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Common acronyms / abbreviations used in the Comment Chart ACOEM - American College of Occupational and Environmental Medicine CCR - California Code of Regulations DWC - Division of Workers' Compensation IMR - Independent Medical Review MPN - Medical Provider Network MTUS - Medical Treatment Utilization Schedule NDC - National Drug Code P&T Committee - Pharmacy and Therapeutics Committee RAND Report - *Implementing a Drug Formulary for California's Workers' Compensation Program*, Wynn, et al, RAND, 2016 UR - Utilization Review				
9792.27.1	Commenter recommends the inclusion of a definition for "Clinical Setting" to avoid disputes over what constitutes a clinical setting as that term is used in the regulations.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD, Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. The term "clinical setting" is used only in section 9792.27.2, and the meaning is sufficiently clear in context.	No action required.
9792.27.1	Commenter is a strong proponent of implementing a step therapy program	Rupali Das, MD, MPH, FACOEM,	First, it appears that commenter is not suggesting a	No action necessary.

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	to work with the proposed drug formulary. This should be a priority of the P&T Committee. Any step therapy program should be designed to work in conjunction with the definitions and usage of Preferred, Non-Preferred, and Unlisted Drugs as defined under Section 9792.27.1. Any step-therapy program must also work seamlessly with the MTUS guidelines. When a step therapy hierarchy is established, it would be beneficial if first line therapies aligned with the Preferred Drug category so that Preferred Drugs must be tried first, a Non-Preferred Drug second and an unlisted drug only if neither a Preferred Drug nor a Non-Preferred Drug is available or has been ineffective.	California Medical Director Raymond Tan, PharmD, Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	step therapy program be adopted in the initial formulary regulations, but is suggesting it be instituted after the P&T Committee is formed and can participate in consulting on the issue. Second, disagree with commenter's suggestion that a step therapy align: Step 1 - Preferred, Step 2 - Non-Preferred, Step 3 - Unlisted drugs. The proposed structure would not align with the MTUS ACOEM guidelines usage recommendations, which are not structured in this way. There is far more nuance to the evidence-based treatment recommendations based on the patient's condition, phase of care, and patient co-morbidities.	
9792.27.1	Because Section 9792.27.21(b)(4) references a therapeutic interchange program and that term may be new to many people in the industry, commenter recommends adding a definition for Therapeutic Interchange to 9792.27.1.	Rupali Das, MD, MPH, FACOEM, California Medical Director Raymond Tan, PharmD	Disagree. There are a variety of ways to structure a therapeutic interchange program and a step therapy program. The definitions should not be added until the scope of such programs is	No action necessary.

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	"Therapeutic Interchange means the substitution of a drug by a pharmacist or payor with a drug that is a therapeutic alternative or equivalent, with the prescribing provider's permission." Commenter also recommends adding a definition for step-therapy. Commenter recommends the following new language: **Step-therapy means the practice of beginning drug therapy for a medical condition with the safest and most cost effective drug and progressing to other higher risk or more costly drug therapy, only if medically necessary.**	Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	further developed, including consulting with the P&T Committee. Moreover, in relation to the suggested definition of "Therapeutic Interchange" it would not be appropriate to include "therapeutic equivalent" as those are drugs identified in the Orange Book as "A" rated equivalents, and which already may be substituted by a pharmacist, for example substituting a generic therapeutic equivalent for a brand name drug.	
9792.27.1	Commenter notes the definitions for Commenter requests that the DWC consider identifying how pain pump refill drugs should be classified and include that in the definitions under both the Formulary regulations and eventually the Physician's Fee Schedule regulations as well.	Suzanne Honor-Vangerov, Esq. May 1, 2017 Written Comment	Disagree. MTUS Low Back Disorders Guideline does not recommend the use of intrathecal pain pumps. However, for existing patients the guideline states that it should not be interpreted as requiring device removal. Commenter states that this issue is a "fee schedule	No action necessary in this regulatory action. DWC will consider these for inclusion in the Physician Fee Schedule and/or the Pharmaceutical Fee Schedule.

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			problem". It is more appropriate to address the issue in a future fee schedule rulemaking action.	
9792.27.1	Commenter recommends the following revised language: (f) "Dispense" means: 1) the furnishing of a drug <u>for outpatient use</u> upon a prescription from a physician or other health care provider acting within the scope of his or her practice, or 2) the furnishing of <u>a</u> drug~~s~~ <u>for outpatient use</u> directly to a patient by a physician acting within the scope of his or her practice. (s) "Perioperative Fill" means the policy set forth in section 9792.27.12 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed <u>for outpatient use</u> ~~within~~ <u>during</u> the perioperative period and meets specified criteria. Commenter states that the changes recommended in (f) are necessary to clarify that the definition of dispense relates to outpatient drugs for the	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Disagree. The definition proposed in the regulations mirrors the definition of "dispense" set forth in the Business and Professions Code §4024. It is beneficial to align the workers' compensation definition with the definition generally applicable to pharmaceuticals statewide. Moreover, in relation to both the definition of "dispense" and "perioperative fill," other provisions of the proposed regulations make it clear that the MTUS Drug List and the formulary are applicable to drugs dispensed for "outpatient use"; duplication of this concept in the definition of "dispense" or "perioperative fill" would not improve the clarity of the regulation.	No action necessary regarding (f). No action necessary regarding (s).

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	purpose of these sections. As currently proposed in (s), the drug must be **prescribed** during the perioperative period. If the intent is for the drug to be **prescribed for use** during the perioperative period, the recommended modification is necessary for clarification, otherwise a prescribing physician could, on the 4th day after surgery, prescribe a 90-day supply of a drug. <u>(z) "Surgery" means a surgical procedure that has "010", or 10 Global Days, listed for the reimbursable CPT code as found in the Medicare National Physician Fee Schedule Relative Value File incorporated into the Official Medical Fee Schedule.</u> Commenter states that adding a definition for "surgery" is necessary to clarify under what specific conditions the "Perioperative Fill" policy is applicable. Spinal injections such as trigger points injections and epidural steroid injections, as well as		Regarding the possibility that the perioperative fill could be used to prescribe a 90-day supply on the 4th day after surgery, that would not be possible under the regulations as drafted. The perioperative fill is specified as not to exceed a supply specified in the MTUS Drug List. Currently anticoagulants are set at a maximum 14-day supply, and all other drugs are set at a 4-day supply. Disagree. The perioperative fill must be prescribed in accordance with the MTUS Guidelines. The medical necessity for a perioperative fill drug may not align with the global days designation in the physician fee schedule. Additionally, although the Zero day procedures are unlikely to warrant opioids, they may be required depending for individual patient circumstances, which the doctor will address using	No action necessary regarding (z).

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	diagnostic procedures such as endoscopy, are all procedures that would not normally necessitate the prescribing of drugs for outpatient use of during the perioperative period but could be considered surgery. Add the definition in order to avoid unnecessary frictional costs.		professional judgment, and in accordance with the MTUS. A pattern of inappropriate prescribing by a physician for the perioperative fill is likely to be identified on retrospective review and will be addressed through the remedies set forth in Labor Code section 4610.	
9792.27.1(a)	Commenter recommends adding clarification to the word "device" to specify that it means "devices" that are used to deliver a drug to the body. "(a) "Administer" means the direct application of a drug or **drug delivery** device to the body of the patient by injection, inhalation, ingestion, or other means."	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. The definition in the regulation conforms to the definition of "administer" in the Business and Professions Code section 4616, which is in Division 2 - Healing Arts, in Chapter 9 – Pharmacy.	No action necessary.
9792.27.1(e)	The current proposed definition for compounded medications could leave open a loophole for compounds that involve only active ingredients or for only altered ingredients.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--	Agree in part. The proposed definition should be modified to be more comprehensive so a loophole in the definition of "compounded drug" is not	Modify proposed language to reference the governing regulations promulgated by the

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	Recommend defining "compounded medication" as follows: ***<u>A pharmaceutical product that results from the combining, mixing, or altering of one or more active or inactive ingredients, excluding flavorings, to create a customized drug (not typically produced by a manufacturer) for an individual patient in response to a licensed practitioner's prescription.</u>***	- Fault April 28, 2017 Written Comment May 1, 2017 Oral Comment	created. The regulation will be modified to tie the compounded drug definition to regulations of the California Pharmacy Board and federal law governing compounding. It would be preferable to tie the definition of "compounded drug" to the governing statutes; the suggested definition may still be subject to creating loopholes and can be out of sync with the relevant legal authority.	California Board of Pharmacy, and the governing federal statute.
9792.27.1(e)	The current definition is overly-specific may create unintended loopholes. This dangerous level of specificity is unnecessary since the proposed rules already recognize a protected class of FDA-approved "combination drugs" as a separate defined, category. Suggested revision: "Compounded drug" means a drug that is created by combining one or more active pharmaceutical ingredients~~, and one or more inactive ingredients, to meet specific patient~~	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Agree in part. See response above to comment of Brian Allen, Optum, dated April 28, 2017.	See action described above in relation to the response to Brian Allen, Optum.

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	~~medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace;~~ **however, this definition shall not include "Combination drugs" as defined in 9792.27.1(d).**			
9792.27.1(h)	Section 9792.27.1(h) includes a definition of Expedited Review; however, this term is also defined in Section 9792.6.1(j) [utilization review regulations]. Commenter recommends only referencing the prior definition and not including any additional language. Commenter recommends revision: "(h) "Expedited review" means the utilization review conducted prior to the delivery of the requested medical services, in accordance with Labor Code section 4610 and title 8, California Code of Regulations section 9792.6.1 et seq., ~~**where the injured worker's condition is such that the injured worker faces an imminent and serious threat to his**~~	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Agree.	Revise section 9792.27.1(h) to delete the repetition of the definition language included in section 9792.6.1(j). For clarity, add the word "expedited": "(h) "Expedited review" means the expedited utilization review conducted prior to the delivery of the requested medical services…"

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	~~**or her health, including, but not limited to, the potential loss of life, limb, or other major bodily function or the normal prospective review timeframe would be detrimental to the injured worker's life or health or could jeopardize the injured worker's permanent ability to regain maximum function.**~~"			
9792.27.1(n); 9792.271.10 9792.27.14	Commenter is concerned that the designation of many medications as "Non-Preferred," the meaning of which could be misinterpreted by some payers as "should be denied." Many such "non-preferred" drugs are useful and potentially critical in some situations. The Division should make it clear in these regulations that non-preferred drugs are appropriate in certain instances and not automatically denied for use based upon this designation.	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017	Agree that some payers may misinterpret the meaning of "Non-Preferred," although the regulations are structured to make it clear the drugs so designated are available to treat the injured worker when authorized through prospective review. The terminology will be modified from "Preferred/Non-Preferred" to "Exempt/Non-Exempt." This terminology will align more closely with the effect of the designation. Exempt means exempt from prospective review, and "Non-Exempt" means the drug is not exempt from authorization through prospective review.	The terminology will be modified from "Preferred/Non-Preferred" to "Exempt/Non-Exempt."

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9792.27.1(s)	Commenter states that the proposed definition of Perioperative Fill fails to define or identify the location of the definition for the specified criteria in the rules. Commenter recommends that a clarifying citation to be added to make the definition more clear. " 'Perioperative Fill' means the policy set forth in section 9792.27.12 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed within the perioperative period and meets specified criteria~~.~~, ***as defined in section 9792.27.12(b).***"	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Disagree. Not necessary and appears duplicative.	No action necessary.
9792.27.1(s)	Commenter recommends the following revised language: " 'Perioperative Fill' means the policy set forth in section 9792.27.12 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed within the perioperative period **for a *surgical procedure that has "010" or 10 Day Post-operative Period or has "090", or 90 Day Post-operative Period, listed for the reimbursable***	Jeremy Merz American Insurance Association Jason Schmelzer California Coalition on Workers' Compensation May 1, 2017 Written Comment	Disagree. See response above to comment of CWCI dated May 1, 2017, suggesting adding a definition of "surgery.".	No action necessary.

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	CPT code as found in the Medicare National Physician Fee Schedule Relative Value File incorporated into the Official Medical Fee Schedule and meets specified criteria."			
9792.27.1(t) 9792.27.16	Commenter states that there will be a need for further assessment and ongoing updating of the drug formulary as time goes on. The Division should act swiftly to select and appoint members of this committee so that they are prepared to meet ASAP after the implementation date.	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017	Comment is not directed at the regulatory text. Nevertheless, DWC is cognizant of the need to expeditiously recruit, select, and convene the P&T Committee after adoption of the regulations.	No action necessary.
9792.27.1(t) 9792.27.16	Commenter recommends accelerated constitution of the P&T Committee.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Comment is not directed at the regulatory text. Nevertheless, DWC is cognizant of the need to expeditiously recruit, select, and convene the P&T Committee after adoption of the regulations.	No action necessary.
9792.27.1(v)	Commenter recommends the revised language that replaces the word	Mitch Seaman Legislative Advocate	Disagree with the suggested modification. Substituting	No action necessary.

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	"does" with "shall." "Preferred drug" means a drug on the MTUS Drug List which is designated as being a drug that ~~does~~ **shall** not require authorization though prospective review prior to dispensing the drug….	California Labor Federation Written Comment May 1, 2017 Oral Comment	"shall not", for "does not", require authorization through prospective review, would not make a substantive difference in the meaning of the sentence.	
9792.27.1(y)	Commenter recommends: "Special Fill" means the policy set forth in section 9792.27.11 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed or dispensed ~~at the single initial treatment visit following a workplace injury, where the visit occurs within 7 days of the date of injury~~. ***in accordance with the criteria set forth in section 9792.27.11(b).***	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Agree.	The modified regulation proposal includes the suggested language, except for a format modification to the statutory citation.
9792.27.2	Commenter recommends revisions: "(b) Except for continuing medical treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after January 1, 2018 ~~July 1, 2017~~ for outpatient use shall be subject to the MTUS Drug Formulary, regardless of	Joe Paduda, President CompPharma May 1, 2017 Written Comment	Agree that the implementation date of the regulations should be January 1, 2018.	Section 9792.27.2 subdivision (b) is modified to delete "July 1, 2017" and replace with "January 1, 2018".

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	the date of injury."			
9792.27.2	Since ongoing non-drug medical treatment is not subject to the Drug Formulary, an exception is only necessary for continuing drug treatment. Recommend revisions: "(b) Except for continuing ~~medical~~ drug treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after July 1, 2017, for outpatient use shall be subject to the MTUS Drug Formulary, regardless of the date of injury. (1) A drug is for "outpatient use" if it is dispensed to be taken, applied, or self-administered by the patient at home or outside of a clinical setting. "Home" includes an institutional setting in which the injured worker resides, such as an assisted living facility." A listing of dispensing individuals and entities is not necessary, and creates a loophole whereby any other individual or entity dispensing drugs prescribed by physicians for outpatient use may claim exemption from the	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Agree subdivision (b) should be revised to improve the clarity of the provision. Agree.	Modify regulation to state the formulary shall apply to continuing *drug* treatment rather than continuing *medical* treatment. Revise subdivision (b)(2) as commenter suggests, to delete the listing of entities.

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	requirements of the Formulary. Recommend the following: "(2) The MTUS Drug Formulary applies to drugs prescribed by a physician and dispensed for outpatient use ~~by any of the following:~~ ~~(A) A physician;~~ ~~(B) A pharmacy;~~ ~~(C) An inpatient hospital;~~ ~~(D) An outpatient department of a hospital;~~ ~~(E) An emergency department of a hospital;~~ ~~(F) An ambulatory surgery center;~~ ~~(G) Any other health care provider or health care entity~~."			
9792.27.2	The effective date of these proposed regulations should be extended to January 1, 2018 due to the delayed publishing of finalized regulations and to allow for a smoother transition.	Lisa Anne Bickford Director, Workers' Comp Government Relations – Coventry May 1, 2017 Written Comment	Agree that the implementation date of the regulations should be January 1, 2018.	Section 9792.27.2 subdivision (b) is modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.2	Recommend that the Division target July 1 as the day for all the rules to be properly and completely established and designate the six months thereafter to building and testing systems. Implement the formulary for	Stephen J. Cattolica Director of Government Relations CSIMS May 1, 2017	Agree in part. Agree that the implementation date of the regulations should be January 1, 2018. Disagree that six months are needed between adoption and effective date.	Section 9792.27.2 subdivision (b) is modified to delete "July 1, 2017" and replace with "January 1, 2018".

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	dates of service on or after January 1, 2018.	Written Comment		
9792.27.2	Commenter suggests DWC does not have any "evidence-based, peer reviewed and nationally recognized" studies from which to draw its conclusions about which drugs are preferred and which are not, thus the "preferred list" must be fundamentally changed or eliminated. The option of eliminating the preferred list for lack of an evidentiary basis leaves the formulary dependent upon the clinical guidelines that are at the foundation of the MTUS in the first place. That is where the Formulary belongs.	Stephen J. Cattolica Director of Government Relations CSIMS May 1, 2017 Written Comment	Disagree with the suggestion to eliminate the "Preferred" drug list. However, the Division believes that the terminology "Preferred" is confusing and misleading. The terminology "Preferred/Non-Preferred" will be changed to "Exempt/Non-Exempt", which better aligns with the intent of the list, i.e. to provide an indication of which drugs can be dispensed without authorization through prospective review. Underlying the entire MTUS Drug List, and the other formulary rules, is the MTUS. The MTUS contains evidence-based treatment guidelines, and rules governing the method for treatment of conditions not covered by the guidelines. The proposed formulary rules require that all	The terminology will be modified from "Preferred/Non-Preferred" to "Exempt/Non-Exempt."

