significant added cost above what would occur in a pharmacy setting. Every patient received direct consultation with a physician or physician assistant upon receipt of his/her medication. This cost alone can approach $50 (15 minute consultation at $200 per hour). There are also costs for ordering medication, maintaining records, storage costs, and inventory costs. There are costs for producing written instructions both in English and Spanish for each medication. There are ongoing costs for frequent follow up phone calls to review proper medication instructions, and answer questions or address complications that arise. Unlike most pharmacies, we are available 24 hours a day, seven days a week to answer patient questions. Finally, billing costs and costs to collect and appeal unpaid bills add an additional 10-15% to the cost for each medication. It is difficult to exactly calculate all the added incremental costs associated with dispensing medication in the office, but his estimate, taking all of the above into account, is a minimum of $75.00 per medication dispensed. If the new price reductions are passed, he will no longer be able to afford to dispense medications in the office, depriving his patients of a high quality, more convenient and effective way to receive prescription		Educating the patient on the proper use of a prescribed drug is already compensated under the physician services fee schedule, and is expected to be done whether or not the physician dispenses a drug. Also, in a concurrent regulation, the physician fees for these services are proposed to be increased. While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ form those of pharmacies.	No action to be taken. No action to be taken.

	medication.			
General Comment	The State of California thinks that Medi-Cal insurance is real insurance. In fact, no one in private practice will actually take Medi-Cal because the reimbursement rates are below the cost of providing the service. Commenter points out that the division is currently recommending that workers' compensation patients receive pharmacy medications on the basis of the Medi-Cal payment system and asserts that the division fails to understand how convoluted and arcane the workers' compensation payment system is. Any pharmacy who accepts a Medi-Cal reimbursement under workers' compensation is going to lose money. Commenter states that anyone would have to be stupid to agree with what the division is proposing. Many other physicians are going to write to the division suggesting that the proposed changes are bad. Their motive is simply that they are not going to make the unconscionable profits that they have been in dispensing medications. Frankly, the current system is an abuse of everyone. However, as always, the pendulum seems to swing too far to the other side. What is about to happen is that workers' compensation patients are simply going to be denied medication. If you paid all of the orthopedic surgeons at Medi-Cal rates for workers' compensation patients, all of them would simply refuse to see them. It would cost more money than it is worth and they would seek business	George A. Pugh, M.D. East Bay Orthopaedic Specialists Medical Corporation October 4, 2006 Written Comment	The Division does not disagree that that many physicians regard Medi-Cal rates for treatment to be too low to be profitable. The pricing in the regulation is authorized by Labor Code §5307.1.	No action to be taken.

	elsewhere. That is exactly what is going to happen with the current system. Commenter states that the proposed system is draconian and misguided.			
General Comment	In general, commenter supports the proposed regulations to better contain costs for repackaged medications. Commenter supports parity in reimbursement for workers' compensation prescriptions regardless of the dispensing entity, however, parity is not truly achieved since pharmacy dispensed medications will still be tied to Medi-Cal while repackaged medications will be reimbursed at the AWP, less 17% plus dispensing fee. Commenter is certain that the intent of the legislature is passage of SB 228 was to control pharmacy costs, but not to force continued reimbursement reductions on pharmacists who serve injured workers. Continued linkage of the WC pharmacy to Medi-Cal will endanger the ability of California pharmacists, and their membership companies to serve injured workers. Commenter encourages the Division to adopt a workers' compensation-specific fee for the following reasons: 1. Patient characteristics and desired medical outcomes are vastly different in the practice of workers' compensation pharmacy and bear no resemblance to patient populations and treatment protocols found in Medi-Cal, which the current and proposed methodology does not acknowledge;	Kevin C. Tribout Executive Director Worker's Compensation Pharmacy Alliance October 10, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	2. Ever-changing reimbursement policies force pharmacists dispensing workers' compensation medications to face future uncertainties and restrict their ability to build long-range business plans based on anticipated reimbursement levels; 3. The excessive administrative time required to process a claim, endless gamesmanship and delays in payment, and a pharmacist bad-debt associated with workers' compensation are not taken into consideration when setting the Medi-Cal reimbursement rate; and 4. With CMS exploring adoption of AMP (average manufacturing price) as a basis for Medicare and Medicaid pharmacy reimbursement, the Medi-Cal fee schedule will again be reduced and even fewer drugs listed by Medi-Cal will be utilized in workers' compensation. Recent analysis by member companies indicate that drugs found in the current CMS AMP listing account for only 1% of medications used in treating work related injuries. Commenter proposes the following fee language to help bring stability and predictability to prescription drug reimbursement for workers' compensation claims. The proposed language would also provide an incentive for providers and carriers to work together to bring administrative efficiencies to the system and ultimately lower costs for employers. 1. Prescription drugs dispensed to an injured		The Commenter suggests language very similar to what was proposed by the Division. However, the language proposed by the Administrative Director is more inclusive, and covers all currently excepted drugs, not only repackaged drugs.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	worker for a workers' compensation claim will be reimbursed at: a. The average wholesale price (AWP) less 17% plus a dispensing fee of $7.25; or b. a negotiated rate between the provider and payer. 2. The average wholesale price (AWP) be established based on either Red Book, MediSpan or First Data or other nationally recognized publication. 3. For repackaged medications, if the drug product dispensed is not listed in the National Drug Code, the average wholesale price can not be greater than the lowest-priced, therapeutically equivalent drug that is found in the National Drug Code. 4. For the purposes of this section: a. "therapeutically equivalent drugs" means drugs that have been assigned the same Therapeutic Equivalent Code starting with the letter "A" in the Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book".) The Orange Book may be accessed through the Food and Drug Administration's website: http://www.fda.gov/cder/orange/default.htm.; b. "National Drug Code for the			

	underlying drug product from the original manufacturer" means the National Drug code of the drug product actually utilized by the repackager in producing the repackaged project. The schedule proposed above would be predictable, could be changed with adequate public input from stakeholders in the workers' compensation system, and would provide incentives for providers and carriers to work together to reduce costs. Further, commenter feels that there would be no loss of cost savings from de-linking the reimbursement from Medi-Cal. According to the recent RAND study, closing the current repackager 'loophole' will stop suspected abuses of the system and inject massive savings into the system, savings that would far outpace any loss associated with de-linking from Medi-Cal.		Any schedule adopted by the Administrative Director may be changed.	No action to be taken.
General Comment	Commenter has concerns about the proposed regulations for a number of reasons revolving around patient care. Physicians are in a unique position to ensure injured employees have readily available access to medications – a critical step in ensuring proper care. If patients are required to take additional steps to obtain medication that is instrumental to their healing process, they are much less likely to access that medication. OPSC member physicians have already been made aware of horror stories in which post operative patients have been unable to access pain medication	Joseph A. Zammuto, DO Chair, Workers' Compensation Com. October 13, 2006 Written Comment	The Division does not disagree that there are advantages to physician dispensing.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	and patients with infections have been unable to obtain antibiotics, all resulting from carriers that do not allow physicians to dispense. The propose regulations will discourage physicians from dispensing medications, with detrimental consequences. Often the medications supplied by the physician's offices are purchased from repackagers who charge a mark-up for their involvement. Physicians are unable to return expired or overstocked medications. They do not purchase in large quantities and therefore are ineligible for discounts. And the $7.25 dispensing fee does not provide sufficient compensation for physicians educating patients on medication use, drug interactions, etc. Commenter recommends the withdrawal of these regulations. If that is not feasible, another possibility would be reconsideration of the issue as part of the review		The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them. While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ from those of pharmacies.	No action to be taken. No action to be taken.
General Comment	Commenter has been a sales rep for a re-packager for about 9 years and lives in southern California. He/She is unable to attend the October 31st meeting, however, would like the division to know he/she is supportive of the proposed regulations to decrease the reimbursement to the physician /provider and offers the following observations: 1. Why should it be higher than a regular pharmacy who lives with the Medi-cal fee schedule.	Anonymous October 13, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.

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	2. If Wal-Mart or Target can come out with a $4 generic pharmacy program (as they have done) for the consumer, what does that tell you about the inflated amount over reimbursed by the payer to the provider. This is another good way to save the money for the businesses of California. 3. The division's proposed reimbursement allowances are fair and in accordance with other items a physician might dispense to the patient such as crutches, braces, etc.			
	Commenter applauds the Division of Workers Compensation in drafting regulations to reasonably control pharmaceutical costs for physician-dispensed drugs for workers compensation patients. There are times that this method is appropriate for the injured worker; however, there must be cost containment measures on these drugs just as they are on the pharmacies. Commenter supports the proposed fair and equitable reimbursement schedule that allows this practice to continue without abuse and in a cost effective manner. Recent reforms of the California Workers Compensation system have established fee schedules for pharmacy benefits for injured workers. A loophole that has been exploited is about to be closed. Physicians' offices have been able to dispense and sell medicines out of their office at inflated prices well in excess of the established fee schedule. These proposed regulations will reduce the cost of pharmaceuticals in the workers' compensation system while not adversely impacting the	Marti Fisher Legislative Advocate California Chamber of Commerce October 17, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.

	injured workers. The practice when necessary can continue and physicians will be compensated at fair rates – the same as pharmacies.			
	Commenter urges the Administrative Director to protect physician dispensing.	Mary Grace Balkney October 18, 2006 Written comment	This comment does not suggest a change.	No action to be taken.
	The adoption of this proposed regulation will not create jobs for the state of California, in fact, it will eliminate existing small and large businesses altogether. Eliminating businesses will cause a significant amount of people to lose their livelihood. The adoption of the proposed regulation will not allow our doctors to provide the best possible care to their patients. Many times the patient is injured at work and has no access to medical care when the employer or insurance company does not accept the injury as work related. Commenter has observed countless cases denied by the workers comp insurance companies, and then, 6 months to a year later, the denial is overturned. Many cases are pending for various reasons, or the patient is injured on the weekend and has no access to medication or treatment. Many of their patients are unable to work due to their injury. How will these patients afford their medications? Commenter has a significant amount of patients with limited mobility. These patients have just had surgery or they have serious neck and back injuries that make it extremely difficult to get to and from the doctor's office. Sending them to a pharmacy after they can barely make it to the doctor's office causes the patient unnecessary pain and	Tamara Sanders Collection Manager Pacific RX October 18, 2006 Written Comment	The Division disagrees that adoption of the regulation will prevent physicians from providing the best care to patients.	No action to be taken.

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	stress. Commenter's doctors provide treatment and medication to their patients, no matter what the worker comp carrier does or does not dictate and would like to continue providing the best possible care for their patients. There has to be a middle ground that both sides can agree upon. Elimination of small and large businesses is clearly not the answer. Commenter proposes that the Division adopt the State Compensation Insurance Fund's order to comply with the intent of SB228. State Compensation Insurance Fund adopted their own process of 93% of the Redbooks AWP plus a dispensing fee. Doctors could still provide their patients with medications in the event that their case is pending, being reviewed or denied at a rate that is fair on both sides. This adoption would not change the way pre-packaged medications are process by insurance companies. There would be no need to create a new program. Medical providers could use the Redbook for the AWP and receive a fair price for medications. This will keep commenter's company from going out of business and countless others. State Compensation has a fair solution to the SB228 loophole.			
	Commenter supports the proposed regulations promulgated by the Division of Workers' Compensation to incorporate a fee schedule for doctor dispensed prescription drugs for injured workers. This regulation addresses a loophole in reimbursement rates for pharmaceuticals not covered under the current workers compensation fee schedule. In 2003,	Angie Wei Legislative Director California Labor Federation October 19, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.

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	a fee schedule for pharmaceuticals was established that was tied to the Medi-Cal reimbursement system. Prescription drugs that are repackaged and dispensed by physicians directly are given a new National Drug Code (NDC) number. Medi-Cal's system doesn't recognize this number and, therefore, the Medi-Cal fee schedule does not apply. Instead, dispensing doctors are subjected to the prior fee schedule that is based on the Average Wholesale Price (AWP). The AWP is the drug manufacturers self-reported price and can he compared to the sticker price of a car. These doctors are actually getting reimbursed 110% of AWP for brand name drugs plus a $4 dispensing fee, and 140% for generic drugs with a $7.50 dispensing fee. The result of this loophole is that some dispensing doctors are receiving outrageously higher payment than retail pharmacies. As documented by a study performed by RAND, generic Ultram dispensed by a pharmacy could cost (including dispensing fee) $37.93 for 100 tablets, but as much as $234.05 for the same quantity when the physician-dispensed drug was purchased from a repackager. More and more doctors who treat injured workers are directly dispensing prescription drugs from their offices to increase their profits. Drug repackagers are promoting their services to these doctors as a way for them to increase their bottom lines. But, when prescribing patterns are directly tied to financial profits, dangerous outcomes for injured workers can occur. For example, an			

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	injured worker's pain may be alleviated with an over the counter analgesic. But, a dispensing doctor could prescribe Oxycontin instead. The retail pharmacy price for Oxycontin is $283.02 for 60 units. The repackager's price is $358.56, over 25% higher in price. This type of prescribing decision can present addictive and dangerous medical outcomes for injured workers. This proposed regulation would generally conform repackaged drug prices to the same prices that are charged for drugs by the workers' compensation system through a retail pharmacy the Medi-Cal price plus the same $7.25 dispensing fee paid to pharmacies. Pharmaceutical costs have become one of the fastest growing components of medical care for injured workers. The Workers' Compensation Insurance Rating Bureau estimated in 2004 that the new pharmacy fee schedule would generate savings as high as 37%. Post data analysis by the California Workers' Compensation Institute, the average unit payments per prescription drugs has thus far have been down less than 10% from 2004 levels. In 2004, repackaged drugs not subject to the Medi-Cal fee schedule, accounted for 30% of workers' comp prescriptions, 43% of the total amount billed, and more than half of the total dollar amount paid for prescription drugs. This proposed regulation saves the State money. As a payer of worker's compensation coverage, the State of California will save			

	money under this fee schedule for repackaged drugs. The State Compensation Insurance Fund (SCIF), the state's payer, estimates that SB 292 will save the state over $2.5 million in workers' compensation costs. When workers' compensation vendors offensively profit from the system, ultimately it is the workers and the employers who suffer. System costs rise and injured workers benefits are slashed as a response. Employers unnecessarily pay for care. Both labor and management organizations have supported such a fee schedule because neither of us wants to suffer at the hands of profiteering vendors. Commenter thanks the Division for the efforts undertaken to impose such a schedule.			
General Comment	AFCMS and UAPD feel that the Administrative Director's proposal was contrary not only to Business & Professions Code 4170 but also to 5703.1 of the Labor Code which authorizes and permits physician dispensing. AFCMS and UAPD supports physician dispensing and the proposal that physicians should have their own dispensing fee. AFCMS and UAPD has sent two letters in support of physician dispensing, both signed by Willie Pelote, AFSCME, Assistant Director, Political Action, AFSCME International. The first of these letter was also	Robert L. Weinmann, MD Union of American Physicians & Dentists October 19, 2006 Written Comment	The Division disagrees. The regulation does not limit physician dispensing.	No action to be taken.

	co-signed by the commenter. AFCMS and UAPD understand that the California Labor Federation is opposed to proposals to enable physician-dispensing. Commenter also understands, perhaps not correctly, that the California Labor Federation is also asserting that they represent a unified labor front on this matter. This assertion, if it is being made, is incorrect. AFCMS and UAPD support physician dispensing. The California Labor Federation does not speak for AFSCMS in this regard.			
	The proposed regulation will make it very difficult, if not impossible accurately to calculate allowable fees for drugs whose NDC is not part of the Medi-Cal database due to the language requiring use of an NDC number that is not contained on the product labeling: Section 9789.40 (b) (1) (proposed): If the National Drug Code for the drug product is not in the Medi-Cal database the maximum fee shall.... using the National Drug Code for the underlying drug product from the original labeler The determination of the NDC of the underlying drug product of a repackaged drug creates an extremely difficult audit trail due to the fact that a repackaged drug has been listed under the NDC of the repackager, and it is a violation of FDA policy to have more than one NDC number on a product label. In addition, repackagers utilize therapeutically	Robert H. Goodrich Director of Operations Southwood Pharmaceuticals, Inc. October 20, 2006 Written comment	The Division disagrees. If a repackaging labeler cross-references its supplies of a drug with the sources, it can, if it chooses, provide this information to the purchasing physician.	No action to be taken.

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	equivalent generic drug products from a variety of sources depending on market availability and there exists no methodology to consistently identify which underlying NDC would apply to different packages of what is marketed as a single drug product with one NDC. This rule would place an unreasonable burden of cross-referencing repackaged drugs, by lot number, with underlying NDC numbers in order to place a claim for pharmaceutical services. Requiring the use of the underlying NDC numbers also creates inconsistencies in reimbursement rates for products that are not included in the MAIC or FUL schedules. For example, a repackager would always distribute the same therapeutically equivalent drug under an identical label and NDC; examples to follow: NDC		That a drug product may be differently reimbursed from another, because it is from a different NDC and a different manufacturer is not significant. The same discrepancies may already occur for the same drug product purchased from different manufacturers.	No action to be taken.

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	Product:Pentazocine/Naloxone Tablets #60 NDC Labeler Reimbursement 52152021102 Amide $63.78 00591039501 Watson $55.54 00406311801 Mallinckrodt $54.06 Product: Nambutone 500mg Tablets #60 NDC Labeler Reimbursement 00185014505 Sandoz (Eon) $75.77 49884064905 Par $68.59 Product: Ketoprofen 50mg Capsules #60 NDC Labeler Reimbursement 00603417721 Qualitest $47.40 00904771160 Major $51.70 00378407001 Mylan $55.30 Product: Dicloxacillin 500mg Capsules #20 NDC Labeler Reimbursement 00093312501 Teva $27.17 00904264860 Major $18.36 00603324221 Qualitest $17.29 These examples illustrate how the proposed rule requires different reimbursements for the same repackaged drug NDC number. These transactions would be extremely difficult and costly to audit and would require an unreasonable burden on dispensers to justify the claim amount. It also poses an unreasonable burden on suppliers who will be asked to provide this "underlying" information to the dispenser. Commenter proposes that reimbursement for repackaged drugs utilize the Medi-Cal method of AWP less l7% plus dispensing fee using the NDC of the repackaged product as it appears on the label of the medication. This method incorporates Medi-Cal methodology		(per DWC calculator) (per DWC calculator) This method would be inappropriate for repackaged drugs, as Medi-Cal does not reimburse physician for dispensing of repackaged drugs.	No action to be taken.

	and utilizes completely auditable data readily available to both payers and providers.			
	The proposed regulations have been reviewed Commenter is in total agreement with them as written. Commenter appreciates the fact that the DWC has equated the pricing for repackaged drugs with that currently allowed for drugs purchased through Medi-Cal.	Tina Coakley Legislative/Regulatory Analyst The Boeing Company October 24, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.
	An administrative agency derives its authority to issue regulations solely from the Legislature. (Gov. Code, §§ 11342.1, 11342.2; *Grimes v. State Dept. of Social Services* (1999) 70 Cal.App.4th 1065, 1072-1073.) The Legislature has the exclusive authority to make key policy decisions, and the agency has the "power to fill up the details" of that policy. (*First Industrial Loan Co. v. Daugherty* (1945) 26 Cal.2d 545, 549, citations omitted.) If in the course of "fill[ing] up the details" the agency overreaches or undermines the policy set by the Legislature, the resulting regulation will not be allowed to stand. (*Boehm & Associates v. Workers' Comp. Appeals Bd.* (1999) 76 Cal.App.4th 513, 518-519; *see also Association for Retarded Citizens v. Department of Developmental Services* (1985) 38 Cal.3d 384,	Margaret R. Prinzing Remcho, Johansen & Percell October 26, 2006 Written Comment		

[1] Senate Bill 1852, effective January 1, 2007, amends this provision to state that "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." (Stats. 2006, ch. 538, § 491.) The changes in Senate Bill 1852 are only "technical, nonsubstantive changes in various provisions of law to effectuate the recommendations made by the Legislative Counsel to the Legislature." (Legis. Counsel's Dig. Bill No. 1852 (2005-2006 Reg. Sess.).) The amendments to Labor Code section 5307.1 have no impact on the provision's meaning generally or on this analysis in particular.

[2] *See, e.g., Bakanauskas v. Urdan*, 206 Cal.App.3d 621, 626-628 ("comparable" apartments must be determined with reference to the qualities relevant to the rent control statute requiring the comparison); *In re Marriage of Newman* (2000) 80 Cal.App.4th 846, 849-850 ("comparable" pleadings must be determined with reference to the spousal support issues addressed by the statute, not issues relating to the dissolution of marriage outside the scope of the statute).

