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

NOTICE OF PROPOSED RULEMAKING

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

TITLE 8, CALIFORNIA CODE OF REGULATIONS
ADOPT SECTIONS 9792.27.1 – 9792.27.21

NOTICE IS HEREBY GIVEN that the Acting Administrative Director of the Division of Workers' Compensation, Department of Industrial Relations (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, proposes to adopt sections 9792.27.1 through 9792.27.21, to establish a drug formulary and related rules as part of the workers' compensation Medical Treatment Utilization Schedule (MTUS).

PROPOSED REGULATORY ACTION

The Administrative Director proposes to adopt the following regulations into Article 5.5.2 of Division 1, Chapter 4.5, Subchapter 1, of title 8, California Code of Regulations:

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

Adopt section 9792.27.17	Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form
Adopt section 9792.27.18	Pharmacy and Therapeutics Committee – Conflict of Interest
Adopt section 9792.27.19	Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form
Adopt section 9792.27.20	Pharmacy and Therapeutics Committee – Meetings
Adopt section 9792.27.21	MTUS Drug List Updates

TIME AND PLACE OF PUBLIC HEARING

A public hearing has been scheduled to permit all interested persons the opportunity to present statements or arguments, oral or in writing, with respect to the proposed regulatory action, on the following date:

Date: May 1, 2017
Time: 10:00 a.m. to 5:00 p.m., or until conclusion of business
Place: Elihu Harris State Office Building – Auditorium
1515 Clay Street
Oakland, CA 94612

The State Office Building and its Auditorium are accessible to persons with mobility impairments. Alternate formats, assistive listening systems, sign language interpreters, or other type of reasonable accommodation to facilitate effective communication for persons with disabilities, are available upon request. Please contact the Statewide Disability Accommodation Coordinator, Maureen Gray, at 1-866-681-1459 (toll free), or through the California Relay Service by dialing 711 or 1-800-735-2929 (TTY/English) or 1-800-855-3000 (TTY/Spanish) as soon as possible to request assistance.

Please note that public comment will begin promptly at 10:00 A.M. and will conclude when the last speaker has finished his or her presentation or 5:00 P.M., whichever is earlier. If public comment concludes before the noon recess, no afternoon session will be held.

The Administrative Director requests, but does not require, that any persons who makes oral comments at the hearing also provide a written copy of their comments. Equal weight will be accorded to oral comments and written materials.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department of Industrial Relations, Division of Workers' Compensation. The written comment period closes at **5:00 P.M., on May 1, 2017.** The Division of Workers' Compensation (Division) will consider only comments received at the Division by that time. Equal weight will be accorded to oral comments presented at the hearing and written materials.

Submit written comments concerning the proposed regulations prior to the close of the public comment period to:

Maureen Gray
Regulations Coordinator
Division of Workers' Compensation, Legal Unit
P.O. Box 420603
San Francisco, CA 94142

Written comments may be submitted by facsimile transmission (FAX), addressed to the above-named contact person at (510) 286-0687. Written comments may also be sent electronically (via e-mail) using the following e-mail address: dwcrules@dir.ca.gov.

All written comments must be received by the regulations coordinator no later than **5:00 P.M., on May 1, 2017.**

AUTHORITY AND REFERENCE

The Administrative Director is undertaking this regulatory action pursuant to the authority vested in him by Labor Code sections 59, 133, 4600, 4604.5, 5307.3, and 5307.27.

Reference is to Government Code sections 11120 through 11132, Labor Code sections 4600, 4600.2, 4604.5, 5307.27, and 5307.29.

INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

Existing law establishes a workers' compensation system, administered by the Administrative Director of the Division of Workers' Compensation, to compensate an employee for injuries sustained in the course of his or her employment. Labor Code section 4600 requires an employer to provide medical, surgical, chiropractic, acupuncture, and hospital treatment, including nursing, medicines, medical and surgical supplies, crutches, and apparatus, including orthotic and prosthetic devices and services, that is reasonably required to cure or relieve the injured worker from the effects of his or her injury. Labor Code section 4600, subdivision (b) provides that the medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the MTUS guidelines adopted pursuant to Labor Code section 5307.27. Labor Code section 5307.27 requires the Administrative Director to adopt a Medical Treatment Utilization Schedule (MTUS) that "shall incorporate the evidenced-based, peer-reviewed, and nationally recognized standards of care" and "that shall address, at a minimum, the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases."

