STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION

FINAL STATEMENT OF REASONS

Subject Matter of Regulations:
Workers' Compensation – Medical Treatment Utilization Schedule – Formulary

TITLE 8, CALIFORNIA CODE OF REGULATIONS
ADOPT SECTIONS 9792.27.1 – 9792.27.23

The Administrative Director of the Division of Workers' Compensation (hereinafter "Administrative Director") pursuant to the authority vested in him by Labor Code Sections 59, 133, 4603.4, 4603.5, 5307.3, and 5307.27 has adopted the following regulations:

Section 9792.27.1.	Medical Treatment Utilization Schedule (MTUS) Drug Formulary – Definitions.
Section 9792.27.2.	MTUS Drug Formulary; MTUS Drug List; Scope of Coverage; Effective Date.
Section 9792.27.3.	MTUS Drug Formulary Transition.
Section 9792.27.4.	MTUS Drug Formulary – Pharmacy Networks; Pharmacy Benefit Manager Contracts.
Section 9792.27.5.	MTUS Drug Formulary – Off-Label Use.
Section 9792.27.6.	MTUS Drug Formulary – Access to Drugs Not Listed as an Exempt Drug on the MTUS Drug List.
Section 9792.27.7.	MTUS Drug Formulary – Brand Name Drugs; Generic Drugs.
Section 9792.27.8.	Physician-Dispensed Drugs.
Section 9792.27.9.	Compounded Drugs.
Section 9792.27.10.	MTUS Drug List; Exempt Drugs, Non-Exempt Drugs, Unlisted Drugs, Prospective Review.
Section 9792.27.11.	Waiver of Prospective Review.
Section 9792.27.12.	MTUS Drug List – Special Fill.
Section 9792.27.13	MTUS Drug List – Perioperative Fill.
Section 9792.27.14.	Treatment Provided Under Applicable Health and Safety Regulations.
Section 9792.27.15.	MTUS Drug List.
Section 9792.27.16.	National Drug Codes, Unique Pharmaceutical Identifier - MTUS Drug List
Section 9792.27.17.	Formulary – Dispute Resolution.
Section 9792.27.18.	Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.
Section 9792.27.19.	Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

Section 9792.27.20.	Pharmacy and Therapeutics Committee – Conflict of Interest.
Section 9792.27.21.	Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form.
Section 9792.27.22.	Pharmacy and Therapeutics Committee – Meetings.
Section 9792.27.23.	MTUS Drug List Updates.

REQUEST AND GOOD CAUSE FOR EFFECTIVE DATE UPON FILING WITH THE SECRETARY OF STATE

The Administrative Director requests that the regulations become effective January 1, 2018 for the reasons set forth below.

First, the adopted formulary regulations address the national concern regarding adverse health impacts and other unintended consequences due to opioid misuse. The Centers for Disease Control and Prevention (CDC) has declared a national opioid epidemic, publishing statistics showing that drug overdose death reached 47,000 in 2014, 60.9% of which involved an opioid. (ISOR, p. 19). The CDC emphasizes the role of prescription medication in the epidemic. The CDC's Morbidity and Mortality Weekly Report (MMWR) states in part:

> "The ongoing epidemic of opioid deaths requires intense attention and action. … The misuse of prescription opioids is intertwined with that of illicit opioids; data have demonstrated that nonmedical use of prescription opioids is a significant risk factor for heroin use, underscoring the need for continued prevention efforts around prescription opioids….Continued improvements in guideline-recommended opioid prescribing practices for chronic pain, increased improving access to and use of prescription drug monitoring programs, and increased utilization of nonopioid pain treatments are needed."
> (MMWR, December 30, 2016.)

The CDC has published data showing continued increase in opioid related deaths, stating:

> "[I]n 2015 there were over 22,000 deaths involving prescription opioids, equivalent to about 62 deaths per day. This is an increase from approximately 19,000 in 2014. [¶] Regardless of the analysis strategy used, prescription opioids continue to be involved in more overdose deaths than any other drug, and all the numbers are likely to underestimate the true burden given the large proportion of overdose deaths where the type of drug is not listed on the death certificate. The findings show that two distinct but interconnected trends are driving America's opioid overdose epidemic: a 15-year increase in deaths from prescription opioid overdoses, and a recent surge in illicit opioid overdoses…"
> (CDC, Opioid Data Analysis, accessed 9/23/2017
> https://www.cdc.gov/drugoverdose/data/analysis.html .)

The adopted regulations provide critical support for the effort to encourage safer prescribing of opioid pain relievers. A primary goal of the formulary regulations is to significantly reduce the rate of opioid-related adverse events, substance misuse and abuse. It is critical to put these regulations in place as soon as possible, the health and safety of injured workers constitutes good cause for the regulations to be effective January 1, 2018.

