MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.27.1 9792.27.15 9792.27.16	**The Definition of "Drug Ingredient" in the Draft Exempt Drug List Should Be Appended to Include a Cross-Walk to Allow System Participants to Identify Exempt Drugs at the Dispensing Level via NDC**	Lisa Anne Bickford Director, Workers' Comp Government Relations Coventry August 2, 2017 Written Comment	Disagree that a "crosswalk" using 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. NDC codes identify drug products at the level of the manufacturer, 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 proposed, the Administrative Director is not	No action needed.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			distinguishing between the manufacturer of the drug or the NDC code. Adopting the GPI would be problematic as it is proprietary to the Medi-Span 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 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 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	

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			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 between systems not using the same software and vocabulary." (https://www.nlm.nih.gov/research/umls/rxnorm/).	
9792.27.1(f)	Using the term "dispense" to describe both prescribing and dispensing is potentially problematic and is confusing. Recommends creating a distinction between "prescribe" when a prescription is issued to the patient to be taken to a pharmacy to fill and "dispense" when the physician provides the medication to the patient at the time of the office visit.	Alan E. Randle, MD Medical Director Allied Managed Care/AIMS July 21, 2017 Written Comment	Disagree. "Dispense" is not used to describe "prescribing". "Dispense" means the *furnishing* of drugs…. In subdivision (f)(1), the furnishing is "upon a prescription from a physician or other health care provider" and in subdivision (f)(2), the furnishing is "directly to a patient by a physician…."	No action necessary.
9792.27.1(h)	Section 9792.27.1(h) provides a	Lisa Anne Bickford	Disagree. It does not improve	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	definition of "Exempt Drug". In order to make the language more clear, the following additional phrase is suggested: "Exempt drug" means a drug on the MTUS Drug List which is designated as being a drug that does not require authorization through prospective review **as referenced in CCR Section 9792.6.1 *et. seq.*** prior to dispensing the drug, provided that the drug is prescribed in accordance with the MTUS Treatment Guidelines…."	Director, Workers' Comp Government Relations Coventry August 2, 2017 Written Comment	clarity to add the utilization review regulation citation in this definition. Adding the citation would add unnecessary verbiage to the sentence. The "prospective review" definition contains the reference to the utilization review regulations at section 9792.6.1 et seq., and provides clarity for anyone who is unclear on what is meant by "authorization through prospective review."	
9792.27.1(h)	Commenter recommends revisions: "(h) "Exempt drug" means a drug on the MTUS Drug List ~~which is designated as being a drug~~ that does not require authorization through prospective review prior to dispensing the drug, provided that the drug is prescribed in accordance with the MTUS Treatment Guidelines and does not otherwise require prospective review under the MTUS Drug Formulary. Exempt drugs are deemed "covered by the formulary" for	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Disagree that the suggested language should be adopted. Disagree. The concept of being "designated" should remain in the definition. Disagree. First, "compounded drugs" and "unlisted drugs" are not on the MTUS Drug List, nor designated as "exempt". Second, the suggested addition is not necessary in relation to	No action necessary. No action necessary. No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	purposes of prospective review in accordance with Labor Code section 4610(i)(1). The Exempt status of a drug is designated in the column with the heading labeled "Exempt / Non-Exempt."~~:~~ A minor typographical correction is recommended at the end of (h).		brand name drugs or physician-dispensed drugs as section 9792.27.10 (b) makes it clear that the regulations governing physician-dispensed drugs and brand name drugs apply. The proposed section states in pertinent part: "(a) The MTUS Drug List is set forth by active drug ingredient(s). (b) A drug that is identified as ~~"Preferred"~~ "Exempt" 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: (1) Brand name drugs are subject to section 9792.27.7; (2) ~~that p~~Physician-dispensed drugs are subject to section 9792.27.8." Agree.	Punctuation correction will be made.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.27.1(o)	(o)"Non-Exempt drug" means a drug on the MTUS Drug List ~~which is designated as~~ requiring authorization through prospective review prior to dispensing the drug, and is deemed "covered by the formulary" for purposes of prospective review in accordance with Labor Code section 4610(i)(1). The Non-Exempt Drug status of a drug is designated in the column labeled "Exempt / Non-Exempt."~~.~~		Disagree. The interpretation of "covered by the formulary" for purposes of implementation of the utilization review statutory provisions in Labor Code section 4610(i)(1) should be addressed in the utilization review regulations rather than the formulary regulations.	No action necessary.
	A minor typographical correction is recommended at the end of (o).		Agree.	Punctuation correction will be made.
	Recommends that surgery be defined so that zero day ("000") post-operative period procedures are specifically excluded from the Perioperative Fill policy.		The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day comment period.	No action necessary.
9792.27.1(k)	It is self-limiting to state an exact Federal or State Code as the codes change each year. Better to current state according to FDA, or California State Board of Pharmacy regulations and guidelines.	Robert P. Nickell Pharmacist July 31, 2017 Written Comment	Disagree. The proposed language provides more clarity for the public by providing the name and citation of the federal act that governs FDA approval of prescription and	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Recommends: " 'FDA approved drug' means a product manufactured and approved for sale by the FDA following all current FDA regulations and guidelines."		non-prescription drugs.	
9792.27.1(s)	Recommends that this definition include both "exempt" and "non-exempt" medications. If the Division intends to include both "exempt" and "non-exempt" drugs in the definition, it should be so stated.	Lesley Anderson, MD, Chair Workers' Compensation Committee, California Orthopaedic Association July 26, 2017 Written Comment	Disagree. The specific purpose of the Perioperative Fill is to allow a short course of the identified *Non-Exempt* drugs to be dispensed without prospective review. It would not be logically consistent to include Exempt drugs in the Perioperative Fill provision. Exempt drugs are exempt from prospective review pursuant to section 9792.27.10. Moreover, the Perioperative Fill has additional restrictions which do not apply to exempt drugs (number of days supply, dispensed during the perioperative period, etc.)	No action necessary.
9792.27.1(s) 9792.27.13(4)(b)	Recommends the following revised language: (s) "Perioperative Fill" means the	Jeremy Merz American Insurance Association	The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day comment	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	policy set forth in section 9792.27.12 allowing dispensing of identified Non-Exempt 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 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. (4)(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" **for a surgical procedure that has "010" or 10 Day Post-operative Period or has "090", or 90 Day Postoperative Period, 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.**	Jason Schmelzer CCWC Kevin McKinley California Chamber of Commerce August 3, 2017 Written Comment	period.	