Assembly Bill 1124 (Statutes 2015, Chapter 525) amended Labor Code section 5307.27 to require the Administrative Director to adopt and incorporate an evidence-based drug formulary into the MTUS by July 1, 2017. Labor Code section 5307.27 requires the formulary to apply to all prescribers and dispensers of medications in the workers' compensation system and to include a phased implementation for workers injured prior to July 1, 2017. The statute provides that non-formulary medication may be authorized when the need is demonstrated in accordance with Labor Code section 4604.5 subdivision (a) which allows treatment outside of the MTUS when the preponderance of scientific medical evidence

establishes that a variance is required to cure or relieve the injured worker from the effects of the injury.

Assembly Bill 1124 also adopted Labor Code section 5307.29, which requires the formulary to be updated at least quarterly to allow provision of all appropriate medications, including those new to the market. The updates to the list of formulary drugs are to be made through an Administrative Director order exempt from the rulemaking provisions of the Administrative Procedure Act and the Labor Code. The update orders are to be published on the Division's website, informing the public of the changes and the effective date. The statute directs the Administrative Director to establish an independent Pharmacy and Therapeutics Committee (P&T Committee) to review and consult with the DWC on available evidence of the relative safety, efficacy and effectiveness of drugs within a class of drugs. The P&T Committee is required to be composed of the Division of Workers' Compensation Executive Medical Director, three physicians, and three pharmacists. The committee members must have knowledge or expertise in one or more of the following areas: clinically appropriate prescribing of covered drugs; clinically appropriate dispensing and monitoring of covered drugs; drug use review; evidence-based medicine. The statute requires that a committee member must not be employed by a pharmaceutical manufacturer, pharmacy benefits management company, or commercial formulary development company, nor be so employed during the previous 12 months. The statute also directs the Administrative Director to establish standards to prohibit substantial financial conflicts of interest and gives the Administrative Director sole discretion to disqualify a member or potential member if he determines a substantial conflict of interest exists.

The regulations proposed in this notice of rulemaking are intended to improve the provision of medical care to injured workers by establishing a list of preferred medications, with the goals of encouraging the use of the most appropriate medications, minimizing disputes and associated administrative costs, and addressing escalating rates of opioid addiction. The broad objective is to include the drug formulary into the workers' compensation MTUS.

The proposed regulations implement, interpret, and make specific the above sections of the Labor Code as follows:

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

- The Administrative Director proposes to adopt definitions of the terms that are necessary for establishing the drug formulary and for regulating the drug formulary update process. The definitions provide clarity for the public regarding the meaning of terms used in the regulatory text.

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

- The proposed regulation states that drugs prescribed or dispensed to treat a work related injury or illness fall within the Labor Code's definition of "medical treatment." The proposal makes it clear that the drug treatment is subject to the MTUS Guidelines and rules, including the presumption of correctness, and methods to rebut the presumption.

- The proposed regulation states that, except for continuing medical treatment, any drug dispensed on or after July 1, 2017 for outpatient use is subject to the MTUS Drug Formulary, regardless of

the date of injury.

- The proposed regulation defines "outpatient use" as a drug to be taken, applied, or self-administered by the patient at home or outside of a clinical setting, including "take home" drugs at the time of discharge from a facility. The proposed regulation specifies that drugs dispensed for outpatient use by any of the following are subject to the formulary: a physician; a pharmacy; an inpatient hospital; an outpatient department of a hospital; an emergency department of a hospital; an ambulatory surgery center; any other health care provider or health care entity.

- The proposed regulation clarifies that the MTUS Drug Formulary does not apply to physician-administered drugs, but other relevant portions of the MTUS do apply to physician-administered drugs, for example, steroid injections into the shoulder joint.

Section 9792.27.3. MTUS Drug Formulary Transition.

- The regulation contains provisions to carry out the statutory directive that there should be a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to formulary medications.

- For a worker injured before July 1, 2017 the drug formulary will apply to drugs dispensed on or after July 1, 2017 unless the injured worker is on an ongoing course of drug treatment.

- For workers injured prior to July 1, 2017, who are receiving ongoing drug treatment, the claims administrator is precluded from unilaterally terminating or denying a previously approved drug treatment.

- The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period in accordance with the MTUS.

- Where the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, unlisted drug, or compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations shall apply.

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

- The proposed regulation implements the statutory provision that drugs provided pursuant to a pharmacy benefit network contract or pharmacy benefit manager contract are subject to the drug formulary. The regulation states that the drugs available to the injured worker must be consistent with the MTUS guidelines and MTUS Drug Formulary for the injury or condition being treated and may not be restricted pursuant to the contract.

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

- Assembly Bill 1124 sets forth the legislative intent that the formulary include guidance regarding how an injured worker may access off-label use of prescription drugs, when evidence-based and medically necessary. The proposed regulation states that off-label use of a drug should be in

accordance with the MTUS Guidelines and the MTUS Drug Formulary rules. When off label use of a Preferred Drug is recommended by the MTUS Guideline for off-label treatment of a condition, the drug may be dispensed without prospective review.