Second, the January 1, 2018 effective date will support the broader updates to the Medical Treatment Utilization Schedule (MTUS). The MTUS Drug List is based upon the most recent treatment guidelines of the American College of Occupational and Environmental Medicine (ACOEM). These treatment guidelines, identified in this rulemaking as documents relied upon, are currently being adopted by the Administrative Director through a new procedure mandated for evidence-based updates to the MTUS. Senate Bill 1160 (Statutes 2016, Chapter 868) amended Labor Code section 5307.27, subdivision (a), authorizing evidence-based updates to the MTUS by an Administrative Director order exempt from Labor Code sections 5307.3 and 5307.4, and the rulemaking provisions of the Administrative Procedure Act. Pursuant to this authority, a public hearing was held on September 6, 2017 to receive public comment on the proposed adoption of the updated ACOEM treatment guidelines. Comments are being reviewed, and it is anticipated that the updated guidelines will be adopted before January 1, 2018. The formulary will support usage of the updated guidelines and promote treatment that is in accord with the most recent standards of evidence-based care.

Accordingly, for the reasons stated above, there is good cause for these regulations to have an effective date of January 1, 2018.

UPDATE OF INITIAL STATEMENT OF REASONS AND INFORMATIVE DIGEST

No revision of the original informative digest, as published March 17, 2017 in the notice of rulemaking action, is needed.

As authorized by Government Code section 11346.9, subdivision (d), the Administrative Director hereby incorporates by reference the entire Initial Statement of Reasons prepared in this matter, except that there are updates as set forth below.

Problem Addressed / Specific Purpose, Rationale, and Necessity of Each Section of the Adopted Regulations

Unless a specific basis is stated below for any modification to the regulations as initially proposed, the problem addressed, specific purpose and necessity for the adoption of the new regulations as set forth in the Initial Statement of Reasons continues to apply to the regulations as now adopted. The Administrative Director made modifications to the originally proposed text as a result of comments received during the comment period. All modifications from the initially proposed text of the regulations are summarized below.

Section 9792.27.1. Medical Treatment Utilization Schedule (MTUS) Drug Formulary – Definitions

(c) Modified definition of "brand name drug" to improve accuracy by tying it to FDA approval of drugs under an original New Drug Application or Biologic License Application, and related products marketed under those approvals.

(e) Modified definition of "compounded drug" as a drug that is subject to the California Board of Pharmacy compounding regulations, or federal compounding law. This is necessary to improve the clarity and accuracy by tying the definition to applicable state and federal standards governing compounding. It avoids loopholes that could be inadvertently created by the originally proposed definition.

(h) and (o) and throughout the regulations: Modified the "Preferred/Non-Preferred" nomenclature to "Exempt/Non-Exempt" in order to improve the clarity of the designation and more closely align with the intended effect of the designation. Deleted "Preferred drug" definition originally proposed in subdivision (v). This is necessary so that the terminology aligns 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 original language "Preferred/Non-Preferred" appeared to engender confusion, causing some to erroneously think that a "Preferred" drug is always superior to a "Non-Preferred" drug, or should be used prior to using a Non-Preferred drug.

(h) (Re-lettered to (i)) Modified definition of "expedited review" to simplify, so that it cross-references to utilization review regulations rather than repeats utilization review regulation provisions. This modification improves the clarity of the regulation.

(i) Definition of "FDA" and (j) definition of "FDA-approved drug", as originally proposed, were re-lettered to (j) and (k) to maintain alphabetical order, but were not otherwise modified.

(k) Definition of "generic drug" moved to (l). Modified definition of "generic drug" to improve accuracy by tying it to drugs approved by the FDA under an Abbreviated New Drug Application. Further, added language that a generic may be substituted for therapeutic equivalent brand name drug pursuant to state and federal law. This is necessary for consistency with other applicable law.

(l) Re-lettered former subdivision (l) "MTUS Drug Formulary" to (m). Modified cross-references to other regulation sections to reflect the revised numbering due to changes in the modified text.

(m) Re-lettered former subdivision (m) "MTUS Drug List" to (n). Modified "MTUS Drug List" definition to substitute "Exempt" for "preferred" and "Non-Exempt" for non-preferred to reflect revised nomenclature. This is necessary for consistency. Modified

"active drug ingredient" to "active drug ingredient(s)" to reflect the fact that some of the listed drugs have more than one active ingredient.

(n) Re-lettered former subdivision (n) "Non-Preferred drug" definition to (o); substitute "Non-Exempt" for "Non-Preferred" and substitute "Exempt" for "Preferred", for consistency to reflect revised nomenclature.

(o) Re-lettered former subdivision (o) "Nonprescription drug" or "over-the-counter drug" (OTC) to (p), and added the word "drug" to the parenthetical as follows: "(OTC drug)" in order to improve clarity.

(p) Re-lettered former subdivision (p) "off-label use" to (q). Revised language for clarity. Modified definition of "off-label use" to improve clarity.

(q) Deleted former subdivision (q) to streamline the regulation because subdivision (p) defines "'nonprescription drug' or 'over-the-counter drug'" and subdivision (q) was duplicative.