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.27.1(s) 9792.27.1(x) 9792.27.12 9792.27.13	The regulations provide for "peri-operative" and "special" fills of hydrocodone, oxycodone, and morphine without the need for prospective UR with the only restriction being that the "supply not to exceed the number of days indicated." There should be some parameter of what an appropriate "supply" should be for the specific number of days to deter providers from dispensing an excessive or inappropriate dosage or amount of medication. Retroactive review does not help after the patient has already obtained medication and not paying for excess medication does not solve the problem.	Alan E. Randle, MD Medical Director Allied Managed Care/AIMS July 21, 2017 Written Comment	Disagree. There are several reasons that it is not advisable to try to define "supply not to exceed the number of days indicated" by imposing a maximum number of pills or dosage within the Perioperative Fill and Special Fill provisions. 1) Pharmaceutical usage falling within the Perioperative Fill and Special Fill must be consistent with the MTUS, which does provide the dosage guidance for certain medications. For example, the ACOEM guidelines address maximum recommended dosage for acute severe pain: "maximum recommended opioid dose for opioid naïve, acute pain patients should not exceed 50 mg MED…per day". 2) Patient characteristics (such as weight, age, co-morbidities) may impact the appropriate dosage; therefore it would be	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			difficult to establish parameters in the formulary regulations. 3) Physicians are subject to ethical and professional obligations to prescribe medically appropriate dosage and supply of medication. For a physician who is engaging in inappropriate prescribing, remedies exist such as through retrospective utilization review, through the Medical Board of California, or through fraud prosecutions where egregious prescribing rises to the level of a criminal violation.	
9792.27.1(u)	Commenter recommends adding the following new language at the end of this section: **All physicians treating within the workers' compensation system are presumed to have knowledge of the treatment guidelines, formulary and reporting requirements of this section.**	Jeremy Merz American Insurance Association Jason Schmelzer CCWC Kevin McKinley California Chamber of Commerce	Disagree. Physicians treating injured workers should be aware of and comply with all of the laws and regulations that govern treatment of injured workers. Lack of knowledge of the legal requirements does not excuse failure to comply with the requirements. Moreover, establishing a	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
		August 3, 2017 Written Comment	presumption that the physicians have knowledge of the guidelines, formulary and reporting requirements would not have an effect on whether physicians actually do have such knowledge, which is important for patient care.	
9792.27.1(x)	Questions why the Division removed the definition of "retrospective review," formerly subsection (x).	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Disagree. The definition of "retrospective review" was removed as it is not a term used in the formulary regulations. The utilization review regulations govern retrospective review.	No action necessary.
9792.27.1(x) 9792.27.12	Recommends that this definition be modified to include "exempt" and "non-exempt" medications. Recommends that the Division consider language to allow for the "Special Fill" to be covered within "7 days of the initial visit to the physician" not the initial date of injury.	Lesley Anderson, MD, Chair Workers' Compensation Committee, California Orthopaedic Association July 26, 2017 Written Comment	Disagree. The specific purpose of the Special Fill is to allow a short course of the identified *Non-Exempt* drugs to be dispensed without prospective review at the outset of an injury. It would not be logically consistent to include Exempt drugs in the Special Fill provision. Exempt drugs are exempt from prospective review pursuant to section 9792.27.10. Moreover,	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			the Special Fill has additional restrictions which do not apply to exempt drugs (number of days supply, prescribed at the single initial visit following injury, etc.)	
9792.27.1(y)	Recommends that the DWC define "surgery" for purposes of the Perioperative Fill policy. "(y) "Surgery" means any surgical procedure that has "010" (ten Global Days) or "090" (ninety Global Days) listed for its reimbursable CPT code as found in the Medicare National Physician Fee Schedule Relative Value File incorporated into the Official Medical Fee Schedule."	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day comment period.	No action necessary.
9792.27.2(b)	Supports the delay in implementation date to January 1, 2018.	Stacey Wittorff Legal Counsel California Medical Association July 28, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
9792.27.2(b) 9792.27.3(a) 9792.27.3(b)	Requests that the Division consider retaining a fixed, six-month implementation period regardless of when that six-month period starts or	Steve Cattolica ADVOCAL August 2, 2017 Written Comment	Disagree. It is important to implement the drug formulary as soon as possible to enhance the provision of medically	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	ends.		appropriate care to injured workers. A six-month delay is not needed for implementation.	
9792.27.3	Supports the new language which addresses injured workers who may need to be transitioned from non-exempt medications. The submission timeframe for progress reports within 45 days of the last office visit or no later than April 1, 2018 are reasonable and appropriate.	Sandy Shtab AVP, Advocacy and Compliance HealtheSystems August 2, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
9792.27.3	DWC should heed ACOEM's August 2016 position paper's recommendations when finalizing the regulatory process for the implementation of the MTUS drug formulary, including a recommendation to pay physicians for time they spend dealing with utilization review.	Diane Worley California Applicants' Attorneys Association August 2, 2017 Written Comment	The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day comment period.	No action necessary.
9792.27.3	Applauds the additional language in section 9727.27.3 requiring that the physician submit an RFA along with either a treatment plan to safely transition patients to the MTUS Drug Formulary or, alternatively, a report justifying the continued use of Non-	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017	DWC notes the commenter's support for additional language in section 9792.27.3.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Exempt drugs. However, there is concern that in the absence of consequences for the physician's failure to comply, this regulatory requirement becomes merely optional.	Written Comment	Disagree that the formulary regulations should address a physician's failure to comply. Disagree that the regulatory requirement becomes "merely optional." There are already mechanisms in place to address the failure to comply with the physician's obligations. 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	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			review quality of care and performance of medical personnel, utilization of services and facilities, and costs."	
9792.27.3	DWC should heed ACOEM's August 2016 position paper's recommendations when finalizing the regulatory process for the implementation of the MTUS drug formulary, including a recommendation to pay physicians for time they spend dealing with utilization review.	Steve Cattolica ADVOCAL August 2, 2017 Written Comment	The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day comment period.	No action necessary.
9792.27.3(a)(3)	Requests that the timeframe for physicians to supply a progress report justifying the need to continue non-exempt drugs be shortened from April 1, 2018 to February 1, 2018.	Edward E. Canavan VP Workers' Compensation Practice and Compliance Sedgwick Claims Management Services, Inc. August 2, 2017 Written Comment	Disagree. The Division is very concerned about the adverse effects of high risk pharmaceuticals such as opioids, and the interaction with other high risk drugs such as benzodiazepines. However, it would not be beneficial to move the deadline for submitting the transition plan to February 1, 2018. The normal timeframe for progress reports is no less than every 45 days during ongoing treatment,	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			and ideally most physicians will submit the report on time without delay. Updated treatment guidelines, including Opioid guideline, are currently proposed to take effect on January 1, 2018. It is prudent to extend the time for submitting a treatment plan as specified in §9792.27.3(a)(3) in order to assure physicians have adequate time to familiarize themselves with the formulary rules, the updated treatment guidelines, and to prepare the report and RFA.	
9792.27.3(b)	As proposed, this section continues to prescribe a transition plan contrary to the legislative intent of AB 1124. Subsection (b)(4) allows immediate denial if the MTUS (current or updated) does not call for use of the standing therapy. Likewise, if the treating physician's report and accompanying documentation (subsection (b)(A)) is not up to a utilization reviewer's satisfaction, the same issues will arise	Steve Cattolica ADVOCAL August 2, 2017 Written Comment	Disagree. Proposed subdivision (b)(4) does NOT allow immediate denial if the MTUS does not call for the therapy. The proposed language states: "Previously approved drug treatment shall not be terminated or denied except as may be allowed by the MTUS **and** in accordance with applicable utilization review and independent medical review regulations."	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	as exist today - the same issues that the formulary was meant to alleviate. <u>The DWC is obligated to provide for a transition period of some predictable length of time for an alternative to be decided</u>.		[Emphasis added.] This does not allow immediate termination of treatment that does not conform to the MTUS. It specifically states that treatment can only be denied in accordance with the UR regulations and IMR regulations, which provide a process before treatment could be terminated. Disagree. There is nothing in the regulation that suggests that "the injured worker will go without until an alternative is found." It is unclear what the commenter is suggesting by stating that there should be a "predictable length of time for an alternative to be decided." Timeframes for submitting a progress report, RFA, and treatment plan, and for conducting UR and IMR are set forth in regulations and are thus "predictable."	No action necessary.
9792.27.3(b)(1)	Opposes the DWC's proposed deletion of this language from the	Stacey Wittorff Legal Counsel	Disagree. The regulation is improved by the new language	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	originally proposed 8 C.C.R. §9792.27.3(b)(1), as it will weaken protections for injured workers.	California Medical Association July 28, 2017 Written Comment	which states that "Previously approved drug treatment shall not be terminated or denied except as may be allowed by the MTUS and in accordance with applicable utilization review and independent medical review regulations." The originally proposed language, by stating that the "claims administrator shall not unilaterally terminate or deny previously approved drug treatment" was incomplete as it did not take recognition of the utilization review and independent medical review processes that are applicable to terminating or denying treatment.	
9792.27.3(b)(2)	Section 9792.27.3(b)(2) addresses submission by the treating physician of a report addressing continued use of Non-Exempt medication. In order to clarify the provisions contained therein, the following additional language is suggested: "If the injured worker with a date of	Lisa Anne Bickford Director, Workers' Comp Government Relations Coventry August 2, 2017 Written Comment	Disagree. Adding the phrase "to the Claims Administrator" would not improve the clarity of the regulation and would add unnecessary verbiage. Transmission of a physician report, including the identity of the recipient of the physician's report, is governed by title 8,	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	injury prior to January 1, 2018 is receiving a course of treatment that includes a Non-Exempt drug, an unlisted drug, or a compounded drug, the physician shall submit a progress report to the Claims Administrator issued pursuant to section 9785 and a Request for Authorization that shall address the injured worker's ongoing drug treatment plan".		section 9785. For example, see section 9785, subdivision (c): "The primary treating physician, or a physician designated by the primary treating physician, shall make reports to the claims administrator as required in this section. A primary treating physician has fulfilled his or her reporting duties under this section by sending one copy of a required report to the claims administrator. A claims administrator may designate any person or entity to be the recipient of its copy of the required report."	
9792.27.3(b)(2)	The provision states that the physician must submit a progress report and an RFA that addresses the treatment plan, includes a weaning plan or provides documentation to substantiate medical necessity. However, under (b)(3), the this submission is due no later than April 1, 2018 if it is not "feasible" to submit it sooner. This creates a disruption in the normal flow of status reports on files that have been opened.	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Disagree. The normal timeframe for progress reports under section 9785 is no less than every 45 days during ongoing treatment; ideally most physicians will submit the report on time without delay. Updated treatment guidelines, including Opioid guideline, are currently proposed to take effect on	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	It is appropriate to allow time for weaning; however, progress reports and RFAs for continued medications should be required to be submitted timely and not delayed for a 3-month period to accommodate a weaning program. A special exception should not be made for Non-Exempt, unlisted drugs or compounded drugs. Language is recommended to require timely progress reports on the current schedule.		January 1, 2018. It is prudent to extend the time for submitting a treatment plan as specified in §9792.27.3(a)(3) in order to assure physicians have adequate time to familiarize themselves with the formulary rules, the updated treatment guidelines, and to prepare the report and RFA. In addition, there may be very little time between the effective date of the formulary regulations and the next regular due date for a progress report, depending on the reporting schedule established for that patient. It is therefore preferable to allow the report, treatment plan, and RFA to be submitted by April 1, 2018 if the normal timeframe is not feasible.	
	Recommends revision to (b)(2): "safe" should be changed to "medically appropriate" since that ties more closely with clinical practice and medical necessity. The progress report shall "[i]nclude a		Agree. The term "medically appropriate" is preferable; the term "safe" is too narrow as it only encompasses one aspect of a treatment plan.	Modify language by substituting "medically appropriate" for "safe".