- Authorization through prospective review must be obtained for off-label use of a Non-Preferred drug, an unlisted drug, or for a Preferred drug lacking recommendation in the MTUS Treatment Guideline for the intended off-label use. If the required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.

- The proposed regulation addresses the off-label use of drugs when the off-label use in not recommended in the MTUS Treatment Guidelines or is not addressed by the MTUS Treatment Guidelines. Where the physician believes the off-label use is medically necessary, but the off-label use is not recommended in the MTUS Treatment Guidelines or is not addressed in the MTUS Guidelines, the permissibility of the treatment outside of the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence.)

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

- Labor Code section 5307.27 includes a provision stating that the statute shall not prohibit the authorization of medications that are not in the drug formulary when a variance is demonstrated consistent with Labor Code section 4604.5. Section 4604.5 states that the MTUS is presumed correct on the extent and scope of medical treatment and may be rebutted by a preponderance of scientific medical evidence establishing that a variance from the guidelines is reasonably required to cure or relieve the effects of the injury. Regulations adopted to carry out section 4604.5 set forth standards for rebutting the MTUS guidelines (sections 9792.21, 9792.21.1, 9792.25.) The proposed section 9792.27.6 carries out the statutory directive in Labor Code section 5307.27 by specifying that medically necessary drugs outside of the formulary may be authorized through prospective review and dispensed to an injured worker in accordance with section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence.) The regulation states that payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.

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

- Assembly Bill 1124 sets forth the legislative intent that the formulary include use of generic drugs pursuant to evidence-based practices, with consideration given to use of brand name drugs when it would be cost-effective, medically necessary, and evidence-based. Proposed section 9792.27.7 implements this legislative intent by allowing more expensive brand name drugs to be specified by the physician ("Do Not Substitute" or "Dispense as Written"), provided that the physician document the medical necessity of the brand name drug. The documentation must be on the patient's medical chart and in the Doctor's First Report of Injury (Form 5021) or the

Progress Report (PR-2), and must include patient-specific factors that support the conclusion that the brand name drug is medically necessary. The proposed regulation specifies that the physician must obtain authorization through Prospective Review prior to the time the brand drug is dispensed. However, if the required authorization is not obtained prior to dispensing, there may be retrospective review to determine if the drug is medically necessary, and whether the brand version rather than the generic version is necessary. If it is found on retrospective review that the drug was not medically necessary, payment may be denied. If the drug was necessary, but it was not medically necessary to dispense the brand version of the drug, payment may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand drug.

Section 9792.27.8. Physician-Dispensed Drugs.

- The proposed regulation requires a physician to obtain authorization through prospective review prior to dispensing a drug, unless a specified exception applies. The exceptions to the requirement to obtain authorization include the following.
    - The physician can dispense up to a seven-day supply of a drug that is listed as "Preferred" on the MTUS Drug List, on a one-time basis.
    - Non-Preferred drug as allowed in the "Special Fill" rule.
    - Non-Preferred drug as allowed in the "Perioperative Fill" rule.
- Preferred Drugs dispensed by a physician without prospective review as allowed by this section (one-time 7 day supply, Special Fill or Perioperative Fill) may be subject to retrospective review to determine medical necessity. Payment may be denied if the drug was determined not to be medically necessary.
- The regulation allows a Medical Provider Network agreement to contain a provision which restricts physician dispensing by medical providers within the network.

Section 9792.27.9. Compounded Drugs.

- The proposed regulation requires compounded drugs to be authorized through prospective review prior to being dispensed.
- A doctor may prescribe a medically necessary compounded drug instead of an FDA-approved drug, or over-the-counter drug that complies with an OTC Monograph.
    - Physician must document in the patient's medical chart and in the Doctor's First Report of Injury or Progress Report
    - Must document the patient-specific factors that support the physician's determination that a compounded drug is medically necessary.
- The regulation allows a Medical Provider Network agreement to restrict physician-dispensing of compounded drugs by medical providers within the network.

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

The proposed regulation sets forth details regarding the structure of the MTUS Drug List, and the rules applied to a drug based on its status as preferred, non-preferred, or unlisted.