(r) Deleted second sentence, regarding the effect of FDA adoption of a final OTC Monograph, as it is not necessary for purposes of the formulary, and may be confusing to the public.

(s) Substituted "Non-Exempt" for "Non-Preferred" in the definition of Perioperative Fill for consistency to reflect revised nomenclature.

(v) Added definition of "prescription drug" to improve clarity of regulations.

(x) It was necessary to delete the originally proposed subdivision (x), "retrospective review" definition, as that term is no longer used in the regulations. "Retrospective review" is governed by the utilization review regulations, which are cross-referenced in proposed section 9792.27.17. It would be confusing and unnecessary to include a definition of a term that is not used in the regulation.

The adopted subdivision (x) substitutes "Non-Exempt" for "Non-Preferred" to reflect revised nomenclature and changes cross-reference to regulation section to reflect the revised numbering due to changes in the modified text. Revised "Special Fill" definition for clarity to cross-reference the special fill regulation rather than repeat a portion of that language. This was necessary to avoid duplication of provisions.

(y) Deleted sentence that sets forth internet address of the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Modify language to indicate that the Orange Book is available on the FDA's website and will be accessible via a link provided on the department's website. Posting the FDA Orange Book's web address on the department website is preferable to adopting it in regulation, as it would make it more difficult to maintain accurate and up to date access information.

(z) The original proposed language defining "unlisted drug" was modified to simplify and coordinate with revised definition of "FDA-approved drug" which includes both prescription and non-prescription drugs approved by the FDA. This was necessary for consistency and clarity. The provision was re-lettered from (aa) in the original proposal to (z) in the adopted regulation.

Section 9792.27.2. MTUS Drug Formulary; MTUS Drug List; Scope of Coverage; Effective Date.

(a) Added the word "and" to improve grammatical structure.

(b) Modified the section to state that all drugs dispensed for outpatient use **on or after January 1, 2018** are subject to the MTUS Drug Formulary, regardless of date of injury, except as specified regarding continuing drug treatment in the transition regulation. Modified language from "continuing medical treatment" to "continuing drug treatment", to improve clarity since the regulation applies to *drug* treatment and not more broadly to medical treatment.
(b)(1) The subdivision states that a drug is for outpatient use if it is dispensed to be taken, applied, or self-administered by the patient at home or outside a clinical setting. Modified language for clarity to say that home includes an institutional setting in which the injured workers resides *including but not limited to,* an assisted living facility.
(b)(2) The subdivision was deleted as duplicative and unnecessary. The subdivision states the formulary applies to drugs prescribed by a physician and dispensed for outpatient use by specified entities. Deleted language specifying dispensing entities covered by the section, as it may be too restrictive. Emphasis should be on the provision that the drug is for self-administered outpatient use, which is adequately set forth in (b)(1).
(b)(3) renumbered as (b)(2). Deleted example of physician-administered treatment in order to streamline the regulation text, and based on the determination that an example is not necessary to understand the meaning.

Section 9792.27.3. MTUS Drug Formulary Transition.

(a) Modified effective date to provide that the MTUS Drug Formulary applies to drugs dispensed on or after January 1, 2018 for all dates of injury, except as specified.

(b)(1) – (5) Modified as follows:

- For injuries prior to 1/1/2018, added specificity for actions the physician must take in regard to a patient who is receiving a course of treatment that includes a Non-Exempt drug, unlisted drug, or compounded drug.
    - Physician shall submit §9785 Progress Report and Request for Authorization (RFA) to address ongoing drug treatment plan.
        - Treatment plan to include medically appropriate weaning, tapering, or transitioning to a drug pursuant to the MTUS, or

        - Provide supporting documentation to substantiate medical necessity, and obtain authorization, for Non-Exempt drug, unlisted drug, or compounded drug.
    - Progress Report, including treatment plan and RFA to be submitted at next regular due date if feasible, but no later than April 1, 2018.
        - Add language to emphasize that previously approved drug treatment shall not be terminated or denied except pursuant to the MTUS and in accordance with UR and IMR regulations
    - Added language to clarify that the claims administrator shall process the progress report, treatment plan, and RFA within standard procedures and timeframes in the UR regulations.

Section 9792.27.4. MTUS Drug Formulary – Pharmacy Networks; Pharmacy Benefit Manager Contracts.

Modified to correct a technical omission. The section provides that drugs available to the injured worker must be consistent with the MTUS guidelines and formulary, and cannot be restricted by a pharmacy network or Pharmacy Benefit Manager contract pursuant to Labor Code section 4600.2. Added the word "pharmacy" to the regulation, as section 4600.2 recognizes an employer/insurer contract with a pharmacy, in addition to contracts with pharmacy networks or PBMs.

Section 9792.27.5. MTUS Drug Formulary – Off-Label Use.

(b) Modified the language from "Preferred" drug to "Exempt" drug for consistency.

(c) Modified the language from "Preferred/Non-Preferred" drug to "Exempt/Non-Exempt" drug for consistency.

Deleted language that relates to retrospective review as that is governed by the UR regulations.

