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

INITIAL 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 – 9792.27.21

INTRODUCTION

This Initial Statement of Reasons ("ISOR") describes the purposes, rationale, and necessity of the proposed adoption of the Medical Treatment Utilization Schedule (MTUS) drug formulary and related regulations to be codified at title 8, California Code of Regulations §9792.27.1 through 9792.27.21. This Initial Statement of Reasons (ISOR) is issued pursuant to the requirements of the California Administrative Procedure Act (Government Code section 11340 et seq.).

BACKGROUND / PROBLEM TO BE ADDRESSED BY THE REGULATORY PROCEEDING

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 a work related injury or illness. Labor Code section 4600, subdivision (b), states: "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 guidelines adopted by the administrative director pursuant to Section 5307.27." Labor Code section 5307.27 requires the Administrative Director of DWC 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." The Administrative Director conducted formal rule making and the MTUS was adopted effective June 15, 2007, consisting of sections 9792.20 through 9792.26, title 8 of the California Code of Regulations. The MTUS has been subsequently amended several times.

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.

Labor Code section 5307.29 directs 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. The P&T Committee is required to be composed of the Division of Workers' Compensation's 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 or she determines that a substantial conflict of interest exists.

PROBLEM ADDRESSED BY THE PROPOSED RULEMAKING ACTION

This rulemaking action allows the Acting Administrative Director of the Division of Workers' Compensation (Administrative Director) to establish a workers' compensation drug formulary, and a process for updating the drug formulary, in compliance with the mandate of Assembly Bill 1124, as reflected in Labor Code sections 5307.27 and 5307.29. The proposed regulations address the need for an evidence-based drug formulary within the Medical Treatment Utilization Schedule.

Specific Purpose, Rationale, and Necessity of Each Section of the Proposed Adoptions

In accordance with Government Code section 11346.2, subdivision (b)(1), the specific purpose of each adoption, and the rationale for the determination that each adoption is

reasonably necessary to carry out the purpose for which it is proposed, together with a description of the public problem, administrative requirement, or other condition or circumstance that each adoption is intended to address, is provided below.

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

The purpose of this section is to list and define the key terms used in the drug formulary regulations. The terms include: "administer," "authorization through prospective review," "brand name drug," "combination drug," "compounded drug," "dispense," "Executive Medical Director," "expedited review," "FDA," "FDA-approved drug," "generic drug," "MTUS Drug Formulary," "MTUS Drug List," "Non-Preferred drug," "Nonprescription drug," "over-the-counter drug (OTC)," "off-label use," "OTC Monograph," "Perioperative Fill," "P&T Committee," "Physician," "Preferred drug," "prospective review," "retrospective review," "Special Fill," "therapeutic equivalent," and "unlisted drug." Setting forth definitions is necessary to ensure that the meaning of key terms used in the regulation is clear and the terms will be interpreted consistently by members of the public reading the regulation.

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

The purpose of this section is to clearly explain the relation between the MTUS, MTUS Drug Formulary, and MTUS Drug List. Labor Code section 5307.27 requires the Administrative Director to include a drug formulary using evidence-based medicine as part of the medical treatment utilization schedule. The regulation states that drug treatment falls within the Labor Code definition of "medical treatment," is governed by the MTUS treatment guidelines, and is subject to the rules applicable to the MTUS, including the presumption that the guidelines are correct, and the rules to obtain treatment outside of the guidelines. These provisions are necessary to let the public know that the drug formulary is not a "stand alone" provision, but is a component of the broader MTUS and rules for determining appropriate evidence-based medical treatment.

The proposed regulation also includes provisions defining the applicability of the MTUS Drug Formulary. The specific purpose of these provisions is to alert the public to the scope of treatment that is subject to the formulary rules. The section states that the MTUS Drug Formulary is applicable to a drug dispensed on or after July 1, 2017 for "outpatient use", and defines "outpatient use." The section contains an exception for injuries prior to July 1, 2017 which are subject to the transition provisions of section 9792.27.3.