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	treatment plan setting forth a ~~safe~~ medically appropriate weaning, tapering, or transitioning of the worker to a drug pursuant to the MTUS.~~, or~~" Also, in (b)(4), recommends using the term "authorized" for consistency with other sections. Language suggested: "(4) Previously ~~approved~~ authorized drug treatment shall not be terminated or denied except as may be allowed by the MTUS and in accordance with applicable utilization review and independent medical review regulations, including weaning, tapering, or transitioning the worker to another drug when medically necessary and safe to do so."		Disagree. "Approved" is preferable to "authorized." Treatment may have been "approved" by a means other than prospective authorization, for example if the drug treatment was not formally authorized through prospective utilization review, but was "approved" upon retrospective review. "Authorization" is defined in title 8, CCR §9792.6.1(a) in part as follows: "Authorization" means assurance that appropriate reimbursement will be made for an approved specific course of *proposed* medical treatment to cure or relieve the effects of the industrial injury pursuant to section 4600 of the Labor Code…" [Emphasis added.] Where an injured worker is on an ongoing course of drug treatment that has not been	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			"authorized", but has been approved (for example, on retrospective review), the treatment should not be terminated or denied except as may be allowed by the MTUS and in accordance with applicable utilization review and independent medical review. The language suggested at the end of (b)(4) ("including weaning…" does not fit grammatically with the sentence, and is unnecessary.	No action necessary.
9792.27.3(b)(2) 9792.27.3(b)(3)	Commenter suggests modifying the proposed rules to specify what course of action the Claims Examiner should take in the event that § 9792.27.3(2)(b)(3) documentation requirements are not met by the treating physician and what action is to be taken in the event that the mandatory prospective reviewed sections is not obtained.	Lisa Anne Bickford Director, Workers' Comp Government Relations Coventry August 2, 2017 Written Comment	Disagree. The usual remedies to address a physician's failure to submit a treatment plan or ongoing progress reports, or to obtain authorization through prospective review are applicable. It is not necessary to establish additional systems for handling these lapses by the physician. See response above to the comment of Denise Niber, Claims & Medical Director, California	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
			Workers' Compensation Institute (CWCI), August 2, 2017.	
9792.27.3(b)(2)(A) 9792.27.3(b)(2)(B) 9792.27.3(b)(3)	Is concerned with the requirement in this subsection that doctors submit a progress report with a treatment plan and RFA no later than April 1, 2018. Robust education programs for the provider community to learn the new formulary rules are essential. It is doubtful that significant physician education efforts by the DWC will be in effect by January 1, 2018.	Diane Worley California Applicants' Attorneys Association August 2, 2017 Written Comment	Disagree. Physicians are already required to submit a report no less frequently than every 45 days (title 8, CCR §9785). With the target effective date of the formulary regulations 1/1/2018, the April 1, 2018 deadline for a report doubles the usual allotted time allowed. Moreover, the Division is planning an educational program for the public, including treating physicians, to begin shortly after the regulations are filed with the Secretary of State.	No action necessary.
9792.27.3(b)(2)(B)	A minor typographical correction is recommended. "(b)(2)(B) Provide supporting documentation, as appropriate, to substantiate the medical necessity of, and to obtain authorization for, the Non-Exempt drug, unlisted drug, or compounded drug, pursuant to the MTUS (via guidelines, Medical	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Agree.	Punctuation correction will be made.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	Evidence Search Sequence, and/or Methodology for Evaluating Medical Evidence-)." "			
9792.27.3(b)(3)	Recommendation: (b)(3) The progress report, including the treatment plan and Request for Authorization provided under this subdivision, shall be submitted at the time the next progress report is due under section 9785(f)(8), however, if that is not feasible, no later than April 1, 2018. If a physician fails to submit the documents required under this subdivision, 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; further, reports from the physician shall not be admissible and the physician's treatment bills shall not be reimbursable until the documents required under this subdivision are received by the claims administrator.		Disagree (b)(3). The usual remedies to address a physician's failure to submit a treatment plan or ongoing progress reports, or to obtain authorization through prospective review are applicable. It is not necessary to establish additional systems for handling these lapses by the physician. See response above to the comment of Denise Niber, Claims & Medical Director, California Workers' Compensation Institute (CWCI), August 2, 2017.	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
9792.27.3(b)(4)	The current draft of the regulations contains **no** timeframe for a worker to be allowed to transition from a non-formulary drug to a formulary drug. As an alternative to a two year phased implementation date, commenter recommends language from LC 4616.2 (d) (3) (B) regarding continuity of care for serious and chronic conditions to serve as an established model for a safe transition period to formulary drugs. Modified language for proposed § 9792.27.3(b)(4) follows: "Previously approved drug treatment shall not be terminated or denied for a period of time necessary to complete a course of treatment and to arrange for a safe tapering and weaning plan as recommended by the treating physician. Drug treatment approved before implementation of the MTUS drug formulary may not be terminated based on the MTUS or in accordance with applicable utilization review and independent medical review regulations until a safe tapering and weaning treatment plan has been in	Diane Worley California Applicants' Attorneys Association August 2, 2017 Written Comment	Disagree. The formulary regulations should not govern the timeframe for transitioning from Non-Exempt drugs to drugs in accordance with the MTUS. The medical necessity of medications for chronic conditions is already address by the MTUS guidelines. Any medical need for transition from one medication to another is specified in the guidelines and would be applied on a case-by-case basis per the MTUS. It would not be possible to standardize the time for transitioning to a safer drug, as each patient circumstance must be considered in crafting a treatment plan. This is the responsibility of the physician. There is no basis for mandating a minimum 12 month plan. Safe tapering and weaning is addressed in the MTUS evidence-based guidelines in great detail, may be subject to update depending on the medical evidence, and	No action necessary.