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			drugs, exempt, non-exempt, and unlisted be used in accordance with the MTUS. The formulary overlays rules to ease prospective review requirements for drugs in light of evidence-based recommendation in the ACOEM treatment guidelines. The following weighed in favor of designating a drug as "exempt": 1) Being noted as a first line therapy in the ACOEM guidelines; 2) Having a "Yes" recommendation for most acute or acute/chronic conditions addressed in the ACOEM guidelines; 3) Having a safer adverse effects (risk) profile; 4) Drugs listed for the treatment of more common work-related injuries and illnesses. The Labor Code § 4610, subdivision (a), states: "(a) For purposes of this section, "utilization review"	

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			means utilization review or utilization management functions that prospectively, retrospectively, or concurrently review and approve, modify, or deny, based in whole or in part on medical necessity to cure and relieve, treatment recommendations by physicians, as defined in Section 3209.3, prior to, retrospectively, or concurrent with the provision of medical treatment services pursuant to Section 4600." The MTUS formulary rules, including the drug list, provide the framework for allowing some drug treatment to be provided without the prospective review of medical necessity; the treatment must still be in accordance with the evidence-based adopted guidelines, or other evidence based recommendation for conditions not in the guidelines or rebutting the guidelines.	
9792.27.2	Commenter recommends delaying the implementation date of the regulations	Mark Pew PRIUM	Agree that the regulations should be implemented	Section 9792.27.2 subdivision (b) is

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	to January 1, 2018.	May 1, 2017 Oral Comment	January 1, 2018.	modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.2(b)	It is vitally important that a drug formulary is based on strong foundational treatment guidelines. Commenter is supportive of the language in the rule requiring the prescribing of preferred and other medications in accordance with the treatment guidelines. Commenter supports responsible variations based on the unique medical needs of a particular injured worker, enabling both the treating physician and the employer/claims administrator to facilitate the safest and most effective care. Commenter recommends that the Division work with the legislature to extend the effective date time frame an additional 60-90 days to allow for adequate education of stakeholders and to accommodate those stakeholders who may need additional programming and testing time.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	Agree that drug formulary should be based on treatment guidelines. The formulary is based on the ACOEM treatment guidelines. The MTUS Drug List will be updated in light of changes to the ACOEM guidelines since the MTUS Drug List was first proposed. Agree that the July 1, 2017 statutory target date is not feasible. The implementation date will be modified to January 1, 2018.	The MTUS Drug List in section 9792.27.15 will be updated in light of the new and revised ACOEM recommendations. Section 9792.27.2 subdivision (b) is modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.2(b)	Commenter recommends revision:	Kim Ehrlich Workers'	Agree. See the response above to Lisa Anne Bickford's	Section 9792.27.2 subdivision (b) is

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	"(b) Except for continuing medical treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after ~~July 1, 2017~~ January 1, 2018 for outpatient use shall be subject to the MTUS Drug Formulary, regardless of the date of injury."	Compensation Compliance Express Scripts May 1, 2017 Written Comment	comment dated May 1, 2017 regarding this section.	modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.2(b)(1)	In order to distinguish between "outpatient treatment" and "outpatient use," it would be helpful to define "clinical setting" for purposes of this section. Commenter recommends the following definition: **"Clinical setting" means a** **(a) physician's office;** **(b) hospital;** **(c) outpatient department of a hospital;** **(d) urgent care clinic;** **(e) emergency department of a hospital;** **(f) ambulatory surgery center;** **(g) inpatient rehabilitation centers;** **(h) any other facility, including a skilled nursing facility, that provides medical treatment**	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. The section states that "outpatient use" is if the drug "is dispensed to be taken, applied, or self-administered by the patient at home or outside of a clinical setting, including "take home" drugs dispensed at the time of discharge from a facility." The meaning is sufficiently clear in context.	No action necessary.

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	to the injured worker onsite at the facility.			
9792.27.3	The proposed regulations are vague and they require a physician to submit a proposed treatment plan through the normal procedures and prohibit a claims administrator from simply terminating or denying previously approved prescriptions, but provide little clarity around timelines. There should be a timetable by which insurers need to evaluate and approve treatment plans; without one it is possible that the formulary will go into effect before a treatment plan is approved for a patient, leaving practitioners and pharmacies uncertain about what to do. Commenter recommends a staggered implementation, which has worked successfully in other states, that depicts clear timelines for payers, physicians, and patients that either must be met or require the development of alternative plans. This would allow physicians the opportunity to collaborate with their patients in establishing a treatment plan and would reduce administrative work for all parties.	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	Agree in part. Agree that it would be beneficial to provide more detail regarding the transition for injured workers receiving ongoing drug treatment when the formulary is implemented. It is desirable to utilize the existing mechanisms in place for physician reporting, development and communication of treatment plans, and procedure for utilization review of the medical necessity of treatment. However, the regulation can be improved by providing more direction on the applicability of these provisions, and by providing an extension to the usual deadline for physician reporting/submission of the treatment plan.	Modify proposed regulation to add specificity for actions the physician must take for a patient with a date of injury prior to 1/1/2018 who is receiving a course of treatment with a Non-Exempt drug, unlisted drug, or compounded drug. Physician to submit treatment plan, Request for Authorization and progress report pursuant to 9785 to address the ongoing treatment and either: set a safe plan to wean, taper, or transition to a drug pursuant to formulary or substantiate medical necessity of the Non-Exempt

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				drug, unlisted drug, or compounded drug pursuant to MTUS. Report to be submitted at next due date, or, if not feasible, no later than April 1, 2018. Claims administrator to process the report and RFA within usual mandated timeline.
9792.27.3	We are concerned about "legacy" prescriptions, or prescriptions already filled or authorized as of July 1, 2017, but which may not be "Preferred" medications. Efforts to initiate changes in these situations should originate with the payer, not with the treating physician. It should be up to the payer to initiate an outreach to both the provider and the patient in writing, and first to take an educational approach. Commenter recommends that the MTUS Drug Formulary "**shall** be phased in to ensure that injured	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017 Don Schinske WOEMA May 1, 2017 Oral Comment	Disagree with the suggestion that "Efforts to initiate changes in these situations [chronic medications, including chronic pain regimens] should originate with the payer, not with the treating physician." The physician has an ongoing duty to report on the treatment regimen of patients during continuing treatment; section 9785 requires a progress report no less frequently than every 45 days during ongoing treatment. The physician should be aware of the provisions of the MTUS,	See action described above in relation to the response to the comment of Danielle Jaffee, Esq., IWP, dated April 4, 2017.

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	workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment." We recommend that the DWC establish administrative or other informal procedures in order to transition patients to "Preferred" medications in situations where such a transition is appropriate, rather than turning immediately to processes requiring more RFAs and UR. The length of the transition period will be variable. For some patients on complex chronic pain regimens, a two-year transition period may sometimes be needed. In cases where a change in regimen is judged desirable, initiation of such transition should begin promptly and perhaps even before July 1, 2017. For many cases where the provider and patient have agreed to such a transition process, evidence of dose reduction or other optimization may need to be developed if requested in a peer-to-peer conversation, and such evidence may require 90 days or more to collect.		including the treatment guidelines, and endeavor to provide the best evidence-based care to the patient. The Opioid Guideline and Chronic Pain Guideline provide the recommendations for handling patients on long term opioid therapy or suffering from chronic pain. The Division is aware that chronic pain patients may be difficult to manage and that some patients may need an extended period of tapering, and some will need to continue without tapering. The Division agrees with commenter's statement that the "transition period will be variable. For some patients on complex chronic pain regimens, a two-year transition period may sometimes be needed." There is no mandatory time for completing the transition. The physician needs to document and support the basis for the plan, there is no mandatory requirement to wean the patient, or for the	

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			patient to complete a transition by a set time. Disagree with the suggestion to modify to "shall be phased in…." The Division is modifying the language by adding a subdivision (b) to set forth more detail on transition procedures. In context of the mandatory actions set forth in the new subdivision (b), changing "should" to "shall" is not necessary.	No action necessary.
9792.27.3	Commenter notes that particularly problematic are non-preferred drugs that are both recommended and not recommended for the same body part. Due to the need for complex system reprogramming for Pharmacy Benefit Managers, carrier and pharmacies, commenter recommends a longer period of time for implementation, therefore a delay to the proposed July 1, 2017 effective date.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Agree. See the response above to Lisa Anne Bickford's comment dated May 1, 2017 regarding section 9792.27.2.	Section 9792.27.3 subdivisions (a) and (b) will be modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.3	The language in 9792.27.3 (b) stating, "*The claims administrator shall not unilaterally terminate or deny*	Brian Allen, Vice President, Governmental Affairs	Agree in part. Agree that the term "unilaterally" should be removed. The term may be	Modify subdivision (b)(1) to delete the sentence that states:

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	previously approved drug treatment," creates a potential barrier to making a transition since the rule expressly prohibits unilateral action. Commenter believes the Division intends for every reasonable, cooperative effort to be made by the claims administrators and the treating physicians to transition injured workers to preferred medications wherever possible. Recommend the following revised language, or something similar, be amended into the rule in paragraph 9792.27.3 (b): "*If the injured worker is receiving a course of treatment including a Non-Preferred Drug, an unlisted drug or a compounded drug, the* ***treating physician shall submit a transitional*** ~~*existing procedures for submitting the*~~ *treatment plan in accordance with MTUS formulary rule*~~*., and*~~ ***The existing procedures for submitting*** *the* ***treatment plan and*** *for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.*	Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment May 1, 2017 Oral Comment	confusing in this context. Agree that the language regarding the transition should be modified, and agree with the concept that the physician shall create a treatment plan, and that existing procedures for submitting the plan and reviewing the plan shall be utilized. However, the Division will propose modified language that is more specific and that emphasizes that the plan should be in accordance with the MTUS.	"The claims administrator shall not unilaterally terminate or deny previously approved drug treatment." Modify (b)(1) and add new subdivisions (b)(2) through (b)(5).

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9792.27.3	The proposed rules do not go into detail regarding the length of time for changes to be "phased in" or even the process by which they should be "phased in". The transition period language should be amended to clarify or include definitions for ambiguous terms (ex.: "phased-in," "unilaterally," "previously approved") and to provide guidance to stakeholders on the process and timing for transitioning existing claims, as well as the penalties associated for failing to adhere to the process. The statement by Rand indicates that a transition period is less important because "UR typically occurs for all prescriptions on a prospective basis." Commenter states that for his organization, a URO in the state of California, it has not been their experience. Commenter states that that beginning July 1, 2017, more payers are going to be subjecting medications to utilization review, thereby increasing	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment May 1, 2017 Oral Comment	Agree that there should be more specificity regarding the transition process and timing. The Division will propose modified language that is more specific and that emphasizes that the plan should be in accordance with the MTUS. The modified proposal will state that the physician shall create a treatment plan, describe what should be addressed in the plan, and shall specify existing procedures which are to be used for submitting the plan, and for reviewing the plan for medical necessity. During ongoing medical treatment, current regulations require the physician to submit a report no less frequently than every 45 days (section 9785), which includes any updates to the treatment plan or support for the continued treatment plan. The modified proposal will continue the use of this process, but will allow an extended timeframe of April 1,	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition.

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	"the administrative burden and the associated administrative costs," which is antithetical to the legislature's goal.		2018 to submitted the report. The Division is aware of the RAND report's statement that utilization review typically occurs on a prospective basis for all prescriptions, and that some members of the public disagree with that statement. The Division appreciates the concern expressed by commenter that formulary rules will increase "the administrative burden and the associated administrative costs." The legislature's expressed intent is that the formulary include: "Guidance on the use of the formulary to further the goal of providing appropriate medications expeditiously while minimizing administrative burden and associated administrative costs." (AB 1124, Statutes 2015, Chapter 525.) The legislative intent makes it clear that an important part of the formulary is to support appropriate care.	The regulations will be modified to highlight the provision recognizing "prior authorization" program in a utilization review plan by moving it from 9792.27.10, subdivision (f), to its own section, §9792.27.11 Waiver of Prospective Review.

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			In the workers' compensation system, medical necessity is determined by utilization review. Pharmaceutical treatment is subject to utilization review pursuant to Labor Code §4610. As revised by SB 1160 (Statutes 2016, Chapter 868), effective 1/1/2018, Labor Code §4610 (c) (1) provides that prospective utilization review is required, unless authorized by the employer or rendered as emergency treatment, for "pharmaceuticals to the extent they are neither expressly exempted from prospective review nor authorized by the drug formulary…" The Division has crafted the formulary to support evidence-based high quality care by designating specified drugs as exempt (originally proposed terminology "preferred") in light of these criteria which weighed in favor of exempt status: 1) Being noted as a first line	

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			therapy in the ACOEM guidelines; 2) Having a "Yes" recommendation for most acute or acute/chronic conditions addressed in the ACOEM guidelines; 3) Having a safer adverse effects (risk) profile; 4) Drugs listed for the treatment of more common work-related injuries and illnesses. Non-Exempt (originally Non-Preferred) drugs are appropriately subject to prospective review. Pursuant to Labor Code §4610(c), medical treatment "authorized by the employer" does not require prospective utilization review. The proposed formulary rules acknowledge that the prospective utilization review may be waived by the employer where an employer's utilization review plan contains a "provision of prior authorization without necessity	

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			of a request for authorization, where that provision is adopted pursuant to section 9792.7(a)(5)." The regulations will be modified to highlight this provision by moving it from 9792.27.10 subdivision (f) to its own section 9792.27.11 Waiver of Prospective Review. The "prior authorization" programs within a utilization review plan can decrease the number of medical treatments that go through prospective UR.	
9792.27.3	Commenter suggests the new language prohibits a claims administrator from unilaterally terminating or denying a treatment plan that was previously approved provides protection from termination of existing treatment approved prior to July 1, 2017, but is concerned that transition treatment plans developed on or after July 1, 2017 do not appear to be afforded the same protection. Commenter requests that the DWC provide corresponding assurance that transition treatment plans developed	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association (CMA) May 1, 2017 Written Comment	Disagree that the originally proposed language prohibiting a claims administrator from "unilaterally" terminating or denying "previously approved drug treatment" should be retained. The provision using the term "unilaterally" should be removed. The term may be confusing in this context. The Division will propose modified language that is more specific and that emphasizes	Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment." Add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition.

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	on or after July 1, 2017 will be approved so that all injured workers may safely be transitioned from prescription drugs approved pursuant to the current formulary onto medications consistent with the new formulary.		that the plan should be in accordance with the MTUS and existing procedures. The modified proposal will state that the physician shall create a treatment plan, describe what should be addressed in the plan, specify existing procedures which are to be used for submitting the plan, and for reviewing the plan for medical necessity. During ongoing medical treatment, current regulations require the physician to submit a report no less frequently than every 45 days (section 9785), which includes any updates to the treatment plan or support for the continued treatment plan. The UR statute and regulations set timeframes and procedures for responding to treatment plan authorization requests. The Labor Code addresses the rescission or modification of authorization as follows: "Regardless of whether an employer has established a medical provider network	

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			pursuant to Section 4616 or entered into a contract with a health care organization pursuant to Section 4600.5, an employer that authorizes medical treatment shall not rescind or modify that authorization after the medical treatment has been provided based on that authorization for any reason, including, but not limited to, the employer's subsequent determination that the physician who treated the employee was not eligible to treat that injured employee. If the authorized medical treatment consists of a series of treatments or services, the employer may rescind or modify the authorization only for the treatments or services that have not already been provided." Labor Code §4610.3, subdivision (a).	
9792.27.3	Commenter recommends revisions: "(a) Except as provided in subdivision (b), the MTUS Drug Formulary	Joe Paduda, President CompPharma May 1, 2017 Written Comment	Disagree with the suggested language. In particular, it is not clear what is meant by "at a minimum" in the suggested	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	applies to drugs dispensed on or after July 1, 2017 except for those claims with a date of injury prior to July 1, 2017 as outlined in subsection (b), regardless of the date of injury. (b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary shall be implemented on a schedule intended to ensure injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. No later than January 1, 2018, a treating physician shall request a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which shall at a minimum include use of a Non-Preferred drug or unlisted drug for an extended period where that is necessary for the injured worker or necessary for safe weaning, tapering or transition to a Preferred drug. If the above required documentation is submitted in a timely manner by the treating physician and is consistent with MTUS, the claims administrator shall not unilaterally terminate or deny previously approved drug treatments which are included in the request		language: "a treating physician shall request a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which shall at a minimum include use of a Non-Preferred drug or unlisted drug for an extended period where that is necessary". The Division appreciates and shares commenter's concern for patients on long-term pain medication regimes. It is not the formulary itself, but the treatment guidelines, including the Opioid Guideline and the Chronic Pain Guideline which govern the selection of appropriate medication and the process of weaning, tapering, or transitioning the patient to a safer medication. Currently, prior to adoption of the formulary, physicians should be creating treatment plans in light of evidence-based standards of care in accordance with the MTUS. In workers'	detailed directions for the transition.