The provision setting forth the applicability by date of dispensing, and cross reference to the transition rule, are necessary to carry out the statutory intent that there be a "phased implementation" for injuries prior to July 1, 2017. It is necessary to define "outpatient use" as "dispensed to be taken, applied, or self-administered by the patient at home or outside of a clinical setting, including "take home" drugs dispensed at the time of discharge from a facility" to distinguish the dispensed drugs from the physician-

administered drugs. Labor Code section 5307.27 (d) states that the section "shall apply to all prescribers and dispensers of medications" serving injured workers. The statute does not include language making the formulary applicable to drugs administered by a physician. Nevertheless, physician-administered drugs may fall within the MTUS Treatment Guidelines, such as steroid injections into a joint, and it is necessary for the regulation to make it clear that the relevant MTUS provisions would apply even if the MTUS Drug List does not. It is necessary to include "take home" drugs dispensed from a facility as these are not physician-administered, but will be self-administered by the patient.

Section 9792.27.3. MTUS Drug Formulary Transition.

Labor Code section 5307.27 subdivision (c) requires a "phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary." The purpose of the regulation is to implement the phase-in provision by distinguishing between situations in which the injured worker is receiving ongoing drug treatment and those situations not involving ongoing drug treatment. The regulation states that the MTUS Drug Formulary will apply to drug dispensing on or after July 1, 2017 for all dates of injury, unless there is ongoing drug treatment. If the injured worker is receiving a new drug prescription on or after July 1, 2017, there is no reason to forgo application of the formulary, as there is no ongoing treatment that could be interrupted. It is necessary to make the dispensing of new prescriptions subject to the formulary rules in order to give those patients the same opportunity to obtain Preferred Drugs without Prospective Review as other patients.

For the patients injured before July 1, 2017 who are on an ongoing course of drug treatment, the regulation's purpose is to phase in the formulary so that there is not an abrupt change to the course of treatment that could harm the patient. The regulation provides that the physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include non-preferred or unlisted drugs. The regulation provides that the claims administrator shall not unilaterally terminate or deny previously approved drug treatment. The regulation further specifies that the existing procedures for submitting a treatment plan in accordance with the MTUS, and for obtaining authorization in accordance with the utilization review regulations will apply. The regulation is necessary to carry out the statutory directive for a phased implementation, and to ensure patient safety. Medical treatment, including drug treatment should currently be in accordance with the existing MTUS Guidelines and rules. Therefore, when the MTUS Drug Formulary goes into effect on July 1, 2017, ongoing drug treatment for pre-July 1st injuries is expected to already be in conformity with the guidelines. To the extent that the new drug formulary rules may apply for dispensing after July 1st where there is ongoing care, the normal rules for requesting and approving the treatment plan will apply to ensure appropriate care is not interrupted.

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

The purpose of this section is to ensure that an injured worker will not be deprived of medication that is within the MTUS Treatment Guidelines and MTUS Drug Formulary because of a pharmacy benefit contract pursuant to Labor Code section 4600.2 that has been entered into by the employer or insurer. This is necessary so that injured workers are able to access evidence-based medications, and to ensure that appropriate treatment is not limited by a contract. It is necessary to prohibit the application of a contractual provision limiting availability of drug treatment that is in accordance with the MTUS so that contractual financial incentives do not interfere with the treatment of the injured worker.

Section 9792.27.5. MTUS Drug Formulary - Off Label Use.

The purpose of this section is to ensure that appropriate evidence-based off label use of drugs is available to the injured worker. The legislative intent section of Assembly Bill 1124 specifies that the formulary regulations should contain "Guidance regarding how an injured worker may access off-label use of prescription drugs, when evidenced-based and medically necessary." The proposed regulation allows the off-label use of a Preferred drug without authorization through prospective review where the MTUS Treatment Guideline recommends the off-label use of the drug for the condition being treated. "Off-label" use of a drug consists of drug treatment for a condition, or in a dosage or method of administration, not listed in the FDA approved labeling. By statute, the MTUS Treatment Guidelines are presumed correct on the issue of what constitutes reasonable and necessary medical treatment. Labor Code section 4604.5. The recommendations in the MTUS Treatment Guidelines are based on scientific medical evidence of efficacy and safety of drugs, and therefore do include recommendations for off-label use where the evidence supports such use. In order to streamline the availability of appropriate off-label use in accordance with the MTUS Treatment Guidelines, the regulation specifies that a Preferred Drug used in accordance with MTUS Treatment Guidelines' off-label recommendation does not need Prospective Review.