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	effect for 12 months."		are not appropriately addressed in these formulary regulations.	
9792.27.3(b)(5)	Notes that the reference in this subsection to "section 9792.6.1 et seq." is vague, as the abbreviation "et seq." is used to signify sections that follow the delineated section. Recommends the deletion of this abbreviation and that the DWC instead identify the specific sections it intends to reference here.	Stacey Wittorff Legal Counsel California Medical Association July 28, 2017 Written Comment	Disagree. The reference is to the applicable utilization review regulations which begin at section 9792.6.1. There is nothing vague about this. The public is put on notice that reference is made to all applicable UR regulations. This is sufficiently clear presently, and will also ensure that the reference does not become out of date as the UR regulations are revised in the future.	No action necessary.
9792.27.3(c)	States that the transition process described in section is well crafted; however, remains concerned that there are no consequences should the primary treating physician fail to comply with the process. States that this section should also delineate the consequences for failing to comply with the transition process.	Jeremy Merz American Insurance Association Jason Schmelzer CCWC Kevin McKinley California Chamber of Commerce August 3, 2017 Written Comment	Disagree. See response to comment of Denise Niber, Claims & Medical Director, California Workers' Compensation Institute, August 2, 2017, above.	No action necessary.

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9792.27.4	Commenter recommends inserting a comma between "pharmacy benefit manager" and "or pharmacy network" in order to promote clarity.	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Agree.	Modify punctuation by adding two commas to improve clarity.
9792.27.8	Commenter recommends the following language for subsection (b): "(b) If a physician prescribes and dispenses a drug at specific (unique) 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 and that the lower cost alternatives do not achieve the same medical necessity. The physician must obtain authorization through prospective review prior to the time the drug at the more costly dosage	Jeremy Merz American Insurance Association Jason Schmelzer CCWC Kevin McKinley California Chamber of Commerce August 3, 2017 Written Comment	Disagree. 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 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	No action necessary.

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	strength is dispensed. If required authorization through prospective review is not obtained prior to dispensing the more costly dosage strength, payment shall be withheld." Appreciates the updates to this section relative to the Pharmacy Benefit Networks that thoroughly addressed his prior concern.		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 would detract from patient care. The Division is exploring other options for a more tailored response to the problem. DWC notes the commenter's support.	No action necessary.
9792.27.8(b)	This subsection allows a physician to dispense a 7 day supply of an Exempt drug at the time of an initial visit that occurs within 7 days of injury. Subdivision (d) allows networks to determine whether the network will allow office dispensing or not.	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Agree in part. Agree that the language referencing "Pharmacy Benefit Network" should be revised to better align with Labor Code §4600.2, because that section recognizes a variety of	Modify proposed language so that it references "pharmacy benefit" contract pursuant to subdivision (a) of Labor Code section

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	Recommends that if the network does not allow office dispensing, the network should also be permitted to limit the initial dispensing of an Exempt drug to a 7 day supply when it is not clear the Exempt drug is consistent with MTUS Treatment Guidelines per Section 9792.27.6(a).		pharmaceutical contracts, not just "network" contracts. However, disagree with the suggested language as it is too unwieldy.	4600.2, rather than "Pharmacy Benefit Network" contract
	Commenter recommends revisions: "(d) Nothing in this Article shall permit physician dispensing where otherwise prohibited by a ~~Pharmacy Benefit Network contract~~ self-insured employer, group of self-insured employers, insurer of an employer, or group of insurers contracts with a pharmacy, a group of pharmacies, or pharmacy benefit network pursuant to subdivision (a) of Labor Code 4600.2. When office dispensing is prohibited, the self-insured employer, group of self-insured employers, insurer of an employer, or group of insurers contracted with a pharmacy, a group of pharmacies, or pharmacy benefit network may require the physician to modify the prescription to allow an up-to-seven-day supply of an Exempt drug subject to authorization to be		Disagree with remainder of comment. Subdivision (d) acknowledges that a pharmacy benefit contract between the employer/insurer may specify the "manner" for providing pharmaceuticals to workers subject to the contract. Thus the pharmacy benefit contract could provide "all pharmaceuticals shall be dispensed by X Pharmacy," which would mean the pharmaceuticals would not be dispensed by a physician. However, the language commenter suggests strays into the area of medical necessity determination by stating that a contract limiting physician dispensing could also require a	No action necessary.

MTUS DRUG FORMULARY	RULEMAKING COMMENTS 1st 15 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	dispensed by a pharmacy following an initial visit that occurs within 7 days of the date of injury."		physician to "modify" a prescription to "to allow an up-to-seven-day supply of an Exempt drug" The pharmacy network contract cannot limit the use of a medication on the basis of medical necessity, the UR/IMR processes must be used to determine consistency with the MTUS.	
9792.27.8(b)	Recommends that consideration be given regarding physician dispensing and the ability to direct dispense a seven day supply unfettered. "(b) A physician may dispense up to a **three-day** supply of one or more drugs that are designated as Exempt in the MTUS Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Treatment Guidelines and the up-to-**three-day** supply is dispensed at the time of an initial visit that occurs within 7 days of the date of injury. **Any duration longer than a three-day supply shall be subject to prospective review and the**	Edward E. Canavan VP Workers' Compensation Practice and Compliance Sedgwick Claims Management Services, Inc. August 2, 2017 Written Comment	Disagree. There is nothing in the regulations that gives a physician "the ability to direct dispense a seven day supply unfettered" of opioids. Opioids are designated as "Non-Exempt" and require authorization through prospective review prior to being dispensed. A seven-day supply of an "Exempt" drug may be dispensed by a physician; none of the opioid drugs are designated as "Exempt." Some opioids are allowed as a "Special Fill" or "Perioperative Fill", but these are restricted to a 4-day supply.	No action necessary.

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	pharmacy formulary."			
9792.27.9(b)	Notes that this subsection has not been modified during this comment period. There is an error in subsection (b) that requires modification in order to be consistent with Labor Code 4600.2. This subsection focuses on Medical Provider Networks. Recommends the following change to make this section consistent with Labor Code 4600.2(a): (d) Nothing in this Article shall permit physician dispensing where otherwise prohibited by a ~~Pharmacy Benefit Network contract~~ self-insured employer, group of self-insured employers, insurer of an employer, or group of insurers contracts with a pharmacy, a group of pharmacies, or pharmacy benefit network pursuant to subdivision (a) of Labor Code 4600.2.	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Agree in part. Agree that the language referencing "Pharmacy Benefit Network" should be revised to better align with Labor Code §4600.2, because that section recognizes a variety of pharmaceutical contracts, not just "network" contracts. However, disagree with the suggested language as it is too prescriptive and could create unintended exceptions.	Modify proposed language so that it references "pharmacy benefit" contract pursuant to subdivision (a) of Labor Code section 4600.2, rather than "Pharmacy Benefit Network" contract.
9792.27.10(b)(3)	Commenter recommends the following proposed language: (3) Compounded drugs are subject to section 9792.27.9 even if one or more of the ingredients is listed as "Exempt" on the Drug List.	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017	Agree that the suggested language would be appropriate as clarifying language.	Modify §9792.27.10, subdivision (b), to include a new (b)(3). Adopt suggested language, but add: "MTUS" Drug List.