	391, citations and internal quotations omitted [finding that administrative action "must be declared void" if it "alter[s] or amend[s] the statute or enlarge[s] or impair[s] its scope"]; *J.R. Norton Co. v. Agricultural Labor Relations Bd*. (1979) 26 Cal.3d 1, 29, citation omitted [court has "obligation to strike down" regulations that exceed statutory authority].) Regrettably, proposed section 9789.40 both overreaches and undermines the policy set forth by the Legislature in Labor Code section 5307.1. It overreaches because the Legislature simply did not give the Division of Workers' Compensation authority to set fees of this nature for medical services that – like physician dispensing – are neither covered by Medicare, Medi-Cal nor a Medi-Cal compensated service that requires comparable resources. Proposed section 5307.1 also undermines the Legislature's decision to endorse physician dispensing within the workers' compensation system because the regulation imposes fees so low that few physicians could afford to offer the service. These artificially low fees directly conflict with the mandates in Labor Code section 5307.1(a) and (f) requiring the DWC to establish "reasonable" fees that "shall be adequate to ensure a reasonable standard of services and care for injured employees."		The Division disagrees. The regulation is authorized by Labor Code §5307.1.	No action to be taken.

[3] This does not mean that subdivision (d)'s exception for drugs or services not covered by Medi-Cal applies to physician dispensing. Other provisions would, however, apply, such as subdivision (g)'s requirement that the DWC conform its fee schedule to relevant changes in Medi-Cal (such as any future coverage of physician dispensing) or subdivision (e)'s requirement that the fee schedule in effect on December 31, 2003 apply to any service not covered by Medi-Cal.
[4] *Gould* considered an earlier version of section 5307.1, which permitted a physician to charge in excess of the fee schedule fee "when reasonable . . ." (4th Cal.App.4th at 1066.)

	For these reasons, commenter requests that the DWC withdraw proposed section 9789.40, or at a minimum, to amend it to conform with the true costs of physician dispensing. **A. The Labor Code Does Not Permit the Fees for Physician Dispensing Set Forth in Proposed Section 9789.40** Labor Code section 5307.1(a) declares that payments for medical services provided to injured workers must be linked to "the fee-related structure and rules of the relevant Medicare and Medi-Cal payment systems." While most medical services covered by workers' compensation are linked to Medicare, the Legislature linked pharmacy services and drugs that are not covered by Medicare to the fees "prescribed in the relevant Medi-Cal payment system." (*Id*.) For pharmacy services and drugs not covered by Medi-Cal, the administrative director must "establish maximum fees for that item, *provided, however, that 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*." (*Id*. at § 5307.1(d)[1], emphasis added.) In other words, the administrative director may set fees for pharmacy services and drugs not covered by Medi-Cal *if* Medi-Cal covers a pharmacy service or drug "*that require[s] comparable resources*."			

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	As Doctors Wilson and Gitlin note in studies relied upon by the DWC in formulating this proposed regulation, "Medi-Cal doesn't cover physician dispensed pharmaceuticals." (Wilson L. & Gitlin M., *Repackaged Pharmaceuticals in the California Workers' Compensation System*, p. 4 ["*Repackaged Pharmaceuticals*"] Division of Workers Compensation Web site <http://www.dir.ca.gov/DWC/DWCPropRegs/OMFS_Pharmaceuticals/OMFS _Pharmaceuticals__regulations.htm> [visited Oct. 26, 2006]; *see also* Wilson L. & Gitlin M., *New Workers' Compensation Legislation: Expected Pharmaceutical Cost Savings*, p. 16 [noting that the repackaged drugs dispensed by physicians "have no Medi-Cal price."].) Nor does Medi-Cal cover any service that "require[s] comparable resources." Medi-Cal does cover *pharmacy* dispensing, however, and the DWC has apparently chosen Medi-Cal's professional fee for pharmacy dispensing as the basis for setting professional fees for physician dispensing. (*Compare* Welf. & Inst. Code, § 14105.45(b)(1) [setting dispensing "professional fee" for "pharmacy providers" at $7.25 generally or $8.00 when dispensed to a beneficiary residing in skilled nursing or intermediate care facilities] *with* proposed § 9789.40(b) [same].) Yet there is nothing "comparable" about the resources required by pharmacies and physicians to dispense drugs even though both services involve the same mechanical process of delivering drugs to patients. "Comparable"			

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	means "equivalent" or "similar." (Webster's New Collegiate Dictionary (4th ed. 1976) p. 229.) As construed by the courts, matters are not "comparable" within the meaning of a statute if "marked differences . . . distinguish one from the other" in a way that is relevant to the Legislature's purpose in making the comparison. (*Bakanauskas v. Urdan* (1988) 206 Cal.App.3d 621, 626-628.)[2] The comparison that is relevant for purposes of a fee-setting statute is not whether the services are themselves similar, but whether they have equivalent costs. Physician and pharmacy dispensing do not. Pharmacists use far fewer resources to dispense drugs than physicians must use. For example, pharmacists may buy drugs in bulk quantities at low prices and then create the smaller doses that patients need. Physicians must buy drugs that have already been reduced from bulk quantities, and so lose the bulk discounts that pharmacists enjoy while accumulating repackaging fees. In addition, while both pharmacist and physician dispensers must retain staff to assist in dispensing and meeting the regulatory and safety requirements for dispensing drugs, physicians are unable to spread those costs over the larger volume of dispensing performed by pharmacists. Finally, physicians justifiably earn higher professional fees than pharmacists. Physicians have more patient contact and generally offer more expensive services based on their heightened education, training and exposure to liability. It is also apparent from the plain language of section 5307.1(d) that the Legislature did not			

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	intend to grant the administrative director discretion to set fees over whole categories of drugs or services exempted from Medi-Cal. Under the statute, the administrative director may establish maximum fees for an "item" if she determines that "a" pharmacy service or drug is not covered by "a" Medi-Cal payment system. The statute refers to a single item such as a single new drug, and not a whole category of services like physician dispensing. The grant of discretion is, in other words, narrow rather than broad. In short, the administrative director has no authority to sweep physician dispensing into proposed section 9789.40 unless and until the Legislature amends current Labor Code section 5307.1. The Legislature understands and intended this result, and has considered such an amendment. Senator Speier – who in 2003 supported the amendment (SB 228) that linked the workers' compensation fee schedule to the fee schedule for Medicare and Medi-Cal – introduced Senate Bill 292 during the last legislative session. SB 292 would have "prescribe[d] the formula to be used for reimbursement . . . for a drug that is not found in the Medi-Cal database, *including repackaged drugs*." (Leg. Counsel's Digest, emphasis added.) According to the Assembly Appropriations Committee's report on SB 292, this provision would have "addresse[d] an area . . . *that ha[s] been thus far untouched by recent legislative reforms*." (Assem. Com. on Appropriations, Analysis of Sen. Bill No. 292 (2005-2006 Reg. Sess.) as amended Aug. 15, 2005, p. 2, emphasis			

	added.) While "other" workers' compensation reforms such as SB 228 addressed prescription pricing in ways that include establishing a reimbursement fee schedule "for most prescription drugs," SB 228's "fee schedule *does not apply to repackaged drugs prescribed and distributed by a physician in the office setting*." (*Id.* at p. 3, emphasis added.) Because proposed section 9789.40 exceeds the statutory authority granted by the Legislature, commenter urges the DWC to set it aside until such time that the Legislature amends section 5307.1 to empower the DWC to set fees of this nature for physician dispensing. **B. Even if the DWC Could Set These Fees for Physician Dispensing, the Low Fees in the Proposed Regulation Violate the Statutory Requirement that Fees be "Reasonable"** Even if section 5307.1 did vest the DWC with the authority to set fees for physician dispensing through proposed section 9789.40, the statute precludes the drastically low fees prescribed by the DWC. According to one of the studies the DWC relied upon in promulgating this proposed regulation, Medi-Cal payment rates for physician-dispensed repackaged pharmaceuticals "may be extreme." (*Repackaged Pharmaceuticals* at p. 2.) An unreasonably low fee schedule presents the		The Division disagrees. The regulation is authorized by Labor Code §5307.1.	No action to be taken.

	risk that "physicians using repackaged pharmaceuticals for their workers' compensation patients will stop taking workers' compensation patients or stop providing point of service medications to them." (*Id*. at p. 20.) This is not what the Legislature intended. To the contrary, the Legislature plainly sought to protect injured workers' right to receive their prescriptions directly from their physicians. Section 5307.1 expressly applies to certain pharmacy services and drugs "whether furnished through a pharmacy *or dispensed directly by the practitioner* . . ." (Lab. Code, § 5307.1(a), emphasis added.)[3] Similarly, Labor Code section 4600.1(d) states that "[n]othing in this section shall be construed to preclude a prescribing physician, *who is also the dispensing physician*, from dispensing a generic drug equivalent." (Emphasis added.) Furthermore, the Legislature sharply limited the fee-setting discretion it granted the DWC. Section 5307.1 fixes the ceiling on fees with exactitude: the administrative director may not set maximum fees of more than 120% of the fees paid for certain Medicare services or 100% of the fees paid for certain Medi-Cal services. The Legislature established the floor for fees by granting the DWC more but limited discretion: Fees must be "reasonable," and "*shall be adequate to ensure a reasonable standard of services and care for injured employees*." (Lab. Code, § 5307.1(a) & (f), emphasis added.) While this language vests the administrative director with flexibility in		The Division disagrees that the regulation adopts fees which are not reasonable.	No action to be taken.

	defining "a reasonable standard of services and care," it does not allow fees that are so low that the service will no longer be available to most or all injured employees. Whatever else it means, "reasonable standard of services and care," cannot mean no service and no care. In fact, in previous versions of section 5307.1, courts have given the term "reasonable" a robust meaning that section 9789.40 ignores. A fee may be considered "reasonable" based upon many factors including the nature of the services provided, the economics of a physician's practice, the pattern of charges in the general geographical area in which the physician practices, and the inclusion of "a percentage of profit margin." (*Gould v. Workers' Comp. Appeals Bd.* (1992) 4 Cal.App.4th 1059, 1071; *cf. Ameri-Medical Corp. v. Workers' Comp. Appeals Bd.* (1996) 42 Cal.App.4th 1260, 1266, 1284.)[4] By relying on the term "reasonable" in the current version of section 5307.1, the Legislature has endorsed the courts' real-world definition. (*People v. McGuire* (1993) 14 Cal.App.4th 687, 694, internal quotation marks and citation omitted ["[T]he Legislature is deemed to be aware of statutes and judicial decisions already in existence, and to have enacted or amended a statute in light thereof."]; *State of California v. General Ins. Co. of America* (1970) 13 Cal.App.3d 853, 860 ["[W]here legislation is framed in the language of an earlier enactment on the same or an analogous subject, which has been judicially construed, there is a very strong presumption of intent to			

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	adopt the construction . . .”].) Yet proposed section 9789.40 fails to account for the greater expenses incurred by physicians in dispensing drugs, and forces physicians to either deny their patients the service or operate at a loss. In short, the proposed fee is patently unreasonable. Proposed section 9789.40 must also be analyzed in the context of the Constitution, which prohibits price controls that are so arbitrary, discriminatory or demonstrably irrelevant to the Legislature’s policy that they “preclude any possibility of a just and reasonable return.” (*CalFarm Ins. Co. v. Deukmejian* (1989) 48 Cal.3d 805, 816.) Fees that provide no return but instead force physicians to absorb a loss preclude the possibility of a “just and reasonable” result. This raises concerns about the constitutionality of this provision, and underscores the need for an administrative process that will provide relief from confiscatory rates. (*Id*. at 816-817.) Commenter understands that concerns have been raised about the relatively higher costs associated with physician dispensing as compared to pharmacy dispensing. Commenter appreciates that proposed section 9789.40 is offered in part to address those cost concerns. But balancing the relative benefits of physician dispensing against its costs is a fundamental policy determination that can be made only by the Legislature. (*See, e.g., Kugler v. Yocum* (1968) 69 Cal.2d 371, 376-377.) By			

	endorsing physician dispensing, the Legislature endorsed its benefits, including improved compliance, confidentiality and for many injured workers, the avoidance of sometimes difficult and expensive trips to a pharmacy. Because the Legislature intended that injured workers have access to physician dispensing, the service must be preserved through "reasonable" fees that are "adequate to ensure a reasonable standard of services and care for injured employees." Accordingly, if the DWC proceeds with proposed section 9789.40, CPM urges the adoption of a reasonable $30 handling fee. Such a fee would constitute "more moderate repricing" that "might compensate physician dispensing time more fairly and preserve patient access," as suggested by Doctors Wilson and Gitlin in their study of physician dispensing. (*See Repackaged Pharmaceuticals* at p. 2.)		The Division does not have evidence establishing that the adoption of a $30 dispensing fee would be appropriate, reasonable, or required.	No action to be taken.
	CONCLUSION The legislative history and text of Labor Code section 5307.1 indicate that the Legislature did not intend to empower the DWC to set fees for physician dispensing, or to permit fees that are patently unreasonable. Because proposed section 9789.40 does both, commenter urges the DWC to set the proposed regulation aside until such time that the Legislature grants it the necessary authority or until Congress acts on the issue. In the alternative, CPM asks the DWC to amend the proposed regulation to include a reasonable professional fee of $30.		The Division disagrees. The regulation is authorized by Labor Code §5307.1.	No action to be taken.

	A number of studies have been released highlighting the existence of abusive practices relevant to repackaged drugs and many have suggested significant savings will accrue from closing the exception on pricing of repackaged drugs. The California Medical Association ("CMA") in previous comments noted its shared concerns about abuses of the current exception and offered alternatives to stem these abuses while preserving the ability of physicians to dispense. The DWC has heard testimony from patients about the value of receiving their medications from the physician and the reality for many of them that the physician is their only accessible and responsive option. CMA has previously shared the results of studies that give support to the claim of improved compliance when the drug is dispensed at the time the patient is treated. CMA has provided documentation that the physician cannot afford to dispense drugs at the rates set forth in the regulations. CMA believes that only entities relying on dispensing as a loss leader for retail sales can afford to dispense to injured workers under	Nileen Verbeten Vice President Center for Economic Studies California Medical Association October 26, 2006 Written Comment		

[5] The Lewin Group, "A Study of the Relative Work Content of Evaluation and Management Codes", April 29, 2003, prepared for the Industrial Medicine Council of the Department of Industrial Relations.

[6] Resource Based Relative Value System Relative Value Units (RBRVS RVUs), conversion factors (CF) and calculation formulas taken from Web accessible Federal Registers setting forth the final regulations for the physician payment system for each of the years reported were the basis of the following charts.

[7] Centers for Medicare & Medicaid Services; Medicare Program; Five-Year Review of Work Relative

[8] Data from Centers for Medicare & Medicaid Services, Office of the Actuary N3-26-04 Centers for Medicare & Medicaid Services Baltimore, MD 21244, [kent.clemens@cms.hhs.gov] December 21, 2005.

	current operational realities of the workers' compensation program in California. However, rather than re-exploring these issues, our earlier comments are attached (June 12, 2006 letter to Carrie Nevans from Nileen Verbeten). If the DWC finds any value in physician dispensing, CMA requests the division consider alternatives to its proposed rule for we believe the rule as proposed will terminate the option for physicians. CMA does not defend abusive practices but does understand, however, that living organisms must adapt to the requirements of their environment in order to survive. The outdated Official Medical Fee Schedule has made it exceptionally difficult, if not impossible, for practices rendering primary care services to injured workers to survive. The pharmacy loophole has underwritten physician services that the DWC has devalued for years. Therefore CMA asks the Division to consider the implications of its piecemeal solution to problems for which it shares culpability. If the DWC is willing to allow physician dispensing to be financially prohibitive, the DWC at a minimum link correction for the grossly under funded evaluation and management ("E&M") codes to its correction of the pharmacy fee schedule loophole. We provide the following five points to support our request: 1. A study by the Industrial Medicine Council		The Division has proposed regulations which increase physician fees for evaluation and management. The Comment does not relate to the	No action to be taken. No action to be taken.

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	released in 2003[5] documented the significantly higher physician time requirements to render E&M services under the Workers' Compensation program. Page v of the Executive Summary stated: "2. Overall and Participant Group Mean Ratios of Surveyed Physician Work RVUs to RBRVS Physician Work RVUs The ratios of the surveyed physician work value to the RBRVS physician work value were comparable across all respondent groups. The overall mean ratio of surveyed physician work RVUs to RBRVS physician work RVUs for the 20 surveyed codes was 1.28. The ratio of 1.28 suggests that physician work for E&M codes for workers' compensation patients was about 28% greater than that for other types of patients…" This study found that requirements of the Workers' Compensation program in California required 28% more physician time than is required under the Resource Based Relative Value System ("RBRVS") used by Medicare. In essence, to offer roughly equivalent compensation, E&M services rendered under the Workers' Compensation program would need to be paid at a significantly greater level. 2. California ranked second to the bottom among 15 western states – better only than Montana – in its payment for office visits. The Workers' Compensation Research Institute ("WCRI") in 2003 released findings from a study comparing		subject matter.	

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	compensation in workers' compensation to Medicare based on 2001 data. Slide 15 from their presentation "Benchmarks for Designing Workers' Compensation Medical Fee Schedules" shows the woeful treatment of E&M codes in California compared to other states. (Figure 1 is a chart that is included in the original letter in the rulemaking file.) 3. Even without consideration for the additional work required under the Workers' Compensation program in California, Medicare valuation of E&M codes increased considerably over the past 11 years while the OMFS has changed only once. Chart 1 (Chart 1 entitled "Change in Compensation for Mid Level Office Visits Under Medicare, 1995-2006" and Chart 2 entitled "Trend of Changes for Medicare Mid Level Office Visits 1995-2006" are included in the original letter and is in the rulemaking file) shows the percent change in compensation for common E&M services under the Medicare program between 1995 (the earliest year for which RBRVS RVU detail could be obtained) and 2006. For the sake of simplicity, Level 3 office visits for new and established patients are used for this comparison. Level 3 represents the most common office visit billed. The percent change for each year was calculated based on the RBRVS relative value units for each year, the conversion factors for each year and the formula incorporating the two as it changed over this period.[6] 4. Compensation for all services has lost ground under the OMFS. This lost ground is			

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	highly evident when reviewing the declining value of E&M services within the OMFS. Chart 3 compares the OMFS value to the Medicare allowable across the same 11 years. Things improved in 1999 when the conversion factor for E&M codes increased from $7.15 to $8.50 per RVU. This gain eroded quickly. Note, Chart 3 (Chart 3 is entitled "Without Adjustments for Inflation, OMFS E&M Lose Ground to Medicare" is included in the original letter in the rulemaking file) compares the OMFS to Medicare with no adjustment for the 28% additional requirement for physician work under California Workers' Compensation. Were this factored in, at no time during the last 11 years would the OMFS for these services come even close to parity with Medicare. This erosion will be even more magnified in 2007 as Medicare, realizing the work required for the office visit for established patients (99213) is undervalued by nearly 50%, has proposed to raise the RVUs associated with this code accordingly.[7] This unfavorable comparison to Medicare is exacerbated by the realization that Medicare has not kept pace with inflation. Medicare's own actuary has provided statistics comparing the Medicare updates over this time period to the Medicare Economic Index ("MEI") the statistic used to measure inflation in the provision of medical services. The comparison of the MEI and Medicare updates[8] for the period between 1995 and 2006 is shown in Chart 4. (Chart 4 is entitled "Medicare Failing to Keep Pace with Cost to Practice" is			

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	included in the original letter in the rulemaking file.) 5. Inadequate compensation produces unsustainable results. In 2004 CMA published "Physician Practice Cost Survey", a study of medical practice costs in California based on 2003 data. This survey generated responses from over 300 California practices of all types and geographic areas. Although occupational medicine practices did not report in sufficient numbers to particularly evaluate their cost structure, other primary care physicians did. Using data from the experience of family practice physicians, we found the average practice overhead of one full time physician was $184,538. This was the cost to operate the practice – rent, utilities, staff, medical supplies, etc. – before the physician earned anything. In point 1, we note that studies prove the existing OMFS undervalues E&M codes in comparison to Medicare. In point 2, we note California lags all of its neighbors in compensation for these services. In point 3, we note that the erosion in value of these codes has increased as Medicare's reimbursement has adjusted over time. In point 4 we note that Medicare has failed to keep up with inflation as its own resources measure it. Together, these factors produce an absurd result: Average Overhead per FTE Physician = $184,538; Compensation for 99213 under OMFS = $47.60; Number of visits per			

	physician required to cover practice overhead = 3,877 If the physician actually expects to have any income, he/she will have to increase visits accordingly. Yes, this is a simplified equation. Diagnostic testing, injections, or additional services will accompany many of the visits the physician renders. The physician will bill for reports. However, the physician will also experience a significantly greater number of denials and costly appeals, significantly higher cost of collections and older accounts receivable whose costs are also not factored in. A physician expected to churn through patients at the volumes dictated by the compensation offered under the OMFS cannot provide the services necessary to properly treat the injured worker, cannot examine alternatives to keep the worker at work, cannot be concerned with the issues of importance to the employer. In short, cannot do professional work. Most physicians solve this problem by providing better-reimbursed procedures. Some address it by reducing the numbers of injured workers they treat. Some have no alternative to remain solvent except through revenues such as has been permitted through repackaged drugs. CMA is not opposed to closing the repackaged drug loophole in the OMFS. CMA is opposed to the DWC closing this loophole without addressing issues that may			

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	force honest practices to fail. CMA is also apposed to a pharmacy reimbursement proposal so draconian that it will virtually eliminate repackaged drugs from the services of physicians. CMA asks the Division to: ▪ Reconsider their earlier recommendations. Commenter believes the use of average wholesale prices ("AAWP") in the current formula eliminates the ability to abuse the system and will encourage the dispensing of lower cost drugs. If the DWC believes it has no legal authority to deviate from the Medi-Cal Pricing system, then commenter encourages consideration of the greater cost and risk of dispensing in the physician office. ▪ Delay implementation of this proposed regulation until in can come forth with an acceptable proposal to increase E&M services, even if only on an interim basis, and implement the two simultaneously. ▪ Arrange for a credible study to evaluate the impact of its policy on dispensing drugs to injured workers. ▪ Remember that fees under the OMFS have been little changed in 20 years. Physicians are way past due an increase – for many of then, the increase needed is significant.		The use of the suggested formula for repackaged drugs is inappropriate, as the repackager is a labeler and may arbitrarily set an unjustifiably high AWP on the drugs it repackages. The Division disagrees. This regulation has been under study for several years. The Comment does not relate to the subject matter.	No action to be taken. No action to be taken. No action to be taken.