(d) Corrected punctuation by moving "period" outside of parenthesis.

Section 9792.27.6. MTUS Drug Formulary – Access to Drugs Not Listed as an Exempt Drug on the MTUS Drug List.

(a) Modified "Preferred" drug to "Exempt" drug for consistency.

(b) Modified language to simplify and coordinate with revised definition of "FDA-approved drug" which includes both prescription and non-prescription drugs approved by the FDA.

Modified the language that states that any medically necessary drug can be authorized through prospective review to better align with the MTUS regulations regarding rebutting

the MTUS treatment guidelines or obtaining treatment not addressed by the MTUS treatment guidelines.

Corrected punctuation by moving "period" outside of parenthesis.

Deleted language that relates to retrospective review as that is governed by the UR regulations.

Section 9792.27.7. MTUS Drug Formulary – Brand Name Drugs; Generic Drugs.

Modified the section to clarify that the physician must submit a Request for Authorization in order obtain authorization (based on patient-specific factors showing medical necessity) before the brand drug is dispensed, where a less expensive generic version of the drug exists.

Deleted language that relates to retrospective review as that is governed by the UR regulations.

Section 9792.27.8. Physician-Dispensed Drugs.

(a) Changed cross-reference to Special Fill and Perioperative Fills regulations to reflect the revised numbering due to changes in the modified text. Deleted language that relates to retrospective review as that is governed by the UR regulations.

(b) Section provides that physician-dispensed drugs require authorization through prospective review and provides an exception allowing a physician to dispense up to a 7-day supply of an Exempt drug.

- Modified the proposal to provide that the *exception* allowing the up-to-7-day supply without prospective review is *only applicable* if the drug is dispensed at the time of an *initial visit that occurs within 7 days of the injury*.
- Modified proposal to allow one *or more* medically appropriate exempt drugs to be dispensed as the injured worker may need more than one medication.
- Deleted language that relates to retrospective review as that is governed by the UR regulations.

(d) Added provision to recognize that a pharmacy benefit contract pursuant to LC § 4600.2 may prohibit physician dispensing. This is necessary for consistency with Labor Code section 4600.2, subdivision (a) which states in pertinent part that "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 relieve the injured employee from the effects of the injury."

Section 9792.27.9. Compounded Drugs.

(a) Deleted language that relates to retrospective review as that is governed by the UR regulations.

Added language clarifying that the physician must submit a Request for Authorization to obtain prospective authorization before a compounded drug is dispensed.

(c) Added language stating that nothing in the Article shall permit physician dispensing of compounded drugs where otherwise prohibited by a pharmacy benefit contract pursuant to Labor Code section 4600.2, subdivision (a). This language was adopted to provide additional clarity and parallels the language in the physician dispensing regulation section. Moreover, this is necessary for consistency with Labor Code section 4600.2, subdivision (a) which states in pertinent part that "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 relieve the injured employee from the effects of the injury."

Section 9792.27.10. MTUS Drug List; Exempt Drugs, Non-Exempt Drugs, Unlisted Drugs, Prospective Review.

(a) Modified to state that the drug list is set forth by drug "ingredient(s)" rather than "ingredient."

(b) Changed "drug identified as Preferred" to "drug identified as Exempt" for consistency.

Clarified that brand name versions of otherwise "Exempt" drugs are subject to the brand drug regulation by adding cross reference to section 9792.27.7.

Deleted language that relates to retrospective review as that is governed by the UR regulations.

Adopted a subdivision (b)(3) stating that compounded drugs are subject to the compounded drug regulation even if one or more of the ingredients are listed as "Exempt" on the MTUS Drug List. This modification improved the clarity; it is expected to avert the possibility that someone could argue that a compounded drug using one of the listed drugs is "Exempt."

(c) Changed "drug identified as Non-Preferred" to "drug identified as Non-Exempt".

Deleted language that relates to retrospective review as that is governed by the UR regulations.

(d) Changed cross-reference to Special Fill and Perioperative Fills regulations to reflect the revised numbering due to changes in the modified text. Changed "Non-Preferred" to "Non-Exempt" for consistency with revised terminology.

(e) Deleted language that relates to retrospective review as that is governed by the UR regulations.

(f) Deleted provision allowing waiver of prospective review if the drug falls within a UR plan's provision of prior authorization without necessity of a request for authorization, where that provision is adopted pursuant to section 9792.7(a)(5). Deleted from this section because the substance of the provision is moved to a new section 9792.27.11 in order to give more prominence to the provision.

Section 9792.27.11. Waiver of Prospective Review.

Added new section to recognize that "prior authorization" provisions in Utilization Review plans adopted pursuant to section 9792.7(a)(5) may waive prospective utilization review requirements for Non-Exempt or unlisted drugs. This is necessary for consistency with the Utilization Review regulations.

The sections that follow were re-numbered due to the addition of this new section.

Section 9792.27.12 MTUS Drug List – Special Fill.