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		Written Comment		
9792.27.12 9792.27.17	Notes the proposed regulations contemplate that "retrospective review" of a prescription for a drug might find that a prescription already filled was not "medically necessary" and thus payment could be denied. If the dispensing entity is ultimately not paid despite prospective assurances, then dispensers may reasonably refuse to take part in filling any workers' compensation prescriptions, badly damaging the whole formulary enterprise. Commenter states that this situation must be avoided, and requests that the DWC address this problem explicitly.	Robert Blink, MD President WOEMA August 2, 2017 Written Comment	Disagree. The definition of "retrospective review" was removed as it is not a term used in the formulary regulations. The utilization review regulations govern retrospective review. In addition, see previous detailed answer to Rupali Das, MD, Zenith Insurance comment dated July 28, 2017, with respect to prospective review and payment authorizations.	No action necessary.
9792.27.12	Additional medications deserve a place on the formulary as "Exempt" in appropriate situations. In particular, those listed in ACOEM's "Drug Formularies in Workers' Compensation Systems" (August 2016), Section G, should be strongly considered for inclusion in order to protect patient health in urgent and/or non-controversial situations.	Robert Blink, MD President WOEMA August 2, 2017 Written Comment	The comment does not address the substantive changes made to the proposed regulations during the 15-day comment period. (Also, the Division has responded to this same comment submitted during the 45 day comment period. See prior response.)	No action necessary.

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	In addition to the ACOEM recommendations, the Washington Worker's Compensation Drug formulary has a more expansive list of medications that should be readily available to injured workers.			
9792.27.12	Is concerned regarding the designation of medications as being "Non-Exempt" yet both recommended and non-recommended within MTUS. The mechanism for the physician to understand the formulary requires both knowledge of the formulary, and reference to the MTUS for the clinical indication. States that this will lead to a number of challenges for prescribers.	Robert Blink, MD President WOEMA August 2, 2017 Written Comment	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	No action necessary.

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			the physician's evaluation of the patient, and is taken into 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.	
9792.27.12(a) 9792.27.12(b)(4)	Commenter recommends the following revised language: (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-Exempt," will be allowed without prospective	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Disagree. See the above response to comment of Alan E. Randle, MD, Medical Director, Allied Managed Care/AIMS, July 21, 2017. In addition, adding the suggested language is not advisable for the following	No action necessary.

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	review as specified in subdivision (b). (b)(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines~~.~~; and (5) The Special Fill supply does not exceed the maximum recommended daily dose, as applicable, in the FDA-approved label and/or prescribing information.		reasons. 1) It is unnecessary, as physicians would already be expected to observe dosage maximums on FDA-approved label 2) In particular cases, the FDA-approved label maximum may be excessive for the particular patient. 3) It may be confusing and distract from the MTUS Guidelines recommendations. FDA-approved label maximum may conflict with the MTUS Guideline, e.g. "maximum recommended opioid dose for opioid naïve, acute pain patients should not exceed 50 mg MED…per day."	
9792.27.13(a)(4)	Commenter recommends the following revised language: "(a)(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines~~.~~; and (5) The Perioperative Fill supply does not exceed the maximum recommended daily dose, as	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Disagree. See the above response to comment of Alan E. Randle, MD, Medical Director, Allied Managed Care/AIMS, July 21, 2017. See above response to the comment of Denise Niber, Claims & Medical Director,	No action necessary.

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	applicable, in the FDA-approved label and/or prescribing information."		California Workers' Compensation Institute (CWCI), August 2, 2017 regarding section 9792.27.12.	
9792.27.15	Recommends that DWC amend the MTUS Drug List's introductory language with regard to perioperative fills to reflect the proposal that the perioperative period be extended to four days before through four days after surgery, rather than two days before through four days after surgery. Recommends that the DWC clarify how certain medications listed as available without prospective review for a fourteen day period will be treated, as this period is inconsistent with the regulations that limit perioperative fills to a shorter period.	Stacey Wittorff Legal Counsel California Medical Association July 28, 2017 Written Comment	Agree that MTUS Drug List Introductory language should be consistent with the regulatory text. The inadvertent oversight of making conforming changes to the introductory language will be corrected. Disagree. There is no inconsistency between the MTUS Drug List and the regulatory text. The regulatory text states that the perioperative fill will be available without prospective review for no more than the number of days specified on the MTUS Drug List. For anticoagulants, the MTUS Drug list specifies 14-day supply.	Modify the introductory language to indicate that the beginning of the perioperative period commences 4 days, rather than *2 days*, prior to surgery.
9792.27.15	Commenter is concerned that there is no psychiatric medication listed as	Pamela Meadows July 19, 2017	Disagree that a psychiatric medication should be listed as	No action necessary.

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	Exempt.	Written Comment	Exempt. The psychiatric drugs currently listed in the MTUS Drug List have indications for use to treat conditions other than mental health, for example some may be recommended to treat particular orthopedic conditions or chronic pain. Specified psychiatric drugs can be used in accordance with the MTUS ACOEM Guidelines, but are generally not first line treatment, and tend to have a higher risk profile than many drugs. The Reference in Guidelines does not cite a Psychiatric Guideline, because the Division does not have a current adopted psychiatric guideline. ACOEM is working on updating its Behavioral Health/Stress/Mental Health guideline which will be considered for adoption by the Division as soon as it is published. In the meantime, the MTUS allows treatment in	

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			accordance with other evidence-based recommendations where the MTUS does not address the condition. The Division has proposed adoption of the ACOEM Chronic Pain chapter which addresses psychiatric conditions related to Chronic Pain. It should also be noted that revised Labor Code §4610, subdivision (c), to be effective 1/1/2018, states that: "…unless authorized by the employer or rendered as emergency medical treatment, the following medical treatment services, that are rendered …within the 30 days following the initial date of injury, shall be subject to prospective utilization review under this section: … Psychological treatment services…"	
	Concerned about confusion over the check marks, x and null signs,		Regarding the legend symbols ("check marks, x and null	

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	sometimes denoted several times for the same drug.		signs"), see the response above to the comment of Lesley Anderson, MD, Chair, Workers' Compensation Committee, California Orthopaedic Association, July 26, 2017.	
9792.27.15	Requests that an anti-nausea medication be added the Exempt drug list for post-op patients, who may have an adverse reaction to surgery/medication that may cause nausea and/or vomiting and the inability to keep fluids down.	Lesley Anderson, MD, Chair Workers' Compensation Committee, California Orthopaedic Association July 26, 2017 Written Comment	Disagree with adding an anti-nausea drug at this time. There are no anti-emetics identifies in the ACOEM guidelines at this time. When there is evidence to address the recommended usage, they will be added to the guidelines and will be addressed in the MTUS Drug List. In the meantime, it may be that these are provided through expedited review, or on an emergency basis if necessary in light of the patient circumstances.	No action necessary.
9792.27.15	States that this section creates the place holder for the MTUS Drug List. The drug list is based on the ACOEM list. Recommends including the reference to ACOEM in this section as	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017	Disagree with the suggestion. It is true that the MTUS Drug List is based on ACOEM guidelines, but it would not be helpful to cite the ACOEM	No action necessary.

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	well as completing other columns of the list before implementation.	Written Comment	Guidelines here. Other parts of the MTUS regulations reference the ACOEM guidelines.	
9792.27.15	Has serious concerns with the addition of the fields "dosage" and "strength" to the MTUS Drug List, as limitations on dosage and strength have the potential to further restrict the ability of physicians to provide appropriate, effective medications to injured workers. If the DWC intends to place limitations on the dosage and strength of exempt medications via the MTUS formulary, it must include those proposed limitations in its regulatory proposal for public comment. Without the opportunity to review the specifics of such a proposal, commenter is unable to meaningfully evaluate their impact on the ability of physicians to prescribe appropriate and effective medications to injured workers.	Stacey Wittorff Legal Counsel California Medical Association July 28, 2017 Written Comment	Disagree. The "dosage form" and "strength," columns have potential for beneficial additional instructions for drug use. (For example, as noted in the ISOR, WCRI research has indicated that there may be a need to address "new" strengths that appear to be incentivized by financial gain rather than patient needs.) The columns will not interfere with the ability of a physician to provide appropriate, effective medication. Medications recommended by the ACOEM guidelines will be available. In addition, drugs not addressed in the ACOEM guidelines will continue to be available in accordance with other evidence-based treatment recommendations as provided in the MTUS rules.	No action necessary.
9792.27.15	Concern how the P&T committee will	Robert P. Nickell	The P&T Committee is an	No action necessary.