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	Serious concerns with the current Official Medical Fee Schedule related to repackaged drugs are well documented. Much has been reported about abuses resulting from loopholes in the law and many of these abuses are egregious and indefensible. California Medical Association ("CMA") appreciates and supports the desire of the Division for Workers' Compensation ("DWC") to stop these abuses. CMA is concerned that the approach as offered by the DWC goes beyond the steps necessary to prevent abuses and that the proposed regulations will cause considerable harm. As CMA understands them, the proposed regulations will flatten the dispensing fee currently applying to repackaged drugs from $7.50 for generics and $4.00 for brands to a single dispensing fee of $7.25 regardless of the generic or brand nature of the drug. CMA appreciates DWC's increasing the lower dispensing fee, although our analysis indicates the dispensing fee should be considerably higher to cover the uniquely high administrative costs associated with getting paid under the workers' compensation program. The proposed regulations require that the	Nileen Verbeten Vice President Center for Economic Studies California Medical Association June 12, 2006 written comment – resubmitted on October 26, 2006 Written Comment	While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ from those of pharmacies.	No action to be taken.

[9] Front end products, in addition to prescription drugs are identified as "over-the-counter medications, health and beauty aids, personal care items, cosmetics, household items, beverages, convenience foods, greeting cards, seasonal merchandise and numerous other everyday and convenience products, as well as photo processing"
http://www.sec.gov/Archives/edgar/data/84129/000110465906029024/a068190_110k.htm#Item1_Business_150942

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	NDC for the manufacturer of the drug be used when billing. CMA's analysis of the problems with this program also suggests that use of the manufacturer's NDC would curtail the most egregious abuses of the system. The proposed regulations require that if the NDC is found in the Medi-Cal data base, then the Medi-Cal price be used and if not found, then the reimbursement would be set at AWP less 17% for the lowest priced therapeutically equivalent drug. CMA has significant concerns with the use of Medi-Cal pricing as the basis for reimbursement for repackaged drugs. CMA believes the there must be more flexibility for this segment of the OMFS and believes the DWC recommended approach will have negative consequences. First, the proposed approach will result in the essential elimination of physician dispensing to the injured worker. Perhaps that is the intent. If so, CMA believes this is poor public policy. There is public benefit in getting the injured worker immediately engaged in a constructive drug regimen when medications are needed. To the extent this can be accomplished, CMA believes the injured worker's suffering is reduced and the deterioration of function delayed. While no studies could be found to examine injured workers' medication compliance, reviewing studies of other populations finds failure to fill rates from 1 in		The regulation does not limit physician dispensing. The Division does not disagree that there are advantages to physician dispensing.	No action to be taken. No action to be taken.

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	8 to 1 in 2, depending on the population and condition under review. These studies present ample evidence that compliance can be compromised when drugs are not immediately dispensed. See Attachment 1. (Attachment 1 is included with the original letter in the rulemaking file) Testimony was given by many injured workers at the DWC at a hearing on repackaged drugs on January 10, 2006. Worker after worker complained of being unable to get a prescription filled at a pharmacy unless they paid for it. Several workers complained about language barriers that complicated both the transaction and the worker's ability to understand what the medication was for and how to use it. Several workers described transportation difficulties that made the additional stop difficult. CMA does not have data on the frequency of patient turn away by pharmacies. Many physicians inform CMA that they are dispensing needed medications at the request of patients who have been turned away by pharmacies. A study conducted for California Pharmacists Association Educational Foundation by SA|Opinion Research reported in June 2003, "A Survey of Pharmacists' Attitudes on Workers' Compensation", reported that 7% of pharmacies routinely charged injured workers upfront and an additional 15% of pharmacies reserved the right to do so. At the time of this study, reimbursement for prescriptions under the OMFS was higher than it is today. It is noteworthy that 88% of pharmacists		The conclusions of the Commenter that access will be reduced are not substantiated by scientific study. It is not legal for pharmacies to charge workers' compensation patients for their prescriptions.	No action to be taken. No action to be taken.

	responding to the survey said a reduction in reimbursement would make it more difficult for workers to get the medications they needed. What is the impact to the injured worker who is already of limited means who is purposefully turned away by a pharmacy or effectively turned away by the difficulties posed by language, sophistication, transportation or lack of assistance? Are they to be caught in a vicious system that imposes barriers to the medications they need? If not through alternative sources, how will this be addressed? Is the DWC's position, "Tough luck"? California Constitution Article 14 Section 4 requires …"full provision for such medical, surgical, hospital and other remedial treatment as is requisite to cure and relieve from the effects of such injury; full provision for adequate insurance coverage against liability to pay or furnish compensation…" Does the DWC plan to aggressively enforce the requirement that no pharmacy may turn away or charge an injured worker for prescription drugs? If not, how are the constitutional rights of the injured worker protected once alternative sources for prescriptions are eliminated? Second, the reimbursement is just too low. CMA appreciates it is the legislature that enacted the statute establishing the pharmacy reimbursement rate, not the DWC. However,		The Division disagrees. The Division concludes that the regulation provides a reasonable rate of reimbursement. The Commenter does not establish that the level of	No action to be taken.

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	it is not clear to CMA that the DWC is lacks some latitude to produce a less onerous rule. The pharmacy report cited above noted that two thirds of pharmacists in 2003 said that it cost them more to dispense drugs for the workers' compensation than it did for Medi-Cal or other insurances. The excess cost of collection in the workers' compensation program is certainly the experience of physicians. Attachment 2 provides an assessment of the cost to bill and collect from the workers' compensation program. This assessment estimates the cost to bill and collect under this program to exceed $14 per claim, before the cost of the item dispensed or the physician's time to dispense is considered. This greater cost follows from: Uncertainty in eligibility for coverage and determining who to bill The cost of submitting claims on paper The cost of following up claims that are not paid timely The time value of money and the excessive time required for payment High volumes of erroneous denials and associated appeals In this context, physicians complain about the same problems as pharmacists. Unlike pharmacists, physicians have not required patients to pay for the drug at the time it is dispensed. Also different from most pharmacies,		reimbursement is "too low."	

	physicians do not use the activity of dispensing drugs as a loss leader for retail sales. The economic model of a physician practice primarily includes the sale of time, skill and expertise of the physician and; potentially, midlevel practitioners and ancillary staff; technical fees associated with the use of specialized equipment and the cost of drugs, equipment and supplies consumed in the rendering of care. Time is bounded and rarely is anything the injured worker gains from the visit to the physician billable to that worker. Pharmacies, on the other hand, have a very different economic model. Their economy is not tied to the service capacity of their pharmacist. Their revenue associated with an injured worker is not limited to the payment for the dispensed drugs. Rather, the pharmacy is a retail operation, highly invested in commercial sales of a multiple of products. It is the rare pharmacy that contains only the drug counter. Pharmacies are increasingly set up with the pharmacy far from the entry with considerable merchandise for sale between the injured workers' entry into the store and that prescription counter. For example, Rite Aid, in its 10-K filing with the SEC for 2006, noted that in addition to prescription drugs, it sells 25,000 "front end products"[9], has an alliance with GNC and offers its own branded products. Physicians cannot provide this service at the same reimbursement a pharmacy may accept. They cannot obtain the level of discounts that			

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	pharmacy dispensing volumes permit. Increasing traffic through their offices does not result in the sale of and revenue from beauty aids, convenience foods, greeting cards, seasonal merchandise and photo processing. SEC filings for the large chains documents the importance of sales other than prescription drugs to the strength of their companies: Walgreen – 36.3% of sales are associated non-prescription drugs and general merchandise. Rite Aid – 36.8% of sales were for non-prescription drugs and general merchandise. Longs – 52% of sales were for non-prescription drugs and general merchandise. . Albertson – prescription drugs were so small a portion of sales their percentage was not noted. Safeway – prescription drugs were so small a portion of sales their percentage was not noted. Costco – listed prescription drugs in a category containing several other items as accounting for less than 12% of sales. Target mentioned prescription drugs only in a footnote as among the items available. While the scale for an independent pharmacy would definitely differ from the large chains, a walk through most independent pharmacies suggests their economic model is also strongly supplemented by retail sales – an option that is not presently relevant to physician offices. In short, the Medi-Cal fee schedule is too low to cover anyone's dispensing costs, given the costs resulting from the uniquely expensive			

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	administrative burdens inherent in this program. The Medi-Cal fee schedule is also prohibitively low for practices that do not have extensive purchasing power and when retail sale of general merchandise is not a major business goal. In light of the cost to collect under the workers' compensation program, the inability of physicians to leverage volume purchasing to minimize acquisition costs, and the economic model of physician practices that does not provide the retail sales subsidization of drug dispensing, CMA requests that the dispensing fee be raised to $22 for brand and generic drugs until such time as efficient claim submission and payment processes are evident and the law supports more realistic pricing for prescription drugs. This request is based upon the cost to bill under the workers' compensation program of $14.26, described in Attachment 2 and the cost to dispense, which CMA finds to exceed $7.25. Third, decoupling reimbursement policy for repackaged drugs from other physician services in the existing Official Medical Fee Schedule ("OMFS") also ignores the reliance on revenue from drug dispensing to compensate for the serious inadequacies of the OMFS. As is very well known by the DWC, physicians who primarily offer evaluation and management services are very poorly compensated under the OMFS. The proposed regulations will not only cause a cessation of		While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ from those of pharmacies. The Comment does not relate to the subject matter. However, the Division has proposed regulations to increase fees for evaluation and management. The Comment does not relate to the subject matter.	No action to be taken. No action to be taken. No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	dispensing by physicians, but many physicians report this change will jeopardize their ability to continue treating injured workers as profits from this sector have subsidized other services. Changing the pharmacy portion of the OMFS would be much less destructive to these physicians if it were accompanied by correction of the under funding for other services. Forth, controlling abusive practice is not possible through the fee schedule. California already has one of the lowest fee schedules in the nation. Until the DWC develops programs that identify abusers and curtail their ability to abuse the system, abuse will continue, outrage against obvious abuse will continue, and the untargeted response to the outrage will harm quality physicians and the injured workers they treat. The data released by the industry on abuses of the repackaged drug loophole are a basis for outrage. Employers should feel outrage. The DWC should feel outrage. Physicians feel outrage. Contributing to physician outrage, however, is the inability to escape tarring by the broad brush of uninformed opinion. Why, for instance, is the industry so capable of raising this issue to its current level of attention but incapable of figuring out where abusive behavior is occurring and place those practices on prior review as a way of fixing this problem? CMA also urges DWC to complete its work on the workers compensation information			

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	system ("WCIS"), to become aggressively engaged in monitoring claims level detail and to develop the necessary protocols to isolate and stop abusive practices (to whomever they may belong).			
General Comment	Commenter objects to the proposed changes in section 9789.40 to amend the fee schedule for in-office drug dispensing and states that if these regulations are adopted most of his patients will see their treatment come to a sudden end. Commenter began dispensing drugs just this year due to the fact that he could no longer consistently find pharmacies that would dispense to denied cases on a lien, and without a dispensing pharmacy his prescriptions are worthless. Commenter has treated some denied cases on a lien basis that he felt had merit, and most of the time a workers' compensation judge has agreed with him and ruled in his favor. Since SB 899, denied cases have gone from a minority of his practice to a vast majority, as MPN orthopedists rarely refer their depressed or chronic pain patients for psychiatric treatment. The avenue for patients to get denied treatment on a lien basis forms an important check and balance in the system. If keeps insurers honest in their denial of cases and lets patients get necessary treatment while waiting, perhaps years, for the wheels of justice to turn.	Todd M. Hutton, MD Diplomate, American Board of Psychiatry and Neurology AME – QME October 26, 2006 Written Comment		

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	If this new fee schedule is adopted commenter will no longer be able to dispense in his office, and hundreds of his patients will see their treatment abruptly end. They will be forced to suddenly discontinue medication that keeps them medically in balance, that keeps them functioning, and keeps at bay suicidal thoughts. Commenter feels that adopting this fee schedule will have profoundly negative effects on his patients and practice and the entire workers' compensation system.		The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them.	No action to be taken.
	This letter is written in strong opposition to the proposal to adopt the amendment of Article 5.3 of Chapter 4.5, Subchapter 1 of Title 8, California Code of Regulations, Section 9789.40. Passage of this amendment will decrease health care access and especially hurt the ethnic minorities and lower income injured worker. Many ethnic minority workers do not have private health insurance. Many pharmacies already do not accept Worker's Compensation prescriptions. By decreasing reimbursement, it would become increasingly more difficult for the injured worker to obtain necessary medications. If the reimbursement of medications decreases to Medi-Cal rates, physicians will no longer be able to dispense from their offices as the cost of medications far exceeds the Medi-Cal reimbursement. Passage of this bill will, therefore, limit the number of physicians who would treat the industrially injured worker,	Wilma Chan Assemblymember 16th District October 26, 2006 Written comment	The regulation does not limit the practice of physician dispensing. The Division disagrees that the regulation will cause undue hardship on minority workers' because they will no longer be able to obtain medications.	No action to be taken.

	many of who are minorities, or who would no longer provide medication to the injured worker. Moreover, the immediacy of obtaining medications from the physicians prevents delays in medical care due to lack of authorizations. Without adequate treatments and medications, the injured worker would be unable to return to work. I must stress that the workers are the ones that will suffer. Passage of this amendment will most certainly increase the health care disparity in California.			
	Commenter is concerned that if this new fee schedule is adopted and places repackaged medications under the Medi-Cal fee scheduled, that it will have a deleterious effect on his ability to get his patients their prescription medications. The new margins that he could charge under this new system makes it non viable economically for him to continue dispensing medications from his office. Currently under the workers' compensation system he extends medication he has purchased to patient with the expectation that he will be reimbursed in the future – often years later. He has tried unsuccessfully to have non-approved, contested patient's medications delivered from retail pharmacies. These large retail pharmacies still need to have the medications first approved by the insurance company. This has caused delays of weeks or when a case is completely denied, no medication is ever received by the patient. If the proposed regulations are adopted, he will	Thomas Apostle, MD American Board of Psychiatry and Neurology October 29, 2006 Written Comment Stephen Volk, MD American Board of Psychiatry and Neurology October 29, 2006 Written Comment	The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them.	No action to be taken.

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	no longer be able to treat patients on a line when he cannot guarantee they will receive their medications. The workers' compensation is a difficult system to operate as they are frequently denied compensation for office visits by insurance companies as they contest the claims. When payment finally comes through, it is after prolonged administrative hearings where he is represented by a collection agency. This process can take years after we have seen the patient and costs 25-30% of all accounts receivables. It is much easier to make a living seeing Medicare, HMO and private insurance patients. The added reimbursement from the re-packaged pharmaceuticals is the only thing that allows him to run the clinic and support his overhead. Without this revenue he will cease treating workers' compensation patients and refer these patients to the over burdened county mental health system.		The Comment does not relate to the subject matter.	No action to be taken.
	Clearly, the current physician dispensing reimbursement rate is too generous. But, the extreme proposed regulation is going to have a far greater negative impact on the availability of medical providers to injured workers than the statistical hindsight reports generated by CHSWC claims. If this regulation passes, there will be fewer physicians providing services to injured workers. A number of current medical specialists serving injured workers are going to take early retirement. With all the new legislation and regulations, the workers	Charles Smith Special Account and Projects October 30, 2006 Written comments	The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them.	No action to be taken.

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	compensation system has gotten so complex, so bureaucratic, and so frustrating, that medical providers are going to exit the system. This is particularly true when there is not enough profitability to cover all these additional bureaucratic costs. For better or for worse, physician dispensing is the one area that still provides enough reimbursement for many medical providers to continue to be willing to serve injured workers. This is particularly true of medical specialists who have 25% or less exposure to workers compensation. These medical specialists can and will drop workers compensation promptly. Based on commenters discussion with a number of them, they are close to that point now. A slight push, and they will opt out of the system entirely. The Division's Medical Director has spent time in these specialty offices. The business professionals who manage these practices have been very clear about the negative consequences of slicing 70-90% of a business's revenue. This is the equivalent of telling an automobile dealer who specializes in SUVs that the sales price can't exceed that of the cheapest compact econo-box on the market. By forcing such a low price, you effectively kill the business by regulation. A number of third party billing companies			

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	working with chain-store pharmacy are charging AWP minus 17 to 22%. The reason for this is that most states work comp reimbursement rates are still based on AWP. AWP-17% complies with current Medi-Cal regulation and will enable medical providers to continue to dispense while saving the system 57% — 62%. That is a huge slice in medical provider reimbursement, but is a number that will keep most providers in who are ready to exit the system now. If the DWC is determined to continue down this path, there is another issue that should be addressed in the dramatic cut in reimbursement. Unlike pharmacy, physicians provide these services to a specific population. They don't have other patient populations who can utilize the specialized service and formulary. By implementing the regulation on December 1, 2006, medical providers will not have time to adjust their practice to the below breakeven Medi-Cal rate dictated in the regulation. This will likely generate lawsuits. At the very minimum, commenter strongly suggest that the DWC implement an extended step down approach to the cut in reimbursement so that medical providers can adjust their practice accordingly. With longer time frames and step down reimbursement rates, medical providers and businesses can adjust to the changes without immediate massive losses.		While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ from those of pharmacies. The Division concludes that, as these regulations were first proposed in January, 2006, the physician community which dispenses drugs not in the Medi-Cal database has had adequate time to prepare for the changes in pricing.	No action to be taken. No action to be taken.

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	Lastly, if the DWC is dead set on the time line and existing regulation, why even call a public hearing? It wastes everyone's time and is disingenuous. It will likely take a couple of weeks to collate the information provided at the meeting. If the DWC is actually considering public testimony, is it wise to implement two weeks after review of that input?			
	There are a number of other challenges with implementing this regulation. One of those is the fact that the FDA does not want any other NDC on the package except for the last company who modified the product. The FDA regulations on NDC are getting stricter all the time. Original pharmaceutical manufacturers are surfing in, and out of the market based on their required profitability. This is making product and NDCs more volatile, rather than less. In a medical providers billing office now, they only have to track one NDC per drug & #/vial. With this new regulation, billing offices will have to potentially bill 2, 3 and sometimes 4 different NDC numbers rather than only 1. The paper billing process is already fraught with costs and delay. This regulation will increase those costs and issues. The current system is working well---it automatically puts the charges for pharmaceutical together with the patient treatment program. Splitting off pharmacy costs additional time and money.		The Division acknowledges that there may be some additional tasks required in tracking the NDC's of repackaged drugs.	No action to be taken.
	1.The insurance company has to make sure the patient is eligible. This can take days before a		Insurance companies are legally obligated to work promptly to	No action to be taken.

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	patient gets their script increasing the chance the patient will not get back to work. In a medical provider's office, they know immediately if the patient is eligible. 2.An insurance company has to match up the pharmacy bill with the injured worker. Each piece of paper an insurer has to touch costs at least $5 in handling and bureaucratic overhead. 3.The insurance company has to cut a check for prescription. With medical offices billing, the charge is included with the service saving adjudication, check printing, mailing and the additional clerical support required to manage pharmacy. 4.It saves the patient time and energy and gets them back to work more quickly. For all these reasons, commenter strongly recommends implementation of an AWP - 17% formula for NDC5 not in the Medi-Cal database rather than the existing proposal.		provide initial claimants with medical treatment. The Division anticipates that much paper handling will disappear with the adoption of electronic billing.	No action to be taken.
	The American Federation of State, County and Municipal Employees (AFSCME), the Union of American Physicians and Dentists (UAPD), and the Union of American Physicians and Dentists Independent Practice Association (UAPD IPA) have studied opinions and advice forwarded to the Division with reference to the Official Medical Fee Schedule -- Pharmaceuticals, Title 8 California Code of Regulations, Sections 9789.40. Here is our conclusion: the best and most well reasoned opinion we've seen so far has been	Robert L. Weinmann, M.D. October 30, 2006 Written Comment		

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	submitted by Stephen J. Cattolica, 27 September 2006. The proposed physician's dispensing fee recommended in this document is a minimum of $15. This fee preserves 98.6% to 98.8% of the savings estimated by CHSWC that has been attributed to the Administrative Director's current proposal without the physicians' dispensing fee. We feel that setting this fee will go a long way to preserving the injured worker's access to care and medications and would do so at negligible cost.		While the Division agrees that it is possible that physician expenses may differ from pharmacy expenses in dispensing a drug, no scientific economic study undertaken by impartial economists has been encountered which adequately determines what expenses are incurred by California physicians in various areas of the state, or how they differ from those of pharmacies.	No action to be taken.
	Commenter is opposed to proposed regulation section 9789.40, as currently drafted. Commenter proposes that pursuant to Government Code section 1 1346.5(a)(13), a reasonable alternative that closes the apparent loophole in current law in a manner that is consistent with applicable legal requirements, while preserving injured worker access, not only to drugs, but to qualified physicians. Introduction: Commenter has reviewed the comments of the California Medical Association, dated October 27, 2006, and June 12, 2006 and shares the CMA's desire to redress the potential for abuse in the system in a manner that ensures continued physician participation in the California workers' compensation system and that ensures that injured workers receive their prescribed drugs. Commenter also shares, based on experience with managing physician practices, the CMA's view that further reform in this area consider	Michael Tichon General Counsel California Pharmacy Management, LLC October 30, 2006 Written Comment	See response to comments of Nileen Verbeten.	No action to be taken.

