STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
Division of Workers' Compensation

NOTICE OF MODIFICATION OF TEXT OF PROPOSED REGULATIONS AND NOTICE OF ADDITION OF DOCUMENTS TO THE RULEMAKING FILE

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

NOTICE IS HEREBY GIVEN, pursuant to Government Code section 11346.8(c) that the Acting Administrative Director of the Division of Workers' Compensation, proposes to add two new sections and modify the text of the following proposed regulations to be adopted into title 8, California Code of Regulations:

Section 9792.27.1. Definitions
Section 9792.27.2. MTUS Drug Formulary; MTUS Drug List; Scope of Coverage
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 [New]
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 [Excel document]
Section 9792.27.16. National Drug Codes, Unique Product Identifier - MTUS Drug List
Section 9792.27.17. Formulary – Dispute Resolution [New]
Section 9792.27.20. Pharmacy and Therapeutics Committee – Conflict of Interest.
Section 9792.27.22. P&T Committee – Meetings
Section 9792.27.23. MTUS Drug List Updates

PRESENTATION OF WRITTEN COMMENTS AND DEADLINE FOR SUBMISSION OF WRITTEN COMMENTS

Members of the public are invited to present written comments regarding this proposed modification and documents added to the rulemaking file. **Only comments concerning the proposed modification to the text of the regulations, and documents added to the rulemaking file will be considered and responded to in the Final Statement of Reasons.**

All written comments concerning the proposed modifications to the regulations must be received by the regulations coordinator no later than **5:00 P.M.**, on **August 2, 2017**.

Written comments may be submitted as follows:

By Mail addressed as follows:

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
Post Office Box 420603
San Francisco, CA 94142

By Hand Delivery addressed as follows:

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street 18th Floor
Oakland, CA 94612

By FAX addressed to Maureen Gray, Regulations Coordinator, Department of Industrial Relations, Division of Workers' Compensation at the following number:

(510) 286-0687

By e-mail to the following e-mail address:

dwcrules@dir.ca.gov

Comments sent to other e-mail addresses or facsimile numbers will not be accepted. All comments, including comments sent by e-mail or facsimile are subject to the deadline set forth above for written comments.

AVAILABILITY OF TEXT OF REGULATIONS AND RULEMAKING FILE

Copies of the original text, the modified text with modifications clearly indicated and the entire rulemaking file, are currently available for public review during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, excluding legal holidays, at the offices of the Division of Workers' Compensation. The Division is located at 1515 Clay Street, 18th Floor, Oakland, California. Please contact the Division's regulations coordinator, Ms. Maureen Gray, at (510) 286-0676 or (510) 286-7100 to arrange to inspect the rulemaking file.

NOTICE OF ADDITION OF DOCUMENTS TO THE RULEMAKING FILE, RELIED UPON IN PROPOSING THE MODIFIED REGULATIONS

Pursuant to the requirements of Government Code section 11347.1, the Division of Workers' Compensation is providing notice that documents which the agency has relied upon in proposing the modifications to the proposed regulations have been added to the rulemaking file. The documents are available for public inspection and comment during the written comment period, see "Presentation of Written Comments and Deadline for Submission of Written Comments" set forth above. The Division will respond to comments regarding the documents in the Final Statement of Reasons. The documents may be inspected as part of the rulemaking file; see "Availability of Text of Regulations and Rulemaking File" above for the place and time the documents will be available and the name and phone number of the contact person.

Documents added to the rulemaking file after close of the 45-day comment period include the written comments received, the transcript of the public hearing, and the following:

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

FORMAT OF MODIFIED PROPOSED REGULATORY TEXT

The original proposed text of regulation (all new) is in plain text.

Deletions proposed during the 15-day comment period, to the original proposed text of regulation, are indicated by strikethrough, thus: ~~deleted language~~.

Additions proposed during the 15-day comment period, to the original proposed text of regulation, are indicated by underlining, thus: <u>added language</u>.

On the MTUS Drug List, section 9792.27.15, strikethrough/underline changes are also in red text.

SUMMARY OF PROPOSED CHANGES

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

(c) Delete prior subdivision (c) which defined "brand name drug". Add 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) Delete original definition of "compounded drug". Add new definition of "compounded drug" as a drug that is subject to the California Board of Pharmacy compounding regulations, or federal compounding law.

(h) Change the "Preferred/Non-Preferred" nomenclature to "Exempt/Non-Exempt" in former subdivision (v) in order to improve the clarity of the designation and more closely align with the intended effect of the designation. Move the definition to subdivision (h) from former subdivision (v) to maintain alphabetical order of the definitions.

(h) Re-letter former subdivision (h) to (i). Modify definition of "expedited review" to simplify, so that it cross-references to utilization review regulations rather than repeats utilization review regulation provisions. Add the omitted word "expedited" in the first sentence.

(k) Delete original definition of "generic drug".

(l) Add new definition of "generic drug" to improve accuracy by tying it to drugs

approved by the FDA under an Abbreviated New Drug Application. Further, add language that a generic may be substituted for therapeutic equivalent brand name drug pursuant to state and federal law.