(a) Changed "Non-Preferred" to "Non-Exempt". Deleted potentially ambiguous language stating that a "Non-Exempt" drug will be allowed without prospective review "in very limited circumstances, and for a short period of time"; modified for clarity to indicate that the Non-Exempt drug must meet the Special Fill requirements of subdivision (b).

(d) Deleted language that relates to retrospective review as that is governed by the UR regulations.

Re-lettered (e) to (d) and clarified that an employer/insurer contract with a pharmacy (not just a pharmacy network), or an MPN that includes a pharmacy, can have a longer special fill period.

Section 9792.27.13 MTUS Drug List – Perioperative Fill.

(a) Modified language for clarity to add reference to the "Non-Exempt" drug, because the Perioperative Fill policy relates only to the identified Non-Exempt drugs. The purpose of the policy is to ease the usual prospective review requirements applicable to Non-Exempt drugs in the specified circumstances.

(b) Modified the perioperative period by expanding the pre-operative days from 2 to 4 in order to provide additional flexibility regarding drugs urgently needed in the perioperative period.

(c) Deleted language that relates to retrospective review as that is governed by the UR regulations.

Re-lettered (d) to (c) and clarified that an employer/insurer contract with a pharmacy (not just a pharmacy network), or an MPN that includes a pharmacy, can have a longer perioperative fill period. This is necessary for consistency with Labor Code 4600.2 which recognizes pharmacy benefit contracts other than "network" contracts.

Section 9792.27.15. MTUS Drug List.

Re-numbered section from section 9792.27.14 to 9792.27.15. Modified the excel spreadsheet containing the MTUS Drug List as follows:

- Changed designation of drugs to Exempt/Non-Exempt rather than Preferred/Non-Preferred to better align with the concept of the drug being exempt from prospective review, or not exempt. This improves clarity and consistency of terminology.
- Added new column and data for "Reference Brand Name" for each drug ingredient.
- Updated drug list to add drugs that have been added by ACOEM in guideline updates that have occurred since initial drafting of the MTUS Drug List. This is necessary to improve consistency between the guidelines and the MTUS Drug List.
- Added a muscle relaxant and a corticosteroid to the "Special Fill".
- Changed one corticosteroid drug from "Perioperative Fill" to "Special Fill".
- Changed two antibiotics from Non-Preferred to Exempt based on ACOEM Guideline update.
- One drug deleted because it is injectable drug that is not self-administered.
- Increased the "Perioperative Fill" from 4-day supply to 14-day supply for the anticoagulants.
- Made technical corrections to identification of drug names to improve accuracy.
- Made updates to "Reference in Guidelines" data to conform to ACOEM Guideline changes to improve consistency between the guidelines and the MTUS Drug List.
- Modified the MTUS Drug List introductory language to improve clarity and conform to proposed changes in text.
- Added columns with following headings: "Dosage Form", "Strength" and "Unique Pharmaceutical Identifier(s)". Currently without data in the fields, but included in the adopted drug list in order to allow MTUS Drug List updates to capture this information after further analysis and consultation with the P&T Committee.

Section 9792.27.16. National Drug Codes, Unique Product Identifier - MTUS Drug List.

(a) Modified to allow the drug product list to use RxCUI (National Library of Medicine drug coding system) or other unique pharmaceutical identifier in addition to, or as alternative to, NDCs (National Drug Codes). It is important to provide the option of using the RxCUI as the drug identifier, as it has many advantages, including the fact that it is non-proprietary and in the public domain, and it identifies drugs by ingredient, dosage form, and strength without regard to manufacturer. Modifications were made to clarify terminology, spelling out "National Drug Code", and including identifying information regarding RxCUI by adding the parenthetical "(clinical drug concept unique identifier maintained by the National Library of Medicine)".

(b) Modified language to specify that only drug products that can be self-administered would be on the list. This is needed for clarity, and to support the distinction between physician-administered drugs and dispensed drugs.

(d) Modified the language to state that the "listing may include, but is not limited to, the following data elements" in order to provide greater flexibility to include data elements determined to be useful on a drug product listing.

Eliminated requirement that route of administration is required to be included, as inclusion of the dosage form is expected to generally serve the same purpose.

Changed the "Preferred/Non-Preferred" nomenclature to "Exempt/Non-Exempt" for consistency with terminology used in other sections of the formulary and to better align with the purpose of the designation.

Modified the original text to delete the original subdivision (d) which specified that the list shall exclude repackaged drugs. The current structure of the MTUS Drug List does not require identification of a drug's status as repackaged. Therefore this provision is not necessary at this time.

The originally proposed subdivision (e) was re-lettered subdivision (d)(1), and was modified. The original proposal stated that the data elements on the list may include NDC codes; the adopted regulations also allow "RxCUI or other pharmaceutical identifier" to be used on the list. This modification is made for consistency with the terminology in subdivision (a), and for the reasons set forth above.

Section 9792.27.17 Formulary – Dispute Resolution.

Add new section to clarify that:

(a) Medical necessity disputes are governed by utilization review and independent medical review statutory and regulatory provisions.