For a Non-Preferred drug, unlisted drug, or Preferred drug lacking recommendation in the MTUS Treatment Guideline for the intended off-label use, authorization through prospective review must be obtained before the drug is dispensed. The proposed regulation contains a provision stating that payment for the drug may be denied if required authorization through prospective review is not obtained before dispensing the drug, and it is determined upon retrospective review that the drug treatment was not medically necessary. This provision is necessary in order to serve as a disincentive for inappropriate prescribing of drugs.

It is possible that there may be a medical need for off-label use of a Non-Preferred drug, unlisted drug, or Preferred drug which lacks an off-label recommendation in the MTUS Treatment Guidelines. It is necessary for the regulation to specify a way for an injured worker to access off-label use of a Non-Preferred drug, unlisted drug, or Preferred drug

which lacks an off-label recommendation if such use is medically necessary and supported by evidence. The proposed regulation informs the public how an injured worker can access such drugs by cross referencing to the MTUS regulations which apply to all medical treatment, including drug treatment. The regulation specifies that 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.

Assembly Bill 1124 specifies that the establishment of an evidence-based drug formulary shall not prohibit the authorization of non-formulary medication when the variance is demonstrated consistent with subdivision (a) of Labor Code section 4604.5. That statutory provision states that the MTUS guidelines are presumed correct on the extent and scope of medical treatment, but that the presumption may be rebutted by a preponderance of the scientific medical evidence establishing that a variance from the guidelines is required to cure or relieve from the effects of the injury. The purpose of the regulation is to implement the provisions of AB 1124 regarding access to non-formulary medication, and to ensure that injured workers have access to appropriate medical treatment. The regulation states that any medically necessary FDA-approved prescription drug, FDA-approved nonprescription drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, may be authorized through prospective review and dispensed to an injured worker if it is shown in accordance with the MTUS regulations that a variance from the guidelines is required to cure or relieve the injured worker from the effects of the injury.

The formulary is part of the MTUS, and therefore it is necessary to integrate the medical necessity determination procedures and standards for drug treatment into the overarching MTUS regulations. The proposed section cross-references to the MTUS regulations that implement Labor Code section 4604.5 and govern access to treatment outside of the guidelines: condition not addressed by the MTUS or seeking to rebut the MTUS, the medical evidence search sequence, and the quality and strength of evidence criteria. These provisions are necessary so that it is clear that the formulary does not prohibit access to non-formulary drugs when treatment outside the guidelines is appropriate in accordance with the established medical necessity framework.

The proposed regulation contains a provision stating that payment for the drug may be denied if authorization through prospective review is not obtained prior to dispensing the drug, and it is determined upon retrospective review that the drug treatment was not medically necessary. This provision is necessary in order to serve as a disincentive for inappropriate prescribing of drugs.

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

The legislative intent section of Assembly Bill 1124 specifies that the formulary regulations should address: "Use of generic or generic-equivalent drugs in the formulary pursuant to evidence-based practices, with consideration being given to use of brand name medication when its use is cost-effective, medically necessary, and evidence-based." The purpose of this section is to promote the use of cost-effective evidence-based drug treatment by adopting rules regarding the documentation needed for use of a brand name drug rather than a generic drug.