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	both the inadequacies of physician income and physician dispensing. Therefore, commenter incorporates the CMA's comments as he shares those concerns. Commenter believes that if the current regulatory proposal is adopted, many excellent physicians will be motivated to move from a workers' compensation practice to one that excludes treatment of injured workers. There is a general shortage of orthopedic surgeons, the income available in other markets combined with less costly overhead requirements, means there is a ready market for orthopedic physicians if there is no income advantage to continue to treat injured workers. The current regulatory proposal, as will be shown, will reduce physician incomes and eliminate their ability to provide satisfactory patient care. Therefore, the current proposal will give incentive to physicians to shift to treating group health or Medicare patients to the detriment of injured workers. There are other reasonable alternatives that accomplish the reform objectives without negative consequences. The Proposed Reimbursement Level is Below Cost: Attached to these comments as Attachment 1(included in the rulemaking file) are a series of dispensing profiles showing that the costs inherent in dispensing drugs commonly used to treat injured workers are greater that the reimbursement available under the proposed regulation.		Although the Commenter presents conclusions as to the cost of some drugs being below the proposed reimbursement rate, that is not the case for all drugs. It is also not knowable at this time for how many repackaged drugs repackagers will reduce the prices to a point where it may be cost efficient to dispense them.	No action to be taken.

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	In practice, below cost reimbursement means that physicians will not be able to dispense drugs to injured workers. Several adverse consequences flow from the denial of physician dispensing. As the CMA has demonstrated in its comments, the reality is that injured workers will have difficultly finding pharmacies to fill prescriptions, or will not comply with the physicians' prescriptions. (See CMA letter to Carrie Nevans, June 12, 2006). Commenter believes that there is an even more serious problem: namely, whether qualified physicians will remain in the California workers' compensation system. Physician Shortage: There doesn't seem to be a debate over the growing demand and short of orthopedic and other surgical specialties. Attachment 2 (included in the rulemaking file) is a series of three articles, demonstrating the growing shortage. For example, a California Healthline news brief from June 5, 2006, quoting a Los Angeles Times article, indicated that the current average wait time to see an orthopedic physician is 17 days. The point to make here is that the shortage creates a ready market for physicians willing to shift their practices from treating injured workers to treating Medicare or group health patients. Income Levels and Costs of Practice Favor Group Health and Medicare: According to the American Academy of Orthopedic Surgeons, (AAOS Bulletin,		The Division does not disagree that individual physicians will make individual decisions on whether physician dispensing will be sufficiently profitable for them. It is not knowable at this time whether, or how many physicians may decide to cease treating workers' compensation patients because the profit they receive on repackaged drugs is reduced or eliminated.	No action to be taken.

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	August, 2006) the 2005 mean Net Income for orthopedic surgeons was $394,000. Only 12% of patients seen were workers' compensation patients. According to the MGMA, as reported in Modem Healthcare, Orthopedic Surgeons reported an average margin of $621,700 (See attachment 3 for both articles). While individual income figures are confidential, our managed physicians, without any income from pharmacy, have incomes that are less than the MGMA figure, but are slightly higher than the AAOS figure. As noted in the CMA comments of October 27, 2006, physician work for treating injured workers is approximately 28% greater than for other types of patients. In commenter's experience managing physician practices, the overhead involved in treating injured workers is also about 25 to 30% greater than the overhead and requirements necessary to treat other types of patients. Therefore, the loss of income resulting from the proposed regulation will create a substantial incentive for quality physicians to move their practices to group health and Medicare patients, where the income levels are similar, but the practice expenses are much lower. Commenter believes this means the proposed regulation is not a reasonable reform, especially when other reasonable alternatives are considered. These facts validate the concerns raised by material recently added to the DWC's own regulatory file. Gitlin and Wilson, writing in			

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	their American Journal of Industrial Medicine article, "Repackaged Pharmaceuticals in the California Workers' Compensation System From Distribution and Pricing Options to Physician and Retail Dispensing, " issue a caution: "However, if the workers' compensation legislation suggests a fee schedule that is too low, it is possible that physicians using repackaged pharmaceuticals for their workers' compensation patients will stop taking workers' compensation patients or stop providing point of service medications to them. In fact, such fears are outlined in the draft legislation to revise CCR 9789.40 (Draft Version as of 09/06). This could lead to patient access problems to physicians and to patients receiving their medications. " (at page 20 of the article) What Will Be Lost if Physicians Can't Dispense: In the same article, Gitlin and Wilson weigh the advantages of physician dispensing, namely, convenience to the patient, avoidance of medication errors, and possible cost savings, against conflict of interest and similar ethical concerns, and end up proposing a reform that preserves physician dispensing while making moderate reforms to avoid abuses of over pricing or over prescribing. We believe that the patient physician relationship will be damaged by the proposed regulation. Physicians will begin to leave the workers' compensation system, patients will have difficulties getting drugs, and those physicians			

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	who treat injured workers will face the kinds of patient compliance problems outlined by the CMA in their June 12, 2006 letter. Statutory Comments: A. The Proposed Regulation is Contrary to the Intent of S.B. 228: S.B. 228 attempted to link payment for all medical services provided to injured workers to the Medicare system, with a 20% positive adjustment. However, at the time, January 2003, Medicare didn't pay for most drugs furnished patients. Therefore, S.B. 228 provided that the payment for drugs furnished injured workers, by either a pharmacy or a physician office, would be at 100% of the "relevant Medi-Cal payment system. (L.C. Section 5307.1) The use of the term "relevant Medi-Cal payment system," and the use of only l00%, as opposed to 120% for Medicare-based services, was based on a series of studies that suggested a reduction in pharmacy reimbursement by approximately 35 to 40 %. Just prior to the adoption of S.B. 228, CHSWC had done a series of studies indicating that California's workers' compensation system was paying more for drugs than most other states. At the time, California was paying 140 96 of the Average Wholesale Price (AWP) for drugs; the studies indicated that other states paid approximately 100 % of AWP. The study looked for alternative fee schedules, and concluded that the use of Medi-Cal would bring California's pharmacy payments in line with other states, reducing expenses		The Division disagrees. The pricing in the regulation is authorized by Labor Code §5307.1.	No action to be taken.

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	significantly. For example, one CHSWC study said using Medi-Cal would reduce pharmacy costs by 37%. Comparing California to Washington, a subsequent study concluded that using Medi-Cal would reduce costs by approximately 44%. ((1) Neuhauser, Swedlow, Gardner and Edeilstein, "Study of the Cost of Pharmaceuticals in Workers' Compensation," Report to CHSWC, June 2000, and (2) CHSWC, Pharmacy Report, 911 0103, pages 16 and 17, hereafter, both referred to as the "CHSWC Studies") 'The studies, especially the latter one, involved industry representatives, who were familiar with the complexities of pharmaceutical distribution. To accomplish the intended result, the legislature used the phrase "relevant Medi-Cal payment system." Under Medi-Cal, section 14150.45 of the W&I Code, there are really four payment systems, only one of which, AWP minus 17% plus a $7.25 handling fee, accomplished the necessary reduction. The other Medi-Cal formulae result in much more drastic reductions than the one intended. (In 2003, the actual Medi-Cal formula was AWP-5%) Proof of legislative intent is found in the scoring of S.B. 228's pharmacy provisions by the WCIRB after passage. Relying on the CHSWC Studies, the WCIRB scored the savings from the adoption of Medi-Cal at $400 Million, or 37%. (WCIRB, "January 1, 2004 Pure Premium Rate Filing, As Amended," September 29,2003, at page A-6) The Proposed Regulation does not accomplish			

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	the legislative intent, as it forces almost all drugs to be paid at Medi-Cal rates lower than AWP- 17%, specifically the price for the original manufacturer of the drug without regard to the actual price or AWP of the drug actually dispensed. Instead of addressing the statutory requirements to look for the "relevant Medi-Cal payment system," and use "comparable resources," the Proposed Regulation violates these statutory dictates. To correct this problem, the proposed regulation must be revised to find the "relevant Medi-Cal payment system" to be AWP-17%. B. The Proposed Regulation is Contrary to Section 5307.1 of the Labor Code: Section 5307.1 clearly allows for physician office dispensing, a practice long allowed under the Business and Professions Code section 41 70. However, the Proposed Regulation is structured to prohibit physician dispensing without honestly saying so. The reimbursement formula provided does not address the statutory requirements of S.B. 228 for payment based on comparable resources, and does not address S.B. 228's use of the phrase, "relevant Medi-Cal payment system." As indicated in Attachment 1, analysis of the total costs of frequently dispensed drugs shows that the reimbursement scheme being proposed would force physicians to dispense drugs at a loss. This result is a disingenuous attempt to prohibit by		The Division disagrees. Nearly all of the drugs to which this regulation applies are repackaged drugs. Medi-Cal will not pay for physician dispensing of repackaged drugs, requiring all Medi-Cal drug prescriptions to be filled by a pharmacist; Medi-Cal has no system for paying for these drugs. The Division disagrees that the regulation will require physicians to cease dispensing drugs from their offices. Whether or not physician can dispense drugs from their offices is governed by other law.	No action to be taken. No action to be taken.

	regulation what the law plainly allows, namely, physician dispensing. The Proposed Regulation ignores the substantial costs of physician dispensing. Unlike large retail operations or Kaiser, each physician dispenser cannot buy in huge bulk quantities at low prices and then create the unit doses to be dispensed to patients. Instead, a physician must buy the drugs after they've already been reduced from bulk quantities to individual unit doses. In addition, the typical physician dispenser must retain a pharmacy tech and/or physician assistant to assist in dispensing and meeting the regulatory and safety requirements for dispensing drugs. The Proposed Regulation, by only paying a hypothetical original manufacturer's cost, ignores the real costs incurred in dispensing. C. The Proposed Regulation is Contrary to Medi-Cal section 14105.45, and is so vague it will Create Unnecessary VVCAB appeals: The Proposed Regulation introduces a new concept, "therapeutically equivalent drugs," not found in Medi-Cal's section 14105.45. That section relies on actual drug prices and not some other standard. This provision of the Proposed Regulation will create many disputes as carriers seek to minimize payments by arbitrary selection of the equivalent drug, without regard to the drug actually dispensed, and the costs in dispensing this drug. 3. Alternative Regulation: Commenter is not opposed to reform. Commenter is opposed to proposed regulation		The Division disagrees that the regulation is contrary to (Medi-Cal) [sic] Welfare & Institutions Code § 14105.45.	No action to be taken.

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	section 9789.40, as currently drafted. Commenter hereby proposes, pursuant to Government Code section 111346.5(a)(13), a reasonable alternative. This alternative is designed to reduce reimbursement for repackaged drugs to the levels intended by the Legislature in S.B. 228. It is based on the national standard used by most insurance companies, including the State Compensation Insurance Fund, but prevents abuse by capping average wholesale price at the highest level existing on January 1, 2005. In so doing, our proposal will allow for price decreases, but will prevent the abuse of repackagers marketing excessively high AWP's. Commenter believes that the following proposal presents a reasonable balance between the need to reform the current system and the need to preserve injured workers' access to medical care. In our proposal, we've kept the format of the current proposal, including its underlining. We have added our deletions by strikethroughs, and our additions are in bold and italics.		The Division disagrees that the proposed alternative is a better one. It does not address drugs which may not have had a wholesale price on the selected date. The Division has also concluded that the appropriate price for many commonly used drugs is lower than that selected by The Commenter.	No action to be taken.
Section 9789.40(b)(1)	Commenter suggests the following modification: (2) If the National Drug Code for the drug product as dispensed is not in the Medi-Cal database, ~~and the National Drug Code for the underlying drug product from the original labeler is not in the Medi-Cal database, then the reimbursement shall be 83 percent of the average wholesale price of the lowest priced therapeutically equivalent drug, calculated on a per unit basis.~~ ***then the allowable fee shall***	Michael Tichon General Counsel California Pharmacy Management, LLC October 30, 2006 Written Comment		

	be the estimated acquisition cost as specified in section 14105.45 of the Welfare and Institutions Code, except that the administrative director finds that the comparable resources requirement of section 5307.1(d) of the Labor Code requires setting the estimated acquisition cost at 83 percent of the average wholesale price, not to exceed the average wholesale prices published in Redbook; Pharmacy's Fundamental Reference, 2005 Edition, Thomson Healthcare, Inc., Montvale, New Jersey ("the Redbook") on January 1, 2005. For drugs not published in the Redbook on January 1, 2005, and not in the Medi-Cal database, the administrative director shall set the fee at 83 percent of the average wholesale price, not to exceed the price of the brand name equivalent. The maximum fee shall include only a single professional fee for dispensing for each dispensing.			
Section 9789.40 (b)(2); (c)(1) and (c)(2)	Commenter suggests that this language be stricken.	Michael Tichon General Counsel California Pharmacy Management, LLC October 30, 2006 Written Comment		
Section 9789.40(d)	Commenter suggest that following language: (d) The changes made to this Section in 2006 shall be applicable to all pharmaceuticals dispensed or provided on or after ~~December 1, 2006.~~***January 1, 2007 for services rendered prior to January 1, 2007, for repackaged drugs not found in the Medi-Cal data base of National Drug Codes, reimbursement***	Michael Tichon General Counsel California Pharmacy Management, LLC October 30, 2006 Written Comment		

	shall comply with the fee schedule previously adopted by the administrative director that was in existence on December 31, 2003; namely, for brand name drugs, 1.1 times the Average Wholesale Price, plus a $4.00 dispensing fee, and for generic drugs, 1.4 times the Average Wholesale Price, plus a $7.50 dispensing fee.			
	Over the past several years, injured workers have been significantly impacted by the major changes adopted in California's workers' compensation system. Many of those changes were adopted to try to control rapidly rising medical costs, and pharmaceutical costs were among the fastest rising costs in the medical area. A new pharmaceutical fee schedule mandated by SB 228 was designed to address this problem. However, subsequent studies revealed that major problems still remained because the new fee schedule did not apply to repackaged drugs. The proposed regulation places these repackaged drugs under a fee schedule. In view of the documented abuses under the unregulated fee environment, we support the extension of the fee schedule to cover repackaged drugs. However, in order to prevent unintended consequences, we strongly recommend that the revised fee schedule recognize that repackaged drugs fill an important role in our system and that adoption of this fee schedule must provide a fair reimbursement for pharmaceuticals distributed in this manner. In one of the documents recently added to the	Linda F. Atcherley President California Applicants' Attorneys Association October 31, 2006 Written comment	The Division has concluded that the regulation will provide a fair reimbursement rate for physician dispensing drugs.	No action to be taken.

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	hearing file entitled "Repackaged Pharmaceuticals in the California Workers' Compensation System: From Distribution and Pricing Options to Physician and Retail Dispensing," it was noted that a national study in 2005 found that "20% of patients failed to get a prescription filled and 30% of patients don't obtain refills." Commenter believes that this problem is at least as bad in California's workers' compensation system. Many of our members tell us that their clients still have trouble getting a workers' compensation prescription filled at a pharmacy within a reasonable driving distance. In other cases, workers may have language problems that keep them from getting a prescription filled at a pharmacy. Other workers become frustrated and "give up" when UR, ACOEM, or paperwork delays force them to return to the pharmacy multiple times to get a single prescription filled. Consequently, the ability to obtain repackaged drugs directly through a doctor's office or clinic is extremely important to injured workers. But it is likewise important to their employers, because the ability to immediately fill a prescription will have a beneficial impact on the recovery from the injury or illness, which can significantly increase the chance that the worker will be able to return to work quickly. Conversely, the inability to promptly obtain necessary pharmaceuticals can prolong illness or injury, increasing both medical and indemnity costs. Thus, it helps both the injured worker and the employer when			

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	necessary medical treatment, including prescribed pharmaceutical drugs, is promptly provided. We believe that repackaged drugs have a role to play in this regard. However, as noted in the above cited study, adopting a fee schedule which applies Medi-Cal payment rates to repackaged drugs "may be extreme, and more moderate repricing might compensate physician dispensing time more fairly and preserve patient access." We therefore support the proposal made on behalf of the California Society of Industrial Medicine and Surgery to adopt a dispensing fee of $15 where the pharmaceutical drugs are dispensed by a physician or $8 where dispensed by a skilled nursing facility or intermediate care facility. Although this change will have a minor impact on costs, we believe that these separate dispensing fees are fully justified to assure that the new fee schedule does not exacerbate medical access problems for injured workers. Furthermore, it must be recognized that if injured workers are no longer able to obtain pharmaceutical drugs from a treating physician or clinic, the worker will need to make a separate trip to the pharmacy to fill the prescription. Since, as noted above, workers often find it necessary to make multiple trips to the pharmacy to get a prescription filled while UR, ACOEM, or paperwork problems are worked out, this could add significant new travel expenses to the system, offsetting some of the potential savings from the new fee schedule. Any analysis of the added costs due			

	to a higher dispensing fee must also consider this likely increase in travel expenses. In summary, CAAA supports the adoption of a fee schedule applicable to repackaged drugs, but strongly urges the adoption of a higher dispensing fee for physicians and other medical facilities as recommended by CSIMS. If you have any questions concerning our position, please contact our Legislative advocate in Sacramento.		See response to comments of Stephen J. Cattolica.	No action to be taken.
General Comment	Fee schedule loopholes lead to "cottage industries." This was the case for ambulatory surgery center facility fees and it is now the case for repackaged drugs. In AB 228 the Legislature required a pharmacy fee schedule that would reimburse drug products and services at Medi-Cal rates. But an unexpected loophole emerged because Medi-Cal does not determine reimbursement under repackager's National Drug Codes (NDCs) since it does not pay for repackaged drugs. CWCI supports modifying the Pharmacy Section of the Official Medical Fee Schedule to eliminate the loophole for repackaged drugs and other drugs and pharmacy services not covered by Medi-Cal. According to the plain language and intent of the statute, maximum fees for pharmacy services and drugs may not exceed 100% of Medi-Cal fees for comparable drugs and services, regardless of whether they are furnished by a pharmacy or a practitioner (Labor Code section 5307.1(a) and (d)). It is commenter's understanding is this proposed regulation is attempting to close the loophole which allows a drug dispensed by a	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute October 31, 2006 Written Comment		

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	physician to be reimbursed at a different level than the same drug dispensed by a pharmacy. Commenter supports that goal but questions whether the language in the proposed regulation has accomplished this objective and offers some refinements to help achieve the goal. When the Medi-Cal fee schedule does not determine a fee under the NDC of the dispensed drug, commenter recommends that the maximum reasonable reimbursement be determined in the following order of priority: 1. Medi-Cal fee from dispensed NDC 2. Medi-Cal fee from NDC of original labeler 3. Medi-Cal fee from NDC of therapeutic/pharmaceutical equivalent 4. Medi-Cal estimated acquisition cost for the lowest therapeutic/pharmaceutical equivalent and add Medi-Cal dispensing fee 5. Medi-Cal estimated acquisition cost for the dispensed drug and add Medi-Cal dispensing fee		Although this proposal is very similar to the regulation proposed by the Division, the Division concludes that the regulation as proposed will be easier to apply.	No action to be taken.
	To apply the schedule, bills for drugs and pharmacy services must be required to include the dispensed NDC, and bills for repackaged drugs must also include the NDC of the underlying drug product from the original labeler.		The Division is aware that not all physicians will know the NDC Code for the underlying drug, and thus has not required that they provide this information.	No action to be taken.
	To forestall disputes over whether or not the Medi-Cal dispensing fee must be paid twice, the language should be modified so that it is clear that a single dispensing fee is required.		The Division agrees that the text may be improved so as to eliminate any doubt that only one dispensing fee is to be paid.	The final text has been revised to eliminate possible ambiguity.