(b) Formulary rule disputes other than medical necessity disputes are resolved through the non-IMR/IBR procedure of the WCAB rule 10451.2, Determination of Medical Treatment Disputes.

Section 9792.27.20. Pharmacy and Therapeutics Committee – Conflict of Interest.

(c)(2)(C) Made punctuation and grammatical corrections.

Section 9792.27.22. Pharmacy and Therapeutics Committee – Meetings.

(e) Modify section to state that the Medical Director shall maintain and post *a summary*, rather than documentation, of P&T Committee meetings and recommendations.

Section 9792.27.23. MTUS Drug List Updates.

(a) Modify language to specify that the Administrative Director shall consult with the P&T Committee *as needed* on updates to the drug list in order to make the most efficient use of the committee.

(b)(1), (2) Modify language to better identify scope of recommendations that the P&T Committee may address relating to prospective review requirements, special fill and perioperative fill designations, by removing language that could be too restrictive.

Update to Technical, Theoretical, Or Empirical Studies, Reports, Or Documents Relied Upon – Government Code § 11346.2(b)(3):

The following additional documents beyond those identified in the Initial Statement of Reasons were relied upon by the Administrative Director and added to rulemaking file after close of the 45 day comment period. They were identified in the "Notice of Modification of Text of Proposed Regulations and Notice of Addition of Documents to the Rulemaking File" (1st 15-Day Comment Period) and were available for 15-day public review and comment from July 18, 2015 – August 2, 2017.

The following documents are added to the list of documents relied upon:

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Chronic Pain Guideline, Effective May 15, 2017

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Eye Disorders, Effective April 1, 2017

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Hip and Groin Disorders Guideline, Effective May 1, 2011

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Initial Approaches to Treatment, Effective June 30, 2017

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Opioids, Effective April 20, 2017

Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Vol 66, No. 10, March 17, 2017

Economic and Fiscal Impact Statement (Form STD 399), revised

Modeling the Economic Impact of a California Workers' Compensation Formulary, Mulcahy, et al, RAND

LOCAL MANDATES DETERMINATION

The Administrative Director has made the following determinations regarding local mandates.

- Local Mandate: None. The adopted regulations will not impose any new mandated programs or increased service levels on any local agency or school district. The adopted regulations do not apply to any local agency or school district.
- Cost to any local agency or school district that is required to be reimbursed under Part 7 (commencing with Section 17500) of Division 4 of the Government Code: None. The adopted regulations do not apply to any local agency or school district.
- Other nondiscretionary costs/savings imposed upon local agencies: There are no costs imposed on local agencies. It is anticipated there will be savings to local agencies in the role of employer of injured workers who receive treatment in the workers' compensation system. It is estimated the regulation will decrease California workers' compensation premiums by $22,693,000, in the first 12 months after the regulation is fully implemented. Local public self-insured employers account for approximately 15% of total drug spending based on the overall share of workers' compensation costs for these employers. This share of total estimated savings is $3,404,000 in the first 12 months after the regulation is fully implemented.

Updated Evidence Supporting Finding of No Significant Statewide Adverse Impact Directly Affecting Business

The Administrative Director has determined that the proposed regulations will not have a significant statewide adverse impact on business. It is anticipated there will be a reduction in pharmaceutical spending as a result of the regulations, which will result in reduced workers' compensation expenses for self-insured employers and ultimately reduced premiums for insured employers.

All California businesses are required to purchase workers' compensation insurance or self-insure against losses related to workplace injuries (see Labor Code Section 3700). The California Employment Development Department (EDD), Labor Market Information Division estimates that there were 1,424,141 businesses in California in the third quarter of 2015. California Government Code section 11346.3 subdivision (b)(4)(B) defines small businesses as businesses that are independently owned and operated, not dominant in their field of operation, and have fewer than 100 employees. EDD reports that 98.3% of the businesses in California have fewer than 100 employees.

In a study conducted by RAND, Workers' Compensation Information System data on 2014 California workers' compensation prescription drug utilization and spending were used as a baseline to model the likely impacts of the formulary in terms of changes in prescribing patterns and spending. (*Estimating the Economic Impact of a California Workers' Compensation Formulary*, Mulcahy, et al., RAND, March 2017.) This analysis included five sequential modules that separately model the likely changes associated with the formulary on physician dispensing, generic substitution, prescribing of drugs subject to prospective review, prescribing of ingredients used to make compounded drugs, and prescribing of drugs that do not require prospective review. The specific assumptions and steps in each module were based on estimates from the literature where possible. The main outcomes from the analysis were an estimated change in California workers' compensation prescription drug spending and an estimated change in net revenue for prescription-dispensing California health care providers. The change in prescription drug spending would correspond to a reduction in workers' compensation premiums paid by employers.