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9792.27.22 9792.27.23	address new medications that are introduced on the market, such as new **non-narcotic** pain relievers, or other anti-abusive opioid products. Also concern about the timeline for reviewing and deciding on the inclusion of new drugs. Requests clarification about the process for new drug consideration by the committee.	Pharmacist July 31, 2017 Written Comment	advisory body that consults with the Administrative Director. It will consider new drugs using principles of evidence-based medicine. There is no way to set a standardized timeframe for a new drug to be incorporated into the drug list, nor to set a timeframe for determining whether a drug should be listed as exempt from prospective review. The timeframe will vary for each drug and may depend on the availability of the scientific literature. A pharmaceutical company is free to submit information to the Administrative Director, along with a request to consider its product. The Administrative Director may consult with the P&T Committee on assigning exempt status to a drug. A pharmaceutical company may also wish to contact ACOEM to consider including its	No action necessary. No action necessary.

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			product in the ACOEM treatment guidelines. ACOEM performs thorough and systematic evidence reviews to establish treatment recommendations.	
9792.27.15	Concerned by absence of a National Drug Code (NDC) or Generic Product Identifier (GPI).	Kevin Tribout Executive Director of Government Affairs Optum August 2, 2017 Written Comment	See response above to the comment by Lisa Anne Bickford, Director, Workers' Comp Government Relations Coventry, August 2, 2017.	No action necessary.
9792.27.15	Supports the inclusion of the new data elements within the formulary drug list such as dosage, strength and NDCs/unique drug product identifiers.	Sandy Shtab AVP, Advocacy and Compliance HealtheSystems August 2, 2017 Written Comment	DWC notes the commenter's support. Disagree with the recommendation that an NDC list be issued before adoption of the formulary. See response above to the comment by Lisa Anne Bickford, Director, Workers' Comp Government Relations Coventry, August 2, 2017.	No action necessary.
9792.27.15	Recommends providing complete information (first and foremost) for all "Exempt" drugs, as well as those eligible for Special Fill and	Denise Niber Claims & Medical Director California Workers'	Agree in part. The new columns for dosage form, strength and unique pharmaceutical identifier will	No action necessary.

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	Perioperative Fill to enable cost savings while not limiting injured employees' access to all reasonable and necessary drugs.	Compensation Institute (CWCI) August 2, 2017 Written Comment	be useful for additional instructions regarding exempt/non-exempt status. However, the Division plans to perform more detailed analysis regarding usage of these columns, and intends to consult with the P&T Committee on the most advantageous approach to populating these fields. The Division recognizes that there may be wide variation in the prices for drugs that have the same dosage form, and strength and there will generally be no medical necessity for the more expensive drug if the drugs are therapeutic equivalents.	
9792.27.15	Recommends the following revised language to the introduction: "***Perioperative Fill – Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) Rx issued during the perioperative period (~~2~~4 days before through 4 days after	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Agree in part. Agree that correction is needed to the MTUS Drug List introduction to conform the perioperative period to a modification in the text of section 9792.27.13, subdivision (b).	The introductory matter is modified to state that the perioperative fill period begins 4 days, rather than 2 days, before surgery. No action necessary.

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	surgery), and 2) Supply not to exceed #days indicated (subject to any applicable maximum recommended daily dose), and 3) is a generic or single source brand, or brand where physician substantiates medical necessity, and 4) ~~if~~ is in accord with MTUS. (See 8 CCR § 9792.27.13.)" The introduction to the Drug List needs to be updated to reflect the modified proposed regulations concerning the Perioperative Fill (9792.27.13) # days, and as noted in the actual MTUS Drug List.		Disagree in relation to suggested language adding "subject to any applicable maximum recommended daily dose". See response above to comment of Ms. Niber, CWCI, regarding §9792.27.13, subdivision (a)(4). Agree that the word "if" should be changed to "is". This modification to the introductory language will to better align it with the language in the text of the regulation section 9792.27.13	Modify the MTUS Drug List introductory language.
9792.27.15 – Drug Class	Recommends that the source for the Drug Class be revealed/provided for transparency.	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Disagree that the regulatory text should identify the source of the drug class. That said, the drug class on the MTUS Drug List is derived from the ACOEM Guidelines.	No action necessary.
9792.27.15 – Reference to Guidelines Column	Commenter finds this column confusing. Provides the example of the drug Amyltriptyline. Column states that it is 1) recommended, 2) not recommended, and 3) no	Lesley Anderson, MD, Chair Workers' Compensation Committee,	Disagree that any change is needed to understand the Reference in Guideline column. It appears that commenter is overlooking the	No action necessary.

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	recommendation for "knee disorders." Questions how physicians are supposed to interpret the guidelines when they submit an RFA for one of the non-exempt drugs for a "knee disorder."	California Orthopaedic Association July 26, 2017 Written Comment	fact that the "Reference in Guideline" annotations must be used in connection with the guideline itself. The MTUS Drug List boxed introductory language states: "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 - §9792.27.2123.) "Reference in Guidelines" indicates guideline topic(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (✕), or No Recommendation (⃠). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use." Regarding commenter's question re amitriptyline and the knee disorders, the physician would need to examine the ACOEM guidelines, because there are many different types of knee disorders, and many phases of	

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			a care (e.g., acute, chronic) and a particular drug would not be used to treat all of the various conditions and phases of care. The legend provides a helpful indication to the physician that the Knee Disorders guideline addresses the drug and has 3 different types of recommendations. The RFA should be based on the underlying Knee Disorders Guideline.	
9792.27.16(a)	This section uses the terms NDC Code, RXCUI and "unique product identifier". Recommends that these terms be included in the definitions section.	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Disagree that the terms should be in the definitions section, since they are not used throughout the regulations. Agree in part, insofar as additional definitional material should be added to this section. In addition, the Division believes "unique product identifier" should be changed to "unique pharmaceutical identifier" to avoid the "unique product identifier" concept used in the Drug Supply Chain Act requirements to track the actual products / lots shipped.	Modify §9792.27.16, subdivision (a) • Spell out NDC as "National Drug Code", which is universally recognized in this context and not in need of further definition. • Add parenthetical to define RxCUI "clinical drug concept unique identifier maintained by the

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	The RXCUI cannot be used by itself. Commenter suggests it is critical to be certain that the appropriate unique product identifier is used and sufficient information is provided to support the dispensing and payment processes.		Disagree with the broad statement that the "RXCUI cannot be used by itself." It identifies a drug by "drug ingredient(s), strength, and dosage form." The RxCUI could be used by itself for the MTUS Drug List. For *payment purposes*, under our current fee schedule structure, an NDC code of the product actually dispensed would be required to be submitted in the paper or electronic bill. This is because pricing is linked with the NDC code which includes the identification of the labeler / manufacturer of the drug. Different manufacturers may have different prices for the same drug ingredient, dosage form and strength; and the fee	National Library of Medicine" • Substitute "unique pharmaceutical identifier" for "unique product identifier" No action required.

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			schedule maximums are tied to the NDC. Up front, when prescribing a drug, or when performing utilization review, the NDC is not needed, nor would it necessarily be available, as the manufacturer of the drug will depend on which pharmacy fills the prescription. Wolters Kluwer, the publisher of the Medi-Span proprietary Generic Product Identifier touts the benefits of the RxCUI, which is part of the RxNorm, as follows: "Simplifying Drug Data Data normalization in the drug data space is well underway. RxNorm incorporates a number of drug vocabularies including Medi-Span, while NDC-to-RxNorm mapping provides additional clarity. A common drug nomenclature provides a number of advantages, from data exchange to compliance with major healthcare initiatives."	