In California, a physician may prescribe a brand name drug and specify that the prescription should be filled by the brand name product rather than a generic drug by writing "Do Not Substitute" or "Dispense as Written" on the prescription. The proposed regulation specifies that the physician must obtain prospective authorization and must document the need for the brand name drug where a less costly generic equivalent exists. The documentation must cite patient-specific factors that make the brand name drug medically necessary. For example, the patient may have an allergy to an inactive ingredient in the generic drug product, where that ingredient is lacking in the brand name drug. This section is necessary to ensure that an injured worker can obtain cost effective medically necessary treatment.

In order to create a drug formulary to implement Labor Code section 5307.27, the Department of Industrial Relations contracted with the RAND Corporation, an independent research firm, to explore options and identify issues that need to be addressed in the formulary–related rules. The study report, *Implementing a Drug Formulary for California's Workers' Compensation Program*, Wynn, et al, 2016, addressed the issue of generic drugs, stating, "The tools for encouraging cost-effective drug use include … use of substitutable generics instead of brand-name drugs, except when there is a clinical rationale for prescribing the brand…." (Wynn, 2016, p. 5.)

The RAND analysis of 2013 data from the California Workers' Compensation Information System showed that the cost of brand name prescriptions was proportionally larger than the number of brand name drugs dispensed: "In 2013, an estimated 5.4 percent of prescriptions and 10.2 percent of drug spending was for brand-name drugs for which one or more generic equivalents were available (compared to 4.8 and 8.3 percent, respectively, in 2007.)" (Wynn, 2016, p. 14) Currently, prior to implementation of the formulary, there is a statutory generic substitution mandate unless the physician specifies the brand name drug is to be dispensed. Labor Code section 4600.1. However, there are no criteria to determine when a brand name drug is appropriate instead of a generic equivalent. In order to allow for appropriate use of brand name drugs, and achieve cost effective appropriate use of generic drugs, it is necessary to require the physician to document the medical necessity of the brand name drug. This is anticipated to reduce the number of brand name drugs prescribed without a medical reason to prefer the more costly drug, resulting in cost effective and appropriate care. The proposed regulation is supported by the RAND study, which recommended the following policy: "Require PR

[Prospective Review] if a brand name is prescribed when a generic equivalent is available at lower cost." (Wynn, 2016, page xv, Table S.4.)

The section requires the physician to obtain authorization through prospective review before the brand name drug is dispensed where there exists a less costly generic drug equivalent. If prospective authorization is not obtained before dispensing the brand name drug, retrospective review may be conducted. If it is determined that the generic drug but not the brand name drug was medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic drug therapeutic equivalent. If it is determined that neither the brand name drug nor generic drug is medically necessary, payment for the drug may be denied. These provisions are necessary: 1) to serve as an incentive for the physician to document the medical justification where a more costly brand name drug is necessary, and 2) to discourage the use of medically unnecessary drugs.

Section 9792.27.8. Physician-Dispensed Drugs.

The purpose of this section is to specify the circumstances in which a physician may dispense a drug without obtaining authorization through prospective review, in addition to the "Special Fill" and "Perioperative Fill" provisions set forth in other sections. The proposed regulation specifies that the physician may dispense up to a seven-day supply of any "Preferred" drug on a one-time basis without obtaining authorization through prospective review. The purpose is to allow the physician to dispense needed preferred drugs without delay, so that authorization through prospective utilization review can be obtained if the injured worker will need more than a seven-day supply of the medication.

Decisions on routine prospective utilization review must be made in a timely fashion that is appropriate for the nature of the condition, not to exceed 5 business days from the receipt of the completed request for authorization. (Title 8, Cal. Code Regs. §9792.9.1(c)(3).) The decision on the request for prospective review must be communicated to the physician within 24 hours of the decision. (Title 8, Cal. Code Regs. §§9792.9.1(d)(2), (e)(3).) A seven-day supply allows sufficient time for the physician to request authorization and receive a decision if he or she believes that the patient will need more than a seven-day supply. Alternatively, the physician may issue a prescription for a preferred drug that can be filled at a pharmacy. The purpose is to require physician-dispensed drugs to obtain prospective authorization before dispensing except for the seven-day fill, the perioperative fill, or the special fill.