- The MTUS Drug List is set forth by active drug ingredient.
- A drug identified as "Preferred" may be dispensed without obtaining authorization through prospective review if the drug treatment is in accordance with the MTUS Treatment Guidelines.
- For a drug that is identified as "Non-Preferred" authorization through Prospective Review must be obtained prior to dispensing the drug.
- For a drug that is identified as eligible for "Special Fill" or "Perioperative Fill", the usual requirement to obtain authorization through prospective review is altered in specified circumstances. The regulation cross references to the sections governing "Special Fill" or "Perioperative Fill".
- For an unlisted drug, authorization through Prospective Review must be obtained prior to dispensing the drug.
- Retrospective review may be conducted to determine if the drug was medically necessary, and payment for the drug may be denied if it is determined the drug was not medically necessary.
- The regulation specifies that the prospective review requirement may be waived if the drug falls within a utilization review plan's provision of prior authorization adopted pursuant to section 9792.7(a)(5).

Section 9792.27.11. MTUS Drug List – Special Fill.

The proposed regulation sets forth rules to allow a short fill of specified Non-Preferred drugs without obtaining Prospective Review prior to dispensing the drug. The requirements for the "Special Fill" include all of the following.

- The drug is prescribed at the single initial treatment visit following a workplace injury, provided that the initial visit is within 7 days of the injury, with the day after injury counted as "day one".
- The prescription is for a supply of the drug not to exceed the limit set forth on the MTUS Drug List.
- The prescription is for an FDA-approved generic or single source brand name drug, or a brand name drug where the physician substantiates the medical need for the brand product, and the drug is prescribed in accordance with the MTUS Guidelines.

The Special Fill dispensing may be subject to retrospective review, and payment may be denied if the drug was not medically necessary.

The regulation allows an employer or insurer with a pharmacy network, pharmacy benefit manager, or medical provider network to provide a longer Special Fill period or cover a broader set of drugs pursuant to a contract.

The regulation states that the impact of the Special Fill provision on the use of opioids by injured workers shall be evaluated by the Administrative Director after the provision has been in effect for one year. As part of the evaluation process the Administrative Director shall solicit feedback from workers' compensation system participants.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

The proposed regulation sets forth rules to allow a short fill of specified Non-Preferred drugs without obtaining Prospective Review prior to dispensing the drug if the drug is prescribed during the "Perioperative Period". The requirements for the "Perioperative Fill" include all of the following.

- The drug is prescribed during the perioperative period, defined as two days before the date of surgery through four days after the date of surgery, with the day of surgery counted as "day zero".
- The prescription is for a supply of the drug not to exceed the limit set forth on the MTUS Drug List.
- The prescription is for an FDA-approved generic or single source brand name drug, or a brand name drug where the physician substantiates the medical need for the brand product, and the drug is prescribed in accordance with the MTUS Guidelines.

A drug dispensed under the Perioperative Fill policy may be subject to retrospective review, and payment may be denied if the drug was not medically necessary.

The regulation allows an employer or insurer with a pharmacy network, pharmacy benefit manager, or medical provider network to provide a longer Perioperative Fill period or cover a broader set of drugs pursuant to a contract.

Section 9792.27.13. Treatment Provided Under Applicable Health and Safety Regulations.

The proposed regulation states that the formulary does not relieve the employer of responsibilities under health and safety regulations such as the occupational blood borne pathogens standard.

Section 9792.27.14. MTUS Drug List.

The MTUS Drug List is proposed to be adopted at section 9792.27.14, as an excel spreadsheet setting forth data under the following headings: Drug Ingredient; Preferred/Non-Preferred; Special Fill; Peri-Op; Drug Class; Reference in Guidelines. The top of the MTUS Drug List includes a box which highlights essential provisions from the formulary regulations and emphasizes the need to consult the MTUS Guidelines.

Section 9792.27.15. National Drug Codes - MTUS Drug List.

The regulation sets forth the authority for the Administrative Director to maintain and post on the Division's website a drug listing which includes at least the following: National Drug Codes, drug

ingredient, therapeutic class, strength, dosage form, route of administration, preferred or non-preferred status as applicable, and applicable Special Fill or Perioperative Fill policies.

Section 9792.27.16. Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.

Labor Code section 5307.29 requires the Administrative Director to establish an independent Pharmacy and Therapeutics Committee (P&T Committee) to review and consult with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs in the updating of the formulary. The statute provides that the committee shall be composed of the Executive Medical Director and six other members, who shall be licensed physicians and pharmacists. The proposed regulation implements this directive by establishing rules for the composition of the committee, and the process for appointing members.

- P&T Committee shall consist of Executive Medical Director, 3 physicians, and 3 pharmacists. At least one of the physicians shall be actively engaged in treatment of injured workers; at least one of pharmacists shall be an actively practicing pharmacist.

- P&T Committee members appointed by the Administrative Director shall serve a 2-year term, and shall remain in the position until a successor is appointed. The Administrative Director may cancel the appointment of a committee member if a substantial conflict of interest exists, or for other good cause.