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	submitted by the physician" Commenter is concerned about the lack of direction regarding the handling of a "transition" period for claims with a date of injury prior to the implementation date. Providing a transition timeline will inform prescribers of the need to start the tapering/transition process.		compensation in California, the MTUS treatment guidelines are presumed correct on the scope of appropriate treatment. Labor Code §4604.5. The treatment guidelines will continue to govern once the formulary is adopted. The proposed regulations will be modified to supply additional detail on the procedures relevant to submitting the physician report and treatment plan, request for authorization, and for reviewing the plan for medical necessity.	
9792.27.3	Commenter recommends revisions: "(a) Except as provided in subdivision (b), the MTUS Drug Formulary applies to drugs dispensed on or after ~~July 1, 2017~~ January 1, 2018, regardless of the date of injury. (b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving	Kim Ehrlich Workers' Compensation Compliance Express Scripts May 1, 2017 Written Comment Oral Comment	Agree in part. Agree that the formulary should be applicable to drugs dispensed on or after January 1, 2018. Disagree with the suggested change for subdivision (b) which would apply the transition requirements to injuries prior to July 1, 2017, but make the formulary applicable (by subd. (a)) to	Section 9792.27.3 subdivisions (a) and (b) will be modified to delete "July 1, 2017" and replace with "January 1, 2018". Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	ongoing drug treatment are not harmed by an abrupt change to the course of treatment. No later than January 1, 2018, the physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS…" Regarding those injured workers receiving ongoing drug treatment which would be subject to prospective review, commenter recommends inserting "no later than 1/1/2018" to ensure all system participants are working towards a clearly stated goal and that conversations about current treatment plans and any needed changes in treatment be clearly communicated eliminating any disruption for the injured worker.		drugs dispensed on or after January 1, 2018. This would cause a gap in the applicability of the transition provisions. Under the suggested language, injuries occurring during the period 7/1/17 to 12/31/17, would not be subject to the transition provisions, even though the worker may be on ongoing treatment on 1/1/18. AB 1124 specified that the formulary should be phased in for dates of injury prior to July 1, 2017, but also specified that the formulary was to be effective on or before July 1, 2017. Due to the complexity of the issues and process necessary to develop the regulations and conduct the rulemaking action, it is clear that a July 1, 2017 effective date is not feasible. It will carry out the apparent legislative intent to move the date to which the transition applies to coincide with the effective date of the formulary. (dates of injuries prior to	the transition.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			1/1/2018 involving ongoing treatment.) Disagree with the suggestion to have the treatment plan no later than 1/1/2018. It is beneficial to provide that the progress report and treatment plan is to be submitted on the next regular due date, but allow extra time until April 1, 2018 if needed by the physician. Also, see response above to comment of Ben Roberts, PRIUM, dated April 29, 2017.	
9792.27.3	Commenter is concerned there is no timeframe for a worker to be allowed to transition from a non- formulary drug to a formulary drug. The language "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment" provides little to no protections to the worker because the claims administrator can send the request for a renewal of a previously authorized prescription drug to utilization review where it may be	Diane Worley California Applicant's Attorneys Association (CAAA) May 1, 2017 Written Comment Oral Comment	Disagree with the suggestion that "a two year timeline be added to § 9792.27.3 for "legacy" workers to be covered by the formulary." There cannot be a set time period for an injured worker to transition. This should be determined in light of the individual patient circumstances and in light of the evidence-based treatment guidelines in the MTUS. Disagree with the statement	No action necessary.

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	promptly denied if a non-formulary drug. Since the statute mandates a phased implementation for workers injured prior to July 1, 2017, it is recommended that a two year timeline be added to § 9792.27.3 for "legacy" workers to be covered by the formulary. Commenter recommends that until such time as ACOEM updates their Opioid Guidelines, that the administrative director adopts regulations for weaning which are evidence-based which may include the weaning protocols followed by ODG and implemented last year.		that "the claims administrator can send the request for a renewal of a previously authorized prescription drug to utilization review where it may be promptly denied if a non-formulary drug." The MTUS treatment guidelines govern the issue of whether there is medical necessity for the drug, and for the treatment plan to wean or taper a drug. The status of the drug on the formulary as Non-Exempt/Exempt (originally Non-Preferred/Preferred) is not determinative of the medical necessity. The ACOEM guidelines are evidence-based. The commenter has not presented any evidence to back up the assertion that "as ACOEM does not appear to have a multidisciplinary approach to weaning that is evidence-based similar to that provided for in the ODG guidelines which were incorporated into the Chronic Pain and Opioid Guidelines	

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			approved last year."	
9792.27.3	Commenter agrees with other commenters that a January 1, 2018 implementation date would be appropriate. Commenter also recommends that the Division implement an education program regarding provisions of the MTUS so that stakeholders who are struggling to cite the MTUS correctly enough to get treatment approved can get some help.	Mitch Seaman Legislative Advocate California Labor Federation Oral Comment May 1, 2017	Agree with January 1, 2018 implementation date. Agree that stakeholder education is valuable. The Division is planning to hold training sessions on the MTUS and the formulary.	Section 9792.27.3 subdivisions (a) and (b) will be modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.3	Commenter notes that this section now includes language preventing claims administrators from "unilaterally" terminating or denying previously approved treatment. This addition strengthens and improves the tapering provisions; however, he finds the word "unilaterally" confusing in this context. Commenter recommends a different phrasing that specifically prohibits terminating or denying previously approved treatment for reasons other than a significant change in the worker's condition—and only following proper UR and IMR—which would clarify this section's intent.	Mitch Seaman Legislative Advocate California Labor Federation Written Comment May 1, 2017	Agree in part. Agree that the word "unilaterally" is confusing and should be deleted. See the response above to comment of Stacey Wittorff, California Medical Association (CMA) dated May 1, 2017, which discusses the removal of "unilateral" and the replacement provisions. Disagree with the suggestion that the regulation should contain a provision that "specifically prohibits terminating or denying previously approved treatment for reasons other than a significant change in the	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter also approves of replacing the phrase "…preponderance of scientific medical evidence" with "…in accordance with MTUS regulations" in the new draft, a change that will ease compliance and reduce confusion for physicians treating those who require unlisted drugs.		worker's condition…" The MTUS treatment guidelines and evidence-based recommendations govern appropriate care; recommended treatment may change based on new evidence, new FDA – approved labeling, such as new black box warnings, etc. Therefore, evidence-based treatment recommendations may change even if the worker's condition does not undergo a significant change. That does not mean that the treatment should be abruptly curtailed or changed if it is not safe to do so, the treatment guidelines address the need for careful tapering of medications such as opioids, benzodiazepines, and anticonvulsants. Agree that terminating or denying previously approved treatment can only be done in accordance with the proper UR and IMR procedures, and this will be included in the modified proposal.	

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.27.3	Commenter recommends the following revised language: (a) Except as provided in subdivision (b), the MTUS Drug Formulary applies to drugs dispensed on or after ~~July 1, 2017~~January 1, 2018, regardless of the date of injury. (b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary ~~should~~ shall be phased in by April 1, 2018, ~~to ensure that~~ for injured workers who are receiving ongoing drug treatment to ensure that they are not harmed by an abrupt change to the course of that drug treatment. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include use of a Non-Preferred drug or unlisted drug ~~for an extended period~~ where that is necessary ~~for the injured worker's condition or necessary~~ for safe weaning, tapering, or transition to a Preferred drug. ~~The claims administrator shall not unilaterally~~	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Agree in part. Agree that the term "for an extended period" should be deleted. It is vague and not necessary to carry out the purpose of the provision. Disagree with the suggestion to eliminate the phrase "for the injured worker's condition or necessary" for safe weaning… as it helps emphasize the appropriateness of the medication for the patient's condition. Disagree with the suggestion to require the treatment plan by February 1, 2018. Modified proposal maintains the current reporting timetable (no less than every 45 days), but allows the transition treatment plan/report to be submitted by April 1, 2018 if it is not feasible to submit the plan by the next progress report due date. Disagree with the suggested language for a new subdivision (d). There are already regulatory provisions to	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition. Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment."

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	~~terminate or deny previously approved drug treatment.~~ (c) If, on January 1, 2018, the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug, or a compounded drug, the physician shall, by February 1, 2018, submit to the claims administrator a revised treatment plan for the safe weaning, tapering, or transition to a Preferred drug, and existing procedures for submitting the treatment plan and for obtaining authorization for the treatment in accordance with utilization review regulations in accordance with MTUS regulations shall apply. (d) If a physician fails to submit the report required under section 9792.27.3(c), such failure may constitute a showing of good cause for a claims administrator's petition requesting a change of physician pursuant to Section 4603; and may serve as grounds for termination of the physician from the medical provider network or health care organization;		address a physician's failure to report and submit a treatment plan, Title 8, CCR §9786 provides a remedy for failure to comply with physician reporting obligations for physicians that are not within a Medical Provider Network (MPN). The claims administrator can file a request for change of physician. For physicians within an MPN, the MPN plan contains provisions that allow review of the performance of the physician. Title 8, CCR §9767.3, subdivision (d)(8)(S) states that the MPN plan must: "Describe the MPN's procedures, criteria and how data is used to continuously review quality of care and performance of medical personnel, utilization of services and facilities, and costs."	

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	and reports from the physician shall not be admissible and the physician's treatment bills shall not be reimbursable until the report required by 9792.27.3 is received by the claims administrator.			
9792.27.3	Commenter recommends the following revised language in subdivision (b): "(b) For injuries occurring prior to July 1, 2017, the ~~*MTUS*~~ Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. The physician *shall be* responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include use of a Non-Preferred drug or unlisted drug for an extended period where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a Preferred drug. ~~The claims administrator shall not unilaterally terminate or deny~~	Jeremy Merz American Insurance Association Jason Schmelzer California Coalition on Workers' Compensation May 1, 2017 Written Comment	Disagree with the suggestion to delete the word "MTUS" in subdivision (b); the term "MTUS Drug Formulary" is consistent with the terminology in subdivision (a). It also emphasizes the concept that the formulary is part of the MTUS, which is important for encouraging appropriate care. Disagree with the suggestion to revise to state that "The physician *shall be* responsible for requesting a medically appropriate and safe course of treatment" rather than the proposed "The physician **is** responsible for requesting a medically appropriate and safe course of treatment." [Emphasis added.] The suggested revision would not	No action necessary. No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	~~previously approved drug treatment.~~ If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply." The drug formulary is part of the MTUS. It is important to emphasize that most of the substantive provisions of proposed section 9792.27.3 are more appropriately codified in various other parts of the MTUS, including but not limited to chronic pain guidelines. Labor Code § 5307.27(c) states, "(t)he drug formulary shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary". To meet this statutory mandate, reference should simply be made in the formulary to MTUS provisions now existing or as may be added regarding		create a meaningful improvement in the expression of the mandatory professional obligation indicated by the sentence. Disagree with the statement that "most of the substantive provisions of proposed section 9792.27.3 are more appropriately codified in various other parts of the MTUS, including but not limited to chronic pain guidelines." The proposed section 9792.27.3 does not contain the evidence-based recommendations that are in the treatment guidelines, but rather facilitates application of those treatment guidelines by outlining procedural steps relating to preparing, communicating and obtaining	No action necessary.

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	the proper methods by which to adjust long-term medications used by injured workers prescribed and dispensed prior to July 1, 2017. Concomitant with those anticipated amendments should be guidance for use of medications from the onset of illness or injury (dates of injury on and after July 1, 2017) consistent with the MTUS and its incorporated formulary. In both cases, this includes but is not limited to the use of opioids and medications associated with opioid use for the treatment of chronic pain.		approval of the treatment plan.	
	Commenter notes that he has previously commented on the difficulties associated with the language, "(t)he claims administrator shall not unilaterally terminate or deny previously approved drug treatment."		Agree with the suggestion to delete the sentence regarding "unilaterally terminate or deny". The term may be confusing in this context.	Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment."
	In order to bring about the best results for injured workers and to realize the highest potential of the MTUS, there needs to be a process by which a claims administrator may require a review of existing drug regimens regardless of whether these have been approved in the past. Labor Code §		It is unclear what the commenter means by the suggestion that the "phased implementation" should be able to be initiated by the claims administrator. It is the responsibility of the physician to create a transition plan or	Add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	5307.27(c) clearly sets forth how this can be accomplished: "(t)he drug formulary shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary." That "phased implementation" should be initiated by the physician, but it should be able to be initiated by the claims administrator as well. Commenter recommends that such language be incorporated into the next iteration of the substantive provisions in the MTUS and not the formulary.		support continued use of the current drug regimen. There are already mechanisms in place to address a physician's failure in regard to reporting, RFAs and treatment plans. See the response above to the comment of CWCI dated May 1, 2017.	
9792.27.3	Commenter recommends adopting rules that become effective January 1, 2018 to allow for PBMs, networks and all other stakeholders time to transition.	Don Lipsy First Script Network Services May 1, 2017 Oral Comment	Agree that the implementation date should be modified to January 1, 2018.	Section 9792.27.3 subdivisions (a) and (b) will be modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.3(b)	Commenter states that this subsection should be substantively revised; in its current form, it is immune to sensible interpretation and cannot be operationalized.	Robert Ward Clinical Director CID Management Written Comment April 28, 2017	Disagree with the statement that the section is "immune to sensible interpretation." However, agree that it could be improved to provide more	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for

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	Under this subsection, the provider is to transition the patient from previously approved medications that are not Preferred; but no time frame for this process or this exemption from standard application of the MTUS is given. A provider could simply elect to ignore the need to transition, and to provide medication exempt from necessity determinations for the remainder of the injured worker's life. The claims administrator is prohibited from a "unilateral" denial of such medication, possibly exempting such medication from denial for the injured worker's life span. There is no indication as to what party or parties, or process, would constitute an acceptable collective decision for permissible denial. The final sentence of this subsection effectively contradicts the all of the language in 9792.27.3(b) that precedes it, by making all of the medication use discussed in 9792.27.3 subject to standard UR procedures.		specificity. Agree that the term "unilateral" is confusing and should be deleted. It is the date of injury AND ongoing drug treatment with a non-exempt drug that warrants a "phase in" and transition period. The modified proposal subdivision (a) will specify that the formulary applies to all drugs dispensed on or after 1/1/2018 regardless of date of injury, but subdivision (b) will be structured to apply the transition to dates of injury prior to 1/1/2018 where there is "course of treatment that includes a Non-Exempt drug, an unlisted drug, or a compounded drug." The standard UR procedures and physician reporting are needed to protect injured workers. Commenter's concern evidenced in the statement that: "Using the date of injury permits providers to begin treatment with Non-preferred	the transition. Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment."

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	Commenter recommends the following two changes: 1) "For injuries occurring prior to July 1, 2017" should be amended to "For drugs in use prior to July 1, 2017". It is not the date of injury that requires a transition to the formulary, but the ongoing treatment when the formulary goes into effect. Using the date of injury permits providers to begin treatment with Non-preferred or unlisted drugs after 7/1/2017, and to apply the exemptions in this subsection. 2) The DWC should determine, in conjunction with its medical experts, a reasonable upper limit for the time period during which such transition should have been completed; and to set that as an expiration date for any exemption in this subsection.		or unlisted drugs after 7/1/2017, and to apply the exemptions in this subsection" will not be relevant in light of the modification which requires both pre-1/1/2018 date of injury AND ongoing course of treatment with a non-exempt drug. Disagree that the regulations should set "a reasonable upper limit for the time period during which such transition should have been completed" as that would not comport with the MTUS which requires individualized treatment plan based on the injured worker's condition in light of the guidelines. The time period for transition cannot be standardized due to individual clinical considerations.	
9792.27.3(b)	Commenter recommends revisions: "For injuries occurring prior to July 1, 2017~~, the MTUS Drug Formulary should be phased in to ensure that~~	Ben Roberts Executive Vice President and General Counsel PRIUM	Agree in part. Agree that the language of subdivision (b) should be modified. However, disagree with commenter's suggested language. It is	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for

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	~~injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. he~~ the physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include use of a Non-Preferred drug or unlisted drug for an extended period where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a Preferred drug. **The request must be accompanied by a plan to wean, substitute, or discontinue the requested medication, as applicable, over a period of time in order to bring the treatment of the injured worker into compliance with the MTUS. If the provider feels that the treatment cannot be brought into compliance with the MTUS, the request shall be accompanied by an explanation and documentation demonstrating why a variance from the MTUS is appropriate for the particular patient.** The claims administrator shall not **withdraw authorization for**	April 29, 2017 Written Comment	important to link formulary physician reporting, treatment plan and RFA submission, and UR with the procedures that are already in place for all workers' compensation medical treatment. Currently, prior to adoption of the formulary, physicians should be creating treatment plans in light of evidence-based standards of care in accordance with the MTUS. The treatment guidelines will continue to govern once the formulary is adopted. The proposed regulations will be modified to supply additional detail to guide the public to the existing relevant procedures for submitting the physician report and treatment plan, request for authorization, and for reviewing the plan for medical necessity. Disagree with adding the suggested language: "The claims administrator shall not **withdraw authorization for an authorized fill of a**	the transition. Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment."

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	an authorized fill of a medication. The claims administrator shall not deny reimbursement for any drug treatment without utilization review, except where these rules explicitly permit payers to deny reimbursement for failure to obtain authorization ~~unilaterally terminate or deny previously approved drug treatment~~. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, ~~the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.~~ **the provider shall request authorization for future treatment, as required by this section, in order to ensure that the injured worker does not suffer an undue delay of treatment."**		**medication. The claims administrator shall not deny reimbursement for any drug treatment without utilization review, except where these rules explicitly permit payers to deny reimbursement for failure to obtain authorization."** The Labor Code addresses the rescission or modification of authorization as follows: "[A]n employer that authorizes medical treatment shall not rescind or modify that authorization after the medical treatment has been provided based on that authorization for any reason, including, but not limited to, the employer's subsequent determination that the physician who treated the employee was not eligible to treat that injured employee. If the authorized medical treatment consists of a series of treatments or services, the employer may rescind or modify the authorization only for the treatments or services	

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			that have not already been provided." Labor Code §4610.3, subdivision (a).	
9792.27.3(b)	Commenter recommends revisions: "For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in **by (<u>insert timeframe</u>)** to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include use of a Non-Preferred drug or unlisted drug for an extended period where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a Preferred drug. ~~The claims administer shall not unilaterally terminate or deny previously approved drug treatment.~~ If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug,	Karin Sims, Assistant Claims Operations Manager State Compensation Insurance Fund April 1, 2017 Written Comment	Agree that the section needs to be modified, but disagree with the suggested language. The section will be modified to remove "unilateral" language and to provide more detail regarding use of existing procedures, and to allow a report, treatment plan and RFA to be submitted by April 1, 2018 if the physician is not able to submit these by the next progress report due date.	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition. Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment."

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	the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply."			
9792.27.3(b)	Commenter recommends deleting the following sentence from this subsection: "The claims administrator shall not unilaterally deny a medication."	Saul Allweiss Schools Insurance Authority May 1, 2017 Oral Comment	Agree that the sentence should be deleted. The word "unilaterally" is confusing and misleading.	Modify subdivision (b)(1) to delete the sentence that states: "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment."
9792.27.3(b)	Commenter recommends revisions: "(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. ***Accordingly, all injured worker claims with a Date of Injury prior to July 1, 2017 shall be exempt from the MTUS Drug Formulary until December 1, 2017,***	Lisa Anne Bickford Director, Workers' Comp Government Relations – Coventry May 1, 2017 Written Comment	Disagree with commenter's suggestion that "***all injured worker claims with a Date of Injury prior to July 1, 2017 shall be exempt from the MTUS Drug Formulary until December 1, 2017***...." An across the board exemption for six months is not necessary as only injured workers that are on a course of treatment with a non-exempt drug will need a "phase in" or	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5) to provide more detailed directions for the transition.