This section is necessary to encourage the provision of cost-effective high quality care. Although physician dispensing can be convenient for the patient, there are countervailing considerations that weigh in favor of requiring prospective review prior to physician dispensing beyond the initial seven-day supply. The proposed regulation is supported by the RAND study, which recommended the following policy: "Curtail physician dispensing by requiring PR [Prospective Review] for all drugs after the first-fill period." (Wynn, 2016, page xv, Table S.4.) The RAND report states as follows:

> "There are issues regarding the impact of physician dispensing on quality, utilization, cost, and patient satisfaction. Proponents of physician dispensing argue that in-office dispensing is convenient for patients, provides more confidentiality, and increases patient compliance in filling and refilling prescriptions. Opponents argue that allowing physicians to profit from dispensing medications could inappropriately influence prescribing practices and encourage the provision of medically unnecessary drug therapies [citation]. High-quality care is also potentially jeopardized because physician-dispensed prescriptions often bypass both a pharmacist's review of prescriptions for errors and drug interactions and a payer's prospective UR process to ensure the proposed treatment therapies are medically appropriate…."
> (Wynn, 2016, p. 15.)

The issue of quality of care is paramount in formulating the policy around physician dispensing. The RAND study cited research on physician dispensing of opioids as another area of concern. The RAND report states:

> "Physician dispensing of opioids is particularly concerning. Studies have identified opioid use as a significant driver of medical and indemnity costs [citations]. The experience in Florida following its prohibition of physician dispensing of Schedule II and Schedule III opioids suggests that there may be overprescribing of physician-dispensed opioid drugs. After the prohibition was implemented, the number of prescriptions for stronger opioids decreased but was offset by a corresponding increase in physician-dispensed weaker opioids (Schedule IV) and NSAIDS, with no change in the number of prescriptions for the stronger opioid prescriptions dispensed by pharmacies [citation]." (Wynn, 2016, p. 18.)

Research conducted by the Workers' Compensation Research Institute (WCRI) raises the concern that some physician dispensing may be driven by financial incentives, increasing costs, but not improving patient care. The report, *Physician Dispensing of Higher-Priced New Drug Strengths and Formulation*, Wang et al, April 2016, examines data of prescribing changes that occurred with the marketing of "new" strengths of commonly prescribed drugs. Most often these new strengths cost substantially more than the common strengths that had been available previously. For example, the WCRI report discusses the trend observed with the prescription of the muscle relaxant cyclobenzaprine HCL:

> "Table 4.1 shows a substantial shift in prescriptions from existing strengths to the new strengths, which is true for all three drugs, especially for 7.5 milligram cyclobenzaprine HCL….For example, before generic cyclobenzaprine HCL of 7.5 milligrams was introduced in 2012, there were two prescription strengths for the drug – 5 milligrams and 10 milligrams. Once the new strength was introduced, it was quickly picked up by physicians in California. In the first quarter of 2012, physician-

> dispensed prescriptions for the 7.5 milligram new strength accounted for 6 percent of cyclobenzaprine prescriptions dispensed by physicians, an increase from none. The figure increased dramatically in subsequent quarters. By the first quarter of 2014, the frequency of physicians dispensing the new strength increased to 55 percent.
>
> When the 7.5 milligram cyclobenzaprine HCL prescriptions were dispensed by physicians in California, the price paid was about $3.01 per pill in the first quarter of 2014, much higher compared with the prices paid for physician-dispensed existing strengths ($0.38 for 5 milligrams and $0.39 for 10 milligrams). By contrast, a vast majority of pharmacy-dispensed cyclobenzaprine HCL was still 5 and 10 milligrams."
> (Wang, 2016, p. 40.)

The WCRI reported similar findings for tramadol HCL, a synthetic opioid. WCRI's data analysis revealed a substantial increase in physician dispensing of an extremely costly new 150-milligram strength extended release formulation of tramadol HCL which was not seen in pharmacy-dispensed tramadol prescriptions. The average price paid per pill for the new 150-milligram extended release was $8.05 in the first quarter of 2014, whereas the price of the 50-milligram regular release product was $0.24. (Wang, 2016, 40.)