- Potential P&T Committee members shall submit an application and Conflict of Interest Disclosure on forms prescribed by the Administrative Director, demonstrating the qualifications required by the statute.

Section 9792.27.17. Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

This section contains the form for potential P&T Committee members to apply for appointment. The name of the proposed form is: DWC MTUS PT-App, and the version is designated as: "(New 7/17)". The form sets forth areas to identify education, qualifying knowledge or expertise, and current professional status. It includes a section for affirmations that the applicant does not possess prohibited affiliations, is in good standing with licensing boards, and does not have specified criminal convictions. The form directs the applicant to attach the Curriculum Vitae, Conflict of Interest Disclosure Form, and other relevant supporting material at the option of the applicant. The form includes a notice that the form is a public document, and includes advisements pursuant to the Information Practices Act. The form also includes a declaration under penalty of perjury stating that the form is correct to the best of the knowledge of the person signing the form.

Section 9792.27.18. Pharmacy and Therapeutics Committee – Conflict of Interest.

The proposed regulation provides that P&T Committee members must impartially perform formulary update duties and be free of conflicts of interest. The regulation defines "pharmaceutical entity" and prohibits a committee member from having a substantial conflict of interest in relation to a pharmaceutical entity. "Substantial financial conflict of interest" is defined. The regulation addresses the types and amount of direct and indirect financial interests that may constitute a disqualifying interest.

The regulation requires members of the P&T Committee to submit an updated Conflict of Interest Disclosure Form annually, and more frequently if there have been changes in circumstances relating to employment by, or financial interests in, a pharmaceutical entity.

Section 9792.27.19. Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form.

This section contains the form for P&T Committee members and potential members to use to disclose financial information and relationships that would constitute disqualifying conflicts of interest. The name of the proposed form is: DWC MTUS PT-COI, and the version is designated as: "(New 7/17)". The form includes a notice that the form is a public document, and includes advisements pursuant to the Information Practices Act. The form also includes a declaration under penalty of perjury stating that the form is correct to the best of the knowledge of the person signing the form.

Section 9792.27.20. Pharmacy and Therapeutics Committee – Meetings.

The proposed regulation requires that P&T Committee meetings may be held when deemed necessary by the Executive Medical Director, but no less frequently than quarterly. The section sets forth provisions relating to the meetings.

- Meetings shall be conducted in accordance with the Bagley-Keene Open Meeting Act.
- Notice of regularly scheduled meetings is to be given at least 10 days in advance of the meeting.
- P&T Committee meetings shall include a period for public comment, limited to 3 minutes per speaker.
- Executive Medical Director shall maintain written documentation of the meetings and recommendations in the manner directed by the Administrative Director. Committee member votes/abstention will be included in documentation of the meeting.

Section 9792.27.21. MTUS Drug List Updates.

The regulation implements Labor Code section 5307.29 by setting forth provisions relating to update of the formulary, including the frequency of updates, scope of issues to be addressed by the P&T Committee, role of the P&T Committee and method of adopting updates.

Updates may be adopted by the Administrative Director on a quarterly or more frequent basis. The updates will be made by issuance of an Administrative Director order which specifies the changes and the effective date, and is posted on the Division's website.

The P&T Committee's role is to review and consult with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs. In carrying out this duty the committee may consider prospective review requirements for new drugs, or existing drugs based on newly available evidence; Special Fill and Perioperative Fill designation and policies for new drugs, or existing drugs based on newly available evidence; review of drug treatment changes in the MTUS Treatment Guidelines to identify needed additions or deletions of drugs from the MTUS Drug List; and recommendations regarding establishing a therapeutic interchange program in order to promote safe and appropriate cost effective care.

The regulation states that the P&T Committee serves in an advisory role only; its recommendations are not binding on the Administrative Director.

Objective and Anticipated Benefits of the Proposed Regulations

The goal is to adopt an evidence-based drug formulary, consistent with California's Medical Treatment Utilization Schedule (MTUS), to augment the provision of high-quality medical care, maximize health, and promote return to work in a timely fashion, while reducing administrative burden and cost.

It is anticipated that the regulations will expedite delivery of appropriate and timely medical care to injured workers because Preferred drugs that are prescribed in accordance with the MTUS Treatment Guidelines will not need to go through prospective utilization review. In addition, the formulary rules include provisions that are expected to encourage use of safe and effective medications, while discouraging inappropriate prescribing influenced by financial motives. These provisions include: a requirement that the need for a brand name drug be medically substantiated where a less expensive generic is available; a requirement that patient-specific medical needs be documented to dispense a compounded drug instead of an FDA-approved drug; and a restriction on physician-dispensing of medication except as specified.