Estimates of the reduction in workers' compensation premiums and the reduction in net revenue of health care providers dispensing prescription drugs were used to estimate the overall impact of the formulary on the macro economy of California. Macroeconomic impacts are modeled within an input-output model, IMPLAN ("IMpact analysis for PLANning".) IMPLAN assumes a linear relationship between production and consumption and bridges these two via local production and consumption as well as sector specific imports and exports to meet demand and supply. There exist 440 sectors within IMPLAN and nine household types segmented by income categories. In order to model the change in workers' compensation premiums, RAND assumes that they are decreases in the costs to employers and firm profits are correspondingly increased. As a result, there is a direct increase in profits to all firms that pay workers' compensation premiums. The profits are then distributed to the owners/shareholders of these firms that induce an increase in the demand for all goods causing a multiplier effect within the economy and the creation of new California jobs. Similarly, RAND assumes that the impact on prescription-dispensing providers and health care delivery systems is not a reduction in output but is a reduction in net revenue. This is because the formulary affects physicians' ability to sell specific medications but does not affect their output of health care services and thus production function in a fundamental way. This has a multiplier effect within the economy similar to that of the workers' compensation premiums.

The change in California workers' compensation spending on prescription drugs is $45,386,000. Lower spending on prescription drugs will over time translate into reductions in workers' compensation premiums. We estimate that half of this reduction ($22,693,000) will translate into lower workers' compensation premiums in the first twelve months following the full implementation of the formulary. We assumed 50 percent because premiums change only at the start of new plan years. Insurers will retain the remainder of the reduction as an increase in reserves. The reductions in workers' compensation premiums translate into an estimated $12,337,000 increase in GSP. There are three reasons why the increase in GSP is less than the full amount of the reduction in premiums. First, the IMPLAN model does not take into account the dynamic nature that some of this increased profit may result in additional capital investments by the firm. Second, the owners of firms will not necessarily spend all their increased profits on increased consumption that is taken into account in the IMPLAN model. Finally, some of the goods that they do purchase will be manufactured outside of California. This estimated increase in California GSP translates into increased employment of approximately 49 jobs.

The estimated reduction in physician net income in the initial 12-month period after the regulation is implemented is $18,253,000. This results in an estimated $9,923,000 reduction in state Gross State Product (GSP). This estimated decrease in California GSP translates into decreased employment of approximately 39 jobs.

Update to Economic Impact Assessment (Government Code § 11346.3(b))

Creation or Elimination of Jobs within the State of California

The Administrative Director estimates that there will be minimal impact on job creation or elimination within the state. The regulations which establish the MTUS Drug List and the related formulary rules will streamline the provision of pharmaceutical treatment, and incentivize cost effective care within the current evidence-based MTUS. The regulations will not directly affect job creation or elimination. A physician who dispenses medication may experience some impact on their income based on the limitations on physician-dispensing, however, such an impact may be negligible since revenue from dispensing of medication is only part of the physician's medical practice. On a system-wide basis, savings from reduced physician-dispensing and other changes to pharmaceutical usage may result in reduced insurance premiums for all employers. As set forth above in more detail under the heading "Evidence Supporting Finding Of No Significant Statewide Adverse Impact Directly Affecting Business", the RAND analysis using the IMPLAN model estimates that 49 jobs will be created and 39 jobs will be eliminated across the state. The estimated impacts are relatively small and apply to a large number of industries.

Creation of New or Elimination of Existing Businesses Within the State of California

The Administrative Director has determined that the proposed regulations will not create or eliminate businesses within the State of California. The regulations which establish

the MTUS Drug List and the related formulary rules will streamline the provision of pharmaceutical treatment, and incentivize cost effective care within the current evidence-based MTUS and care delivery system. Costs and benefits will be borne by existing businesses (e.g. pharmacies, physicians, pharmaceutical benefit managers, insurers, employers) within the existing system. The regulations do not create or eliminate new types of businesses. In addition, the estimated economic impacts are spread across the economy and are not expected to significantly contribute to creation or elimination of businesses within the state. In regard to physician practices that may lose revenue due to physician-dispensing restrictions, it is anticipated that the loss of income would be a relatively minor portion of a physician's income and would not be substantial enough to impact the continued existence of the physician practice.

Expansion of Businesses Currently Doing Business within the State of California

The Administrative Director concludes that it is unlikely that the proposal would cause significant expansion of businesses currently doing business within the State of California. The regulations which establish the MTUS Drug List and the related formulary rules will streamline the provision of pharmaceutical treatment, and incentivize cost effective care within the current evidence-based MTUS and care delivery system. As modeled by RAND, the regulations are anticipated to benefit businesses by reducing workers' compensation insurance premiums and costs, and contribute to overall increase in GSP. (*Estimating the Economic Impact of a California Workers' Compensation Formulary*, Mulcahy, RAND, March 2017.) Reduced costs may allow some businesses to expand, but the overall impact on business expansion is not expected to be significant.