The WCRI's summary of its findings in California evidences the necessity for ensuring that physician-dispensed drugs are appropriately being used to maximize quality of care. The WCRI report states:

> "There is strong evidence that physician dispensing of higher-priced new drug products was prevalent in California. The frequent physician dispensing of these new-strength and new-formulation products outweighed the price reductions seen in the existing strengths of the same drugs, driving up the physician prices in California. The result is unintended and inconsistent with the goals of the reforms in the state. The question is whether these new drug products provide certain clinical benefits that may justify the additional costs. The fact that the higher-priced new drug products were essentially dispensed only by physicians and not by pharmacies suggests that financial incentives and not therapeutic value drove the growth in dispensing these new products."
> (Wang, 2016, p. 43.)

The regulation is necessary to support quality care by allowing the physician to provide a short fill of physician dispensed preferred drugs without prospective review, and requiring authorization for further physician-dispensed drugs.

The proposed regulation contains a provision stating that payment for the drug may be denied if authorization through prospective review is not obtained prior to dispensing the drug, if it is determined upon retrospective review that the drug treatment was not

medically necessary. This provision is necessary in order to serve as a disincentive for inappropriate prescribing of drugs.

Section 9792.27.9. Compounded Drugs.

The specific purpose of this section is to require authorization through prospective review of compounded drugs before the drugs are dispensed. The regulation states that where it is necessary for medical reasons to use a compounded drug instead of an FDA-approved drug, or an over-the counter drug that complies with an FDA-approved monograph, the physician must document the medical necessity in the patient chart, and in the Doctor's First Report of Injury (Form 5021) or Progress Report (PR-2.) The patient-specific factors that support the physician's determination that a compounded drug is medically necessary must be documented.

The FDA has indicated the safety concerns regarding compounded drugs as follows:

> "Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not subject to CGMP [current good manufacturing practice] requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products they compound … because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination."
> *(Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, FDA, December 2016, p. 4.)

The regulation is necessary to encourage evidence-based medicine and to enhance patient safety. The evidence-based MTUS Treatment Guidelines evaluate and make recommendations based on literature reviews of scientific/medical studies. Compounded drugs do not have such a literature base to support them, therefore the safety and efficacy have not been evaluated as FDA-approved drugs have been. The RAND report recommends that compounded drugs be subject to specific Prospective Review requirements.

> "Compounded drugs. The rule should define compounded drugs and include the different forms of administration. The FDA notes that

> compounded drugs that have not been verified to meet FDA quality standards may have associated health risks. One danger is the 'possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective' (FDA, 2015). Because the treatment preference for most patients should be an FDA-approved drug, consideration should be given to requiring PR for any compounded drug…."
> (Wynn, 2016, p. 61.)

The Administrative Director has determined that it is necessary to require authorization through prospective review before dispensing compounded drugs in order to enhance the quality of care, while also allowing for compounded drugs where they are shown to be medically necessary for the patient.

The regulation also includes a provision stating the Article does not invalidate a provision in a Medical Provider Network (MPN) agreement which restricts physician dispensing of compounded drugs by physicians. The purpose of this is to allow an MPN to restrict physician dispensing of compounded drugs since there are sometimes financial motives for physician dispensing that do not serve patient quality of care. It is necessary to allow such a restriction, but the restriction does not allow additional contractual restriction on pharmacy-dispensed compounded drugs. This is necessary in order to ensure an injured worker can access compounded medications where that is warranted for medical reasons.

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

The purpose of this section is to speed the delivery of evidence-based Preferred drugs to the injured workers by setting forth the rules that are needed to implement the MTUS Drug List. The regulation sets forth the structure of the MTUS Drug List, and the rules to be applied to a drug based upon the status as Preferred, Non-Preferred or unlisted. The intent is to expedite the provision of appropriate evidence-based care by eliminating the requirement for prospective utilization review for drugs labeled as "Preferred" when used in accordance with the MTUS guidelines. For Non-Preferred or unlisted drugs, authorization through prospective review must be obtained. The regulation states that if authorization through prospective review is not obtained before dispensing the drug, retrospective review may be conducted to determine if the drug was medically necessary. The section states that payment may be denied if the drug is determined on retrospective review to not be medically necessary. In addition, the regulation provides cross reference to the "Special Fill" or "Perioperative Fill" sections which allow a short supply of specified Non-Preferred drugs without prospective review as set forth in those sections.