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			(http://blog.healthlanguage.com/5-benefits-of-data-normalization-with-medispan-rxnorm-and-ndc 09/12/2014.) Further, the Wolters Kluwer website states: "Most industry professionals agree that medication terminology is one of the most complex domains in healthcare today. RxNorm is the standard of choice due to its straightforward design and comprehensive framework, which supports various levels of granularity. … Many of the systems found in a healthcare organization utilize different standard pharmaceutical terminologies. Because RxNorm contains links or relationships to those terminologies, it serves as a bridge that makes exchanging and aggregating information from those systems simple and efficient." (http://blog.healthlanguage.com/rxnorm-addressing-	

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			medication-information-exchange 08/24/2016) There are many publishers of proprietary pharmaceutical compendia, and use of RxCUI, would allow them to continue to use the compendium of their choice, as there are mappings available. (See also response above to the comment of Lisa Anne Bickford, Director, Workers' Comp Government Relations Coventry, August 2, 2017).	
9792.27.16(e)	Recommends that the DWC revise the proposed MTUS Drug Formulary to include certain repackaged drugs and all NDCs. Recommends adding the following new language: "(e) The listing is not an exhaustive list of all National Drug Codes, RxCUIs, or other identifiers that qualify as a form of any drug ingredient set out in the list. The listing or otherwise of a National Drug	Dario J. Frommer Akin Gump Strauss Hauer & Feld, LLP August 2, 2017 Written Comment	Agree in part. The current structure of the MTUS Drug List does not require identification of a drug's status as repackaged. Therefore, the language excluding repackaged drugs will be removed from the text of this regulation section. In the future, after further evaluation, the Division may address repackaged drugs, and may determine whether particular provisions of the Formulary	Modify the text to delete subdivision (d) which specified that the list shall exclude repackaged drugs.

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	Code, RxCUI, or other identifier on the list does not determine whether any drug requires prospective review."		and MTUS Drug List are needed to address issues raised by use of repackaged drugs. It is noted that research has documented apparent abuse of "new" strengths of common medications, which have disproportionately high prices, and which are almost exclusively physician-dispensed. (See WCRI research referenced in the ISOR.) Although the pharmaceutical fee schedule grapples with repackaged drug pricing abuse by capping prices at the lowest therapeutic equivalent, this cannot remedy all abuses, since a therapeutic equivalent must be the same strength. This complex issue is undergoing further study by the Division, and may be addressed in the future through the formulary, and/or the fee schedule. Since the Division is removing the reference to repackaged drugs at this time, the	

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			remainder of the comments regarding repackaged drugs are moot and therefore need no response.	
	Commenter is concerned about a lack of transparency concerning the selection of "exempt" medications on the proposed MTUS list. Concern over exclusion of physician-administered drugs from the MTUS.		Disagree. The Division explains in the ISOR the factors that were weighed in listing a drug as "Exempt." In addition, the Division has not excluded physician-administered drugs; but has proposed reasonable prospective review procedures to be used.	No action necessary.
	The DWC MTUS list should track the proven Medicare formulary list—which offers a venerable record of cost-effective physician-dispensed drugs and minimal administrative burden.		The comment does not address the substantive changes made to the proposed regulations during the 1st 15-day comment period. In addition, it is erroneous as Medicare does not pay for physician-dispensed drugs.	No action necessary.
9792.27.16(e)(1)	This section uses the phrase "or other identifier." Recommends that the language be changed to "or other unique product identifier" for consistency.	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017	Disagree that the language should be changed to "unique product identifier." However, agree that a modification is needed. See response above to	Substitute "unique pharmaceutical identifier" for "unique product identifier."

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		Written Comment	Dr. Das' comment regarding section 9792.27.16 subdivision (a).	
9792.27.16(e)(7)	Recommends the following revised language: (7) Any applicable Special Fill or Perioperative Fill policies; (8) Reference Brand Name, as applicable	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Disagree. The regulation specifies that the listing "may include, but is not limited to" the data elements listed. Therefore, Reference Brand Name data element could be included in the listing of drugs by NDC, RxCUI, or other identifier if determined to be useful.	No action necessary.
9792.27.17	Notes that the reference in this subsection to "section 9792.6.1 et seq." is vague, as the abbreviation "et seq." is used to signify sections that follow the delineated section. Recommends the deletion of this abbreviation and that the DWC instead identify the specific sections it intends to reference here.	Stacey Wittorff Legal Counsel California Medical Association July 28, 2017 Written Comment	Disagree. See response above to comment of Ms. Wittorff to section 9792.27.3, subdivision (b)(5).	No action necessary.
9792.27.17(b)	Recommends the following revisions: "(b) Formulary Rule Medical Treatment Disputes Other than Medical Necessity Disputes or Disputes Related to Failure to Obtain	Rupali Das, MD California Medical Director Zenith Insurance July 28, 2017 Written Comment	Disagree with suggested modification to (b). Pursuant to Labor Code §4610.5 (as revised to be effective 1/1/2018), medical necessity is defined as follows:	No action necessary. The Administrative Director will consider the issues raised when revising the UR regulations to see if

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	Prospective Review Prior to Dispensing. Disputes over failure to follow formulary rules, other than medical necessity disputes covered by subdivision (a), shall be resolved through the procedure for non-IMR/IBR disputes set forth in WCAB rules, title 8, California Code of Regulations section 10451.2, Determination of Medical Treatment Disputes. Recommends the following addition: (c) Disputes Related to Failure to Obtain Prospective Review Prior to Dispensing. Disputes related to the failure to obtain prospective review and authorization as required by applicable regulations shall be resolved through the IMR process. If it is determined that there was a failure to obtain prospective review, the Administrative Director through the IMR process shall require the provider to submit an RFA for prospective utilization review. There shall be no charge to the claims administrator for the IMR process		"(c) For purposes of this section and Section 4610.6, the following definitions apply: (1) "Disputed medical treatment" means medical treatment that has been modified or denied by a utilization review decision on the basis of medical necessity. (2) "Medically necessary" and "medical necessity" mean medical treatment that is reasonably required to cure or relieve the injured employee of the effects of his or her injury and based on the following standards, which shall be applied as set forth in the medical treatment utilization schedule, including the drug formulary, adopted by the administrative director pursuant to Section 5307.27…" Where the doctor fails to request authorization through prospective review, the failure results in there being no determination of medical	any regulatory approach within the UR regulations could address a provider's failure to request prospective authorization when needed pursuant to the formulary rules.

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	when it is determined that prospective utilization review is required but was not previously obtained."		necessity by the claims administrator/Utilization Review Organization. Disagree with suggested modification to add (c), as it does not comport with the statutory provisions regarding utilization review and Independent Medical Review. Utilization review addresses questions of medical necessity. Pursuant to Labor Code §4610.5 (as revised to be effective 1/1/2018), the employee may utilize Independent Medical Review to dispute a utilization review decision regarding the medical necessity of treatment; it is not a procedure that can be used by an employer/insurer. Labor Code §4610.5 states in part: "(d) If a utilization review decision denies or modifies a treatment recommendation based on medical necessity, the employee may request an independent medical review as provided by this section."	