Benefits of the Regulation

The proposed regulations will be beneficial as they will promote the timely delivery of evidence-based medical treatment by eliminating prospective utilization review for exempt drugs used in accordance with the treatment guidelines. Reduced prescribing volume for some Non-exempt drugs – especially opioid analgesics – may lower rates of adverse events, drug-drug interactions, and, in the case of prescription opioid analgesics, potential misuse and abuse. These health benefits accrue to California residents and may have spillover effects on the broader economy. It is anticipated there will be reductions in prescription costs, which will produce savings for self-insured employers and premium reductions for insured employers. As set forth in more detail above, under the heading "Evidence Supporting Finding Of No Significant Statewide Adverse Impact Directly Affecting Business," it is expected that there will be economic benefits to the state of California as a result of the formulary regulations, which will result in an estimated net increase in GSP.

CONSIDERATION OF ALTERNATIVES

The Division considered all comments submitted during the public comment periods, and based on those comments made modifications to the regulations as initially proposed. The Administrative Director has now determined that no alternatives proposed by the

regulated public or otherwise considered by the Division of Workers' Compensation would be more effective in carrying out the purpose for which these regulations were proposed, nor would they be as effective and less burdensome to affected private persons and businesses than the regulations that were adopted or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

THE FOLLOWING ADDITIONAL NON-SUBSTANTIVE CORRECTIONS WITHOUT REGULATORY EFFECT WERE MADE TO THE TEXT OF THE PROPOSED REGULATIONS AFTER THE CLOSE OF THE FINAL COMMENT PERIOD

Section 9792.27.2. MTUS Drug Formulary; MTUS Drug List; Scope of Coverage; Effective Date.

Corrected the section by deleting an inadvertent inclusion of the number "7" in subdivision (a), as indicated below by bold double strikethrough style: ~~**deletion**~~.

"(a) Drugs prescribed or dispensed to treat a work related injury or illness fall within Labor Code section 4600's definition of "medical treatment" and are subject to the relevant provisions of the MTUS, including the MTUS Treatment Guidelines, provisions relating to the presumption of correctness, and the methods for rebutting the ~~7~~presumption and for substantiating medical necessity where the MTUS Treatment Guidelines do not address the condition or injury."

Section 9792.27.8. Physician-Dispensed Drugs.

Corrected the omission of the word "section" in subdivision (d), as indicated below by underscore style: addition.

"(d) Nothing in this Article shall permit physician dispensing where otherwise prohibited by a pharmacy benefit contract pursuant to subdivision (a) of Labor Code section 4600.2."

Section 9792.27.9. Compounded Drugs.

Corrected the omission of the word "section" in subdivision (c), as indicated below by underscore style: addition.

"(c) Nothing in this Article shall permit physician dispensing of compounded drugs where otherwise prohibited by a pharmacy benefit contract pursuant to subdivision (a) of Labor Code section 4600.2."

Section 9792.27.12. MTUS Drug List – Special Fill.

Corrected the punctuation by removing an extraneous comma in subdivision (a), as indicated below by double strikethrough: ~~deleted~~; and underscore: addition.

"(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,"~~ "Non-Exempt" will be allowed without prospective review as specified in subdivision (b)."

Section 9792.27.15. MTUS Drug List.

The numbering for each of the drug ingredients, which appears in column A of the excel spreadsheet "MTUS Drug List", was corrected to account for additions and deletions of drugs as a result of modifications during the First 15-day comment period.

Section 9792.27.19. Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

The section containing this form was originally numbered section 9792.27.17, but was renumbered to section 9792.27.19 prior to the first 15-day comment period. The footer which contains the title 8 section number was modified after the close of the 2nd 15-day comment period for consistency with the renumbering of the section.

In addition, the regulation and form were originally intended to be adopted in July 2017, and therefore the form name/identifier in the footer included:
"DWC MTUS PT-APP (New 7/17)".

In light of the fact that the regulations will not be filed with the Secretary of State until November of 2017, the form name/identifier is updated to indicate:
"DWC MTUS PT-APP (New 11/17)".

Section 9792.27.19.21. Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form.

The section containing this form was originally numbered section 9792.27.19, but was renumbered to section 9792.27.21 prior to the first 15-day comment period. The form heading which contains the title 8 section number was modified after the close of the 2nd 15-day comment period for consistency with the renumbering of the section.

In addition, the footer was updated. The regulation and form were originally intended to be adopted in July 2017, and therefore the form name/identifier in the footer included:
"DWC MTUS PT-COI (New 7/17)".

In light of the fact that the regulations will not be filed with the Secretary of State until November of 2017, the form name/identifier is updated to indicate:
"DWC MTUS PT-COI (New 11/17)".

SUMMARY OF COMMENTS RECEIVED AND RESPONSES THERETO CONCERNING THE REGULATIONS ADOPTED

The comments submitted of each organization or individual are addressed in the following charts, which are incorporated by reference.

The public comment periods were as follows:

Initial 45-day comment period on proposed regulations:
March 17, 2017 – May 1, 2017

First 15-day comment period on modifications to proposed text:
July 18, 2015 – August 2, 2017

Second 15-day comment period on modifications to proposed text:
September 7, 2017 – September 22, 2017

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