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

(m) Re-letter former subdivision (m) "MTUS Drug List" to (n). Change cross-reference to other regulation section to reflect the revised numbering due to changes in the modified text. Substitute "Exempt" for "preferred" and "Non-Exempt" for non-preferred to reflect revised nomenclature. Modify "active drug ingredients" to "active drug ingredient(s)" to reflect the fact that some of the listed drugs have more than one active ingredient.

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

(o) Re-letter former subdivision (o) "Nonprescription drug" or "over-the-counter drug" (OTC) to (p), and add the word "drug" to the parenthetical as follows: "(OTC <u>drug</u>)".

(p) Re-letter former subdivision (p) "off-label use" to (q). Revise language for clarity.

(q) Delete subdivision to streamline the regulation because subdivision (p) defines "'nonprescription drug' or 'over-the-counter drug'" and subdivision (q) could be regarded as duplicative.

(r) Delete 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) Substitute "Non-Exempt" for "Non-Preferred" to reflect revised nomenclature; change cross-reference to other regulation section to reflect the revised numbering due to changes in the modified text.

(v) Delete former subdivision (v) "preferred drug", change the "Preferred/Non-Preferred" nomenclature to "Exempt/Non-Exempt" in former subdivision (v); move the provision to subdivision (h) from subdivision (v) to maintain alphabetical order of the definitions.

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

(x) Delete former 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.

(y) Re-letter former subdivision (y) to (x). Substitute “Non-Exempt” for “Non-Preferred” to reflect revised nomenclature and change 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.

(z) Re-letter former subdivision (z) to (y). Delete 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) Re-letter former subdivision (aa) to (z). Modify language to simplify and coordinate with revised definition of “FDA-approved drug” which includes both prescription and non-prescription drugs approved by the FDA.

Re-letter intervening definitions as necessitated by changes detailed above.

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

(a) Add the word “and” to improve grammatical structure.

(b) Modify 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. Modify 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. Modify 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 is 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. Delete 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) Modify 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) Modify as follows:

- For injuries prior to 1/1/2018, add 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 safe 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
- Add 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.

Modify 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. Add 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) Modify the language from “Preferred” drug to “Exempt” drug.

(c) Modify the language from “Preferred/Non-Preferred” drug to “Exempt/Non-Exempt” drug.

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

(d) Correct 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) Modify “Preferred” drug to “Exempt” drug.

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

Modify 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.

Correct punctuation by moving “period” outside of parenthesis.

Delete 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.

Modify 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.

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

Section 9792.27.8. Physician-Dispensed Drugs.

(a) Change cross-reference to Special Fill and Perioperative Fills regulations to reflect the revised numbering due to changes in the modified text. Delete 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.

- Modify 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*.
- Modify proposal to allow one *or more* medically appropriate exempt drugs to be dispensed as the injured worker may need more than one medication.
- Delete language that relates to retrospective review as that is governed by the UR regulations.

(d) Added provision to recognize that a Pharmacy Benefit Network contract pursuant to LC § 4600.2 may prohibit physician dispensing.

Section 9792.27.9. Compounded Drugs.

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

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

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

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

(b) Change "drug identified as Preferred" to "drug identified as Exempt".

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

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

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

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

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

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

(f) Delete 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). Delete 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.

Add 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.

The sections that follow are 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". Delete 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"; modify for clarity to indicate that the Non-Exempt drug must meet the Special Fill requirements of subdivision (b).

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

Re-letter (e) to (d) and clarify 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) Modify 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) Modify 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) Delete language that relates to retrospective review as that is governed by the UR regulations.

Re-letter (d) to (c) and clarify 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. .

Section 9792.27.15. MTUS Drug List.

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

- Change 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.
- Add new column and data for "Reference Brand Name" for each drug ingredient.
- Update 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.
- Add a muscle relaxant and a corticosteroid to the "Special Fill".
- Change one corticosteroid drug from "Perioperative Fill" to "Special Fill".
- Change 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.
- Increase the "Perioperative Fill" from 4-day supply to 14-day supply for the anticoagulants.
- Make technical corrections to identification of drug names.
- Make updates to "Reference in Guidelines" data to conform to ACOEM Guideline changes.
- Modify the MTUS Drug List introductory language to improve clarity and conform to proposed changes in text.
- Add columns with following headings: "Dosage Form", "Strength" and "Unique Product Identifier(s)". Currently without data in the fields, but proposed for adoption in order to allow MTUS Drug List updates to capture this information after consultation with the P&T Committee, and allow special instructions for use.

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

(a) Modify to allow the drug product list to use RxCUI (National Library of Medicine drug coding system) or other unique product identifier in addition to, or as alternative to, NDCs (National Drug Codes)

(b) Modify language to specify that only drug products that can be self-administered would be on the list.

(d) Modify 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.
Eliminate requirement that route of administration is required to be included.
Change the "Preferred/Non-Preferred" nomenclature to "Exempt/Non-Exempt"

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.

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