A significant objective of the formulary is to safeguard injured worker health by placing strict parameters on the dispensing of opioid medications. All opioid medications are designated as Non-Preferred on the MTUS Drug List, which supports evidence-based guidelines that indicate that opioids are generally not a first-line treatment. Where opioid medication is medically necessary, the injured worker can obtain the prescription through the normal prospective review process. Additionally, the regulations contain a "Special Fill" and "Perioperative Fill" provisions that allow workers to obtain a short course of opioid medication where needed, allowing time for prospective review if a longer course of treatment is necessary. It is anticipated that there will be better health outcomes due to less opioid use, with better return to work rates, producing benefits for the injured worker and reduced costs to employers.

Another anticipated benefit is the reduction in disputes over medical treatment which will result in a decreased number of Independent Medical Review (IMR) requests. Data shows that the largest portion of IMRs involve disputes over pharmaceuticals. It is anticipated that the adoption of the formulary will clarify rules and streamline the provision of benefits, thereby reducing the need for IMR.

Determination Regarding Inconsistency/Incompatibility with Existing State Regulations:

The Administrative Director has evaluated whether or not the proposed regulations are inconsistent or incompatible with existing state regulations. The proposal would establish a workers' compensation drug formulary that would be part of the existing MTUS that governs medical treatment of injured workers. The proposed regulations are structured to be consistent and compatible with the MTUS regulations. By statute, the adopted MTUS Treatment Guidelines are presumed correct on the extent and scope of medical treatment. The proposed formulary regulations are consistent and compatible with the MTUS since the provisions that eliminate the prospective review requirement for preferred drugs only apply when the drug is used in conformity with the MTUS Treatment Guidelines. In addition, the proposed regulations are consistent and compatible with the existing MTUS as they state that the MTUS regulations for rebutting the MTUS Treatment Guidelines and for substantiating treatment outside of the

MTUS Treatment Guidelines are applicable to drug treatment. In light of the fact that the proposal is structured to be compatible and consistent with the MTUS, and the fact that there are no other regulations governing the workers' compensation drug formulary, the Administrative Director has determined that the proposed regulations are not inconsistent or incompatible with existing state regulations.

ECONOMIC AND FISCAL IMPACT DISCLOSURES REGARDING THE PROPOSED REGULATORY ACTION

The Administrative Director has made the following initial determinations:

- Mandate on local agencies and school districts: None.

- Cost or savings to any state agency: There are no costs imposed on state agencies. It is anticipated there will be savings to state 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 spending on prescription drugs by $22,951,000, in the first 12 months after the regulation is fully implemented. The State of California accounts for 3.5% of total drug spending based on the overall share of injured workers who are state employees. This share of total estimated savings is $803,000 in the first 12 months after the regulation is fully implemented.

- Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

- Other nondiscretionary cost or savings imposed on 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 spending on prescription drugs by $22,951,000, 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 $3,443,000 in the first 12 months after the regulation is fully implemented.

- Cost or savings in federal funding to the state: None.

- Cost impacts on a representative private person or business: Estimated costs include reduced revenue for physician practices and other health care providers. The reduction in revenue is due to lower rates of physician dispensing of drugs. In 2014, physician-dispensed drugs accounted for about half of California workers' compensation prescribing. Under physician prescribing, physician practices and other providers purchase and stock drugs from wholesalers or manufacturers, dispense prescription drugs directly to injured workers, and then bill directly for the dispensed drug. Physicians retain the margin between the payment rate and the acquisition cost. In many cases, the prices for physician-dispensed drugs are higher than similar pharmacy-dispensed drugs. The regulation requires prospective review for physician dispensed drugs except in a small number of exceptions (including a first fill policy designed to ensure access to

necessary prescriptions shortly after an injury and while the prospective review is in progress). As a result of this prospective review requirement, we estimate that physicians will dispense fewer prescriptions and that some of these prescriptions will transition to pharmacy-dispensed prescriptions. It is projected that two-thirds of the ultimate reduction in physician-dispensed prescription fills would occur in the first year after the regulation is fully implemented and that later years would experience the full reduction.

The estimated total cost in the initial 12-month period after the regulation is fully implemented is $10,435,000. This estimate includes a $6,760,000 reduction in net income for physician practices and other providers dispensing drugs directly to injured workers and a $3,765,000 reduction in state Gross State Product (GSP) driven by lower physician practice revenue.

- Statewide adverse economic impact directly affecting businesses and individuals: The regulatory action will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

- Significant effect on housing costs: None.