These provisions are necessary to support the expeditious provision of evidence-based care, and to minimize the administrative burden and cost of unnecessary prospective utilization review. The adoption of the MTUS Drug List is expected to incentivize the use of the Preferred drugs, promote safer and more effective drugs and reduce utilization

review costs and disputes. A decision through utilization review to deny a treatment may be appealed through Independent Medical Review (IMR). This process adds administrative burden and cost. The RAND study notes the prevalence of utilization review and IMR in relation to drug treatment:

> "Drug treatments deemed medically unnecessary during UR [utilization review] account for nearly half of all IMR appeals. IMR decisions uphold 93 percent of the UR denials for medically unnecessary drug therapies, raising additional concerns about the administrative burden imposed by current prescribing practices on the UR/IMR medical necessity dispute-resolution process (RAND Corporation analysis of 2014 IMR decisions.)" (Wynn, 2016, p. 2.)

The regulation is necessary to accomplish the dual goals of promoting high quality treatment and reducing administrative burden and costs involved in dispute resolution.

Section 9792.27.11. MTUS Drug List – Special Fill.

The purpose of this section is to provide an injured worker the ability to obtain a short supply of a specified Non-Preferred drug without prospective review. The section states that a drug designated on the MTUS Drug List as eligible for the Special Fill may be dispensed without prospective review if: 1) the drug is prescribed at the single initial treatment visit following the injury, provided the initial visit is within 7 days of the date of injury; 2) the prescription is for a supply of the drug not to exceed the limit set forth on the MTUS Drug List (currently all are a 4-day supply); and, 3) the prescription is for an FDA-approved generic or single source brand name drug, or brand name where substantiated to be medically necessary; and 4) the drug is prescribed in accordance with the MTUS Treatment Guidelines. These provisions are necessary so that patients with urgent needs do not experience a delay in care at the onset of an injury. The Non-Preferred drugs have a higher risk profile, such as the opioids and muscle relaxants, and normally they should go through prospective utilization review to ensure that they are used appropriately for the condition. However, the utility of prospective review needs to be balanced with the recognition that there are urgent situations which warrant use of these drugs prior to conducting prospective utilization review.

The proposal to allow dispensing of a 4-day supply of opioid pain medication for acute severe pain is necessary in order to balance the risks of opioids with the need for urgent care. The U.S. Surgeon General's Turn the Tide campaign (discussed in further detail below regarding section 9797.27.14) emphasizes the need for caution in beginning opioid prescriptions. The Surgeon General's "Dear Colleague" letter states: "We often struggle to balance reducing our patients' pain with increasing their risk of opioid addiction." The *Turn the Tide: Prescribing Opioids for Chronic Pain* pocket guide urges doctors to "start low and go slow," and states: "For acute pain: prescribe < 3 day supply; more than 7 days will rarely be required." In regard to opioids for acute severe pain, the Special Fill should normally provide an adequate supply of the medication. If it is obvious that the

injured worker will need a longer supply due to the severe nature of the injury, the physician may request authorization through prospective review for a longer fill of the medication.

The Special Fill also applies to allow a short fill of specified Non-Preferred corticosteroids and musculoskeletal therapy agents. These drugs generally have a higher risk profile, and are often not designated as first line treatments in the MTUS Treatment Guidelines. However, these treatments are sometimes urgently needed, for example a course of corticosteroids for a severe case of poison oak. It would not be appropriate to delay the commencement of the injured worker's care. Therefore it is necessary to designate the specified drugs as eligible to be dispensed without prospective review in order to promptly begin treatment while authorization is being sought if more than a 4-day fill will be needed.