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	Commenter has heard a concern that not all NDCs of original labelers appear in the Medi-Cal database. It has been suggested this may be especially true of larger quantity ("barrel quantity") NDCs. Since repackagers order from labelers in large quantities, we recommend looking into this issue to verify that the original labelers' high-quantity NDCs appear in the database. If they do not, a solution would be to modify the pharmaceutical calculator to operate off the first nine digits of the NDC. The last two digits indicate the NDC quantity but do not change the reimbursement for the drug dispensed and are therefore not needed to calculate the allowance. The system could be modified to verify an NDC's first nine digits instead of the usual eleven, then to apply the unit price as before. This would enable the system to accurately calculate the product allowance regardless of the NDC quantity.		The Division does not intend to modify its database and calculator.	No action to be taken.
Section 9789.40(a)	Proposed revised language: (a) the maximum reasonable fee for pharmaceuticals and pharmacy service~~s~~ rendered after January 1, 2004 is 100% of the reimbursement prescribed in the relevant Medi-Cal payment system, including the Medic-Cal professional fee for dispensing. <u>Reimbursement for a pharmacy service or drug not covered by the relevant Medi-Cal payment systems shall not exceed 100% of the fee paid by Medi-Cal for a comparable drug or service.</u> Medi-Cal rates will be made available on the Division of Workers' Compensation Internet Website (http:ww.dir.ca.gov/DWC/dwc_home_page.ht	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute October 31, 2006 Written Comment	The Division disagrees that the proposed language would be a better solution. The proposed alternative, while attempting to clear up certain ambiguities, creates new ones.	No action to be taken.

	m) or upon request to the Administrative Director at: DIVISION OF WORKERS' COMPENSATION (ATTENTION: OMFS – PHARMACY) P.O. BOX 420603 SAN FRANCISCO, CA 94142 **Discussion** Commenter recommends modifications that expressly state the requirement for pharmacy services or drugs not covered by the Medi-Cal payment system as specified in Labor Code sections 5307.1(a) and (d). These modifications are necessary to help prevent additional loopholes that may otherwise arise.			
Section 9789.40 (b)	Proposed revised language: (b) For a pharmacy service or drug that is not covered by a Medi-Cal payment system, the maximum reasonable fee paid shall not exceed the fee determined in accordance with this subdivision~~, plus $7.25 professional fee for dispensing or $8.00 if the patient is in a skilled nursing facility or an intermediate care facility.~~ **Discussion** Commenter recommends removing the language that adds a dispensing fee and replacing it with language in sub-paragraphs to cover those instances where the dispensing fee is not already addressed by the Medi-Cal methodology. Without this change, the regulation could be interpreted to allow two dispensing fees: the one specified here and the one that is already part of the section	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute October 31, 2006 Written Comment	See response to comments of same commenter, above.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	14105.45 Medi-Cal allowance.			
Section 9789.40(b)(1)	Proposed revised language: (b)(1) If ~~the National Drug Code~~ reimbursement for the drug product as dispensed in not in ~~the Medi-Cal database, and the National Drug Code for the underlying drug product form the original labeler appears in the Medi-Cal database~~ determined by Medi-Cal, then the maximum reasonable fee shall be the reimbursement, including the dispensing fee, allowed pursuant to section 14105.45 of the Welfare and Institutions Code ~~using the National Drug Code~~ for the underlying drug product from the original labeler ~~as it appears in the Medi-Cal database, calculated on a per unit basis. The maximum fee shall include only a single professional fee for dispensing for each dispensing.~~ Discussion The recommended change: ➢ Clarifies the amount allowed by Medi-Cal is the maximum reasonable fee ➢ Deletes the reference to the National Drug Code that is addressed, instead, in (b)(3) ➢ Deletes "calculated on a per unit basis" since the Medi-Cal factors are already expressed on a per unit basis ➢ Simplifies the language to make the meaning more easily understood	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute October 31, 2006 Written Comment		
Section 9789.40(b)(2)	Proposed revised language: (b)(2)If t~~he National Drug Code~~	Brenda Ramirez Claims and Medical Director	Although this proposal is very similar to the regulation proposed by the Division, the Division concludes	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	reimbursement for neither the drug product as dispensed ~~is not in the Medi-Cal database and the National Drug Code for~~, nor the underlying drug product from the original labeler is ~~not in the~~ determined by Medi-Cal ~~database~~, then the maximum reasonable fee ~~reimbursement~~ shall be ~~83 percent of~~ the ~~average wholesale price of~~ reimbursement, including the dispensing fee, allowed pursuant to section 14105.45 of the Welfare and Institutions Code of the lowest priced therapeutically or pharmaceutically equivalent drug product covered by Medi-Cal ~~minus 17 percent, calculated on a per unit basis~~. If no reimbursement for a therapeutically or pharmaceutically equivalent drug product is determined by Medi-Cal, then the maximum reimbursement shall not exceed the amount of the lowest priced therapeutically or pharmaceutically equivalent drug product as determined by the formula for the calculation of the estimated acquisition cost of legend and non-legend drugs in section 14105.45 of the Welfare and Institutions Code, plus the dispensing fee allowed pursuant to section 14105.45 of the Welfare and Institutions Code. **Discussion** Therapeutically or pharmaceutically equivalent drugs are comparable drugs. The statute requires drugs and pharmacy services not covered by Medi-Cal to be reimbursed no more than fees paid by Medi-Cal for comparable drugs and pharmacy services (Labor Code section 5307.1(d)). Under the current estimated acquisition cost formula of	California Workers' Compensation Institute October 31, 2006 Written Comment	that the regulation as proposed will be easier to apply. The Division has chosen the term "therapeutically equivalent," because it already has a well established defined meaning, and is used by the Food and Drug Administration.	

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	average wholesale price minus 17 percent (AWP – 17%), reimbursement will often exceed the 100% of Medi-Cal limit. Therapeutically and pharmaceutically equivalent drugs covered by Medi-Cal must be paid, therefore, according to the Medi-Cal methodology, as the statute requires, otherwise the reimbursement will exceed the statutory limit. A drug should only by paid according to the formula in section 14105.45 of the Welfare and Institutions Code (plus the Medi-Cal dispensing fee) if no reimbursement for any therapeutically or pharmaceutically equivalent drug product is determined by Medi-Cal. Although section 14105.45 currently specifies a 17% AWP reduction, and a $7.25 professional fee for dispensing ($8.00 if the patient is in a skilled nursing facility or an intermediate care facility), citing the section in lieu of the percentage or dollar amount will keep the formula and dispensing fees parallel with Medi-Cal's. Without this change, the Division must modify this regulation every time that the Medi-Cal dispensing fee is changed. Those fees have changed about once a year during the past several years. In light of the well publicized AWP abuses, Medi-Cal is now considering moving away from the use of the AWP in favor of a cost-based factor.			
Section 9789.40(b)(3) (proposed new section)	Proposed additional language: <u>(b)(3) Each billing for a drug product shall include an accurate National Drug Code for the product dispensed, and if reimbursement</u>	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute	See response to comments from the same Commenter, above.	No action to be taken.

	for the dispensed drug product is not allowed by Medi-Cal, shall also include the National Drug Code for the underlying drug product from the original labeler. **Discussion** Without the National Drug Code of the underlying drug product from the labeler there will be no way to provide reimbursement equal to that of equivalent or comparable pharmacy products allowed by Medi-Cal. The NDCs must be supplied on the billing otherwise the reviewer will have no way of identifying the labeler and the associated NDC.	October 31, 2006 Written Comment		
Section 9789.40(c)(1)	Proposed revised language: (c)(1) "therapeutically and pharmaceutically equivalent drugs" ~~means~~ are drugs that have been assigned the same Therapeutic Equivalent Code starting with the letter "A" and including "B" codes in the Food and Drug Administration's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book"). The Orange Book may be accessed through the Food and Drug Administration's website: http://www.fda.gov/cder/orange/default.htm; **Discussion** Therapeutically or pharmaceutically equivalent drugs are comparable drugs. To provide equivalent payment for equivalent drugs, it is important to clarify that equivalent payment will be provided to drugs that are therapeutically and/or pharmaceutically equivalent, including drugs with codes	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute October 31, 2006 Written Comment	See response to comments from the same Commenter, above.	No action to be taken.

	beginning with "A" and "B" codes.			
Section 9789.40(c)(2)	Proposed revised language: (c)(2) "National Drug Code for the underlying drug product from the original labeler" ~~means~~ is the National Drug Code ~~of the drug product actually utilized by the repackager in producing the repackaged product~~ assigned to the company that originally labeled the underlying drug product, as it appears in the Medi-Cal database. **Discussion** The recommend language will clarify that National Drug Code for the underlying drug product is the code from the company that originally labeled the underlying drug product and not an NDC from another intermediary. Requiring the NDC from another intermediary will create yet another loophole since reimbursement may not be determined by Medi-Cal for that intermediary's NDC.	Brenda Ramirez Claims and Medical Director California Workers' Compensation Institute October 31, 2006 Written Comment	The Division disagrees.	No action to be taken.
General Comment	Commenter supports the proposed regulations as written. The proposed amendments to Title 8, Section 9789.40 would establish fees for drugs not now covered by the Medi-Cal payment system, including repackaged drugs dispensed by physicians, limiting prices for repackaged drugs to 83% of the average wholesale price of the lowest-priced therapeutically equivalent drug. Studies have shown that half of the pharmaceuticals dispensed to California's injured workers are by physicians at a markup	Brent E. Barnhart Counsel Kaiser Permanente October 31, 2006 Written Comments	This comment does not suggest a change.	No action to be taken.

	that is four times what they would cost if pharmacies filled the same prescriptions. In July, University of California researcher Frank Neuhauser reported to the Commission on Health, Safety and Workers Compensation that insured employers will face premiums for the 2006 policy year that are $490 million higher than if all drugs were dispensed through pharmacies. These are therefore important amendments closing a loophole to 2003 legislation that was intended to limit the high cost of pharmaceuticals borne by employers.			
General Comment	Commenter agrees with and supports the proposed regulations as written.	Alissen Korsgard The Zenith October 31, 2006 Written Comments	This comment does not suggest a change.	No action to be taken.
General Comment	Commenter supports the adoption of the proposed amendments to Section 9789.40 as written. The proposed amendments address a significant issue for California's workers compensation system. The July 2006 study of the Commission on Health and Safety and Workers Compensation found that 30.3% of prescriptions dispensed in the California workers compensation system are dispensed by physicians directly from their offices. And approximately half of the total cost of pharmaceuticals in the workers compensation system is paid to physicians for prescriptions dispensed from their offices. These costs are too high and the fees charged for physician-dispensed drugs are unreasonable. The Commission found that on average, physician-dispensed drugs cost 490% of what is paid to	Samuel Sorich President Association of California Insurance Companies October 31, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.

	pharmacies. The proposed amendments to Section 9789.40 offer a sensible, balanced solution to the problem of exorbitant drug charges. The amendments simply put the charges for physician-dispensed drugs in line with accepted fee schedules. The amendments address a significant component of workers compensation costs, without affecting the quality of medical care for injured workers. The Commission's study found that there is virtually no research demonstrating better health outcomes or more rapid recovery when physicians dispense drugs.			
General Comment	Commenter is writing in support of the proposed regulations, which are intended to ensure that "repackaged pharmaceuticals" and other pharmacy services are not billed at a rate higher than allowed by Medi-Cal for similar services.	Stuart J. Brooker Associate Counsel Property & Casualty Law Department CNA Insurance Companies October 31, 2006 Written Comment	This comment does not suggest a change.	No action to be taken.
Section 9789.40(a)	Commenter recommends that this section specifically state that any drug or service not specifically described in the Medi-Cal payment schedule be reimbursed at no amount higher than 100% than allowed by Medi-Cal for similar products or services. This change will clear up any potential ambiguity, now or later, regarding the fee for any pharmaceutical or pharmaceutical service covered by these regulations. The suggested language is as follows: (a) The maximum reasonable fee for pharmaceuticals and pharmacy services	Stuart J. Brooker Associate Counsel Property & Casualty Law Department CNA Insurance Companies October 31, 2006 Written Comment	The Division disagrees. The Division concludes that such language would be less clear.	No action to be taken.

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	rendered after January 1, 2004 is 100% of the reimbursement prescribed in the relevant Medi-Cal payment system, including the Medi-Cal professional fee for dispensing. Under no circumstances should reimbursement for a pharmacy service or drug not covered by the Medi-Cal payment system exceed 100% of the fee paid by Medical for a comparable drug or service. Medi-Cal rates will be made available on the Division of Workers' Compensation's Internet Website (http://www.dir.ca.gov/DWC/dwc_home_page.htm) or upon request to the Administrative Director at: DIVISION OF WORKERS' COMPENSATION (ATTENTION: OMFS – PHARMACY) P.O. BOX 420603 SAN FRANCISCO, CA 94142			
Section 9789.40(b)	Commenter recommends that the dispensing fee be clearly stated as not to exceed the maximum allowable by Medi-Cal. To that end, commenter suggests the following language: (b) For a pharmacy service or drug that is not covered by a Medi-Cal payment system, the maximum reasonable fee paid, including any dispensing fee, shall not exceed the fee determined in accordance with this subdivision~~, plus $7.50 professional fee for dispensing or $8.00 if the patient is in a skilled nursing facility or an intermediate care facility~~.	Stuart J. Brooker Associate Counsel Property & Casualty Law Department CNA Insurance Companies October 31, 2006 Written Comment	The Division disagrees.	No action to be taken.
Section 9789.40(c)(2)	Commenter respectfully notes that the repackaged rate may be higher than that for	Stuart J. Brooker Associate Counsel	The Division disagrees. The Division concludes that such	No action to be taken.

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	the same pharmaceutical for the original retailer. Therefore commenter requests that the language be narrowly tailored to ensure that no code may be used to justify a higher rate for pharmaceutically similar drugs simply because a different code exists for the repackaged product. Commenter suggests the following language: (c)(2) "National Drug Code for the underlying drug product form the original labeler" means the National Drug Code ~~of the drug product actually utilized by the repackager in producing the repackaged product~~ assigned to the company that originally labeled the underlying drug product, as it appears in the Medi-Cal database.	Property & Casualty Law Department CNA Insurance Companies October 31, 2006 Written Comment	language does not make the pricing scheme more clear.	
	• Government Code Section 11342.1 requires that "[e]ach regulation adopted, to be effective, shall be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law. • Government Code Section 11342.2 states that "no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute." • The legislature, not the Administrative Director of the Division of Workers' Compensation has the exclusive authority to make policy and to establish key standards – the Administrative Director has the power to fill in the details of the legislatively enacted policy. (See, for example, *First Industrial Loan Co. v. Daugherty* (1945) 26 Cal.2d 545, 549.)	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

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	• Administrative regulations that alter or amend the statute or enlarge or impair its scope are void and courts not only may, but it is their obligation to strike down such regulations. (See, for example, *Morris v. Williams*, 67 Cal. 2d 733.) • The Legislature possesses the plenary constitutional authority to create and enforce a workers' compensation system (Cal. Const., art. XIV, § 4); therefore, any regulation promulgated by the Director of the Division of Workers' Compensation in contradiction to the Workers' Compensation Act is invalid. (See, for example, *Boehm & Associates v. Workers' Comp. Appeals Bd.* (1999) 76 Cal.App.4th 513.) For the reasons discussed below, the Proposed Regulation is improper because it: • Overreaches the Administrative Director's regulatory authority under Labor Code Section 5307.1; • Is inconsistent, and in conflict, with Labor Code Section 5307.1; • Violates Article IV, Section 4 of the California Constitution; and • Is inconsistent with the legislative intent of Business and Professions Code Sections 4024 and 4170, which expressly permit physicians to dispense drugs to their patients in the course of treatment. Even assuming that the Proposed Regulation is consistent with relevant statutes and within the Administrative Director's authority, the methodology of the Proposed Regulation exceeds the scope necessary to accomplish the Legislature's stated policy linking reimbursement to Medi-		The Division disagrees with all of the contentions of the Commenter.	No action to be taken.

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	Cal standards.			
	THE PROPOSED REGULATION IS INVALID BECAUSE IT IS NOT CONSISTENT WITH EXISTING CONSTITUTIONAL AND STATUTORY LAW **A. THE PROPOSED REGULATION CONFLICTS WITH THE CALIFORNIA CONSTITUTION** Article IV, Section 4 of the California Constitution provided in part as follows: **The Legislature is hereby expressly vested with plenary power, unlimited by any provision of this Constitution, to create, and enforce *a complete system of workers' compensation . . . A complete system of workers' compensation* includes *adequate provisions* for the comfort, health and safety and general welfare of any and all workers and those dependent upon them for support to the extent of relieving them from the consequences of any injury or death incurred or sustained by workers in the course of their employment**, irrespective of the fault of any party; also full provision for securing safety in places of employment; ***full provision for such medical, surgical, hospital and other remedial treatment as is requisite to cure and relieve from the effects of such injury***; . . . " (Emphasis added.) Denying the ability of physicians to dispense drugs, as discussed in this letter, will result in less than adequate provision for the medical	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		No action to be taken.

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	care of California's injured workers. In essence the "bargain" of Workers' Compensation, the trade-off of the right to sue an employer for negligence resulting in injury in return for the assurance of compensation and necessary medical care and treatment, will be abrogated. The Administrative Director has been provided with information sufficient for her to know, or at least suspect, that injured workers ***will not*** receive prescription medication deemed necessary for their recovery if physicians cease dispensing. The effect of the Proposed Regulation will be to force physicians from dispensing drugs to injured workers. The rate of reimbursement pursuant to the Proposed Regulation, coupled with the behavior of insurance carriers in delaying and simply refusing payment, makes repackaging and dispensing of repacked drugs so economically unattractive that it will drive physicians out of the system. By allowing patients to fall into the identified chasm between what physicians prescribe and what pharmacies and carriers will provide, the Administrative Director will abandon the compromise embodied in the California Constitution. While the Proposed Regulation may not, on its face, conflict with the constitutional mandate, the operation of the Workers' Compensation system must rise to the quality demanded by the Constitution. Cut after cut, adjustment after adjustment, little by little – the system			

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	finally fails the workers it was designed to protect. The Workers' Compensation system, as currently managed, will fail to meet its constitutionally-defined obligation if the Proposed Regulation pushes physicians to cease dispensing pharmaceuticals. **B. CONFLICTS WITH EXISTING STATUTES** Business and Professions Code Section 4170 authorizes a physician to dispense drugs or dangerous devices to patients in the course of their treatment. Labor Code Section 5307.1 expresses the Legislature's intention to protect the rights of physicians to dispense drugs to their injured worker patients and the injured workers' corresponding right to receive prescriptions directly from their physicians. Section 5307.1 applies to certain pharmacy services and drugs "whether furnished through a pharmacy *or dispensed directly by the practitioner*. . ." (Emphasis added.) The Legislature underscores its intention to protect the right of injured workers to receive medications directly from their physicians in Labor Code Section 4600.1(d), which states "Nothing in this section shall be construed to preclude a prescribing physician, *who is also the dispensing physician,* from dispensing a generic drug equivalent." (Emphasis added.) Many other provisions of California law express the legislative policy in favor of allowing physicians to dispense medication			

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	directly to their patients. (See, for example, Health & Safety Code Section 111655, Business & Professions Code Sections 2836.1 and 3502.1) Physician dispensing of drugs is an essential element of the Workers' Compensation system. For one thing, many injured workers do not have transportation to allow them to go to drug stores. *Cf., Poverty Resistance Center*, 213 Cal.App.3d at 611-612 (invalidating regulation that set food allowance for welfare grants at lowest prices available at six chains where record did not support assumption that recipients had means of transportation available to travel to each store with lowest price). **Furthermore, and contrary to the argument of the Workers Compensation Research Institute (which is biased, as addressed below in this letter) pharmacies are not willing to fill prescriptions in connection with litigated (that is, "denied") claims. Nor are they willing to dispense mediation in cases where no claim number has yet been assigned.** Patients who do not speak English need extra services, often provided with the assistance of translators, which are generally given by physicians and but generally denied by pharmacies. (See the attached study on pharmacies' unwillingness to fill Workers' Compensation prescriptions.) The effect of the Proposed Regulation would be to destroy the ability of physicians to			

	dispense medication to injured workers by making it uneconomic for them to do so. The Proposed Regulation thus violates the public policy clearly stated and firmly established by the Legislature in Labor Code Section 5307.1 and other provisions of California law to foster physician dispensing.			
	THE PROPOSED REGULATION CONFLICTS WITH CALIFORNIA LAW THAT REQUIRES A RATE OF REIMBURSEMENT THAT ENSURES A REASONABLE STANDARD OF CARE The Legislature, at Labor Code Section 5307.1 (f) requires 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." Setting fees for physician dispensed drugs at a fraction of the lowest price for a therapeutic equivalent would have the effect of setting the price below what physicians have to pay for drugs. The effect will be to drive physicians from dispensing medication, leaving injured workers struggling to obtain necessary drugs. As evidenced by the study entitled *Injured Workers' Inability To Obtain Prescription Drugs From Pharmacies: Profits Over Care* attached to this letter, pharmacies are not willing to fill prescriptions for Workers' Compensation patients whose cases have not yet been assigned claim numbers or whose	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