Results of the Economic Impact Analysis/Assessment

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. It is estimated that 140 jobs will be created and 41 jobs will be eliminated. Costs and benefits are multiplier impacts that are spread across all industries. The estimated impacts are relatively small and apply to a large number of industries.

Creation of New Businesses or the 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. It is expected that costs and benefits will be borne by existing businesses and the regulations will not create or eliminate businesses.

Expansion of Businesses Currently Doing Business within the State of California

The Administrative Director concludes that it is unlikely that the proposal would cause the expansion of businesses currently doing business within the State of California.

Benefits of the Proposed Action: The proposed regulations will be beneficial as they will promote the timely delivery of evidence-based medical treatment by eliminating prospective utilization review for Preferred drugs used in accordance with the treatment guidelines. Reduced prescribing volume for some non-preferred 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.

Small Business Determination: The Administrative Director has determined that the proposed regulation affects small business. The small businesses that will be impacted by the regulation are primarily physicians and physician practices that dispense medications to their patients.

CONSULTATION WITH THE PUBLIC PER LABOR CODE SECTION 5307.28 AND GOVERNMENT CODE §11346.45

The Administrative Director has complied with the public consultation requirements of Labor Code section 5307.28 and Government Code section 11346.45 through the following actions.

- Convened a public meeting entitled: "Workers' Compensation Drug Formulary Public Meeting – Implementation of Assembly Bill 1124" February 17, 2016
    - Presentation by RAND Consultant Barbara Wynn: California's Drug Formulary: An Overview
    - Public discussion of formulary issues

- Conducted an online Public Forum entitled: "DWC Forums - Implementing AB 1124 Drug Formulary and update of MTUS guidelines". August 26, 2016 through September 16, 2016. Posted documents for public comment.

    - Draft Text of Formulary Regulations
    - Draft MTUS Drug List
    - Consultant report: *Implementing a Drug Formulary for California's Workers' Compensation Program* – RAND, August 2016
    - ACOEM Guidelines (Ankle and Foot Disorders; Cervical and Thoracic Spine Disorders; Elbow Disorders; Eye Disorders; Hand, Wrist, and Forearm Disorders; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; Shoulder Disorders)
    - Comments received during the comment period

CONSULTATION WITH THE COMMISSION ON HEALTH AND SAFETY AND WORKERS' COMPENSATION

The Division has consulted with the Commission on Health and Safety and Workers' Compensation on the development of the formulary. On October 6, 2016 presentation was made to the Commission by the Division of Workers' Compensation's Executive Medical Director and the Division's legal counsel. Commission members had the opportunity to question Division staff and were provided drafts of the formulary rules, and a presentation regarding the progress of the project.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Administrative Director must determine that no reasonable alternative considered or that has otherwise been identified and brought to

the Administrative Director's attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Administrative Director invites interested persons to present reasonable alternatives to the proposed regulations during the written comment period, or at the public hearing.

CONTACT PERSONS

Inquiries concerning the proposed rulemaking action may be directed to:

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
P.O. Box 420603
San Francisco, CA 94142
E-mail: mgray@dir.ca.gov
Telephone: (510) 286-7100

The backup contact person for these inquiries is:

Jacqueline Schauer
Division of Workers' Compensation
P.O. Box 420603
San Francisco, CA 94142
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Please direct requests for copies of the proposed text (the "express terms") of the regulations, the Initial Statement of Reasons, and any supplemental information contained in the rulemaking file, to the contact person at the above address. Requests to be added to the mailing list for rulemaking notices may also be directed to the contact person.

AVAILABILITY OF INITIAL STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, RULEMAKING FILE AND DOCUMENTS SUPPORTING THE RULEMAKING FILE

An Initial Statement of Reasons and the text of the proposed regulations in plain English have been prepared and are available from the contact person named in this notice. The entire set of regulations consists of new sections proposed for adoption, including the MTUS Drug List and the two new forms. The rulemaking file will be made available for inspection and copying at the address indicated below.

Any interested person may inspect a copy or direct questions about the proposed regulations and any supplemental information contained in the rulemaking file. The rulemaking file will be available for

inspection at the Department of Industrial Relations, Division of Workers' Compensation, 1515 Clay Street, 18th Floor, Oakland, California 94612, between 9:00 A.M. and 4:30 P.M., Monday through Friday. Copies of the proposed regulations, Initial Statement of Reasons and any information contained in the rulemaking file may be requested in writing to the contact person.

As of the date of this Notice, the rulemaking file consists of the Notice, the Initial Statement of Reasons, proposed text of the regulations, the Fiscal and Economic Impact Statement (Form STD 399), and the documents relied upon.