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	at which point all injured workers are incorporated by the MTUS Drug Formulary and treatment rendered by prescribers is expected to be fully in compliance with the MTUS Drug Formulary, except where a treatment plan has been documented and authorized to the contrary. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an "unlisted drug")…" The drug formulary transition for workers' injured prior to July 1, 2017 should specify a six month transition timeline. The lack of specificity unintentionally creates a "two-tiered" system of treatment with no specified date of conformity.		"transition" period to make sure there is not an abrupt course of treatment regimen. The Division does recognize that the section needs to be modified in order to improve clarity by guiding the public to the existing relevant procedures for submitting the physician report and treatment plan, request for authorization, and for reviewing the plan for medical necessity. It is also necessary to modify the section to allow a report, treatment plan and RFA to be submitted by April 1, 2018 if the physician is not able to submit these by the next progress report due date. Also, see response above to comment of Robert Ward, CID Management, dated April 28, 2017 for explanation of why it is not appropriate to have a set timeframe for the length of the transition.	
9792.27.3(b)	Commenter is concerned this section does not prescribe a transition plan as the framers of AB 1124 contemplated	Stephen J. Cattolica Director of Government	Agree that the section needs to be modified. The originally proposed language is too open	Modify (b)(1) and add new subdivisions (b)(2) through (b)(5)

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	it. Commenter recommends that treating physicians be required to provide the requested plan as stated, but over a period of time that does not leave the process in limbo. It is recommended that the treating physician be required to request the transition plan for only a proportion of the qualified patient population over a span of time. Commenter recommends that the transition plan be in place within three months of implementation of the formulary and be completed within two years thereafter. Commenter supports that while this is occurring that the employer (claims administrator) "shall not unilaterally terminate or deny previously approved drug therapy." In order to assure that the process goes along as agreed and the employer not be left without some recourse, it is recommended that the claims administrator can submit the transition plan if the provider fails to do so. The claims administrator's plan must be composed of a medically appropriate	Relations CSIMS May 1, 2017 Written Comment	ended as to the timeframe for the physician to request a medically appropriate and safe treatment plan. Disagree with the suggestion that the physician request a transition treatment plan for only a portion of his/her patient population over a span of time. All injured workers are entitled to have the physician review the evidence-based treatment recommendations and create a transition plan without delay. Physicians are already under an obligation to provide the best evidence-based treatment, and to report no less frequently than every 45 days. (8 CCR §9785.) The injured worker should not be deprived of optimal care based on the size of the physician's patient load. It is unclear what is meant be the suggest "that the transition plan be in place within three months of implementation of	to provide more detailed directions for the transition.

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	weaning, tapering or transition.		the formulary and be completed within two years thereafter" as that seems to conflict with the earlier recommendation to allow the physician to prepare a plan for only a portion of patients over a two-year period. See responses above regarding "unilaterally" language. Disagree with the suggestion to allow the claims administrator to submit the transition plan if the physician fails to do so. That is a fundamental responsibility of the treating physician and cannot be performed by the claims administrator.	
9792.27.3	Commenter requests that the division delay the implementation of the proposed drug formulary regulations.	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	Agree that the implementation date should be modified to January 1, 2018.	Section 9792.27.3 subdivisions (a) and (b) will be modified to delete "July 1, 2017" and replace with "January 1, 2018".
9792.27.4	Commenter states that pharmacy benefit managers and pharmacy	Brian Allen, Vice President,	Comment does not recommend any change to proposed text.	No action necessary.

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	networks can play a valuable role in helping to ensure medications are prescribed consistent with the MTUS treatment guidelines and the proposed MTUS drug formulary and that injured workers have access to convenient and appropriate care.	Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment		
9792.27.4	Commenter recommends revisions: "Where an employer or insurer contracts pursuant to Labor Code section 4600.2 with a pharmacy, pharmacy benefit manager, or pharmacy network for the provision of drugs for the treatment of injured workers, the drugs available to the injured worker must be consistent with the ~~MTUS Treatment Guidelines and~~ MTUS Drug Formulary and MTUS Treatment Guidelines for the condition or injury being treated and may not be restricted pursuant to the contract. Pursuant to Labor Code section 4600.2(a), such contracts may limit drug attributes such as dosage, drug delivery system, frequency, or cost, but not the drug ingredient classification of medications prescribed or dispensed pursuant to	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Agree that "pharmacy" should be added to conform to statutory language. Disagree on order reversal. Both the MTUS Treatment Guidelines and MTUS drug formulary are important. However, the guidelines are the primary source of determining appropriate treatment, therefore listing them first places proper emphasis on them. Disagree. Dosage is based on many factors, including the FDA approved product labeling, clinical judgment of the provider, and patient characteristics such as weight, co-morbidities etc. This should not be subject to PBM	Modify the section to include the word "pharmacy." No action necessary. No action necessary.

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	the Drug Formulary." This section needs to be clarified in order to avoid frictional costs of UR, IMR or litigation. For example, where the Drug Formulary or Medical Treatment Guidelines are silent on a particular dosage or duration, it should be clear that these issues can be addressed by a PBM through contract, or through utilization review, without violating the regulation.		contractual limits. Duration of treatment is subject to the MTUS treatment guidelines; if the guideline is silent on the duration of treatment, the appropriate duration is determined according to the adopted rules for identifying evidence-based treatment not covered by the guidelines. (8 CCR §§9792.21, 9792.21.1, 0792.25.1.)	
9792.27.5	Commenter supports a pre-authorization process for off-label medication use.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
9792.27.5	Commenter recommends revisions: "(c) Authorization through prospective review is required prior to dispensing the following drugs for an off-label use: (1) Non-Preferred drug, or (2) Unlisted drug, or (3) Preferred drug lacking	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel	Disagree. This comment is moot as the Division has determined that the sentence regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code	No action necessary.

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	recommendation in the MTUS Treatment Guideline for the intended off-label use. If required authorization through prospective review is not obtained prior to dispensing a drug for off-label use, payment for the drug may be denied if 1) the drug is found upon retrospective review to be not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610." Often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug, in which case there is no documentation upon which to base a decision on the medical necessity of the billed drug. If no diagnosis / ICD-10 is provided, the medical necessity of a drug cannot be determined. It is necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a	May 1, 2017 Written Comment	§4610 and the implementing regulations (8 CCR §9792.6.1 et seq.) Also, note that where a bill comes in without supporting documentation, the billing rules allow the bill to be placed in pending status to allow submission of the supporting documentation, and rejection of the bill if the documentation is not submitted. (See California Division of Workers' Compensation Medical Billing and Payment Guide, version 1.2.2, title 8, CCR §9792.5.1(a).)	

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	retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).			
9792.27.5(c)(3)	Commenter recommends revision: "Preferred drug lacking recommendation in the MTUS Treatment Guideline for the intended off-label use. If required authorization through prospective review is not obtained prior to dispensing a drug for off-label use, payment for the drug may be denied ~~if the drug is found upon retrospective review to be not medically necessary~~."	Karin Sims, Assistant Claims Operations Manager State Compensation Insurance Fund April 1, 2017 Written Comment	Disagree. This comment is moot as the Division has determined that the sentence regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.
9792.27.6	The point of having a drug formulary is to reduce administrative burdens, including costly UR and IMR appeals. In the current proposed drug formulary the vast majority of medications offered to injured workers on a regular basis are non-preferred or not listed. In order to treat their patients, a physician would have to complete the pre-authorization request process. This process has no time limitation imposed by regulation and	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	Disagree with the broad statement that "the point of having a drug formulary is to reduce administrative burdens, including costly UR and IMR appeals", as it focuses only on the aspect of administrative burden. A fundamental purpose of the formulary is to provide appropriate medications in accordance with principles of evidence-	No action necessary.

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	could lead to a delay or the abrupt cessation of an injured workers' treatment. Not only does this process create additional administrative work for physicians that could otherwise be avoided, but with so many common prescriptions left off the list, pharmacy benefit managers (PBMs) and payers will be inundated with prior authorization requests, creating an overwhelming administrative workload for payers, delay for injured workers, and frustrations for all stakeholders.		based medicine. The Labor Code has established utilization review as the process to ensure that drug treatment is medically necessary pursuant to evidence-based recommendations. The Division has structured the regulation to streamline provision of the exempt drugs, by stating that they do not require prospective review. This is expected to reduce UR and IMR for the exempt drugs. For Non-Exempt drugs, the prospective UR is an important tool for reducing inappropriate prescribing, especially of hazardous medications such as opioids.	
9792.27.6	Commenter supports a pre-authorization process for unlisted medications.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.

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9792.27.6	Commenter recommends revisions: "(b) Any medically necessary FDA-approved prescription drug, FDA-approved nonprescription drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, may be authorized through prospective review and dispensed to an injured worker if it is shown in accordance with the MTUS regulations that a variance from the guidelines is required to cure or relieve the injured worker from the effects of the injury. ~~Treatment outside~~ Any such variance from the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence~~.~~). If authorization through prospective review for a drug not listed as Preferred is not obtained prior to dispensing the drug, payment for the	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Agree in part. The language of subdivision (b) will be modified to improve the clarity. The phrase "variance from the guidelines" will be removed and the sentence simplified. The next sentence will be modified to reference "Determination of the medical necessity of treatment based on recommendations found outside of the MTUS Treatment Guidelines…" The phrase "treatment based on recommendations found outside the guidelines" is preferable over "any such variance", because 1) it is broader and encompasses rebutting the guideline as well as conditions not covered by the guideline, and, 2) it improves consistency because the phrase "treatment outside of the MTUS" is used in the MTUS regulation in title 8, CCR §9792.21.21 Disagree with suggested	Modify §9692.27.6 subdivision (b). No action necessary.

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	drug may be denied if 1) it is determined upon retrospective review that the drug treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610."		revision regarding retrospective review. See response above to the comment of CWCI dated May 1, 2017 regarding §9792.27.5.	
9792.27.6(b)	Commenter recommends revision: "(b) Any medically necessary FDA-approved prescription drug, FDA-approved nonprescription drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, may be authorized through prospective review and dispensed to an injured worker if it is shown in accordance with the MTUS regulations that a variance from the guidelines is required to cure or relieve the injured worker from the effects of the injury. Treatment outside of the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search	Karin Sims, Assistant Claims Operations Manager State Compensation Insurance Fund April 1, 2017 Written Comment	Disagree. This comment is moot as the Division has determined that the sentence regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.

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	sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for evaluating medical evidence.) If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied ~~if it is determined upon retrospective review that the drug treatment was not medically necessary~~."			
9792.27.6; 9792.27.10	Prospective review of non-preferred drugs is a key component of the formulary, and it is included in the proposed rules. However, its impact is minimized by the plain language of the rules, which requires retrospective review before a payer may deny a medication.	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	This comment is moot as the Division has determined that the provisions regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.
9792.27.7	Commenter recommends adding a provision in this section to address situations where a brand drug does not have a generic therapeutic equivalent but there are generic drugs with the same active ingredient that will effectively treat the diagnosed	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy	Disagree. This section is directed only to choice of generic vs. brand. In the future, the DWC may consider additional rules regarding alternate dosage forms of the same active ingredient. This	No action necessary.

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	condition.	Benefits Zenith Insurance Written Comment April 27, 2017	would best be accomplished after the P&T Committee is convened so that criteria may be developed regarding alternate dosage forms in light of input from the committee.	
9792.27.7	Commenter recommends breaking this paragraph into multiple paragraphs to make it easier to follow and suggests language.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Agree that the proposed language would be clarified by breaking it into paragraphs due to its length. However, this is not necessary as the section will be modified to delete approximately half of the language. The Division has determined that the provisions regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.
	Commenter recommends including a provision that establishes a preference for use of generic drugs over brand drugs when the brand drug has no therapeutic equivalent but for which		Disagree with mandating a therapeutic alternative at this time. Therapeutic interchange will be considered in the future, including consultation	No action necessary.

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	there are generic drugs that have the same active ingredient and would treat the diagnosed condition as effectively as the brand drug. Commenter recommends adding language to address multiple generic drugs that may be available to treat the same condition but have a cost differential. Commenter also recommends that this section be modified to address over-the-counter (OTC) drugs.		with the P&T Committee. Disagree with requiring the lowest cost generic drug at this time. Such a requirement would need further evaluation to determine if savings would justify the additional administrative burden. In addition, this proposal would need to be evaluated in the context of the pharmaceutical fee schedule. Disagree with mandating OTC drugs at this time. This issue can be studied further to determine if it is a viable method to assure appropriate treatment that is cost effective. It should be noted that OTC drugs are not always less expensive than the prescription version of the drug.	No action necessary. No action necessary.
9792.27.7	The use of therapeutically equivalent generic medications has, over time, proven to be a significant cost saver while still maintaining the safety, efficacy and quality of care. The provision requiring a pre-authorization	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault	DWC notes the commenter's support.	No action necessary.

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	process for prescribing brand-named medications balances the need to contain costs while allowing for medically necessary care adaptations based on the unique medical needs of an injured worker. Commenter supports this provision.	April 28, 2017 Written Comment		
9792.27.7	Recommends language to support the mandatory nature of paragraph: "If a physician prescribes a brand name drug when a less costly therapeutically equivalent generic drug exists, and writes "Do Not Substitute" or "Dispense as Written" on the prescription in conformity with Business and Professions Code section 4073, the physician must document the medical necessity for prescribing the brand name drug in the patient's medical chart and in the Doctor's First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician's determination that the brand name drug is medically necessary. The physician must obtain authorization through prospective review before the brand name drug is	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	For drugs designated as	No action necessary.

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	dispensed. **If any of these requirements are not met** ~~If required authorization through prospective review is not obtained before dispensing the brand name drug, retrospective review may be conducted to determine if it was medically necessary to use the brand name drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand name drug is medically necessary,~~ payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand name drug. If it is determined through prospective or retrospective review that neither the generic drug nor the brand name drug is medically necessary, payment for the drug may be denied, pursuant to section 9792.27.10."		"exempt" (originally "preferred") it is possible that the failure to meet all requirements may not become apparent until retrospective review. The Division has determined that the provisions regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.) In the future, the Division can consider whether it would be appropriate to further address the cost implications, perhaps through UR regulations or fee schedule regulations.	
9792.27.7	Commenter recommends revisions: "…If it is determined that the generic drug but not the brand name drug is medically necessary, payment for the drug may be made at the fee schedule ~~price~~ allowance for the lowest priced generic therapeutic equivalent of the brand name drug. If it is determined	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel	Disagree with comments and suggested revision regarding retrospective review. See response above to the comment of CWCI dated May 1, 2017 regarding §9792.27.5.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	through prospective or retrospective review that neither the generic drug nor the brand name drug is medically necessary, payment for the drug may be denied, pursuant to section 9792.27.10; or if a request for authorization with sufficient information upon which to base a prospective or retrospective review decision is not timely received, payment may be denied pursuant to Labor Code section 4610.	May 1, 2017 Written Comment		
9792.27.8	Commenter recommends an additional subdivision to be inserted between current (b) and (c): ***"(b) If a physician prescribes and dispenses a drug at a specific dosage strength when a lower unit cost of the same drug at an alternate dosage strength exists, the physician must document the medical necessity for prescribing the more costly dosage strength. The documentation must include patient-specific factors that support the physician's determination that the specific dosage strength is medically necessary. The physician***	Alex Rossi, Chief Executive Office RMB Los Angeles County April 4, 2017 Written Comment	Agree that the section regarding physician-dispensed drugs is needed to encourage cost effective high quality care. However, disagree with the suggested revisions. The Division is aware of the development of "new" strengths of commonly prescribed drugs which have a substantially higher per unit cost than the existing strengths. Further, the Division is aware of usage patterns that indicate that prescribing and dispensing of these new strengths by	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	must obtain authorization through prospective review prior to the time the drug at the more costly dosage strength is dispensed. If required authorization through prospective review is not obtained prior to dispensing the more costly dosage strength, retrospective review may be conducted to determine if it was medically necessary to use the more costly dosage strength rather than the less costly dosage strength. If it is determined that the less costly dosage strength is medically necessary and an effective replacement for the more costly dosage strength, payment for the drug may be made at the fee schedule price for the lowest priced alternate dosage strength of the same drug."		physicians are often motivated by financial incentives. (See ISOR, describing studies by Workers' Compensation Research Institute.) Although the Division is analyzing possible approaches to address the issue, commenter's proposed solution has some serious drawbacks. It is overbroad, as it would require a physician to justify (with patient-specific factors) a more costly strength every time there is a less expensive strength available, no matter how trivial the price difference. In addition, requiring the physician to analyze the cost of all products of different strengths would likely be quite onerous, and could detract from patient care. The Division is exploring other options for a more tailored response to the problem	
9792.27.8	Commenter recommends that physician dispensing be disallowed and that pharmaceutical care be directed exclusively to the pharmacy,	Nina Walker Pharmacy Benefits Administrator, Applied	Disagree. A physician is permitted to dispense medication to a patient for conditions being treated by the	No action needed.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	including special fills.	Underwriters, Inc. April 10, 2017 Written Comment	physician pursuant to Business and Professions Code §4170. Moreover, the Labor Code does not permit the complete prohibition of physician dispensing in workers' compensation treatment. (For example, see Labor Code section 5307.1 which contains several references to physician-dispensed pharmaceuticals.)	
9792.27.8	Commenter recommends that this section specify that physicians may dispense a seven-day supply of formulary-allowed medications only at the initial office visit following the date of injury.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Agree with the suggestion to restrict the physician dispensing without prospective review to the initial office visit following the date of injury. This modification balances the need for prospective review to ensure medically appropriate physician-dispensing and the goal of providing needed medication quickly at the outset.	Modify the section to require that "the seven-day supply is dispensed at the time of an initial visit that occurs within 7 days of the date of injury".
9792.27.8	Physician dispensing continues to drive costs in the California workers' compensation system. Commenter	Brian Allen, Vice President, Governmental Affairs	DWC notes the commenter's support. However, note that the	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	supports the proposed language requiring physicians to seek pre-authorization prior to dispensing medications, with the limited exception of the seven-day fill on a one-time basis. The allowance for a retrospective review on the one-time fills creates an added protection against potential abuse of the exception.	Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	Division has determined that the provisions regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	
9792.27.8	Commenter recommends the following revised language: "(a) … If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if 1) the drug is found upon retrospective review to be not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610. (b) … Payment for the drug may be denied if 1) the drug was not medically necessary; or if 2) a request for authorization with sufficient	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Disagree with comments and suggested revision regarding retrospective review. See response above to the comment of CWCI dated May 1, 2017 regarding §9792.27.5. Agree in part. Modify the section to add language proposed by Jeremy Merz, American Insurance Association, and Jason Schmelzer California Coalition on Workers' Compensation in the comment dated May 1, 2017, that is substantially similar to the suggested new subdivision (d).	No action necessary. Modify the section to add a new subdivision (d).

