

**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, subdivision (c) that the Acting Administrative Director of the Division of Workers' Compensation, proposes to modify the text of the following proposed regulations to be adopted into title 8, California Code of Regulations:

- Section 9792.27.1.** Definitions
- Section 9792.27.3.** MTUS Drug Formulary Transition
- Section 9792.27.4.** MTUS Drug Formulary – Pharmacy Networks; Pharmacy Benefit Manager Contracts
- Section 9792.27.6.** MTUS Drug Formulary – Access to Drugs Not Listed as an Exempt Drug on the MTUS Drug List
- 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 9792.27.14.** 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 Pharmaceutical Identifier - MTUS Drug List
- Section 9792.27.17.** Formulary – Dispute Resolution

**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. **Only comments concerning the proposed modifications to the text**

**of the regulations and MTUS Drug List 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 **September 22, 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 18<sup>th</sup> 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](mailto: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, 18<sup>th</sup> 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.

## FORMAT OF MODIFIED PROPOSED REGULATORY TEXT

### 45-day Comment Period:

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

### 1<sup>st</sup> 15-day Comment Period:

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: added language.

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

### 2<sup>nd</sup> 15-day Comment Period:

Deletions to Text of regulation that are proposed during the 2<sup>nd</sup> 15-day comment period are indicated by double strikethrough, thus: ~~~~deleted language~~~~.

Deletions to MTUS Drug List in excel format, that are proposed during the 2<sup>nd</sup> 15-day comment period, are indicated by italic font and strikethrough, thus: ~~*deleted language*~~.

Additions to Text of regulation and MTUS Drug List in excel format that are proposed during the 2<sup>nd</sup> 15-day comment period, are indicated by double underlining, thus: added language.

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

## **SUMMARY OF PROPOSED CHANGES**

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

(h) and (o) Correct punctuation to move the period inside the quotation mark at the end of the sentence.

### **Section 9792.27.3. MTUS Drug Formulary Transition.**

(b)(2)(A) Modify to state that the physician shall prepare a report that sets forth a “medically appropriate,” rather than “safe” treatment plan. The term “medically appropriate” is preferable; the term “safe” is too narrow as it only encompasses one aspect of a treatment plan.

(b)(3) Modify to correct a regulation citation to include a comma and the word “subdivision.”

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

Modify punctuation by adding two commas to improve clarity.

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

(a) Modify to correct a regulation citation to include a comma.

### **Section 9792.27.8. Physician-Dispensed Drugs.**

(d) Modify provision to recognize that a “pharmacy benefit” contract rather than a “Pharmacy Benefit Network” contract pursuant to Labor Code section 4600.2 may prohibit physician dispensing. The modification is needed to make the provision consistent with the language of the Labor Code section 4600.2, which recognizes a variety of pharmacy benefit contracts, and not solely network contracts.

### **Section 9792.27.9. Compounded Drugs.**

(c) Add 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 is proposed to provide additional clarity and parallels the language in the physician dispensing regulation section.

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

(b) Modify to add a new (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 improves 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.”

**Section 9792.27.11. Waiver of Prospective Review.**

Modify to correct a regulation citation to include a comma and the word “subdivision.”

**Section 9792.27.14. Treatment Provided Under Applicable Health and Safety Regulations.**

Modify to correct a regulation citation to include a comma.

**Section 9792.27.15. MTUS Drug List.**

All of the modifications proposed are on page one of the excel spreadsheet; therefore an Excerpt of the MTUS Drug List is issued for public comment.

The modifications proposed to the MTUS Drug List are as follows:

- The introductory matter is modified in relation to the Perioperative Fill to state that the perioperative fill period begins 4 days, rather than 2 days, before surgery. This conforms the perioperative period to a modification in the text of section 9792.27.13, subdivision (b), that was made in the 1<sup>st</sup> 15-day comment period, but mistakenly overlooked on the drug list introductory language.
- The introductory matter language relating to Perioperative Fill is modified to change the word “if” to “is” to better align with the language in the text of the regulation section 9792.27.13.
- Change column heading: from “Unique Product Identifier(s)” to “Unique Pharmaceutical Identifier(s)”. This change is made to be consistent with modified language proposed in section 9792.27.16.

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

(a) Modify heading and subdivision (a) to use the terminology “Unique Pharmaceutical Identifier” rather than “Unique Product Identifier.” Using the term “pharmaceutical” rather than “product” is preferred as “unique product identifier” is a term used for Drug Supply Chain Act product tracing.

Improve the clarity of the regulation by proposing the following modifications.

- Spell out “National Drug Code” rather than using the abbreviation “NDC”
- Add identifying information regarding RxCUI by adding the parenthetical “(clinical drug concept unique identifier maintained by the National Library of Medicine)”

(d) Modify the text to delete 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. In the future, after further evaluation, the Division may address repackaged drugs, and may determine whether particular provisions of the Formulary and MTUS Drug List are needed to address issues raised by use of repackaged drugs.

(e) Is re-lettered to (d). Re-lettered subdivision (d)(1) is modified to add the word "pharmaceutical"; therefore the proposed text states that the listing may include: "National Drug Code, RxCUI, or other pharmaceutical identifier". This modification is made for consistency with the terminology in subdivision (a).

#### **Section 9792.27.17 Formulary – Dispute Resolution.**

(a) Modify to delete "s" from "sections" to correct citation form: "sections 9792.6.1 et seq."

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