The documents relied upon in drafting the proposed regulation include the following:

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Ankle and Foot Disorders, Effective Date: September 2015

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Cervical and Thoracic Spine Disorders, Effective Date: May 27, 2016

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Elbow Disorders, Effective Date: 2013

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Eye Disorders, Effective Date: 2011

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Hand, Wrist, and Forearm Disorders Guideline, Effective June 30, 2016

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Hip and Groin Disorders Guideline, Effective July 29, 2010

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Knee Disorders, Effective October 28, 2015

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Low Back Disorders, Effective February 24, 2016

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Shoulder Disorders Guideline, Effective August 1, 2016

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Occupational Interstitial Lung Disease Guideline, Effective Date: January 4, 2016

American College of Occupational and Environmental Medicine (ACOEM) Practice Guidelines, Occupational/Work-Related Asthma Medical Treatment Guideline, Effective Date: January 4, 2016

Are Physician Dispensing Reforms Sustainable?, Wang et al, Workers' Compensation Research Institute, January 2015

CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Morbidity and Mortality Weekly Report, Vol 65, No. RR-1, March 18, 2016

CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016, Morbidity and Mortality Weekly Report, Erratum, Vol 65, No. RR-1, March 25, 2016

Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry, Draft Guidance, U.S. Dept. of Health and Human Services, Food and Drug Administration, July 2016

Estimating the Economic Impact of a California Workers' Compensation Formulary, Mulcahy, RAND, March 2017.

Facing Addiction in America – The Surgeon General's Report on Alcohol, Drugs, and Health, U.S. Dept. of Health and Human Services, 2016

Implementing a Drug Formulary for California's Workers' Compensation Program, Wynn, et al, RAND, 2016

Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, December 30, 2016

Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, Erratum: Vol 65, Nos. 50 & 51, January 13, 2017

Interstate Variation in Use of Opioids, 3rd edition, Thumula, et al, Workers' Compensation Research Institute, June 2016

Letter of the United States Surgeon General [Dear Colleague], August 2016

Longer-Term Use of Opioids, 3rd edition, Wang, Workers' Compensation Research Institute, June 2016

Physician Dispensing of Higher-Priced New Drug Strengths and Formulation, Wang, et al, Workers' Compensation Research Institute, April 2016

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry, U.S. Department of Health and Human Services Food and Drug Administration, December 2016

The Impact of Physician Dispensing on Opioid Use, Thumula, Workers' Compensation Research Institute, December 2014

The Prevalence and costs of Physician-Dispensed Drug, Wang, et al, Workers' Compensation Research Institute, September 2013

Trends in the Use of Opioids in California's Workers' Compensation System, Hayes and Swedlow, California Workers' Compensation Institute, May 2016

Turn the Tide Prescribing Opioids for Chronic Pain, [Pocket Guide], U.S. Dept. of Health and Human Services, Office of the Surgeon General

Use of Compound Drugs, Medical Foods, and Co-Packs in California's Workers' Compensation, Wynn, RAND Corporation, January 2011

The documents incorporated by reference include the following:

None.

FORMAT OF REGULATORY TEXT

The regulations proposed in this rulemaking action consist of adoptions of new regulations, including a new MTUS Drug List and two new forms. Since all of the text of regulation, including the MTUS Drug List and forms are new, they will be shown in plain text to enhance readability.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received, the Administrative Director may adopt the proposed regulations substantially as described in this notice. If the Administrative Director makes modifications which are sufficiently related to the originally proposed text, the modified text (with changes clearly indicated) will be made available for public comment for at least 15 days prior to the date on which the regulations are adopted. The Notice of Modification of Proposed Rulemaking will be sent to persons who have submitted written comments to the agency during the comment period or at the public hearing, to persons who testified at the public hearing, and to persons who have requested notification of modifications to the proposal. Please send requests for copies of any modified regulations to the contact person at the address indicated above.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, the Final Statement of Reasons will be available and copies may be requested from the contact person named in this notice or may be accessed on the Division's website at www.dir.ca.gov.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Rulemaking, the Initial Statement of Reasons, and proposed text of the regulation, may be accessed and downloaded from the Division's website at www.dir.ca.gov. To access them, click on the "Proposed Regulations – Rulemaking" link and scroll down the list of rulemaking proceedings to find the Medical Treatment Utilization Schedule - Formulary link.

AUTOMATIC MAILING

A copy of this Notice will automatically be sent to those interested persons on the Administrative Director's mailing list.

If adopted, the regulations as amended will appear in California Code of Regulations, title 8, sections 9789.92.27.1 through 9792.27.21. The text of the final regulations also may be available through the website of the Office of Administrative Law at www.oal.ca.gov .

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