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	information upon which to base a review decision is not timely received pursuant to Labor Code section 4610." Commenter suggests addition: "(d) Nothing in this Article shall permit physician dispensing where otherwise prohibited in an agreement with a pharmacy, group of pharmacies, or pharmacy benefit network, pursuant to subdivision (a) of Labor Code 4600.2."			
9792.27.8	Commenter recommends the addition of a new subsection (d) as follows: (d) Nothing in this Article shall permit physician dispensing where otherwise prohibited by a Pharmacy Benefit Network contract pursuant to subdivision (a) of Labor Code 4600.2.	Jeremy Merz American Insurance Association Jason Schmelzer California Coalition on Workers' Compensation May 1, 2017 Written Comment	Agree that a provision should be added to acknowledge that a Pharmacy Benefit Network contract can restrict physician dispensing in light of the language in Labor Code section 4600.2, subdivision (a), which states in part: "those injured employees that are subject to the contract shall be provided medicines and medical supplies in the manner prescribed in the contract for as long as medicines or medical supplies are reasonably required to cure or	Modify the section to add the suggested new subdivision (d).

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			relieve the injured employee from the effects of the injury."	
9792.27.8(a)	This provision essentially removes the mandatory nature of the initial clause and should be removed as indicated: "Drugs dispensed by a physician must be authorized through prospective review prior to being dispensed, except as provided in subdivision (b), section 9792.27.11 ("Special Fill"), and section 9792.27.12 ("Perioperative Fill"). If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied**.** ~~if the drug is found upon retrospective review to be not medically necessary.~~"	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Disagree with the suggested revision. The Division has determined that the provisions regarding retrospective review, and the effects of failing to obtain authorization through prospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.
9792.27.8(b)	Commenter recommends the following revised language: "(b) A physician may dispense up to a seven-day supply of a drug that is listed as "Preferred" in the MTUS Drug List on a one-time basis without obtaining authorization through prospective review, if**: (i) the drug treatment is in accordance with the MTUS Treatment Guidelines; (ii) the seven-day supply is dispensed at**	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Agree in part. Agree that the section should be modified to specify that the physician dispensing without prospective review should be limited to the initial visit that occurs within 7 days of the date of injury. The section will be modified to incorporate these concepts: "initial visit", and "within 7 days of date of injury".	Modify the section to require that "the seven-day supply is dispensed at the time of an initial visit that occurs within 7 days of the date of injury".

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	the time of an initial visit that occurs within 7 days of the date of injury; and (iii) the prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List if the MTUS Drug list recommends less than 7 days of treatment with the drug for the diagnosed medical condition. The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary."		However, disagree with the language suggested. The suggested phrase "the prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List if the MTUS Drug list recommends less than 7 days of treatment with the drug for the diagnosed medical condition" is flawed. The MTUS Drug List does not contain "recommendations." The MTUS *treatment guidelines* contain recommendations for treatment of medical conditions.	
9792.27.8(c)	This provision does not address pharmacy programs or pharmacy networks that are established outside of a Medical Provider Network pursuant to Labor Code 4600.2. Commenter recommends revisions: "(c) Nothing in this Article shall invalidate a provision **that restricts physician dispensing through either a provision** in a Medical Provider Network agreement, **or through a pharmacy benefit**	Rupali Das, MD, MPH, FACOEM, California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Agree in part. Agree that the section should be modified to recognize that pharmacy contracts pursuant to Labor Code §4600.2 may restrict physician dispensing. However, disagree with suggested language which becomes unwieldy when combining language to cover MPNs and pharmacy contracts in one provision. Instead, the Division will modify the	Modify the section to add a new subdivision (d).

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	program or pharmacy benefit network established pursuant to Labor Code Section 4600.2. ~~**which restricts physician dispensing by medical providers within the network.**~~"		section by adding a separate subdivision (d) to address the pharmacy benefit contracts pursuant to Labor Code §4600.2.	
9792.27.8(c) 9792.27.1(u)	The Division should add a section excluding Pharmacy Benefit Networks under section 4600.2(a). The definition of physician in 9792.27.1(u) will make physicians think that it is ok to dispense medication in every circumstance.	Matthew O'Shea Safeway/Albertsons May 1, 2017 Oral Comment	Agree that the section should be modified to recognize that pharmacy contracts pursuant to Labor Code §4600.2 may restrict physician dispensing.	Modify the section to add a new subdivision (d).
9792.27.9	Commenter supports the language requiring pre-authorization of compounded medications. It returns the practice of compounding medications to its intended role and purpose: treating specific, unique medical needs of the individual injured worker as a second-line therapy. This requirement will help reduce unnecessary medication costs in California.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
9792.27.9(a)	Commenter states that this subsection may be inconsistent with the statutory requirements of Labor Code section	Robert Ward Clinical Director CID Management	Disagree with the statement that the subdivision is inconsistent with Labor Code	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	4610(e). Specifically commenter notes the following sentence: "If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied." Commenter notes that Labor Code section 4610(e) states: "A person other than a licensed physician who is competent to evaluate the specific clinical issues involved in the medical treatment services, if these services are within the scope of the physician's practice, requested by the physician, shall not modify or deny requests for authorization for medical treatment for reasons of medical necessity to cure and relieve."	Written Comment April 28, 2017	§4610. Moreover, This comment is moot as the Division has determined that the sentence regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	
9792.27.10	Allowing for a special fill of a seven day supply of non-preferred medications could have an adverse effect on the overall health of the injured worker. Starting a therapy and suddenly stopping that therapy, if not approved through UR, is not appropriate with some medications.	Nina Walker Pharmacy Benefits Administrator, Applied Underwriters, Inc. April 10, 2017 Written Comment	Agree in part. The MTUS Drug List will be modified to expand the number of days supply for the perioperative fill of anticoagulants, as a 4-day supply may not be sufficient from a clinical standpoint. Also, it is unclear why	Modify MTUS Drug List (original 9792.27.14 to be renumbered 9792.27.15) to increase the "Perioperative Fill" from 4-day supply to

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter states that having to wait for a pain medication to go through the UR process could also delay any improvement in function and subsequently the return to work.		commenter references "a seven day supply of non-preferred medications" as the drugs on the MTUS Drug List all were proposed with a 4-day supply. Disagree that having a 4-day supply of non-preferred (non-exempt) without UR would delay improvement in function and return to work. A major benefit of the formulary is to reign in the overuse of highly risky pain medications. UR will support the patient's health and return to work by reviewing proposed treatment to determine if it is guided by evidence-based treatment recommendations. Many preferred (to be renamed "exempt") medications are available to treat the injured worker, a special fill of stronger pain relievers is available for urgent use for a 4-day fill, and will be available after the special fill period if need is supported by medical evidence and approved through UR.	14-day supply for the anticoagulants.

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9792.27.10	Commenter is a strong proponent of implementing a step therapy program to work with the proposed drug formulary. It is recommended that this be a priority of the P&T Committee.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. See response above to comment of Zenith regarding § 9792.27.1.	No action necessary.
9792.27.10	Commenter supports the provision of preferred medications without prospective review when prescribed in accordance with the MTUS treatment guidelines.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
9792.27.10 9792.27.14	The formulary will have minimal impact on reducing frictional costs of UR and IMR because there is such a small number of preferred drugs on the list that are not subject to prospective review. Delays will continue for injured workers in accessing appropriate	Diane Worley California Applicant's Attorneys Association (CAAA) May 1, 2017 Written Comment Oral Comment	Disagree with commenter's statement that "delays will continue for injured workers in accessing appropriate medications while recovering from their work injuries." The formulary is intended to support the provision of timely	No action necessary.

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	medications while recovering from their work injuries.		high quality medical care in accordance with the MTUS. See response above to comment of Stephen J. Cattolica, CSIMS, dated May 1, 2017 regarding §9792.27.2. The Division anticipates an overall positive impact on reducing the utilization review and IMRs and disputes over medications. To the extent that more hazardous drugs are designated as "non-exempt", injured worker health will be supported by the UR process to ensure that treatment is medically necessary. Utilization review is an important tool (along with physician education) to tackle the epidemic opioid drug misuse, abuse and overuse. Also, see the response to the comment of Ben Roberts, PRIUM, dated April 29, 2017 regarding §9792.27.3, which discusses the "prior authorization" programs that can lessen the use of UR.	

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.27.10	Commenter recommends revisions to subdivisions (b) (and the same revision to (c), (e)) to state that payment may be denied if sufficient information is not provided on retroactive review to make the determination: "(b) A drug that is identified as "Preferred" may be dispensed to the injured worker without obtaining authorization through prospective review if the drug treatment is in accordance with the MTUS Treatment Guidelines, except that physician-dispensed drugs are subject to section 9792.27.8. The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if <u>1)</u> it is determined upon retrospective review that the drug treatment was not medically necessary<u>; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor</u>	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Disagree with comments and suggested revision regarding retrospective review. See response above to the comment of CWCI dated May 1, 2017 regarding §9792.27.5.	No action necessary.

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	Code section 4610. Commenter recommends adding a new subdivision: "(g) Nothing in sections 9792.27.1 through 9792.27.21 shall preclude a claims administrator from disputing or objecting to bills on the basis of any provisions available under the law."		Disagree. The suggested provision is not necessary and may create confusion. The interaction between the formulary rules and other provisions of law cannot be subject to this across the board statement.	No action necessary.
9792.27.10(b)	Commenter recommends the following revised language: "The dispensing of the preferred drug may be subject to retrospective review**, but may not be subject to prospective review,** to determine if the drug treatment was medically necessary."	Mitch Seaman Legislative Advocate California Labor Federation Written Comment May 1, 2017	Disagree. This comment is moot as the Division has determined that the sentence regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.
9792.27.10(b)	Commenter is concerned with the provision that preferred drugs still need to adhere to the MTUS guidelines and are subject to retrospective review. There could be an increase in retrospective review because medications being dispensed	Mary Ellen Szabo Enstar Group Paladin Managed Care May 1, 2017 Oral Comment	The legislature's expressed intent is that the formulary include: "Guidance on the use of the formulary to further the goal of providing appropriate medications expeditiously while minimizing	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	are not part of the industrial injury.		administrative burden and associated administrative costs." (AB 1124, Statutes 2015, Chapter 525.) The legislative intent makes it clear that an important part of the formulary is to support appropriate care. In the workers' compensation system, medical necessity is determined by utilization review.	
9792.27.10(c)	Commenter recommends revision: "For a drug that is identified as "Non-Preferred," authorization through prospective review must be obtained prior to the time the drug is dispensed. Expedited review should be conducted where it is warranted by the injured worker's condition. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied**.** ~~if it is determined upon retrospective review that the drug treatment is not medically necessary. "~~	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Disagree. See response above to comment by Mr. Roberts dated April 29, 2017 regarding §9792.27.8(a)	No action necessary.
9792.27.10(c)	Commenter recommends the following proposed language:	Karin Sims, Assistant Claims Operations	Disagree that clarification is necessary, because the section	No action is necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	For a drug that is identified as "Non-Preferred," authorization through prospective review must be obtained prior to the time the drug is dispensed. Expedited review should be conducted where it is warranted by the injured worker's condition. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied ~~if it is determined upon retrospective review that the drug treatment is not medically necessary~~.	Manager State Compensation Insurance Fund April 1, 2017 Written Comment	will be modified to delete language that relates to retrospective review as that is governed by the UR regulations.	
9792.27.10(c)	Commenter appreciates this new language that allows for expedited review when warranted.	Mitch Seaman Legislative Advocate California Labor Federation Written Comment May 1, 2017	DWC notes the commenter's support.	No action necessary.
9792.97.10(e)	Commenter recommends revisions: "For an unlisted drug, authorization through prospective review must be obtained prior to the time the drug is dispensed. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied**.** ~~if it is~~	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Disagree. See response above to comment by Mr. Roberts dated April 29, 2017 regarding §9792.27.8(a)	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	~~determined upon retrospective review that the drug treatment was not medically necessary.~~ A combination drug that is not on the MTUS Drug List is an unlisted drug even if the individual active ingredients are on the MTUS Drug List."			
9792.27.10(e)	This subsection states if authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary. Commenter questions if the carrier would be able to issue an immediate denial of a bill for a non-preferred drug if no utilization review request was received by the time the bill was received. Commenter would like to know if the carrier has to retain the pharmaceutical bill and monitor for a retrospective utilization review request for a specified length of time.	Nina Walker Applied Underwriters May 1, 2017 Written Comment	This comment is moot as the Division has determined that the sentence regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.)	No action necessary.
9792.27.10; 9792.27.16	Commenter recommends that the P&T Committee also address step-therapy for the use of immediate release versus extended release drugs.	Rupali Das, MD, MPH, FACOEM California Medical Director	See response above to comment of Zenith regarding § 9792.27.1.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017		
9792.27.11	Commenter states that this is a provision that will create new programming requirement not previously included in drug formularies in other states. Commenter understands the reasoning and appreciates the limited number of medications listed in this category, however he would like to acknowledge that the added complexity combined with the short window of time between the approval of the final rule and the proposed effective date is creating some concern among stakeholders regarding their ability to fully implement on 7/1/17.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	The Special Fill policy in §9792.27.11 (to be renumbered §9792.12) provides an important mechanism for injured workers to obtain medication needed urgently at the onset of an injury. The 7/1/2017 implementation date will be modified to January 1, 2018.	The 7/1/2017 implementation date will be modified to January 1, 2018.
9792.27.11	Commenter supports the concept of the special fill provisions that will allow physicians to prescribe the appropriate non-preferred medications to acutely injured workers without prospective UR. Commenter is disappointed to see that all of the "special fill" medications are limited to a four day supply. Commenter	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association (CMA) May 1, 2017 Written Comment	Disagree with the suggestion that some of the non-preferred medication (to be renamed non-exempt) be available for a longer than 4 days for the special fill. As noted in the ISOR, the Non-Preferred (to be renamed Non-Exempt) drugs have a higher risk profile, such	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	requests that at least some non-preferred medications be available without prospective utilization review pursuant to the "special fill" provisions be available for an increased number of days.		as the opioids and muscle relaxants, and normally they should go through prospective utilization review to ensure that they are used appropriately for the condition. However, the utility of prospective review needs to be balanced with the recognition that there are urgent situations which warrant use of these drugs prior to conducting prospective utilization review. The 4-day supply provides a reasonable balance of the interests of patient safety and access to urgently needed medication. The U.S. Surgeon General's Turn the Tide campaign emphasizes the need for caution in beginning opioid prescriptions. The *Turn the Tide: Prescribing Opioids for Chronic Pain* pocket guide (designated as a document relied on) urges doctors to "start low and go slow," and states: "For acute pain: prescribe < 3 day supply; more than 7 days will rarely be	

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			required."	
9792.27.11	Commenter recommends revisions: "(a) The MTUS Drug List identifies drugs that are subject to the Special Fill policy. Under this policy, a drug that usually requires prospective review because it is "Non-Preferred-," will be allowed without prospective review in very limited circumstances, and for a short period of time. (b) The drug identified as a Special Fill drug may be dispensed to the injured worker without seeking prospective review if the following conditions are met: (1) The drug is prescribed at the single initial treatment visit following a workplace injury, provided that the initial visit is within 7 days of the date of injury; and (2) The prescription is for a supply of the drug not to exceed the Special Fill limit as set forth in the MTUS Drug List; and (3) The drug is prescribed in	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Agree that punctuation would be improved by deleting the comma from §9792.27.11 subdivision (a). Disagree. The suggested language is unnecessary. The Special Fill supply is very clear on the MTUS Drug List. Disagree with the suggestion.	Modify to delete comma from §9792.27.11 (re-numbered §9792.27.12) and modify "Non-Preferred" to "Exempt". No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	accordance with the MTUS Guidelines; and (4) The prescription for the Special Fill – eligible drug is for: (A) An FDA-approved generic drug or single source brand name drug, or, (B) A brand name drug where the physician documents and substantiates the medical need for the brand name drug rather than the FDA-approved generic drug. ~~and~~ ~~(4)The drug is prescribed in accordance with the MTUS Guidelines~~ (c) When calculating the 7-day period in subdivision (b)(1), the day after the date of injury is "day one." (d) A drug dispensed under the "Special Fill" policy may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if 1) it is determined upon retrospective review that the drug		It is unnecessary to re-order subdivisions (3) and (4), the introductory clause says: "if all of the following conditions are met". Moreover, each of the subparagraphs (b)(1) through (b)(4) ends with "and", which is further indication that each of the subparagraphs sets forth a required element. Disagree with comments and suggested revision regarding retrospective review. See response above to the comment of CWCI dated May 1, 2017 regarding §9792.27.5.	No action necessary. No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610. (e) An employer or insurer that has a contract with a pharmacy, pharmacy network, pharmacy benefit manager, or a medical provider network (MPN) that includes a pharmacy or pharmacies within the MPN, may provide for a longer Special Fill period or may cover additional drugs under the Special Fill policy pursuant to a pharmacy benefit contract or MPN contract.		Agree.	Subdivision (e) (re-numbered (d)) will be modified to include "pharmacy" as suggested by commenter.
9792.27.11(a)	The use of the terms "in very limited circumstances, and for a short period of time" do not provide any additional meaning or clarity to the section and may create confusion as they are undefined terms. Commenter notes that clarification on the Special Fill policy and definition are provided in paragraph (b) of this section.	Ben Roberts Executive Vice President and General Counsel PRIUM April 29, 2017 Written Comment	Agree in part. Agree that the specified language is vague and does not add meaningful direction to the regulation. However, DWC is proposing alternate language: "as specified in subdivision (b)."	Modify section to add language to subdivision (a).