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	cases are being denied by their employer's insurer. Physicians perform an important function in respect of dispensing drugs to injured workers. Consider, for example, an injured worker who is carried into a physician's office with a piece of rebar impaling his foot. After removing the rebar, the physician would of course prescribe and dispense antibiotics. After all, the worker has not yet filed a claim and it would be impossible to obtain medication at any drugstore. Giving the patient a bottle of antibiotics is the first line of treatment – it is also both a necessary mode of treatment and the most conservative mode of treatment. Now consider the result if the Proposed Regulation were adopted. The physician, unable to afford to purchase the antibiotics the injured worker needs, would not be able to provide the vitally needed medication. The worker would be sent to search for a pharmacy where he could obtain it. As the attached study, *Injured Workers' Inability To Obtain Prescription Drugs From Pharmacies: Profits Over Care*, indicates, contrary to the biased information supplied by the insurance company controlled Workers Compensation Research Institute, he would find it impossible to find a pharmacy that would fill a prescription in the absence of an existing filed claim. Even if a claim were immediately filed, the adjuster could put the prescription through the utilization review process, delaying the delivery of antibiotics			

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	for days. Or, the insurer might claim that the injury was not work-related and the injured worker would be unable to obtain the drugs at all under the Workers Compensation system until his claim was litigated and decided. It is important that the Administrative Director understand that the immediate availability of drugs, i.e., drugs dispensed by the treating physician, is an essential element in the overall reduction of Workers' Compensation system costs – even if the reimbursement to physicians were to remain at its present level. Using the above illustration once again: The injured worker unable to obtain the antibiotic will suffer additional illness as a result; that illness will be more expensive to treat; the additional illness will lead to more time missed from work; and, if serious, will lead to greater disability; all of which will culminate in additional expense to employers and their carriers. The Administrative Director should note that the conclusion of the Gitlin and Wilson study, *Repackaged Pharmaceuticals in the California Workers' Compensation System: From Distribution and Pricing Options to Physician and Retail Dispensing*, included in the rulemaking file, states that **"…Medi-Cal payment rates may be extreme, and more moderate repricing might compensate physician dispensing time more fairly and preserve patient access."** The Administrative Director should			

	additionally note that the conclusion of the Gitlin and Wilson study, *The Pricing and Distribution of Repackaged Drugs: Cost Effects to the California Workers' Compensation System, Payers and Providers*, also included in the rulemaking file, concludes that: **•If the Workers' Compensation legislation reimbursement rate is set too low** **•This could lead to patient access problems affecting overall patient care** **•Varying the dispensing fee may allow the dispenser such as a physician to keep more of the payment than if the AWP alone is changed; depending on negotiations made with pharmaceutical repackagers and insurers, mitigating potential access limitations** **•To avoid access problems, step-wise reductions in reimbursement rates are appropriate** **•Future studies should examine if the added price is worth the increased access that repackaged pharmaceuticals afford and what cost and value are acceptable for pricing repackaged drugs** **C. THE PROPOSED REGULATION EXCEEDS THE LEGISLATIVE GRANT OF AUTHORITY** Even if the Administrative Director were to			

	assume that the Proposed Regulation were not in conflict with the Constitution and statutes, the Proposed Regulation exceeds the grant of authority in SB 228 – the origin of Labor Code Section 5307.1 and the sole referenced foundation for the proposed regulation.			
	THE GRANT OF AUTHORITY IS LIMITED TO PROMULGATION OF REGULATIONS THAT TRACK MEDICAL AND/OR MEDICARE If the Administrative Director wants to claim a mandate from the Legislature to create a reimbursement system that tracks Medi-Cal and/or Medicare, then the Administrative Director must acknowledge that the reimbursement formula in the Proposed Regulation deviates from Medi-Cal's reimbursement methodology. Labor Code Section 5307.1 (a) provides that the payment for drugs shall be in accordance with the fee-related structure and rules of the relevant Medicare and Medi-Cal payment systems. Subsection (a) of 5307.1 further provides that pharmacy services and drugs shall be subject to the requirements of Section 5307.1, whether furnished through a pharmacy or dispensed directly by a physician. Physicians furnish repackaged drugs that are, by definition, not covered by the Medicare or the Medi-Cal payment systems. Labor Code Section 5307.1 (d) states: "If the	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

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	administrative director determines that a medical treatment, facility use, product, or service is not covered by a Medicare payment system, the administrative director shall establish maximum fees for that item, provided that the maximum fee paid shall not exceed 120 percent of the fees paid by Medicare for services that require comparable resources. 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, **provided, however, that 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."** Physicians regularly furnish their patients repackaged drugs that are, by definition, not covered by the Medicare or the Medi-Cal payment systems. Under Section 5307.1 (d), therefore, the Administrative Director's authority to establish fees for physician dispensed drugs is limited by the statutory requirement that the fees not exceed 100% of the fees paid by Medi-Cal for pharmacy services or drugs that require comparable resources. **The resources required by a physician to dispense drugs are not comparable to the resources required in a pharmacy.** The Proposed Regulation rests on a false premise or at least disregards an important and irrefutable fact that distinguishes physician			

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	and pharmacy dispensing: the cost of the pills, and of dispensing them to the patient, is significantly different. *Physician dispensing is not at all comparable to pharmacy dispensing, nor do physicians and pharmacies share "comparable resources" in dispensing medication.* Pharmacies buy in large bulk quantity. Because of the volume, both in terms of the number of pills per bottle and the number of bottles, they buy at the lowest possible prices. In filling a prescription the pharmacist draws the number of pills prescribed from bulk supplies and repackages them in the bottle or other small container that is then dispensed to the patient. Physicians, in contrast, buy pills in small quantities already packaged in individual prescription size bottles ready for dispensing. They must pay prices that are much higher than the favorable prices that pharmacies pay. The higher price to the physician reflects the much smaller quantities the physician purchases, as well as the value of the added services the supplier provides in repackaging the pills in individual, prescription size bottles and in providing legally mandated chain of custody and related compliance services. Pharmacies have relatively low labor costs and pharmacists have relatively lower earning power, with pharmacists, supervising technicians, bottling large numbers of individual prescriptions each hour, more or less on a production line basis.			

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	Physicians, on the other hand, have relatively high labor costs and relatively higher earning power, with significant time spent counseling patients on the purpose of, risk factors, and method of use of each drug, often with the additional burden of certified translators. The Proposed Regulations, in treating physician dispensing as if it were identical to the cost of pharmacy dispensing, does not have any reasonable support. It rests on faulty assumptions that are contrary to indisputable economic facts, and therefore lacks a rational basis. *See Poverty Resistance Center v. Hart* (1989) 213 Cal.App.3d 295, 304-305, 311-312. The Administrative Director is not authorized to enact the Proposed Regulation as the Director can set no fee within Section 5307.1 (d)'s limitation that the fee not exceed the Medi-Cal fee for pharmacy services or drugs that require comparable resources, as there are none. There are no comparable resources.			
	THE DIVISION LACKS THE AUTHORITY TO REGULATE ABROAD SWATH OF PHYSICIAN-DISPENSED MEDICATION Labor Code Section 5307.1(d) also provides, "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***, provided, however, that the maximum fee paid shall not exceed 100 percent of the fees paid by Medi-	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

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	Cal for pharmacy services or drugs that require comparable resources." (Emphasis added.) In other words, the Legislature empowered the Administrative Director to adopt rules for ***single items*** not covered by a Medi-Cal payment system. This necessarily requires a case-by-case, individualized determination of the maximum fee for each drug. The Proposed Regulation, however, does not deal with individual drugs. Instead, it broadly seeks to govern all physician-dispensed drugs. No effort is made to make an individualized determination of the fee for any specific medication. The Proposed Regulation paints with a broad brush, treating all physician-dispensed drugs identically. The Proposed Regulation therefore exceeds the Administrator's authority.			
	THE PROPOSED REGULATION WOULD ADOPT A SCHEME INCONSISTENT WITH THE MEDI-CAL SYSTEM, THE LODESTAR PURSUANT TO LABOR CODE SECTION 5307.1 (d) Labor Code Section 5307.1(a) sets forth the guiding principal that "all fees shall be in accordance with the fee-related structure and rules of the relevant Medicare and Medi-Cal payment systems…" Medicare does not reimburse physicians for dispensed drugs. Medi-Cal does reimburse drugs based on a	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

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	formulary. Pricing for formulary drugs is determined by at the lower of several calculations: 1. Maximum Allowable Ingredient Cost (MAIC; usually calculated as a multiple of the lowest published price) plus a Dispensing Fee; or 2. Federal Upper Limit (FUL; a negotiated value used only for generics with high utilization) plus a Dispensing Fee; or 3. Estimated Acquisition Cost (EAC= AWP*0.83) plus a Dispensing Fee; or 4. Charge to the General Public. No matter which element of the Medi-Cal formula is applied, the Medi-Cal pricing scheme is based upon either the drug, identified by NDC number, actually dispensed or price data for the same drug from another supplier. But the formula in the Proposed Regulation does not look to the AWP of the drug dispensed by the physician, which would, by reason of repackaging, not be on the Medi-Cal formulary. Nor does the Proposed Regulation look to the AWP of that same drug from another supplier. Instead it first seeks to peg the fee to that of the National Drug Code ("NDC") of the "underlying drug product," which will be impossible to determine from the NDC of a physician-dispensed, repackaged drug because the original supplier is not identified on the repackaged bottles. Any result of that first test being an impossibility, the Proposed Regulation would			

	peg the fee to the lowest price paid for any other therapeutically equivalent drug. ***Additionally, and most importantly, the Administrative Director completely ignores that Medi-Cal provides for payment in respect of non-formulary drugs.*** This is wholly inconsistent with the express intent of the Legislature to conform to fees paid for drugs dispensed to Medi-Cal patients. In fact, the formula in the Proposed Regulation is a departure from the Medi-Cal standard mandated by the Legislature. It is a completely new scheme devised by the Administrative Director. The Proposed Regulation attempts to accomplish a result administratively that the Legislature refused to adopt. The formula in the Proposed Regulation is based in large part on the language of a legislative bill that failed SB 292 (2005 -2006). Neither the Labor Code nor the California Constitution vest the Administrative Director or the Division of Workers' Compensation with authority to enact administratively rules and policies the Legislature has rejected.			
	REPORTS UNDERLYING THE PROPOSED REGULATION ARE DEFECTIVE AND/OR BIASED **1. THE NEUHAUSER REPORT** The Administrator's Initial Statement of Reasons in connection with the Proposed	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

[10] This information was obtained from the WRCI website at https://www.wcrinet.org/governance.html on 10-27-06.

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	Regulation contains reference to the following as one of the documents relied on: *Study of the Cost of Pharmaceuticals in Workers' Compensation*, Frank Neuhauser, Alex Swedlow, Laura Gardner, and Ed Edelstein, prepared for the California Commission on Health and Safety and Workers' Compensation, **November, 1992**; available on the internet website of the Commission at: www.dir.ca.gov/CHSWC However, a search of the internet website of the Commission at: www.dir.ca.gov/CHSWC leads to a similarly entitled report prepared by the same authors, but **dated June 2000, not November 1992**. It is unclear what report the Administrative Director relies on. In either event, both a 1992 and a 2000 study on pharmaceutical costs are so outdated as to be moot in respect of 2006 regulation. Additionally, we note that Mr. Neuhauser submitted a July 2006 report (the "Report") to the Commission on Health & Safety & Workers' Compensation. In the event that the Initial Statement of Reasons meant to refer to that Report, please note that our client, Dr. Uwaydah, has already offered extensive commentary detailing concerns with its assumptions. Dr. Uwaydah met with Mr. Neuhauser who admitted that his Report was based on data supplied by insurance carriers, not independent investigation, and who agreed		The Division agrees that the Neuhauser report was miss-cited,	The citation has been corrected in the final statement of reasons.

	that the Report is falsely premised in that it assumes that all physician drug claims are paid by carriers, ignoring the critical fact that nearly half of all claims submitted by physicians for reimbursement for pharmaceuticals are denied. Those same denials will prevent patients from receiving the drugs prescribed to them if they are forced to fill their prescriptions through pharmacies. Additionally, the Report's assumptions about the availability of certified translators and the availability of transportation undermine the import of data related to the location of pharmacies relative to the location of injured workers. A copy of Dr. Uwaydah's comment on the Report is attached hereto as Exhibit "A" for reference and inclusion in the administrative record. **2. THE "INDEPENDENT" STUDY OF THE WORKERS' COMPENSATION RESEARCH INSTITUTE IS SUSPECT AT BEST** The Administrative Director recently added to the relied upon studies a report from the "Workers Compensation Research Institute." It is absolutely essentially that the Administrative Director recognizes that the WCRI is controlled by insurance carriers and large employers.[10] Specifically, the Division must consider that the WCRI's board of directors consists of:			

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	Robert Steggert, Chair ***Marriott International, Inc.*** Ronald Walton, Jr., Vice Chair ***A T & T Services, Inc.*** Pete McPartland, Vice-Chair ***General Casualty Companies of Wisconsin*** Kathy Langner, Treasurer ***Chubb & Son, a division of Federal Insurance Co.*** Vincent Armentano ***The St. Paul Travelers Companies, Inc.*** Christopher Colavita ***New Jersey Manufacturers Insurance Group*** Cristina D. Dobleman ***Stanford University*** Vincent Donnelly ***The PMA Insurance Group*** Michael Fenlon ***United Parcel Service*** Roger J. Fries ***Kentucky Employers' Mutual Insurance*** Gregory W. Heidrich ***Property Casualty Insurers Association of America*** Sam Holland ***Accident Fund Insurance Company of America*** Janine Kral ***Nordstrom, Inc.*** David North ***Sedgewick Claims Management Services, Inc.*** David Patterson ***ESIS*** Paul Mattera ***Liberty Mutual Group*** Richard L. Thomas ***American International Group*** Joseph Treacy ***The Hartford Insurance Group*** Joseph Wells ***Zurich North America*** If the Administrative Director knew this already, then it is disturbing that the report from WCRI would be relied upon for such a critical issue. On the other hand, if the			

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	Administrative Director was deceived by the neutral-sounding source of the non-neutral report, then the Administrative Director should consider the "conclusions" contained therein as lobbying. See Exhibit "B" for documentation concerning the WCRI. **3. THE "INDEPENDENT" STUDY OF THE CALIFORNIA WORKERS' COMPENSATION INSTITUTE IS SUSPECT AT BEST** The Administrative Director also relies upon studies from the California Workers Compensation Institute, as well as on studies by other authors which rely on its data. The Administrative Director must recognize that the CWCI is admittedly an insurance company and self-insured employer group. Its website (at http://www.cwci.org/aboutCWCI/WHO_WE_ARE.cfm, viewed on 10-27-06) states that: **The California Workers' Compensation Institute is a private, nonprofit organization working to improve the California worker's compensation system through research, education, information, and representation. Institute members include workers' compensation insurers and self-insured employers.** The CWCI's website also reveals that its members are: **CWCI Member Insurers** ***ALASKA NATIONAL INSURANCE COMPANY*** ***AMERICAN INTERNATIONAL GROUP***			

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	ARGONAUT INSURANCE COMPANY ***CALIFORNIA INSURANCE COMPANY*** ***CHUBB GROUP*** ***COMPWEST INSURANCE COMPANY*** ***CNA INSURANCE COMPANIES*** ***CYPRESS INSURANCE COMPANY*** ***EMPLOYERS COMPENSATION INSURANCE COMPANY*** ***EMPLOYERS DIRECT INSURANCE COMPANY*** ***FARMERS INSURANCE GROUP*** ***FIREMAN'S FUND INSURANCE COMPANY*** ***GENERAL REINSURANCE CORPORATION*** ***GREAT AMERICAN INSURANCE COMPANY*** ***THE HARTFORD INSURANCE GROUP*** ***INSURANCE COMPANY OF THE WEST*** ***LIBERTY MUTUAL GROUP*** ***MAJESTIC INSURANCE COMPANY*** ***PREFERRED EMPLOYERS INSURANCE COMPANY*** ***REPUBLIC INDEMNITY COMPANY OF AMERICA*** ***SAFECO P&C INSURANCE COMPANIES*** ***SEABRIGHT INSURANCE COMPANY*** ***SPRINGFIELD INSURANCE COMPANY*** ***STATE COMPENSATION INSURANCE FUND*** ***STATE FARM INSURANCE COMPANIES*** ***ST. PAUL TRAVELERS*** ***XL AMERICA*** ***ZENITH INSURANCE COMPANY*** ***ZURICH NORTH AMERICA*** **CWCI Associate Members (Self-Insured)** ***ADVENTIST HEALTH***			

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	AGILENT TECHNOLOGIES ***AT&T SERVICES, INC.*** ***CATHOLIC HEALTHCARE WEST*** ***CHEVRON CORPORATION*** ***CITY AND COUNTY OF SAN FRANCISCO-DPH OSH*** ***CITY OF ANAHEIM*** ***CITY OF HUNTINGTON BEACH*** ***CITY OF SANTA ANA*** ***CITY OF SANTA MONICA*** ***CITY OF TORRANCE*** ***CONTRA COSTA COUNTY SCHOOLS INSURANCE GROUP*** ***COSTCO WHOLESALE*** ***COUNTY OF SAN BERNARDINO RISK MANAGEMENT*** ***COUNTY OF SANTA CLARA RISK MANAGEMENT*** ***FOSTER FARMS*** ***KAISER FOUNDATION HEALTH PLAN, INC.*** ***METROPOLITAN STEVEDORE COMPANY*** ***PACIFIC GAS & ELECTRIC COMPANY*** ***REDWOOD EMPIRE MUNICIPAL INSURANCE FUND*** ***SAFEWAY, INC.*** ***SEMPRA ENERGY*** ***SHASTA COUNTY RISK MANAGEMENT*** ***SOUTHERN CALIFORNIA EDISON*** ***SUTTER HEALTH*** ***UNIVERSITY OF CALIFORNIA*** ***THE WALT DISNEY COMPANY*** By its own admission, CWCI is a biased organization. Its reports, and any report relying on its data, must be disregarded or			

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	viewed simply as opinion pieces, not "independent" studies. See Exhibit "C" for documentation concerning the CWCI.			
	NOT THE LEAST IMPACTFUL MEANS "An agency must find that no alternative would be more effective in carrying out the purpose for which a regulation is proposed or would be as effective and less burdensome to affected private persons than the adopted regulation." (See, Office of Administrative Law, *How to Participate in the Rulemaking Process*) **1. THE PROPOSED REGULATION IS CONFISCATORY AND THEREFORE UNCONSTITUTIONAL** The Proposed Regulation would also have the effect of denying substantial justice to physicians treating injured workers by way of its confiscatory level of reimbursement. Physicians have significant stock of drugs, in some cases many hundreds of thousands of dollars worth, which cannot be returned and which will be rendered valueless should the Proposed Regulation be adopted. A confiscatory regulation is unconstitutional. **2. THE INVESTMENT EMBODIED BY PHARMACEUTICAL STOCK-ON-HAND WILL BE EVISCERATED BY THE PROPOSED REGULATION** The Proposed Regulation guts the value from the investment made by physicians who have made capital outlays for the purchase of repackaged pharmaceuticals with the expectation of being reimbursed under the	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

	current formula. The Proposed Regulation changes the market while physicians are part-way through the course of their investment. Those physicians who have stock-on-hand relied on the reimbursement formula when assessing purchase prices and their willingness to pursue carriers for payment. Physicians will not have the opportunity to achieve the return on the investment that was expectable under the current reimbursement rates. Should the Administrative Director determine that physicians were not entitled to rely on the present reimbursement formula when negotiating for the purchase of repackaged pharmaceuticals, the Administrative Director must recognize that the proposed regulation denies the investing physician a reasonable return on his/her investment. This is true whether or not a physician has a right to rely on the present regulatory scheme. Enacting the proposed regulation is a taking that must be considered and remedied if the regulation is to pass Constitutional muster. **3. LONG TERM SUPPLY CONTRACTS** In some instances, repackagers and physicians are in lengthy, exclusive, requirements contracts. For periods of even as long as five (5) years, a physician may be contractually required to purchase *all* pharmaceuticals from a repackager. The proposed regulation dramatically reduces (or eliminates) the economic upside for the physician. He or she may be left in a long-term contract in which			

	he or she is making exceedingly little on what, when the agreement was made, was an economically attractive proposition. The value of the investment and negotiation will be squandered by the regulatory shift. **4. POSSIBLE RESOLUTIONS** The definite way to avoid the confiscatory impact of the Proposed Regulation is to forgo the regulation entirely. At the very least, physicians and repackagers must have a period of time during which they can (a) continue to be reimbursed at the present rates and (b) renegotiate their relationships. A period of one (1) year *might* be sufficient to allow those who made high-value purchasing decisions to dispense any subject pharmaceuticals without being unfairly deprived of the expectable return on investment. The Administrative Director should keep in mind that even the present system, as detailed herein, is fraught with wrongfully denied claims and inexplicable delay. Physicians who have undertaken to provide for their patients and brave the long road to collection must not be further undermined by the proposed regulatory change.			
	THE PROPOSED REGULATION RIPS A HOLE IN THE SAFETY NET SECURED BY PHYSICIAN-DISPENSED PHARMACEUTICALS The Administrative Director appears to have turned a blind eye to the demonstrable fact that carriers and industrial pharmacies ***do not*** provide for Workers' Compensation patients	Mark F. Weiss Advisory Law Group October 31, 2006 Written Comment		

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	(a) in the first days of their claim and (b) when the claim, rightly or wrongly, has been denied by a carrier. In each of those instances, the patient has but one source of the medication deemed necessary for his/her treatment – the physician. The Administrative Director must inquire of carriers and pharmacies as to how patient claims for medication are handled in the early days following an injury. It is not enough to look at the system abstractly and muse about how much money might be saved if physicians were reimbursed less for medication that they dispense. The purpose of the Workers' Compensation system is to provide for injured workers – not to save money. The Administrative Director has access to the carriers and pharmacies. Ask. Ask them if a patient who needs antibiotics on the first day of his injury can walk into a RiteAid at 9:30 p.m., or without a case number, or on a Sunday, and receive the medication that he needs to prevent infection. He or she cannot. In the first days following an injury, a patient does not have a claim number. The carrier may not yet have even heard of the injury. Infection and pain do not wait for adjusters to review files or for utilization review. The mechanism for handling claims inextricably includes delay. The carriers then infuse a second dose of procrastination – patterns of delay, referral to utilization review, etc., even if permissible – that results in more delay in			

	the provision of medication. The patient is left to fend for himself. Before the Administrative Director can contemplate approving a regulation that has the demonstrated and practical impact of denying medication to patients for hours, days, and maybe weeks, she *must* account for the welfare of California workers. Injured workers rely on the system in their time of need as guaranteed by the State Constitution – and in fact, those workers often do not have a second safety net. The Administrative Director has not addressed the fact that those she is charged to protect and provide for will be left empty-handed under the Proposed Regulation. **1. A STUDY CONDUCTED IN THE GREATER LOS ANGELES AREA DEMONSTRATES THE DISCONNECT BETWEEN THE PROPOSED REGULATION AND REALITY** In October 2006, our client conducted an independent study investigating the ability of injured California workers to obtain pharmaceuticals from pharmacies. It studied the issue of language barriers, the ability to obtain pharmaceuticals on an immediate basis, and the impact of denied claims on the willingness of pharmacies to dispense drugs. The study, entitled *Injured Workers' Inability To Obtain Prescription Drugs From Pharmacies: Profits Over Care*, is attached hereto as Exhibit "D" for reference and inclusion in the administrative record.		The comment goes beyond the scope of the regulation.	No action to be taken.