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9792.27.17(b)	Concerned that the language in subdivision (b) dispute resolution [Disputes over failure to follow formulary rules, other than medical necessity disputes] will lead to unnecessary litigation intended to challenge the MTUS and the formulary itself. Suggests adding Dosage Form, Strength and Unique Product Identifiers to alleviate concerns over potential litigation that this paragraph raises.	Jeremy Merz American Insurance Association Jason Schmelzer CCWC Kevin McKinley California Chamber of Commerce August 3, 2017 Written Comment	See response above to the comment of Mr. Merz, et al to section 9792.27.8	No action necessary.
9792.27.18	There should be no delay in convening the Pharmacy and Therapeutics Committee ("P&T Committee").	Robert Blink, MD President WOEMA August 2, 2017 Written Comment	Agree that the P&T Committee should be developed without delay. The Administrative Director intends to form the P&T Committee as soon as possible after the regulations are filed with the Secretary of State.	No regulatory modification necessary. The Administrative Director does intend to develop and convene the P&T Committee without delay once the regulations are filed with the Secretary of State.
9792.27.18 – 9792.27.20	Requests that the DWC finalize the (Formulary Dosage, Strength and Unique Identifier) in order to avoid	Jeremy Merz American Insurance Association	Agree that the P&T Committee should be developed without delay. The Administrative	No regulatory modification necessary. The

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	litigation challenging the lack of updates to the formulary or an effort to invalidate the formulary altogether, as the WCAB similarly ruled in Stevens when they invalidated the entire 2009 MTUS. Believes that the incomplete list will lead to abuse under 9792.27.8. Recommends that the P&T Committee be organized within 60 days of the effective date of the regulations or no later than December 1, 2017.	Jason Schmelzer CCWC Kevin McKinley California Chamber of Commerce August 3, 2017 Written Comment	Director intends to form the P&T Committee as soon as possible after the regulations are filed with the Secretary of State. Disagree with comment to the extent that commenter states that the lack of dosage form, strength, and unique identifier could lead to invalidation of the formulary. The other columns identify the drugs by active ingredient, which is sufficient for implementation of the drug list. The addition of columns with the headings: "Dosage Form", "Strength" and "Unique Pharmaceutical Identifier(s)" are intended to allow the MTUS Drug List updates to capture this information after consultation with the P&T Committee, and allow special instructions for use.	Adminsitrative Director does intend to develop and convene the P&T Committee without delay. No action necessary.
9792.27.23	Strongly opposes the addition of the language "as needed" in 8 C.C.R.	Stacey Wittorff Legal Counsel	Disagree. The "as needed" language is intended to allow	No action necessary.

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	§9792.27.23(a), as it substantially diminishes the Pharmacy and Therapeutics Committee's effectiveness as a consultative body.	California Medical Association July 28, 2017 Written Comment	the Administrative Director to make the most efficient use of the committee, and to acknowledge that there may be situations where consultation is not warranted. There may be need for consultation more frequently than quarterly; the new language supports that concept. Additionally, there may be situations in which the Administrative Director does not need to consult with the P&T Committee on an update to the MTUS Drug List. For example, if a drug is removed from the market or discontinued, the Adminsitrative Director may determine that there is no need to consult with the P&T Committee to update the list by removing a drug that no longer exists. There may also be situations, for example, where there is a drug recall, or where the FDA issues an urgent "Black Box" warning, where the Administrative Director determines an immediate drug	

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			list update is necessary for patient safety. In such a circumstance, the Administrative Director may determine that consultation with the P&T Committee is not needed prior to the drug list update.	
9792.27.23	**Updates to the Formulary Should Occur on a Regularly-Scheduled Basis and Be Effective After a 90-Day Transition Period** Commenter recommends that the following language be appended to Section 9792.27.23: "***Any changes adopted by the Administrative Director will not be effective for a period of ninety (90) days or longer, at the discretion of the Administrative Director***."	Lisa Anne Bickford Director, Workers' Comp Government Relations Coventry August 2, 2017 Written Comment	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 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.	No action necessary.

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			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.	
General Comment	States that these proposed regulations fail to appropriately address the treatment of workers with chronic conditions or injuries and may result delays in the provision of appropriate, effective medications such that the ability of the injured worker to return to work is delayed.	Stacey Wittorff Legal Counsel California Medical Association July 28, 2017 Written Comment	Agree that the purpose of the formulary is to promote the access to appropriate and timely care for all injured workers. The regulations promote timely delivery of care by identifying drugs as Exempt from prospective review, essentially creating a fast track for the specified medications. The formulary will support adherence to the MTUS, including the ACOEM guidelines and rules for substantiating treatment outside the guidelines where	No action necessary.

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			that is necessary. The MTUS ACOEM guidelines are created using principles of evidence-based medicine, incorporating recommendations for all phases of care, acute, sub-acute, chronic and peri-operative. The formulary rules support application of the MTUS to pharmaceutical treatment, which is expected to improve care. A very important aspect of the formulary is the specification that opioids are Non-Exempt, except as allowed where needed as a "Special Fill" at the beginning of an injury or as a "Perioperative Fill." For other circumstances, the opioid medications will require prospective authorization. This ensures that the opioid medications are available if the use is supported by evidence-based medicine, and will help address the use of these highly addictive and hazardous medications.	

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General Comment	Backs the proposal as drafted, noting amplification of the requirements on both providers and payers for handling transitioning claims found in Section 9792.27.3. Pleased to see clarification regarding physician dispensing in Section 9792.27.8.	Kevin Tribout Executive Director of Government Affairs Optum August 2, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
General Comment	Supports the proposed draft language.	Kim Ehrlich Workers' Compensation Compliance Express Scripts' August 2, 2017 Written Comment	DWC notes the commenter's support.	No action necessary.
General Comment	Supports the proposal as drafted. In reviewing the specific provisions of the revised draft, commenter is pleased to see that the DWC has clarified its language with regard to physician dispensing (contained in Section 9792.27.8) to definitively outline the conditions under which physician dispensing is permitted. This formulary, in not being more granular and tied specifically to the NDC level, will create even more	Joseph Paduda President CompPharma August 2, 2017 Written Comment	DWC notes the commenter's support. The MTUS Drug List sufficiently identifies the drugs by active ingredient. It is not necessary to have NDC level	No action necessary. No action necessary.

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	reliance on pharmacy benefit managers and the adjudication process to facilitate and expedite correct prescribing and dispensing.		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.	
General Comment	Concerned that designation of many medications as "Non-Exempt" may be misinterpreted by some payers as meaning "should be denied," when in fact many such drugs may be useful or even critical in some situations. The advent of the formulary should not make legitimate prescription of medications harder, and the DWC should be very clear to so state this when it implements a formulary.	Robert Blink, MD President WOEMA August 2, 2017 Written Comment	The Division understands the concern that some payers may misinterpret "Non-Exempt" to mean "should be denied." However, disagree to the extent that this would be a reasonable interpretation requiring modification of the rules. The regulations make it clear that "Non-Exempt" drugs are available when authorized through prospective review and used in accordance with the MTUS. The MTUS Drug List itself has the "Reference in Guidelines" column, which shows that many of the "Non-Exempt" drugs are a recommended treatment in a guideline. Therefore, disagree that there needs to be any	No action necessary.

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			revision to the regulation to avoid misinterpretation.	
Labor Code section 4610(i)(1)	Clarify Intent of LC §4610(i)(1): The statutory language of Labor Code section 4610(i) ("requests for treatment covered by the formulary") is ambiguous; as such, disputes over what drugs are (and are not) subject to the abbreviated (5 working day) timeframe for review determination will undoubtedly ensue. Recommends that to fast-track review of "Exempt" and "Non-Exempt" drugs expressly listed on the MTUS Drug List, those respective definitions should be amended to provide clarity and avoid unnecessary litigation over application of the formulary rules.	Denise Niber Claims & Medical Director California Workers' Compensation Institute (CWCI) August 2, 2017 Written Comment	Disagree that the formulary regulations should address the issues involved in implementing the statutory changes in the utilization review program mandated by Senate Bill 1160. The changes to Labor Code §4610 mandated by Senate Bill 1160 will require a rulemaking action. The interpretation of the phrase "covered by the formulary" will be addressed in the context of implementing the utilization review statute.	No action necessary. The Division will consider this issue when revising the utilization review regulations.