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Commenter recommends revisions: "The MTUS Drug List identifies drugs that are subject to the Special Fill policy. Under this policy, a drug that usually requires prospective review because it is "Non-Preferred," will be allowed without prospective review ~~in very limited circumstances, and for a short period of time.~~ ***as long as it meets the requirements of this section paragraph (b)."***			
9792.27.11(a)	Commenter recommends revisions: "The MTUS Drug List identifies drugs that are subject to the Special Fill policy. Under this policy, a drug that usually requires prospective review because it is "Non-Preferred," will be allowed without prospective review in very limited circumstances, and for **(insert timeframe)"**	Karin Sims, Assistant Claims Operations Manager State Compensation Insurance Fund April 1, 2017 Written Comment	Disagree with the suggestion. However, the Division recognizes a need to modify the section. See response above to comment of Ben Roberts, PRIUM, dated April 29, 2017 regarding this section.	See action above relating to comment of Ben Roberts.
9792.27.11(f)	This subsection directs the Administrative Director to evaluate the impact of the special fill provisions on the use of opioids by injured workers. Commenter requests that the DWC	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical	Disagree with the suggestion that the section should be amended. The Division does intend to monitor the impacts of the formulary and review	No action necessary. (Note that this section will be renumbered §9792.27.12.)

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	clarify the parameters of this study.	Association (CMA) May 1, 2017 Written Comment	whether modifications are needed to improve the provision of pharmaceutical treatment to injured workers. However, it is not necessary to codify the scope of the study into regulation.	
9792.27.11(f)	Commenter supports this addition and recommends that the proposed study be expanded to include additional elements.	Mitch Seaman Legislative Advocate California Labor Federation Written Comment May 1, 2017 Oral Comment	DWC notes the commenter's support for the section. Disagree with the suggestion to modify the section. See the response to the comment of Stacey Wittorff, California Medical Association dated May 1, 2017 to this section.	No action necessary. (Note that this section will be renumbered §9792.27.12.)
9792.27.11; 9792.27.12	Commenter is concerned about an injured workers' access to sustained treatment. If a patient receives a special four-day fill of a medication, what safeguards are in place for them to continue on their course of treatment after the four days?	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	The injured worker's physician can request authorization for medically necessary treatment. See the response above to the comment of Stacey Wittorff, California Medical Association dated, May 1, 2017.	No action necessary.
9792.27.11; 9792.27.12	These sections include much needed language to create "special fill" and "perioperative fill" policies, respectively, for certain common short-term painkillers and	Mitch Seaman Legislative Advocate California Labor Federation Written Comment	DWC notes the commenter's support.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	musculoskeletal therapy agents.	May 1, 2017		
9792.27.12	Commenter is concerned about implementation by the July 1, 2017 proposed effective date.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	Agree that the July 1, 2017 date should be changed.	Modify proposal to implement this section on January 1, 2018.
9792.27.12	Commenter recommends that at least some non-preferred medications be available without prospective utilization review pursuant to the "perioperative fill" provisions for an increased number of days.	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association (CMA) May 1, 2017 Written Comment	Agree in part. The MTUS Drug List will be modified to expand the number of days supply for the perioperative fill of anticoagulants to 14 days, as a 4-day supply may not be sufficient from a clinical standpoint. A major benefit of the formulary is to reign in the overuse of highly risky pain medications. A CDC study has shown that even short courses of opioids are correlated with long term use. (Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015, Centers for Disease Control and Prevention, Morbidity and	Modify MTUS Drug List (original 9792.27.14 to be renumbered 9792.27.15) to increase the "Perioperative Fill" from 4-day supply to 14-day supply for the anticoagulants. The original perioperative fill § 9792.27.12 is renumbered §9792I.27.13.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Mortality Weekly Report, Vol 66, No. 10, March 17, 2017.) For planned surgeries, the normal prospective UR process should be used to request the opioid pain medication expected to be required. UR will support the patient's health and return to work by reviewing proposed treatment to determine if it is guided by evidence-based treatment recommendations for perioperative pain management. For unexpected needs the 4-day supply, supplemented with preferred medications should be sufficient in most cases. For severe unexpected pain, the non-preferred (non-exempt) medication can be made available as "emergency" treatment, which cannot be denied on retrospective review due to failure to obtain prospective authorization.	
9792.27.12	Commenter recommends that the length of a perioperative drug fill be 7	Diane Worley California	Disagree. See response above to the comment of Stacey	No response necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	days.	Applicant's Attorneys Association (CAAA) May 1, 2017 Written Comment	Wittorff, California Medical Association dated May 1, 2017 to this section.	
9792.27.12	Commenter recommends revisions: "(a) The MTUS Drug List identifies drugs that are subject to the Perioperative Fill policy. Under this policy, the drug identified as a Perioperative Fill drug may be dispensed to the injured worker without seeking prospective review if all of the following conditions are met: (1) The drug is prescribed <u>for outpatient use</u> during the perioperative period; and (2) The prescription is for a supply of the drug not to exceed the <u>Perioperative Fill</u> limit ~~as~~ set forth in the MTUS Drug List; and (3) <u>The drug is prescribed in accordance with the MTUS Treatment Guidelines; and</u> <u>(4)</u> The prescription for the Perioperative Fill - eligible drug is for: (A) An FDA-approved generic drug or single source brand name drug, or~~,~~ (B) A brand name drug where the	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Commenters raise the same issues they raised in relation to §9792.27.11. The Division disagrees with the comments. See the response above to the comment of CWCI dated May 1, 2017 regarding §9792.27.11; the reasons set forth in that response also apply here. The only additional issue relates to subdivision (a)(1), addressed below.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	physician documents and substantiates the medical need for the brand name drug rather than the FDA-approved generic drug~~, and~~. ~~(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines.~~ (b) For purposes of this section, the perioperative period is defined as the period from 2 days prior to surgery to 4 days after surgery, with the day of surgery as "day zero". (c) A drug dispensed under the "Perioperative Fill" policy may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if 1) it is determined upon retrospective review that the drug treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610. (d) An employer or insurer that has a contract with a pharmacy, pharmacy network, pharmacy benefit manager, or a medical provider network that			

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	includes a pharmacy or pharmacies within the MPN, may provide for a longer Perioperative Fill period or may cover additional drugs under the Perioperative Fill policy pursuant to a pharmacy benefit contract or MPN contract. As currently proposed, the drug must be **prescribed** during the perioperative period. If the intent is for the drug to be prescribed **for use** during the perioperative period, the recommended modification is necessary for clarification.		Disagree with the suggested language. The Division does not intend the restriction that commenter inquires about. For the perioperative fill allowed without prospective authorization, the drug is to be prescribed *during* the perioperative period, and the fill is limited to the day's supply specified on the MTUS Drug List. The regulation does not mandate when the medication is used. (Note that the number of day's supply without prospective review is restricted on the MTUS list to 4 days, except anticoagulants, which will be modified to 14 days' supply. Also, note that the perioperative period will be expanded from 2 days before	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			surgery to 4 days before surgery and continue through 4 days after surgery.	
9792.27.12	This section needs to be further defined to eliminate zero day – postoperative day procedures.	Denise Algire Albertson's May 1, 2017 Oral Comment	Disagree. See response above to comment of CWCI dated May 1, 2017 suggesting adding a definition of "surgery" to section 9792.27.1 based on the global days used for the physician fee schedule.	No action necessary.
9792.27.12(b)	Commenter notes that this section includes a definition for perioperative period. Commenter recommends removing the definition from this section and adding it to the definitions under Section 9792.27.1 for consistency.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. Removing the definition of perioperative period from this section and moving it to 9792.27.1 would detract from the clarity of this section. The public's understanding of the parameters of the "perioperative fill" is enhanced when all of definitional components are contained in the section.	No action necessary.
9792.27.12(b)	Commenter recommends revisions: "For purposes of this section, the perioperative period is defined as the period from ~~2~~ 7 days prior to surgery	Karin Sims, Assistant Claims Operations Manager State Compensation Insurance Fund	Agree in part. The suggested timeframes are excessive, however, agree that the pre-operative period should be expanded. It would be	Modify the perioperative period by expanding the pre-operative days from 2 to 4 in order to

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	~~to 4~~ **to 10** days after surgery, with the day of surgery as "day zero"." Commenter states that 4 to 7 days is not enough time. A range of 7 to 10 days is more reasonable.	April 1, 2017 Written Comment	reasonable to increase the pre-operative period from 2 days to 4 days. In general, for planned surgeries, the physician should be able to obtain authorization prospectively at the time surgery is authorized. However, there may be circumstances in which the patient is awaiting the surgery and needs urgent drug treatment with a Non-Preferred drug such as an opioid pain medication. Expansion of the preoperative portion of the perioperative period from 2 days before surgery to 4 days before surgery will provide useful flexibility.	provide additional flexibility regarding drugs urgently needed in the perioperative period. Re-number the section to 9792.27.13.
9792.27.12(b)	Commenter recommends revisions: "For purposes of this section, the perioperative period is defined as the period from 2 days prior to surgery to 4 days after surgery, with the day of surgery as "day zero" **for a *surgical procedure that has "010" or 10 Day Post-operative Period or has "090", or 90 Day Post-operative Period,***	Jeremy Merz American Insurance Association Jason Schmelzer California Coalition on Workers' Compensation May 1, 2017	Disagree. See response above to comment of CWCI dated May 1, 2017 suggesting adding a definition of "surgery" to section 9792.27.1 based on the global days used for the physician fee schedule.	No action necessary.

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	listed for the reimbursable CPT code as found in the Medicare National Physician Fee Schedule Relative Value File incorporated into the Official Medical Fee Schedule."	Written Comment		
9792.27.13	Stakeholders should already be complying with these rules and commenter supports this section.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
9792.27.14 9792.27.15	Commenter questions if there is a corresponding list that contains the NDC codes for the referenced drugs, or alternatively, GPI codes.	Paul Peak AVP Clinical Pharmacy Sedgwick Claims Management Services April 4, 2017 Written Comment	See response below to comment of Lisa Anne Bickford, Coventry dated May 1, 2017 to section 9792.27.14.	No action necessary.
9792.27.14	The formulary is overly restrictive and un-encompassing. The draft formulary did not properly account for common workers' compensation injuries and their treatment. By limiting the list of covered drugs under the formulary, the	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	Disagree. Commenter's statement: "By limiting the list of covered drugs under the formulary, the state is interfering in the patient-physician relationship, limiting	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	state is interfering in the patient-physician relationship, limiting a physician's ability to determine and prescribe appropriate treatment for an injured worker. A restrictive formulary, such as this proposal, forces the physician to either select a preferred drug from a small list simply because of its preferred status or risk delayed treatment for the injured worker.		a physician's ability to determine and prescribe appropriate treatment for an injured worker" is erroneous. The formulary regulations do not "limit covered drugs." All FDA-approved drugs, even those that are not listed on the MTUS Drug List, are available to the injured worker if medically necessary. Under the Labor Code, the MTUS treatment guidelines are presumed correct on the scope of necessary treatment, but additional treatment is available. Importantly for patient quality of care, the MTUS rules allow variance from the guidelines, and the ability to rebut the guidelines, where medically necessary. The following provisions of title 8, CCR, govern the criteria and method for substantiating treatment outside of the adopted guidelines: § 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the	

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			MTUS); § 9792.21.1 (medical evidence search sequence); § 9792.25 (quality and strength of evidence definitions); and § 9792.25.1 (MTUS methodology for Evaluating Medical Evidence).	
9792.27.14	The preferred drug list does not provide adequate preferred alternatives in the treatment of pain or neuropathy.	Nina Walker Applied Underwriters, Inc. April 10, 2017 Written Comment	Disagree with the statement that "the primary goal in developing the formulary is to reduce administrative burden and cost." This ignores the very important goal of encouraging provision of high quality evidence-based medical treatment. UR serves an important function by reviewing treatment for medical necessity. The MTUS treatment guidelines are presumed correct on the scope of treatment and UR can identify if the treatment is not in conformity. The Division recognizes the reduction of administrative burden and cost as one element of the formulary goals, and has	No action necessary.

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			structured the formulary to provide that specified drugs are "Exempt" from prospective review. The Division believes the regulations appropriately take account of the goals of improving the provision of evidence-based care and reducing administrative burden where possible.	
9792.27.14	The proposed formulary is quite limited as there are only 76 preferred drugs, and of those, only 24 of them are for pain indication. The medications are especially inconsistent with the current Chronic Pain Guidelines. For example, medications that are considered first line treatment for neuropathic pain in the Chronic Pain Guidelines (such as gabapentin) are listed as non-preferred.	Joyce Ho, M.D. Medical Director CompPartners, Inc. April 14, 2017 Written Comment	The MTUS Drug List is based on the ACOEM guidelines, including the ACOEM Chronic Pain Guideline. The Division has determined that it would be beneficial to have an integrated set of guidelines, and RAND has indicated that ACOEM utilizes a rigorous methodology to evaluate the medical literature and derive treatment recommendations. Tin the near future the Acting Administrative Director will be proposing to adopt updated ACOEM guidelines, and will hold a public hearing to receive input from the workers' compensation	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			community.	
9792.27.14	Additional medications deserve a "preferred drug" status. Commenter requests that additional medication be included in the formulary to protect patient health in urgent and/or non-controversial situations as described. Alternatively, they should be included as a special fill, and for antibiotics, as a perioperative fill: a) Blood borne pathogen exposure b) Soft-tissue infection complicating a work-related wound c) Acute gout complication a soft-tissue sprain/strain d) Severe hypertension complicating a workplace violence episode e) Nausea and vomiting complicating heat exhaustion f) Asthma exacerbation at work g) Deep vein thrombosis	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017 Don Schniske WOEMA May 1, 2017 Oral comment	Disagree. All medically necessary FDA-approved medications are available to the injured worker. The MTUS Drug List set forth in this section only includes drugs that are addressed in the ACOEM guidelines. The ACOEM treatment guidelines cover many of the most common workplace injuries, but do not address all conditions or illnesses that could be compensable under the workers' compensation system. In relation to the specific conditions set forth, the DWC responds as follows: a) Blood borne pathogen exposure constitutes an emergency situation that is not addressed by the ACOEM guidelines. The regulations specifically address blood borne pathogens. The proposed §9792.27.13 makes it clear that the MTUS Drug Formulary is not an obstacle to proper treatment under the	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			California occupational Bloodborne Pathogens standard and other applicable health and safety regulations. b) – (c) These are all conditions which warrant treatment on an emergency basis. As such, they would not require authorization through prospective review	
9792.27.14	There are nine medication listed as eligible for "Special Fill," and nine listed as eligible for "Perioperative Fill" for a total of fifteen drugs eligible for one or the other category (three drugs are listed for both). In each case, those fifteen drugs are shown as not to be so prescribed for more than 4 (four) days. The existing regulations require that the UR decision must respond to a Request for Authorization (RFA) within 5 (five) days. This leaves the fifth day uncovered for situations in which the drugs are truly necessary. The Division should either change the maximum to five days for consistency with the UR requirements, or acknowledge that in such situations an	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017	Disagree with the suggestion to increase the number of days supply allowed without prospective review beyond 4 days, except that the anticoagulants will be expanded to a 14 day supply. The CDC has stated that 3 days or less of opioids for acute severe pain would usually be adequate. If there is a situation that warrants more than a 4 day supply, and the physician has not obtained prospective review, the physician should seek an expedited review, or address the issue as an emergency if warranted. See the response	Modify the MTUS Drug List (which will be renumbered to §9792.27.15) to expand the anticoagulants to 14-day supply.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	expedited review will be necessary. If a significant increase in expedited reviews are expected, then preparations will be needed for an increase in such requests.		above to the comment of Stacey Wittorff, California Medical Association (CMA) May 1, 2017 regarding §9792.27.11.	
9792.27.14	Commenter is concerned regarding the designation of medications as being "Non-Preferred" yet both are recommended and non-recommended within MTUS. For the physician to understand the formulary requires both knowledge of the formulary, and reference to the MTUS for the clinical indication. The regulations, as currently written will lead to a number of challenges for prescribers.	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017	Disagree with the implication that listing a Non-Exempt drug as both recommended and non-recommended is problematic. The commenter notes the key to successful use of the MTUS formulary when he states "the mechanism for the physician to understand the formulary requires both knowledge of the formulary, and reference to the MTUS for the clinical indication". The MTUS treatment guidelines should be consulted to understand indications for the various drug and other treatments discussed and the clinician should then consider treatment options in light of the clinical facts of the case. The level of patient pain is a normal part of the physician's evaluation of the patient, and is taken into	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			consideration in determining the proper treatment. A treatment recommended for severe pain may not be recommended for minimal pain. The physician would document his or her findings in the clinical record, and consult the MTUS regarding treatment options for the condition and relevant clinical facts. The legend symbols in the "Reference in Guidelines" column of the MTUS Drug List are meant to provide a brief overview of the recommendations found within that Guideline.	
9792.27.14	Commenter recommends that the current drug list be modified to allow for therapeutic interchange. Commenter recommends consideration of usage of lower cost drugs when a particular drug is prescribed, but lower cost alternatives are available using the same active ingredient. Commenter notes that some brand name drugs will have multiple AB rated alternatives which	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. Therapeutic interchange should be considered as a refinement of the formulary in the future. It is listed as a topic for consideration by the P&T Committee, listed in proposed section 9792.27.21 (to be modified to section 9792.27.23.)	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	provides a selection of therapeutically equivalent drug choices. Commenter recommends requiring prospective review for drug products without AB rated substitutes when a broader drug product line is available to provide the same treatment.			
9792.27.14	Commenter recommends including over the counter (OTC) medication in the formulary.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	The MTUS Drug List is by active drug ingredient and some come in OTC forms. Disagree with mandating OTC versions of drugs at this time. This issue can be studied further to determine if it is a viable method to assure appropriate treatment that is cost effective. It would be beneficial for the Administrative Director to consult with the P&T Committee on this issue. It should be noted that OTC drugs are not always less expensive than the prescription version of the drug.	No action necessary.
9792.27.14	The drug list is confusing and difficult to utilize. The current drug list is formatted to indicate whether the	Robert Ward Clinical Director CID Management	Disagree. The MTUS Drug List is not a binary yes/no list, as it must be used in	No action necessary regarding the MTUS Drug List (which will

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	listed drugs are Preferred or Non-Preferred based body parts or regions, corresponding to the treatment guidelines adopted into the MTUS. Because an individual drug may be Preferred and/or Non-preferred and/or unlisted for different conditions within a guideline based on body parts, it is very difficult for a user of the formulary to be able to determine whether any specific drug is Preferred; Non-preferred; or unlisted for a treatment plan that is under consideration. If the DWC intends to institute a formulary where a drug may be Preferred, or Non-preferred, or unlisted; depending on the specific case for which it is to be dispensed; then it is recommended that the listing indicate at minimum for which conditions each medication is Preferred or Non-preferred. It should also be indicated that this approach creates the potential for meaningful disputes over how a specific drug should be classified for a specific case, and the proposed	Written Comment April 28, 2017	conjunction with the MTUS treatment guidelines. Labor Code section 5307.27 requires an evidence-based drug formulary to be included as part of the MTUS. The treatment guidelines are the critical backbone of the drug formulary as they provide the evidence-based recommendations for treatment of specified conditions and phases of care. These recommendations are derived through a robust process of literature review and cannot be ignored to achieve the goal of a "pragmatic" yes/no list. Injured worker health requires that the formulary be used in conjunction with the evidence-based MTUS treatment guidelines. The MTUS Drug List provides "Reference in Guidelines" to give a high level overview of which guidelines have recommendations for the drug. But that does not, and should not, replace consultation with	be renumbered 9792.27.15.) Regarding dispute resolution, the regulations will be modified to add a new section 9792.27.17 entitled "Formulary – Dispute Resolution."