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	The study employed two methods. The first involved calling pharmacies at random and explaining that the caller was an injured worker who had obtained a prescription. The caller asked whether she could bring her prescription to the pharmacy and wait while it was filled. The caller explained that she was not sure if her employer's carrier had accepted or denied the claim. The caller also asked if a certified Spanish interpreter was available to explain side effects as she was more comfortable conversing in Spanish. The second method involved tracking the ability of 50 injured California workers to fill their workers compensation prescriptions, for from one to five drugs, at a pharmacy of their choice. The first method revealed that **0% of pharmacies would fill the prescription while the patient waited**. **0% of pharmacies would fill the prescription without prior authorization from the carrier**. **44% of pharmacies do not fill workers compensation prescriptions**. The remaining **56% of pharmacies will not fill a workers compensation prescription unless the patient has a claim number and insurance information, as prior authorization from the carrier was required**. It also revealed that **0% of pharmacies will fill a prescription on a workers compensation claim that is denied by the carrier**. **0% of**			

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	pharmacies had certified Spanish interpreters available. Only 28% of pharmacies had someone available who spoke some Spanish who could attempt to explain the side effects of the medication in the patient's language. The second study revealed that **0% of pharmacies would fill prescriptions on a denied a workers compensation claim**. **In respect of patients with accepted claims 78% were unable to obtain their medications as they were told that the pharmacy could not verify their claim or obtain authorization. Only 22% of accepted claim patients were able to obtain at least one of their medications**; however, **67% of those accepted claim patients were unable to receive one or more medications due to insurance company refusal to authorize those particular drugs**. Of the patients who did obtain at least one medication, 100% of native English speakers reported they were able to obtain explanation of side effects from the pharmacy; however, **0% of the native Spanish speakers, who spoke little or no English, were able to obtain any explanation at all -- there were simply handed their medication**. **2. NO EFFORT MADE TO REGULATE CARRIERS OR PHARMACIES** There is nothing in the Proposed Regulation to address the conduct of insurance carriers or pharmacies. If pharmacies were required to dispense pharmaceuticals to anyone who presented with a prescription and stated that		The Administrative Director does not have the authority to require pharmacies to dispense to anyone, nor does it have the authority to direct insurance carriers to provide pharmaceuticals on denied claims.	No action to be taken.

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	he was an injured worker, and if carriers were required to pay for prescriptions on the first day of an injury even in the absence of a claim number or even in the event of an actual denial, then perhaps the Workers' Compensation system would not fail its beneficiaries. If pharmacies were required to fill prescriptions on any case for which the physician works on lien so that they, too, take the risk and make the effort to attempt to reverse a denial of the claim by the carrier, then maybe the system would be sufficient to meet its constitutional obligation. The Proposed Regulation does not make any effort to assure adequate care – as is required by the Constitution and statute. The Proposed Regulation does not take a comprehensive approach. The Proposed Regulation, as written, adjusts one politically convenient element of the equation and then leaves carriers and pharmacies to do what they will. These participants – carriers and pharmacies – are not tasked with taking care of patients. The do not have an ethical obligation to do no harm. Their *obligation* is to their shareholders and investors – not to patients. There is no ready recourse against a carrier who refuses to pay for a prescription. The patient just goes home and does without. California will fail its workers and abandon its charge if it leaves the treatment of patients to the varied whims or adjusters, carriers, and pharmacies.		The comments go beyond the scope of the regulation.	No action to be taken.
	The Proposed Regulation must be withdrawn and further study made (1) of the Administrative Director's ability to issue	Mark F. Weiss Advisory Law Group October 31, 2006		

	regulations on physician dispensed pharmacy pursuant to Labor Code Section 5307.1, and (2) of the impact on injured workers and on the Workers' Compensation system as a whole in the event that reimbursement to physicians for dispensed drugs is reduced from current levels.	Written Comment		
	Patients receive medication, or prescriptions for medication, for one or both of two reasons: 1) the medication is therapeutic and valuable in curing a medical problem; or 2) the medication relieves symptoms -- for example, pain, the result of which is patient comfort rather than management of the medical problem. Patients appreciate being able to obtain their medications from their physician rather than having to travel to a site elsewhere. There is significant convenience in obtaining all services, including medications, at one location. Unfortunately, it is difficult to quantify the value of convenience, but one negative outcome of the patient being unable to obtain medications from the treating physician may be that the patient never actually receives the medication, if required to travel elsewhere. Commenter understands and appreciates the concern that billing for repackaged medications has resulted in some abuse, periodically egregious. However, the solution is not to reduce reimbursement so severely as to effectively preclude physician-dispensed medications, but rather to establish a level of reimbursement that allows for reasonable	Henry Monroe, Jr. Concentra, Inc. October 31, 2006 Written Comment	The regulation does not preclude physician dispensing of drugs.	No action to be taken.

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	payment while assuring that charges are not egregious. Commenter believes that medications can be delivered to patients in physicians' offices in a fairly priced manner while assuring the preservation of this valuable and convenient service to our injured and ill workers. However, the proposed pharmaceutical fee schedule does not accomplish this. The severe reduction in reimbursement for physician dispensed pharmaceuticals compounds the difficulties of primary care physicians caused by the inadequacy of physician reimbursement under the current official medical fee schedule. The current inadequacy of physician reimbursement presents an issue that the Division must address in order to assure that injured workers have adequate access to quality medical care. Based on these concerns, commenter urges the Division to revise the current regulations in order to provide for a system that eliminates abuses while allowing for adequate reimbursement for pharmaceuticals. Commenter also urges the Division to accelerate its consideration of revisions to the current physician fee schedule.		The Division has proposed regulations to substantially increase fees paid to physicians for evaluation and management procedures.	No action to be taken.
	As a supporter of a rational Workers' Compensation system, Commenter appreciates the Division's efforts to close a loophole left by SB 228 (Alarcón, 2003). However, he believes the proposed regulations, in addressing the billing abuses of a few bad actors, would make it impossible for almost all physicians and clinics to	Steven C. Schumann, M.D., Legislative Chair Western Occupational & Environmental Medical Association (WEOMA) October 31, 2006 Written Comment	See response to comments of Joseph A. Zammuto.	No action to be taken.

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	dispense repackaged pharmaceuticals. They would thus eliminate an important benefit to California's injured workers. Office dispensing helps patients and the system in important ways: • Patient compliance – Perhaps a quarter or more prescriptions prescribed through a retail pharmacy are never picked up, owing to a number of factors: lack of transportation, language barriers, and the inability or unwillingness to pay out of pocket for initial treatment. Physician dispensing mitigates this problem. • Health outcomes – Office dispensing of antibiotics ensures that infections can be treated as early as possible. Office dispensing of pain medication can avert unnecessary pain and suffering. Commenter believes that office dispensing, by encouraging timely access to medication and patient compliance, serves the underlying return-to-work principles of the reformed system. Commenter is not advocating for a specific schedule for repackaged drugs. However, he does believe statute provides DWC with the latitude to adopt a schedule that allows providers to continue dispensing while ending the egregious billing practices of a few. Commenter encourages DWC to pursue this course.			
Section 9789.40(b)(1)	Commenter agrees that a single professional fee for dispensing per prescription is needed to cover the administrative costs for providing	Jose Ruiz Claims Operations Manager – State	The Division disagrees regulation of the possible abuse proposed by The Commenter is necessary at this time.	No action to be taken.

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	pharmaceutical services. The last sentence in the proposed section 9789.40(b)(1) may further allow inappropriate dispensing practices. Repackagers may provide multiple dispensings in small quantities for the same National Drug Code on the same date of service and include a dispensing fee for each. **Recommendation** Commenter recommends that the language be amended as follows: If the National Drug Code for the drug product as dispensed is not in the Medi-Cal database, and the National Drug Code for the underlying drug product from the original labeler appears in the Medi-Cal database, then the maximum fee shall be the reimbursement allowed pursuant to section 14105.45 of the Welfare and Institutions Code using the National Drug Code for the underlying drug product from the original labeler as it appears in the Medi-Cal database, calculated on a per unit basis. The maximum fee shall include only a single professional fee for dispensing per drug dispensed on the same date of service. ~~for each dispensing.~~	Compensation Insurance Fund October 31, 2006 Written Comment	Should the predicted abuse arise in significant amount, the dad may revisit the issue.	
Section 9789.40(b)(2)	Commenter agrees that the objective of these regulations are to resolve billing disputes for pharmacy services or drugs that are not in the Medi-Cal payment system. However, a potential problem needs to be addressed with regards to repackaged drugs. As stated in "California's New Pharmacy Fee Schedule" and "Repackaged Pharmaceuticals in Workers' Compensation," both reports	Jose Ruiz Claims Operations Manager – State Compensation Insurance Fund October 31, 2006 Written Comment		

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	indicate that 60% of the National Drug Codes (NDC) evaluated in their studies could not be priced by Medi-Cal. A process must be in place that would enable a payer to correctly identify the labeler of the underlying drug in order to reimburse for the Average Wholesale Price associated with the original labeler's NDC. Billing disputes will occur if the payer re-prices using incorrect labeler's NDC. In an effort to avoid re-pricing errors and to allow the system work efficiently, the repackaging provider should be responsible for providing the labeler's NDC number. This would expedite the payment process, reduce billing disputes and achieve intended reform savings. **Recommendation** Commenter recommends the addition of the following language to CCR §9789.40(b)(2): If the National Drug Code for the drug product as dispensed is not in the Medi-Cal database, and the National Drug Code for the underlying drug product from the original labeler appears in the Medi-Cal database, then the maximum fee shall be the reimbursement allowed pursuant to section 14105.45 of the Welfare and Institutions Code using the National Drug Code for the underlying drug product from the original labeler as it appears in the Medi-Cal database, calculated on a per unit basis. The maximum fee shall include only a single professional fee for dispensing per drug dispensed on the same date of service. Repackagers shall provide the		The Administrative Director does not have the authority to regulate the practices of manufacturers or labelers.	No action to be taken.

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	National Drug Code (NDC) when billing for a repackaged product along with the original labeler's NDC number of the repackaged product.			
	Throughout the discussions regarding the in-office dispensing of medications, the California Orthopaedic Association has felt strongly that the regulations should allow physicians to continue to dispense medications in their offices. Commenter believes that there is value added when the medication is immediately available to the injured worker and the physician and/or their staff explains the use of the medication. Commenter appreciates that the Division's regulations continue to allow in-office dispensing. Unfortunately, some carriers refuse to reimburse the physicians for the medications dispensed in their offices. Commenter requests that the regulations clarify that in-office dispensing is permitted and that the payment rules apply. Commenter also requests that any reduction in reimbursement levels be phased in so as to be less disruptive to patient care. Determining what it actually costs an orthopaedic office to dispense medications has been difficult. Reports from our members indicate that their costs are approximately $10-$15 per prescription. Physicians' dispensing fees should be higher than those of a pharmacy for the following reasons:	Diane Przepiorski California Orthopaedic Association October 31, 2006 Written Comment	The Division disagrees that regulation is required to force payers to pay for physician dispensed drugs, as employers are already required to pay for properly prescribed drugs, no matter how dispensed. The Division concluded that it would be simpler for the entire workers' compensation industry if price changes were implemented at a single time. Dispensing costs: See response to comments of Stephen J. Cattolica.	No action to be taken. No action to be taken. No action to be taken.

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	1. a pharmacy can purchase the medications at a discount due to their higher purchasing volume; 2. physicians cannot electronically submit their claims; 3. payment to the physicians is not as timely; and, 4. approximately 20% of the time, the physician is not paid at all for the medications dispensed. To compensate physicians for these higher costs, we would recommend that the dispensing fee be set at $12.50 for each of the first 3 prescriptions dispensed on a single visit. The dispensing fee would drop to $7.25 for the fourth and any additional prescriptions dispensed on that same day. Commenter believes that this tiered system would rein in any potential over utilization of medications dispensed in a physician's office. Commenter urges the Division to encourage the carriers to accept physicians' electronic submission of claims for pharmaceuticals, much like they do for pharmacies, and allow the option for the carrier to also make the payments electronically. This would decrease the additional costs for physicians.			
	COMP has been actively involved in providing comments on these regulations that would close a loophole for physicians to bill egregious amounts for dispensing medications from their office. COMP is in full agreement that this loophole should be closed. We do not	Ronald Crowell, M.D. President California Occupational Medicine Physicians October 31, 2006 Written Comment		

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	support this activity. Unfortunately, the proposed regulations will result in COMP physicians no longer dispensing medications. As we have stated continuously over the past 18 months we believe there is value for both employers and injured workers in ensuring injured workers receive their medications by dispensing them in the office. Commenter urges the Division of Workers' Compensation (Division) to reconsider the regulations and adjust them to close the loophole that allows for egregious billing but leave enough reimbursement to give the physician the option to dispense medications to injured workers without losing money on each prescription. Commenter has worked with the California Medical Association on its previous proposal of increasing the dispensing fee to $22 for both brand and generic drugs and believes this would allow physicians to cover their costs of dispensing medications and maintain this valuable service. Commenter believes that this is a fair compromise that will chase out the "bad actors" while giving the physician the ability to dispense medications. The combination of losing revenue from dispensing medications and continuing to be reimbursed by a physician fee schedule that has not been updated in over 20 years will lead many clinics to either reduce the number of injured workers they treat or completely leave the Workers' Compensation system. Either choice will only further exacerbate the already existent access problems that have		See response to comments of Stephen J. Cattolica.	No action to be taken.

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	begun to show over the past two years. If the Division decides to move forward with the current version of the proposed regulations Commenter would to ask to consider accelerating its review of updating the Official Medical Fee Schedule (OMFS). COMP believes that the loss in revenue from the change in dispensing payments can be greatly absorbed by updating the OMFS to increase the payment for Evaluation and Management (E&M) codes that are most commonly used by primary treating physicians. There are a number of reasons that point to the need to increase the reimbursement of the E&M codes. These reasons include: • In 2003, the Industrial Medical Council released a study performed by the Lewin Group that found that the practice expenses required to perform services captured under the E&M codes on injured workers is 28% greater than the same services performed outside of the Workers' Compensation system. • Focusing on two of the most commonly used CPT codes used by primary treating physicians (99203 & 99213), we have found that Medicare rates have increased on average 4.5% annually for the past 11 years while the reimbursement rate under the OMFS has decreased. Currently, these two CPT codes are reimbursed well below Medicare.		The Administrative Director has currently proposed regulations to substantially increase the physician fees for evaluation and management procedures.	No action to be taken.

	• Medicare reimbursement has not kept up with the Medicare Economic Index which tracks inflationary increase for providing medical services. Our clinics can no longer operate a profitable business under these conditions. The combination of these three facts coupled with a decrease in revenues from dispensing medications is leading to our clinics to face difficult decisions on how long they can afford to continue to practice occupational medicine. Our clinics do not want to leave the Workers' Compensation system. They have chosen this field because they gain great satisfaction in treating injured workers and helping them return to full health. Commenter is asking the Division to reconsider its position on reducing reimbursement for dispensing medications. If the ultimate decision is to keep the current form of the proposed regulations we implore the Division to accelerate its review of the OMFS and bring the E&M reimbursement rates up to date.			
	Commenter dispenses medications to injured workers covered by the California workers' compensation system. Commenter is writing in support of the CMA, and to voice my own opposition to the proposed regulation. The proposed regulation fails to recognize the costs to physicians of obtaining drugs packaged for patient distribution. Information	Daniel J. Paveloff, M.D. September 25, 2006 Eugene Hubbard, JR., M.D., September 25, 2006 Ronald C. Woods, M.D. September 25, 2006	See response to comments of Stephen J. Cattolica.	No action to be taken.

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	has been previously submitted to the DWC demonstrating that the proposal will pay less than the costs of acquiring and distributing the medications. There has been no credible rebuttal or proof to the contrary that the proposed reimbursement formula pays more that the costs of distribution. Similarly, information has been previously submitted, based on in-office tests, that when physicians do not dispense medications, at least 35% of the patients given a prescription fail to fill the prescription at a retail pharmacy. The proposed regulation's attempt to close the loophole in S.B. 228 is an extreme approach that pays physicians less than costs of distribution. This extreme approach prevents physicians from dispensing in their office. Therefore, the proposal is illegal because it is contrary to Business and Professions Code 4170, and 5703.1 of the Labor Code, which authorize and permit physician dispensing. Commenter believes that a careful study of the WCIRB analysis of SB 228 demonstrated the legislative intent to reduce all pharmacy expense, whether dispensed by physicians or pharmacies, by approximately 35-40%. Therefore, the WCIRB scored the savings to be derived from the pharmacy provision on the intent. To effectuate the legislative intent, all dispensers, whether retail pharmacies or physicians should be compensated at AWP 17%, plus a $7.25 dispensing fee. This is the payment approach contemplated by the legislation's authors. It is currently in use by		The Division concluded that using this approach would provide exorbitant compensation for some drugs.	No action to be taken.

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	major carriers, including SCIF. The supporters of the proposed regulation point to instances of abuse. Any abuse is unfortunate, but shouldn't result in the passage of punitive and harmful regulation. Paying AWP-17% will prevent future abuses just as well as the proposed regulation, and is legal and in the interest of injured workers by allowing physicians to dispense and injured workers to obtain their medications directly and immediately. Commenter is opposed to the regulation as currently formulated because it will unfairly discriminate against physicians and in favor of retail pharmacies. Currently, retail pharmacies, paid according to the workers' compensation Medi-Cal formula of SB 228, are paid at AWP-17%, plus a $7.25 handing fee. Commenter is not opposed to reform, but is opposed to punitive and discriminatory reform that pays us physicians at the same level as retail pharmacies, namely, at AWP-17%. + 7.25 dispensing fee.			
	Commenter has been a physician assistant in Northern California for many years. The practice consists of treating injured workers from all over rural Lake Mendocino Counties. Our patients and employers rely on us to provide the best medical care possible. One of the ways that we make a significant difference for our injured workers is by offering prepackaged medication through our occupational medicine clinic.	Emily Frey, PA-CA October 16, 2006 Barry R. Sheppard, M.D. October 16, 2006 Charles E. Evans, M.D. October 16, 2006 Lisa Gamble, PA-C		

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	Commenter offers a small formulary of the most commonly used medications at a reasonable cost to employers and insurers for the sole purpose of medication compliance. Experience has taught us that nearly all employees have difficulty obtaining their prescriptions from an outside pharmacy even when that pharmacy is their own employer. A large number of our patients have significant language barriers and do not have the means to pay cash for their medications. Our office takes the risk of non-payment by dispensing the medication even before the prescriptions have been "authorized" by the insurer. We are able to absorb the cost of non-payment by having a small profit margin. The recent proposal of amendment to Pharmacy Law Section 9789.40 would essentially make our practice of dispensing pre-packaged medications to injured workers impossible. I am afraid that if injured workers are not able to obtain the medications that they need in a timely manner their recovery and return to work will be delayed. Provider dispensing is an important component of health care in workers' compensation. My ability to utilize pre-packaged medication provides a powerful treatment tool. Please consider the adverse impact on quality care if the department provides incentives for physicians to repackage medication on-site like we use to do.	October 16, 2006 Gary W. Fausone, M.D. October 16, 2006 Marvin G. Trotter, M.D. October 16, 2006 Joseph Otto, PA/FNP October 16, 2006 Joanne C. Nelson, M.D. October 16, 2006 Lillian Basner, FNP October 16, 2006 S.P. Wanbli Franklin, M.D. October 16, 2006 Roger Cheitlin, M.D. October 16, 2006 Lisa M. MacCormack, M.D. October 16, 2006	The regulation does not prohibit physician dispensing of drugs. The only subject matter of the regulation is the pricing of drugs.	No action to be taken.
	Commenter is one of hundreds of physicians	Philip A. Sobol, M.D.		