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	regulations offer no suggestion as to who, or by what mechanism, such disputes are to be settled. One anticipates that in the absence of an established dispute mechanism for this situation, such dispute resolution will require the involvement of the WCAB. Alternatively, the DWC may wish to consider a drug list that simply indicates whether a drug is Preferred or Non-preferred, without any case-specific variance from that status. Although that approach is less "clinically robust" than the current proposal, that approach is more pragmatic.		the guidelines which have detailed recommendations. For example, a drug may be recommended as a first line treatment for a condition, but not recommended for someone with that same condition who also has gastrointestinal problems. In regard to dispute resolution, it is clear that disputes over what drug should be used for a specific patient are medical necessity disputes. In order to avert possible misunderstanding, the Division will modify the proposal to add a section which cross references to the medical necessity determination procedures – UR and IMR.	
9792.27.14	Commenter requests that the DWC maintain the proposed drug list in an electronic, downloadable format that can be used by all stakeholders to import into automated systems.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017	DWC plans to maintain the list in excel format. The commenter has not suggested any other specific formats.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		Written Comment		
9792.27.14	Commenter states that it is the experience of her organization's physician members who treat injured workers that the ACOEM Practice Guidelines generally tend to be less appropriate and lacking the flexibility and comprehensiveness necessary for the treatment of those workers whose injuries are non-acute, such as those with work-related chronic injuries and conditions, including chronic pain. After review of the proposed ACOEM formulary, which DWC has proposed for adoption, commenter states it is consistent with this experience. This formulary, in its focus on evidence based medicine (EBM), fails to consider a wide range of treatments that, while not necessarily meeting the rigorous standards for EBM, actually result in better outcomes for patients. Commenter has concerns that, in some instances, the application of the ACOEM formulary may result a delays in the provision of appropriate, effective medications such that the ability of the injured worker to return to work is delayed. DWC consider	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association (CMA) May 1, 2017 Written Comment	Disagree. The proposed MTUS Drug List is based on the ACOEM guidelines, including updated guidelines on Chronic Pain and Opioids. DWC is undertaking the statutory process to adopt those guidelines. The ACOEM guidelines are based on principles of evidence-based medicine and are created using sound methodology. The statute requiring adoption of a drug formulary into the MTUS specifies that the formulary use principles of evidence-based medicine. Labor Code §5307.27, subdivision (b) states: "On or before July 1, 2017, the medical treatment utilization schedule adopted by the administrative director shall include a drug formulary using evidence-based medicine. Nothing in this section shall prohibit the authorization of	No action necessary.

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	adopting a combination of the ACOEM formulary and the Official of Disability Guidelines (ODG) formulary.		medications that are not in the formulary when the variance is demonstrated, consistent with subdivision (a) of Section 4604.5." The RAND Report, page 26, states in pertinent part: "The ACOEM treatment guidelines utilize systematic reviews of published evidence, evidence-based multidisciplinary practice panels, stakeholder input, external review, and pilot testing to assess treatments for particular conditions. Particular drugs are rated based on the strength of the evidence for the given condition. Drugs may be recommended based on strong or even limited evidence for a given condition." DWC is moving away from a "patchwork" approach where the MTUS is based on a variety of guideline sources. The "patchwork" approach adds unnecessary complexity	

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			and costs to the system, and does not improve the quality of the MTUS. Importantly for patient quality of care, the MTUS rules allow variance from the guidelines, and the ability to rebut the guidelines, where medically necessary. The following provisions of title 8, CCR, govern the criteria and method for substantiating treatment outside of the adopted guidelines: § 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS); § 9792.21.1 (medical evidence search sequence); § 9792.25 (quality and strength of evidence definitions); and § 9792.25.1 (MTUS methodology for Evaluating Medical Evidence).	
9792.27.14	Commenter is concerned about the implementation of these regulations and the possible negative impact it will have on injured workers.	Mitch Seaman Legislative Advocate California Labor Federation	Disagree that the formulary will have a negative impact on injured workers. The formulary is expected to	No action necessary.

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		Oral Comment May 1, 2017	support the provision of high quality evidence-based care in accordance with the MTUS. Moreover, it will serve as an important tool in the effort to reign in the excessive use of hazardous medication such as opioids.	
9792.27.14	Commenter recommends revisions: "The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. (See 8 CCR §9792.20 - §9792.27.21) 'Reference in Guidelines' indicates guideline topic(s) which discuss the drug. In each guideline there may be one or more conditions for which the drug is Recommended (✓), Not Recommended (✕), and/or for which No Recommendation (⃠) applies. Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use."	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Disagree. The suggested revisions are not necessary. The language is clear as proposed.	No action necessary.

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9792.27.14	The formulary should have specificity to the GPI or GCN/NDC level for accurate implementation and consistency. DWC must present a formulary that is either: a. More specific in what data mapping should be done b. Is connected to an existing data structure that allows for NDC mapping Commenter recommends modifying the proposed regulations to add a published cross-walk, clearly identifying which specific drugs are "preferred" vs. "non-preferred" at the dispensing level, using a standardized nomenclature. Alternatively, predefined combinations of drug names and drug classifications would be much easier to implement and would facilitate consistency.	Lisa Anne Bickford Director, Workers' Comp Government Relations – Coventry May 1, 2017 Written Comment	Disagree. Disagree that a crosswalk using GCN/NDC or GPI is necessary to implement the regulation. The MTUS Drug List by active ingredient provides sufficient information needed to determine if a drug is exempt from prospective review or must be authorized through prospective review prior to dispensing. It is common for drug formularies to list the drug ingredient without NDC codes. The Division will consider adding NDCs or other identifiers as an enhancement to the list after further review and consultation with the P&T Committee. The MTUS Drug List will be modified to provide columns labelled "Dosage Form," "Strength," and "Unique Product Identifier(s)." The Unique Product Identifier will allow drug list updates to include a more granular identifier. NDC codes identify drug products at the level of the manufacturer,	Modify the section 9792.27.14 (which will be renumbered 9792.27.15) MTUS Drug List to include new column for "Unique Product Identifier" as a place holder for drug list updates. Also add "Unique Product Identifier" to section 9792.27.15 (which will be renumbered 9792.27.16.)

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			and are updated daily on the FDA website. The NDCs are included in published proprietary compendia of drug products, such as First Data Bank, Redbook, and Medi-Span. Pharmacies, Pharmacy Benefit Managers, electronic billing clearinghouses, all have access to the NDC level data as part of their business services. As currently proposed, the Administrative Director is not distinguishing between the manufacturer of the drug or the NDC code. Adopting the GPI or GCN would be problematic as GPI is proprietary to the Medi-Span compendium and GCN is proprietary to the First Data Bank compendium. Additionally, currently the MTUS Drug List does not differentiate the "exempt" vs "non-exempt" drugs based upon dosage form, strength, etc. which are included in the GPI or GCN identifier. Another option is the RxCUI	

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			(Rx Concept Unique Identifier.) When the drug list is updated to include identifiers based on dosage form and strength, the RxCUI may be preferable. It is created and maintained by the National Library of Medicine which as part of RxNorm, and is in the public domain. In addition, there are cross walks available so that entities can continue to use their drug compendium of choice (e.g., First Data Bank, Red Book, Medi-Span). The National Library of Medicine states: "RxNorm [which includes the RxCUI] provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software, including those of First Databank, Micromedex, MediSpan, Gold Standard Drug Database, and Multum. By providing links between these vocabularies, RxNorm can mediate messages	

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			between systems not using the same software and vocabulary." (https://www.nlm.nih.gov/research/umls/rxnorm/)	
9792.27.14 9792.27.15	Commenter recommends revising the proposed sections to create a NDC driven formulary in order to make the system more specific to everyone in the workers' compensation system	Don Lipsy First Script Network Services May 1, 2017 Oral Comment	See response above to comment of Lisa Anne Bickford, Director, Workers' Comp Government Relations – Coventry dated May 1, 2017.	See action described above in relation to the response to Lisa Anne Bickford comment of May 1, 2017.
9792.27.15	The section currently states that the Administrative Director may maintain and post a listing of NDC codes on the web site. The word "may" should be changed to "shall" to make sure that everyone has easy access to the NDC codes.	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. Use of NDC codes should not be mandatory. The MTUS Drug List sufficiently identifies the drugs by active ingredient. It is not necessary to have NDC level detail in the formulary regulations. The Division will continue to examine the inclusion of the pharmaceutical identifiers such as NDC or RxCUI, and will engage the Pharmacy and Therapeutics Committee on the issue. In addition, the Division will add headings for columns labelled "Dosage Form," "Strength," and "Unique	See action described above in relation to the response to Lisa Anne Bickford comment of May 1, 2017.

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			Product Identifier(s)" as possible enhancements to the list when the drug list is updated after consultation with the P&T Committee.	
9792.27.14; 9792.27.15	To reduce confusion and administrative delay in the treatment of injured workers, commenter requests that the regulations be amended to require an NDC code be contained within the formulary, ensuring that it is public knowledge and that providers and payers can pull the information from a single source.	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	See response above to comment of Lisa Anne Bickford, Director, Workers' Comp Government Relations – Coventry dated May 1, 2017. Additionally, see response above to comment of Rupali Das, MD, and Raymond Tan, PharmD, Zenith Insurance comment dated April 27, 2017.	See action described above in relation to the response to Lisa Anne Bickford comment of May 1, 2017.
9792.27.15	The wording in this provision should be changed from a "may" to a "shall". Having the DWC assign the appropriate NDC or GPI numbers to the medications on the MTUS drug list will help eliminate any confusion that might arise if a claims administrator and a physician disagree on how an NDC or GPI for a particular drug was determined.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	Disagree. See response above to comment of Rupali Das, MD, and Raymond Tan, PharmD, Zenith Insurance comment dated April 27, 2017.	See action described above in relation to the response to Lisa Anne Bickford comment of May 1, 2017.
9792.27.15	Commenter recommends revisions:	Joe Paduda, President CompPharma	Disagree. See response above to comment of Rupali Das,	See action described above in relation to

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	"(a) The Administrative Director ~~may~~ shall within six months of the effective date of this rule maintain and post on the DWC website a listing by NDC code of drug products that are embodied in the MTUS Drug List. ~~If posted, the listing will~~ The listing shall be regularly updated to account for revisions to the MTUS Drug list and for changes in drug products that are marketed for outpatient use." The information contained in the proposed drug list does not include the basic level data element of NDC. Being unable to tie a specific medication and treatment back to specific information provided by the NDC could create confusion and lead to delays in the processing of medications.	May 1, 2017 Written Comment	MD, and Raymond Tan, PharmD, Zenith Insurance comment dated April 27, 2017. In addition, in relation to the identification of extended release or immediate release, the "dosage form" includes those concepts. For example, the FDA approved Structured Product Labeling sets forth "SPL Acceptable Term" list to include, e.g. "Capsule," "Capsule, Extended Release," "Capsule, Delayed Release". In relation to topical vs. oral route of administration, the Division is not proposing to include "Route of Administration" on the MTUS Drug List. However, "dosage form" would provide useful information insofar as the FDA's Dosage Form Structured Product Label Acceptable Term list includes such dosage forms as "Cream," "Lotion," and "Ointment." (FDA Dosage Forms: https://www.fda.gov/forindustr	the response to Lisa Anne Bickford comment of May 1, 2017.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			y/datastandards/structuredproductlabeling/ucm162038.htm .)	
9792.27.15	Rather than incorporating specific NDC's into the formulary, simply excluding those dose forms may be a more effective option.	Nina Walker Applied Underwriters May 1, 2017 Written Comments	The Division will consider the issue of how the NDC, or other identifier, could be used most effectively to update the MTUS Drug List. See response above to comment of Lisa Anne Bickford, Director, Workers' Comp Government Relations – Coventry dated May 1, 2017.	See action described above in relation to the response to Lisa Anne Bickford comment of May 1, 2017.
9792.27.15	Commenter recommends the following new subsection (f): (f) Nothing in sections 9792.27.1 through 9792.27.21 shall preclude a claims administrator from disputing the reasonableness of the amount billed for any drug.	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Disagree. The suggested language is unnecessary. The reasonableness of the fee and the methods for disputing a bill are governed by Labor Code §§4603.2, 4603.4, 5307.1, and the regulations that implement those sections. There is nothing in the formulary regulations that casts doubt on a claims administrator's right to contest reasonableness of a bill.	No action necessary.
9792.27.15(a)	The proposed language should be amended to reflect the mandatory nature of this requirement.	Ben Roberts Executive Vice President and General	Disagree. See response above to comment of Rupali Das, MD, and Raymond Tan,	See action described above in relation to the response to Lisa

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	"The Administrative Director ~~may~~ **shall** maintain and post on the DWC website a listing by NDC code of drug products that are embodied in the MTUS Drug List."	Counsel PRIUM April 29, 2017 Written Comment	PharmD, Zenith Insurance comment dated April 27, 2017.	Anne Bickford comment of May 1, 2017.
9792.27.15(a)	Commenter recommends revisions: "The Administrative Director ~~may~~ shall maintain and post on the DWC website a listing by NDC code of drug products that are embodied in the MTUS Drug List. ~~If posted~~, the listing will be regularly updated to account for revisions to the MTUS Drug List and for changes in drug products that are marketed for outpatient use."	Kim Ehrlich Workers' Compensation Compliance Express Scripts May 1, 2017 Written Comment	Disagree. See response above to comment of Rupali Das, MD, and Raymond Tan, PharmD, Zenith Insurance comment dated April 27, 2017.	See action described above in relation to the response to Lisa Anne Bickford comment of May 1, 2017.
9792.27.18	Commenter recommends revisions: "(b) Persons applying to be appointed to the P&T Committee shall not have dispensed drugs to injured employees for outpatient use, nor have dispensed drugs to injured employees for outpatient use from their practice locations during twelve months prior to the appointment. A P&T Committee member who undertakes to dispense drugs during the term of the	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	Disagree. The suggested provision to prohibit any physician from serving on the P&T Committee if he/she has dispensed drugs to injured employees within the past year is not warranted. A physician is permitted to dispense medication to a patient for conditions being treated by the physician pursuant to Business and Professions Code §4170.	No action necessary.

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	appointment shall not be eligible to continue to serve on the committee.		Although there are some physicians who may be inappropriately exercising the prerogative to dispense medications, this does not justify a broad prohibition on serving on the P&T Committee for all doctors who dispense. In addition, the provision of subdivision (c)(2)(A) defining a substantial financial conflict of interest to include: "Receipt of income within the previous 12 months, amounting to a total of $500 or more from the pharmaceutical entity" could conceivably apply to some physician dispensing situations.	
9792.27.16 – 9792.27.20	Commenter is supportive of these provisions related to the P&T Committee. Caution is needed as it relates to conflicts of interest and to undue influence on the committee from outside groups who might lobby to get drug classifications changed or drugs added to the list.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment	DWC notes the commenter's support. Agree that it is important that the process be free of conflict of interest, and free from undue influence on the committee.	No action necessary.
9792.27.5;	These subsections of the proposed	Robert Blink, MD	The Division has determined	No action necessary.