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	who dispense drugs to injured workers covered by California workers' compensation system and is writing in support of the CMA, and to voice my own opposition to the proposed regulation. The proposed regulation fails to recognize the costs to physicians of obtaining drugs packaged for patient distribution. Information has been previously submitted to the DWC demonstrating that the proposal will pay less than the costs of acquiring and distributing the medications. There has been no credible rebuttal or proof to the contrary that the proposed reimbursement formula pays more than the costs of distribution. Similarly, information has been previously submitted, based on in-office tests, that when physicians do not dispense medications, at least 35% of the patients given a prescription fail to fill the prescription at a retail pharmacy. The proposed regulation's attempt to close the loophole in S.B. 228 is an extreme approach that pays physicians less that the costs of distribution. This extreme approach prevents physicians from dispensing in their office. Therefore, the proposal is illegal because it is contrary to Business and Professions Code 4170, and 5703.1 of the Labor Code, which authorize and permit physician dispensing. Commenter believes a careful study of the WCIRB analysis of SB 228 demonstrated the legislative intent to reduce all pharmacy expense, whether dispensed by physicians or	Diplomate, American Board of Orthopedic Surgery QME September 25, 2006 Written Comment Albert M. Tsai, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written Comment Curtis W. Spencer III, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written Comment David S. Morrison, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written Comment Philip S. Yuan, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written Comment Douglas E. Garland, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written Comment	See response to comments of Stephen J. Cattolica. The Division disagrees with the contentions of the Commenter.	No action to be taken. No action to be taken.

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	pharmacies, by approximately 35-40%. Therefore, the WCIRB scored the savings to be derived from the pharmacy provision on the intent. To effectuate the legislative intent, all dispensers, whether retail pharmacies or physicians should be compensated at AWP 17%, plus a $7.25 dispensing fee. This is the payment approach contemplated by the legislation's authors. It is currently in use by major carriers, including SCIF. The supporters of the proposed regulation point to instances of abuse. Any abuse is unfortunate, but shouldn't result in the passage of punitive and harmful regulation. Paying AWP-17% will prevent future abuses just as well as the proposed regulation, and is legal and in the interest of injured workers by allowing physicians to dispense and injured workers to obtain their medications directly and immediately. Most importantly, commenter is opposed to the regulation as currently formulated because it will unfairly discriminate against physicians and in favor of retail pharmacies. Currently, retail pharmacies, paid according to the workers' compensation Medi-Cal formula of SB 228, are paid at AWP-17%, plus a $7.25 handing fee. The proposed regulation would pay physicians less, only the cost of the drug. Commenter does not oppose reform, but is opposed to punitive and discriminatory reform that pays us physicians at the same level as retail pharmacies, namely, at AWP-17%. + 7.25 dispensing fee.	William H. Warden III, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written Comment Signed without name, no date Jonathan Jaivin, M.D. October 5, 2006 Sent 3 Written Comments Brent Pratley, M.D. September 27, 2006 Written comment Noah D. Weiss, M.D. Orthopaedic Surgery No date Written comment Jonathan Rice, P.A. October 5, 2006 Written comment Peter R. Kurzweil, M.D. Memorial Orthopaedic Surgical Group October 12, 2006 Written comment Hiromu Shoji, M.D. No date Written comment	The Division disagrees with the Commenter's analysis of the regulation.	No action to be taken.

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		Jill L. Harrel, M.D. Warbritton & Associates No date Written comment Sherman Tram, M.D. No date Written comment Timothy P. Gray, M.D. No date Written comment John S. Portwood, M.D. October 16, 2006 Written comment Michael Esposito, M.D. September 27, 2006 Written comment Lis Stark, M.D. October 5, 2006 Written comment Gerald Alexander, M.D. October 5, 2006 Written comment Vorakiat Charuvastra, M.D. Orchid Multispecialty Medical Group October 20, 2006 Written comment		

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		Laurence Ponir, M.D. Mission Valley Medical Clinic No date Written comment Timothy J. Hunt, M.D. Intercommunity Medical Group No date Written comment Arnie Leavitt Chief Operating Officer Health First Medical Group October 3, 2006 Written comment		
	Commenter is one of hundreds of physicians who dispense drugs to injured workers covered by California workers' compensation system and is writing in support of the CMA, and to voice my own opposition to the proposed regulation. The proposed regulation fails to recognize the costs to physicians of obtaining drugs packaged for patient distribution. Information has been previously submitted to the DWC demonstrating that the proposal will pay less than the costs of acquiring and distributing the medications. There has been no credible rebuttal or proof to the contrary that the proposed reimbursement formula pays more than the costs of distribution.	Craig Zeman, M.D. Ventura Orthopedics September 28, 2006 Written Comment Andre M. Ishak, M.D. Ventura Orthopedics September 28, 2006 Written Comment Mark J. Ghilarducci, M.D. Ventura Orthopedics September 28, 2006 Written Comment	The Commenter is assuming that repackagers will only continue to sell drugs to physicians at their current prices. The Division concluder that it is not possible to predict whether repackagers may lower the prices on some repackaged drugs to a point at which physicians can dispense without incurring a loss.	No action to be taken.

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	Similarly, information has been previously submitted, based on in-office tests, that when physicians do not dispense medications, at least 35% of the patients given a prescription fail to fill the prescription at a retail pharmacy. The proposed regulation's attempt to close the loophole in S.B. 228 is an extreme approach that pays physicians less that the costs of distribution. This extreme approach prevents physicians from dispensing in their office. Therefore, the proposal is illegal because it is contrary to Business and Professions Code 4170, and 5703.1 of the Labor Code, which authorize and permit physician dispensing. This proposed regulation pretends to reimburse physicians for dispensing, when, in fact, it is a disguised effort to prohibit physician dispensing by paying physicians reimbursement less that the cost of the drug and the dispensing cost. It is disingenuous to say a physician may dispense, but reimburse less than the costs incurred by the physician. Accordingly, the proposal also violates the mandate of the California Supreme Court that a rate regulation system must not be confiscatory, and must pay the regulated entity its costs and a fair return. (CalFarm Insurance Company v. Deukmejian, 48 Cal. 3rd 805, at pages 815-821, hereafter "CalFarm Case") Commenter believes that a careful study of the WCIRB analysis of SB 228 demonstrated the legislative intent to reduce all pharmacy		The Division disagrees with the contentions of the Commenter.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	expense, whether dispensed by physicians or pharmacies, by approximately 35-40%. Therefore, the WCIRB scored the savings to be derived from the pharmacy provision on the intent. To effectuate the legislative intent, all dispensers, whether retail pharmacies or physicians should be compensated at AWP 17%, plus a $7.25 dispensing fee. This is the payment approach contemplated by the legislation's authors. It is currently in use by major carriers, including SCIF. If Medi-Cal is to be used, then the Medi-Cal prompt payment system should also be used. Currently, providers are paid on average within 22 days by Medi-Cal, not 22 months as in workers' compensation. The supporters of the proposed regulation point to instances of abuse. Any abuse is unfortunate, but shouldn't result in the passage of punitive and harmful regulation. ("Profits of the past cannot be used to sustain confiscatory rates for the future." CalFarm Case, at page 819) This recommendation, paying AWP-17% will prevent future abuses like the proposed regulation, matches existing Medi-Cal regulation and in the interest of injured workers because it will allow physicians to continue dispensing and injured workers will continue to be able to obtain their medications directly and immediately. Most importantly, commenter is opposed to the regulation as currently formulated because it will unfairly discriminate against physicians and in favor of retail pharmacies. Currently, retail pharmacies, paid according to the		The Division disagrees with the contentions of the Commenter.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	workers' compensation Medi-Cal formula of SB 228, are paid at AWP-17%, plus a $7.25 handing fee. The proposed regulation would pay physicians less, only the cost of the drug. Commenter is not opposed to reform but opposed to punitive and discriminatory reform that pays us physicians at the same level as retail pharmacies, namely, at AWP-17%.			
	Commenter is a dispensing physician who caters to injured California workers. This proposal is unnecessary, counterproductive, unmanageable, disruptive to my practice of medicine and potentially harmful to the continued care and treatment of injured workers. Unnecessary Regulation: • Existing law states that "the maximum reasonable fees for pharmacy services after January 1, 2004 is 100% of the fee prescribed in the relevant Medi-Cal payment system". • Medi-Cal has a method to pay for all pharmaceuticals, whether or not they are part of the Medi-Cal formulary. • There is a distinct difference between an item that is not part of the Medi-Cal database (formulary), and the payment methodology that would be applied in the Medi-Cal payment system. • For most pharmaceutical drugs that I dispense to my patients, the relevant Medi-Cal payment system would be AWP minus 17%, plus the current professional dispensing fee.	42 Written comments		

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	• On January 27, 3004 DWC decided no to implement the Medi-Cal payment system for drugs with NDCs were not in the Medi-Cal database. • PROPOSAL: Enforce existing law and use Medi-Cal payment methodology of AWP minus 17% (plus a dispensing fee) for all non-formulary items. Counterproductive: • The time and energy spend on this issue has detracted from the time and energy to address more pressing issues to improve health care to injured California workers. • In January of 2004, DWC decided, without public hearings or rulemaking process, to award December 31, 2003 fee schedules for drugs that were not part of the Medi-Cal database. This decision can be changed immediately, with full support of the medical community, without an extensive rulemaking process. • PROPOSAL: Reinterpret the provisions of SB228 to use Medi-Cal payment methodology of AWP minus 17% (plus a dispensing fee) for all products not included in the Medi-Cal database and move on to other concerns. Unmanageable: • It is impossible to tell from a product label what the underlying NDC of a drug product might be, and the federal FDA forbids the use of more than one NDC on a package. Repackaged drugs can be		The Division disagrees with the contentions of the Commenter. The repackaging relabeler has the ability to provide the NDC's of the underlying drug product to the	No action to be taken. No action to be taken.

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	marketed with multiple "underlying NDCs". • It is unreasonable to require a cross-reference of the FDA Orange Book with a national AWP database and then analyze the results for the lowest AWP of all therapeutically equivalent drug products to determine fair and reasonable compensation. • PROPOSAL; Keep it simple and utilize data that is already in place to reimburse dispensed pharmaceuticals. For items that are not in the Medi-Cal database, use the appropriate Medi-Cal payment system of AWP minus 17% (plus a dispensing fee). Disruptive to Practice: • The effective date of December 1, 2006 is 30 days after the public hearing on October 31, 2006. Although it is my sincere hope that this proposed rule be modified or eliminated as a result of the comments and the public hearing, the potential for an immediate, radical change in pharmaceutical reimbursement will disrupt my practice starting TODAY. Without further research, I am unable to decide whether or not I can continue to afford to provide these services to my patients after December 1st. • PROPOSAL: Allow a reasonable period of time in which to implement any rule changes. As this is a significant change, I would suggest at least 90 days after rule is adopted. Potentially Harmful to California Workers:		purchasing physician. The Division disagrees with the contentions of the Commenter. Using the system proposed by the Commenter would continue to allow exorbitant charges for some repackaged drugs. The Division concludes that, as these regulations were first proposed in January, 2006, and have been the subject of widely distributed commentary in the workers'	 No action to be taken. No action to be taken. No action to be taken.

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	• The proposed regulation will have a direct, adverse impact on the ability for injured workers to receive medications from physicians. • By providing medication directly to injured patients, I am able to have them begin drug therapy immediately, which ultimately provides a higher standard of care and speeds their recovery. • By providing medications directly to my patients at the time of medical care I am assured that they understand the proper use and expectations of their treatment, and have a greater assurance that they will follow the course of therapy I have prescribed. • It is Commenter's understanding that when I give a written prescription to and injured worker, they may have to wait hours until their claim is validated by the pharmacy. This is especially disturbing when dealing with an acute care situation that requires immediate treatment for pain or infection. Again, commenter urges the Division of Workers' Compensation to review the text of SB228 and existing law. It was the intent of the legislature to have DWC use Medi-Cal payment systems to establish maximum reasonable fees for pharmaceutical services. An examination of Medi-Cal pharmaceutical reimbursements will determine that Medi-Cal has a method to reimburse any pharmaceutical item, whether it is routinely covered by the Medi-Cal program or not. By using the Medi-Cal method (currently: AWP minus 17% plus		compensation community. The physician community which dispenses drugs not in the Medi-Cal database has had adequate time to prepare for the changes in pricing.	

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	$7.25), the DWC will be embracing legislative language, legislative intent and adopting a program that will automatically be changed due to economic forces affecting the cost of services. In addition, the insurers will realize an estimated 45% saving over the maximum reasonable fees allowed in the OMFS 2003. Please do not adopt cumbersome, limited regulations that adversely impact the quality of care.			
	Commenter's doctor has given the option of having prescriptions filled in office. Commenter likes this because it is easy and simple. If he/she goes to a pharmacy, it is a lot of trouble, they ask for payment for my medications if they are not authorized by my insurance, and bother me about not having the necessary paperwork. They don't understand what it is like to have a work comp injury and the financial burden it causes. Many times, commenter doesn't have a way to get there. The Doctor has informed the commenter that the division has proposed to take away his ability to dispense medications in his office. This will be a great problem for commenter not only physically but also financially, as he/she should expect a more difficult time trying to obtain the resources to obtain my medications. Commenter fears this will not only hurt his/her care but livelihood.	34 Written comments	The Division disagrees that the adoption of the regulation itself will cause the specified inconveniences to the Commenters. The regulation does not prohibit physician dispensing of drugs.	No action to be taken.
	Commenters have been informed that there is a public hearing scheduled on October 31, 2006 regarding the proposed regulation to amend Section 9789.40. Commenters are California injured workers and wish to have their voices heard during this rulemaking process.	39 Written comments		

	The proposed regulation will have an enormous impact on medical treatment. Commenters doctors have been able to dispense medications for chronic pain which has made such an improvement of medical condition and quality of life. Commenters are able to get the medication they desperately need at the time of their visit with the doctor. In the past, Commenters have had to go to different pharmacies and wait hours, days and sometimes, weeks to receive my medication because of extreme delays with the insurance company. If this legislation is amended, the Commenters will suffer the consequences.		The Division disagrees that the adoption of the regulation itself will cause the specified inconveniences to the Commenters. The regulation does not prohibit physician dispensing of drugs.	No action to be taken.
	Commenters doctors have told them they have the option to get my drugs in office. Commenters like this because it is easy and simple. If they go to a pharmacy, it is a lot of trouble, they ask for money, and bother them about not having paperwork. They don't understand the Commenters. Many times they have no way to travel there. Their physicians now tell them that Division has proposed to take away the doctor's ability to give patients their drugs directly. This will be a great problem for the commenters, and will prevent them from getting their medications.	1,026 Written comments	Comment not related to the fee regulation. The regulation does not prohibit physician dispensing of drugs.	No action to be taken.
	The commenter's doctors have told them of the option to get medications in the physician's office. Commenters like this because it is easy and simple. If they go to a pharmacy it is a lot of trouble as they ask for money and bother them about not having paperwork. They do not understand commenters. Many times they do not have a	107 Written comments	Comment not related to the fee regulation. The regulation does not prohibit physician dispensing of drugs.	No action to be taken.

	way to get to the pharmacy. The physician now tells them the Division has proposed to take away their ability to give them medications. This will be a great problem for them and will prevent them from getting my medications. Commenters are afraid this will hurt their care. Please do not take away my physician's ability to dispense medications.			
	Commenter's doctors have told them that if the Division's proposed regulation 9789 is approved, they will no longer be able to get my prescriptions at the office, because what they will be paid for drugs is so low that they will lose money. Commenters have visited pharmacies. They do not understand commenters and they bother them about not having paperwork, and they want them to pay for the drugs. Because commenters are not working, they have very little money and cannot afford the drugs, so they must do without them. Commenters are really concerned about their care and feel that if this regulation is approved, they will not be able to make a full recovery. Please do not take away the physician's ability to dispense medications.	126 Written comments	Comment not related to the fee regulation. The regulation does not prohibit physician dispensing of drugs.	No action to be taken.
	Commenters are in opposition to the proposed regulation, because it proposes to pay less than their costs of obtaining drugs packaged for patient distribution. Physicians have to rely on prepackaged drugs, and, therefore, the DWC cannot simply eliminate reimbursement	3 Written comments	The Division disagrees with all of the contentions of the Commenter.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	for the costs of obtaining drugs in a unit dose, or repackaged, format. The law states that the DWC is to look at comparable resources when promulgating a pharmacy fee schedule for repackaged drugs. Medi-Cal does not have repackaged drugs in its database, therefore, slavish reliance on Medi-Cal is against the law. The proposed regulation doesn't show any evidence that repackaged drug costs are compensated under the proposed fee schedule, therefore it is illegal, both under SB 228 and under Business and Professions Code 4170, and 5703.1 of the Labor Code, which authorize and permit physician dispensing. To effectuate the legislative intent, and allow physicians to dispense, the proposal needs to modify its use of the current Medi-Cal formula to accommodate repackaging costs, not present in the Medi-Cal database. To allow physicians to dispense, they should be compensated at AWP -17%, plus a $7.25 dispensing fee. This is the payment approach contemplated by the legislation's authors. It is currently in use by major carriers, including SCIF The supporters of the proposed regulation point to instances of abuse. Any abuse is unfortunate, but shouldn't result in the passage of a punitive and harmful regulation. Paying AWP-17% will prevent future abuses just as well as the proposed regulation, and is legal and in the interest of injured workers by allowing physicians to dispense and injured workers to obtain their medications directly and immediately.			

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenters are not opposed to reform but are opposed to punitive and discriminatory reform that hurts their patients. Please reconsider and adopt, at least as an interim, a regulation that pays us physicians at the same level as retail pharmacies, namely, at AWP — 17%.			
	El Medico me ha dicho que tengo la opción de obtener mis estupefacientes en su consultorio. Esto me gusta porque es fácil y sencillo. Si voy a la farmacia, es mucho trabajo, me piden dinero y se molestan conmigo por no tener el papeleo. Ellos no me comprenden. Muchas veces, no tengo como llegar alli. El medico ahora me dice que usted ha propuesto quitarle la habilidad para darme mis estupefacientes. Esto será un problema grade para mi, y me impedirla obtener mi medicamento. Temo que esto lastimara mi cuidado. Por favor no le quite la habilidad a mi medico para dispensar mis medicamentos.	77 Written comments	The Division will only address comments made in the English language.	No action to be taken.
	Recently their doctors have told them that the government was planning to change the rules about getting their medications from his office. Please understand how much this service means to them and if they no longer have this option they believe their recovery will be affected. With their conditions it is very difficult for them to make an extra trip to the pharmacy and wait long hours and sometimes days to fill their prescription, not to mention the interrogation and demand for payment that they receive. Commenters were loyal hardworking employees before their injuries and hope to return to work. Commenters are confident that with the continued excellent care and	33 Written comments	The Division disagrees that the regulation will require physicians to cease dispensing drugs from their offices. This comment does not suggest a change.	No action to be taken. No action to be taken.

	medication that they receive directly from their physicians, that day will be sooner than later. However, it appears that the state of California feels that their injuries merit a Medi-Cal classification. Commenters suggest that the DWC put a little more effort in creating a fair and unique reimbursement policy for their treatment and not just copy another agency!			
	Commenter's doctors have informed them that they may soon loose the option of getting drugs in his office. This is very easy and convenient for them. If they go to a pharmacy, it is a lot of trouble, they ask for information that they do not always have or want them to pay for the medications up front then get reimbursed later. They don't seem to understand all the difficulty that they are having or that they just need help in getting my medication. Often times finding transportation or getting to the pharmacy is difficult. Commenters may go several days without my medication as a result of lack of transportation. If they loose the ability to get medication in office it will create a big problem for them. They understand this is being purposed under regulation 9789. Commenters believe that this will make their lives more difficult and increase the amount of stress in their lives. Please do not take away their physician's ability to dispense medications.	84 Written comments	The Division disagrees that the regulation will require physicians to cease dispensing drugs from their offices.	No action to be taken.
	Mi doctor me ha avisado que tengo la opcion de obtener los medicamentos en su oficina. Esto me gusta porque es facil y sencillo. Si voy a una farmacia es mucho problema, me piden dinero, me molestan. por el papeleo que	20 Written comments	The Division will only address comments made in the English language.	No action to be taken.

Official Medical Fee Schedule – Pharmaceuticals	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	no traigo. No me entienden. Muchas veces no tengo como ilegar. El medico me cuenta ahora que han propuesto ustedes quitarle a el su capacidad para darme los medicamentos. Esto sera un gran problema para mi y me impidira el obtener mis medicamentos. Temo que esto perjudique mi tratamiento. Por favor no le quite a mi medico su capacidad para surtirme los medicamentos.			