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9792.27.6; 9792.27.7; 9792.27.8; 9792.27.10; 9792.27.11; 9792.27.12	regulations contemplate that "retrospective review" of a prescription for a drug might find that a prescription already filled was not "medically necessary" and therefore, payment denied. If the dispensing entity is not reimbursed for the medication, despite prospective assurances, it may lead to drug dispensers refusing to take part in filling workers' compensation prescriptions and that would be damaging to the entire drug formulary process. The division should address this potential problem in the proposed regulations.	President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017	that the provisions regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.) Additionally, commenter refers to a situation in which "the dispensing entity is not reimbursed for the medication, despite prospective assurances…." The proposed regulation sections that commenter cites all refer to situations in which required authorization through prospective review was *not* obtained before dispensing.	
9792.27.21	The proposed rule does not currently specify a time between the adoption of a change by the Administrative Director and when the change might become effective. It is important that for any adopted change that sufficient time is allowed between the adoption and the effective date of the change to allow for programming changes and	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault April 28, 2017 Written Comment May 1, 2017	Disagree. Labor Code §5307.29 subdivision (b) states that: 1) the changes to the drug formulary shall be made through an order exempt from the Administrative Procedure Act and Labor Code rulemaking procedures, and 2) the order shall inform the	No action necessary.

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	adequate communication to stakeholders. The only exception to this requirement would be the immediate removal of a drug due to a recall or change creating a potential safety risk for injured workers.	Oral Comment	public of the changes and their effective date. Since the statute gives authority for the order to specify the effective date, it is preferable not to set a mandatory timeframe in the regulation. This provides flexibility for setting the time period for implementation based on complexity of the update, urgency of implementing the changes, etc. The statute and regulations both specify that updates to the formulary are to occur no less frequently than quarterly. It is not advisable to provide more specificity, as the frequency of updates will depend upon many factors, including the number and types of new drugs entering the market, changes in approved usage of drugs, the availability of evidence-based evaluations of drugs, etc.	
9792.27.21	Commenter supports the provisions in this section to the extent they require the Administrative Director to consult with the P&T Committee on updates	Stacey Wittorff Legal Counsel Center for Legal Affairs	Disagree that a revision is needed to increase transparency by making recommendations public, as	The section number will be modified to 9792.27.23. Subdivision (a) will

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	to the MTUS Drug List. In order to further increase transparency, commenter requests that DWC make the recommendations made by the P&T Committee to the Administrative Director public and require the Administrative Director to provide a public response to any recommendation made by the P&T Committee that the Administrative Director does not adopt.	California Medical Association (CMA) May 1, 2017 Written Comment	that is already included in the regulations. Subdivision (e) of section 9792.27.20 of the original proposal (which will be renumbered 9792.27.22), requires the recommendations to be made public and posted on the Division's website. Disagree with the suggestion that the Administrative Director be required to provide a public response to the recommendations. The P&C Committee provides *consultation* to the Administrative Director pursuant to Labor Code section 5307.29; requiring a public response is not required by the statute and would not be helpful. Subdivision (a) will be modified to state that the Administrative Director will consult with the P&T Committee *as needed*. This modification will provide needed flexibility for the Administrative Director to make the most efficient use of	be modified to provide that the "Administrative Director shall consult with the P&T Committee <u>as needed</u> on updates…."

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			the P&T Committee, and to acknowledge that there may be situations where consultation is not warranted.	
9792.27.21(b)(4)	Commenter recommends revisions: "(4) Recommendations on establishing a therapeutic interchange program and a step-therapy process in order to promote safe and appropriate cost effective care."	Rupali Das, MD, MPH, FACOEM California Medical Director Raymond Tan, PharmD Director of Pharmacy Benefits Zenith Insurance Written Comment April 27, 2017	Disagree. It is not necessary to add this to the regulation text. The issue may be considered by the P&T Committee in the future under the language of subdivision (b): "the P&T Committee may provide consultation on a variety of relevant issues, including but not limited to the following…"	No action necessary.
General Comment	The proposed regulations create a potential unintended consequence of requiring the employer to conduct UR twice in order to dispute the medical necessity of some medications. This occurs in instances where the formulary regulations state that the provider may dispense medication without prior authorization, and that the employer may dispute the necessity of the medication on retrospective review. In some instances, it is implied that denial is	Robert Ward Clinical Director CID Management Written Comment April 28, 2017	First, the comment is moot as the Division has determined that the provisions regarding retrospective review should be removed from the formulary regulations. The procedures governing UR are contained in Labor Code §4610 and the implementing regulations (8 CCR §9792.6.1 et seq.) Second, there is no basis for commenter's claim that where a provider elects to seek	No action necessary.

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	only permitted on retrospective review; and in others this is explicit. In circumstances where the formulary states that the dispensing provider need not obtain prior authorization, the dispensing provider may still elect to seek such authorization. In each instance where the dispensing provider elects to seek prior authorization via DWC Form RFA, LC4610 and 8CCR9792.9.1 require that the claims administrator respond to the request within 5 business days. Any dispute of medical necessity would require UR. In the event that a denial of authorization for medication is issued through the UR process, the denial would appear to have no standing under the formulary regulations, and yet could still be challenged via the IMR process. Should the treating physician elect to proceed in spite of the prospective denial through UR, under the formulary regulations, the denied medication would still effectively be authorized unless and until the claims administrator obtained a UR denial		prospective authorization for an exempt drug, "the denial would appear to have no standing under the formulary regulations." If utilization review denies the medical necessity of the medication, there is nothing in the formulary rules which would override that UR determination.	

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	retrospectively.			
General	Could the diagnosis code be required for all prescriptions, regardless of preferred/non-preferred drug status? A decision based on MTUS guidelines cannot be made until the diagnosis is known.	Nina Walker Applied Underwriters May 1, 2017 Written Comments	Disagree to the extent that the diagnosis would be required to be on the prescription. The diagnosis code is not required to be on the prescription under the Business and Professions Code, and is not generally included by physicians. For the non-preferred ("non-exempt") drugs, the physician will need to provide a RFA and report which will contain the diagnosis code(s). Currently, many PBMs have a first fill policy that will come into play at the outset of an injury. These practices may continue once the formulary is instituted.	No action necessary.
General comment	Commenter applauds the Department of Industrial Relations' efforts to adopt an evidence based drug formulary that augments and expedites the provision of quality medical care, promotes improved outcomes for injured workers, and minimizes operational friction and cost. The	Alex Rossi, Chief Executive Office RMB Los Angeles County April 4, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.

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	formulary regulations (CCR 9279.27.1 through CCR 9279.27.18) lay the foundation to achieve these goals.			
General Comment	Commenter is supportive of the efforts by the Department of Workers' Compensation (DWC) to develop and implement a formulary and has observed that in other states that formularies can help reduce unnecessary and costly medications, support evidence based medical treatment, lessen administrative burdens, and help injured workers receive the treatment they need. The proposed formulary and regulations, which remain nearly identical to the pre-regulatory draft posted on the forum last year, would undercut much of the progress made in those areas within California.	Danielle Jaffee, Esq. Manager of Government Affairs IWP April 4, 2017 Written Comment	Disagree with the statement that the proposed formulary "would undercut much of the progress made" in reducing costs and supporting evidence-based medicine. The formulary regulations will enhance the use of the evidence-based treatment guidelines, and will provide a "fast track" for the medications identified as "exempt" from prospective review.	No action necessary.
General Comment	Commenter states that for a pharmacy benefits management organization, the California proposed formulary list of preferred/non-preferred drug would be extremely difficult to manage as she finds them difficult to follow and contradictory. Implementation of this formulary would compromise patient care, prolong disability, and ultimately drive up overall claim costs.	Nina Walker Pharmacy Benefits Administrator, Applied Underwriters, Inc. April 10, 2017 Written Comment	Disagree. The formulary regulations will support the provision of high quality evidence-based medical care in accordance with the MTUS guidelines. In addition, the regulations specifically provide support for the critically important goal of addressing the overuse of	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			highly risky opioid medications.	
General Comment	The establishment of a workers' compensation drug formulary in California has the potential to improve the quality of medical care for injured workers and reduce pharmacy costs in a number of areas, specifically in regards to the prescribing of opioids, non-generic medications and compounded topical medications, as has happened in other states. Commenter is pleased that the proposed chosen list of "preferred" medications is based on the evidence-based reviews contained in the Reed Group formulary, which has its' foundation in the ACOEM Practice Guidelines and their evidence-based methodology. The details of the implementation of the drug formulary are critical to ensuring that application of the formulary does not cause harm through delays in filling appropriately prescribed and sometimes time-critical medications, through decreases in patient compliance, or other factors.	Robert Blink, MD President Western Occupational & Environmental Medical Association (WOEMA) Written Comment Dated April 24, 2017 Received April 27, 2017 Don Schinske WOEMA Oral Comment	DWC notes the commenter's support. The DWC will be monitoring the effects of implementation of the formulary and will evaluate whether refinements are needed to support the provision of timely high quality medical care.	No action necessary. No action necessary.
General Comment	Commenter states that the crafting of	Robert Ward	DWC notes the commenter's	No action necessary.

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	formulary regulations is a complex and daunting task; those who have contributed to the proposed regulations have done well with the challenges.	Clinical Director CID Management Written Comment April 28, 2017	support.	
General Comment	Commenter notes that other states that have implemented a drug formulary have an education process in place to assist medical providers understand the new process. The Division should implement an education process to insure maximum effectiveness of implementation of these new rules.	Brian Allen, Vice President, Governmental Affairs Optum Workers' Comp and Auto No--- Fault May 1, 2017 Oral Comment	Agree that medical provider education is very important. The Division is planning to hold training sessions on the MTUS and the formulary.	No action necessary on the regulations. The Division is planning for post-adoption education of medical providers and other system participants.
General Comment	Commenter's focus when reviewing these proposed regulations is whether the adoption of this formulary and regulations will result in all injured workers having better access to appropriate and timely medical care or whether it will create additional barriers to the provision of this care. The DWC continues to adopt MTUS guidelines that focus on the treatment of workers with acute injuries, without adequate consideration of the medical needs of workers with chronic conditions or injuries. Commenter requests that the DWC reconsider its adoption of the American College of	Stacey Wittorff Legal Counsel Center for Legal Affairs California Medical Association (CMA) May 1, 2017 Written Comment	Disagree. The ACOEM Guidelines address all phases of care, including chronic conditions. The intent of the MTUS Drug List is to expedite provision of care for those drugs that are identified as Preferred (to be modified to Exempt), while still allowing other treatment where authorized through prospective review. For chronic conditions, there is adequate time to obtain prospective authorization to ensure treatment is in accordance with	No action necessary.

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	Occupational and Environmental Medicine (ACOEM) formulary and accompanying regulatory scheme in favor of an approach that better serves all injured workers.		the evidence-based guidelines, or other evidence-based recommendations (where the condition is not covered by the guidelines or if rebutting the guidelines.)	
General Comment	Commenter supports the provision of the highest quality and most effective medical treatment for injured workers. Commenter has concerns about whether this proposed Formulary meets the objectives of AB1124 to adopt a formulary that is based on nationally recognized evidence based guidelines. Commenter notes that the Preferred Drug List in the proposed formulary is restricted to only low cost, non-opioid prescriptions. The current proposal is neither linked to evidence based treatment guidelines nor any scientific literature or studies recommending these preferred drugs over others as an efficacious means of treatment for a particular medical condition or injury. Assigning the "non-preferred" label to so many drugs appears to be based solely on financial considerations and	Diane Worley California Applicant's Attorneys Association (CAAA) May 1, 2017 Written Comment Oral Comment	DWC notes the commenter's support. DWC disagrees with the remainder of the comments. The MTUS Drug List is based on the ACOEM guidelines, and must be used in accordance with the guidelines. It is intended to improve the provision of evidence-based medical care, and will help address the serious issue of the overuse, and abuse, of opioid medication. See also response to the comment of Stephen J. Cattolica, CSIMS dated May 1, 2017, regarding §9792.27.2 in relation to the "Preferred Drug List."	No action necessary. No action necessary.

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	will undoubtedly result in a stigmatization of those drugs by many carriers in their utilization review practices. There are no opioids listed as "preferred."			
General Comment	Commenter notes that as a growing number of states adopt workers' compensation drug formularies, ACOEM released a position paper on formularies in August 2016 that includes a recommendation to pay physicians for time they spend dealing with utilization review. Commenter recommends that the DWC take heed to ACOEM's recommendations when finalizing the regulatory process for the implementation of the MTUS drug formulary.	Diane Worley California Applicant's Attorneys Association (CAAA) May 1, 2017 Written Comment	This comment does not address the regulatory proposal, which is not related to physician fees. In the future, the DWC can consider whether fee adjustments are warranted.	No action necessary.
General Comment	This new language is a significant improvement over the prior version posted on the forum and continues to achieve key goals of a drug formulary as directed by AB 1124 (Perea, 2015).	Mitch Seaman Legislative Advocate California Labor Federation Written Comment May 1, 2017 Oral Comment	DWC notes the commenter's support.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General Comment	The following issues should be a priority for revising these proposed regulations: 1. Delay the implementation date. 2. Provide a definitive transition date for workers injured prior to July 1, 2017. 3. Disallowing payment of the drug in a RFA with sufficient supporting information is not timely received 4. Cost Containment of the proposed drug formulary.	CWCI Brenda Ramirez Denise Niber Claims and Medical Director Ellen Sims Langille General Counsel May 1, 2017 Written Comment	DWC responds as follows: 1) Agree, insofar as the proposed July 1, 2017 implementation date should be changed to January 1, 2018. 2) Disagree that there should be a definitive transition date as that would not comport with the MTUS which requires individualized treatment plan based on the injured worker's condition in light of the guidelines. The time period for transition cannot be standardized due to individual clinical considerations. 3) Disagree. See response above to comment of CWCI dated May 1, 2017 regarding §9792.27.5. 4) Disagree that the suggested cost containment measures should be adopted into the formulary regulations at this time. These suggestions require further evaluation. This would best be accomplished after the P&T Committee is convened so that criteria may be developed regarding	Modify implementation date to January 1, 2018. 2) through 4): No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			alternate dosage forms, new "unique" strengths, etc. in light of input from the P&T Committee.	
General Comment	In order to make the formulary work in the real world of workers compensation, more time is needed to properly understand how the formulary is supposed to work and to put the tools into place to properly do so. Labor Code Section 5307.27 (b), added by AB 1124, mandates that the formulary "include evidence-based, peer-reviewed, nationally recognized standards of care …" Furthermore, subparagraph (c) states that the formulary "shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary." The current formulary proposal falls far short with respect to both of these critical requirements. The formulary's recommendations are not based in	Stephen J. Cattolica Director of Government Relations CSIMS May 1, 2017 Written Comment	Agree, insofar as the proposed July 1, 2017 implementation date should be changed to January 1, 2018. Disagree with commenter's opinion that the regulatory proposal does not meet the statutory directive that the MTUS include evidence-based standards of care and include a phased implementation for workers injured prior to July 1, 2017. The DWC does intend to modify the proposal to include more detail regarding transitioning injured workers who are on a course of treatment with "non-preferred" (to be renamed "non-exempt") drugs. See also response above to the comment of	Modify implementation date to January 1, 2018. No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	evidence-base medicine as defined nor does the current proposal include a phased in implementation.		Stephen J. Cattolica, CSIMS dated May 1, 2017, regarding §9792.27.2 in relation to the "Preferred Drug List." See also response above to the comment of Danielle Jaffee, Esq., IWP, dated April 4, 2017 regarding §9792.27.3.	
General Comment	Commenter notes that ACOEM released a position paper on formularies in August 2016 that includes a recommendation to pay physicians for time they spend dealing with utilization review. =	Stephen J. Cattolica Director of Government Relations CSIMS May 1, 2017 Written Comment	This comment does not address the regulatory proposal, which is not related to physician fees. In the future, the DWC can consider whether fee adjustments are warranted.	No action necessary.
General Comment	Commenter appreciates linking evidence-based medicine, but he notes there is a fundamental problem that needs to be addressed by these regulations. The goal is to control bad behavior and not impact good behavior in relation to physician prescribing but also to UR companies. The plan to have some medications that are non-preferred, but could be recommended or not recommended by ACOEM guidelines is the fundamental flaw to these regulations.	Roman Kownacki Medical Director Kaiser Permanente's Occupational Health Program May 1, 2017 Oral Comment	The Division appreciates the commenter's acknowledgement of the intent to support evidence-based medicine. See response above to the comment of Robert Ward, CID Management dated April 28, 2017 regarding §9792.27.14. Also, it is important to note that the "prior authorization" provisions in utilization plans can provide that certain	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	The division should take more time to develop these proposed regulations to get them right the first time, so there will be no need to revisit this a year later in order to solve the problems that these regulations will create.		medical treatment may be provided without obtaining prospective authorization. To support this, the Division included a regulation to acknowledge "waiver of prospective review". This provision which was originally proposed in §9792.27.10, subdivision (f), will be moved to its own section (new §9792.27.11) to make it more prominent. The "prior authorization" provisions can reduce the need for prospective UR.	
General Comment (possibly 9792.27.10(b))	Commenter states that whenever doctors do not follow the MTUS, they are not going to get reimbursed/paid. Commenter states that this is problem for Pharmacy Benefit Management companies because doctors have already been paid, so that leaves the Pharmacy Benefit Management company not being reimbursed. Therefore, commenter is concerned this is not going to have the desired effect of stopping doctors from prescribing certain medications but could possibly result in more	Devin Motley MyMatrixx Workers' Compensation Pharmacy Benefits Manager May 1, 2017 Oral Comment	Agree that the Division intends to encourage best practices in prescribing medications, and adherence to the MTUS. Commenter has not suggested a solution to the issue they have raised. The Division notes that changes to Labor Code §4610 adopted by SB 1160 have consequences for physicians who have a pattern of prescribing outside of the MTUS, such as removal from the MPN.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 45 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Pharmacy Benefit Management companies leaving the workers' compensation system.			
General Comment	There needs to be more time and education needs to be provided to stakeholders in order to implement these proposed regulations. The Division should check in with stakeholders in four to six months in order to determine how the regulations are working and to address any problems in implementing this new drug formulary.	Mary Ellen Szabo Enstar Group Paladin Managed Care May 1, 2017 Oral Comment	The Division will move the implementation date to January 1, 2018. The Division will be monitoring the effects of the regulations over time and will take action as needed to improve the functioning of the formulary.	Move the implementation date to January 1, 2018.