Although a drug may be eligible for the Special Fill, it must be used in accordance with the MTUS Treatment Guidelines. Therefore it is necessary to specify that the drug dispensed under this policy may be subject to retrospective review, and payment may be denied if it is determined that the treatment was not medically necessary.

The regulation also provides that a pharmacy benefit contract or medical provider network contract may provide for a longer Special Fill period or may cover additional drugs under a Special Fill policy pursuant to contract. This is necessary to recognize that a more "liberal" special fill or "first fill" policy may be appropriate, for example where the parties to the contract have a level of confidence that the prescribing patterns conform to treatment guidelines.

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. These provisions are necessary so that the public will be aware that the use of opioids is a matter of particular concern in relation to the Special Fill provision. The regulation will facilitate communication by alerting the public that the Administrative Director will be seeking input from affected parties regarding the impact.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

The purpose of this section is to make it possible for an injured worker to obtain a short supply (currently 4 days) of a specified Non-Preferred drug without prospective utilization review where the prescription is needed in the perioperative period. The regulation defines "perioperative period" to include 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 regulation states that the prescription for the perioperative drug must be for an FDA-approved generic or single source brand name drug, or brand name drug where substantiated to be medically necessary, and the drug is prescribed in accordance with the MTUS Treatment Guidelines.

For planned surgeries, there will usually be sufficient time to obtain authorization through prospective review for the surgical procedure and related pharmaceutical treatment. However, there may be circumstances in which the patient is awaiting the surgery and needs urgent drug treatment with a Non-Preferred drug such as an opioid pain medication. The regulation is also intended to ensure that a surgeon is able to adjust medications urgently in the perioperative period when it is necessary to change the treatment for a medical reason such as an adverse reaction to the first medication prescribed. It is necessary in order to provide quality patient care to allow the physician to prescribe the specified Non-Preferred drug and have the drug dispensed without the delay of prospective utilization review.

The proposed regulation contains a provision stating that payment for the drug may be denied if authorization through prospective review is not obtained prior to dispensing the drug, and it is determined upon retrospective review that the drug treatment was not medically necessary. This provision is necessary in order to serve as a disincentive for inappropriate prescribing of drugs.

The regulation also provides that a pharmacy benefit contract or medical provider network contract may provide for a longer Perioperative Fill period or may cover additional drugs under a Perioperative Fill policy pursuant to contract. This is necessary to recognize that a more "liberal" perioperative fill policy may be appropriate, for example where the parties to the contract have a level of confidence that the prescribing patterns conform to treatment guidelines.

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

The purpose of this section is to advise the public that the formulary and associated regulations do not lessen the employer's obligations to the employee under applicable health and safety regulations. The regulation references the California occupational Bloodborne Pathogens standard as an example. This regulation is necessary to ensure that the public does not misinterpret the MTUS Drug Formulary as a basis for delaying urgent preventive care, such as post-exposure prophylaxis when there has been a potential exposure to bloodborne pathogens. The regulation is essential to protect the health of employees who need urgent care as mandated by health and safety standards.

Section 9792.27.14. MTUS Drug List.

The specific purpose of this section is to adopt an evidence-based formulary drug list that will encourage the streamlined provision of high quality, safe and effective medical care. The excel spreadsheet sets forth data under the following headings: Drug Ingredient; Preferred/Non-Preferred; Special Fill; Peri-Op; Drug Class; Reference in Guidelines. The drug ingredients listed on the MTUS Drug List are drugs that are addressed in the treatment guidelines of the American College of Occupational and Environmental Medicine (ACOEM), published by the Reed Group. The MTUS Drug List includes only

drugs that are intended to be self-administered by the patient for outpatient use; it does not include physician-administered drugs. It is necessary to focus the formulary drug list on the outpatient drugs, because the statute requires the formulary to apply to "all prescribers and dispensers of medications," but does not state that it should apply to *physician-administered* drugs. In addition, this interpretation is supported by Assembly Bill section 1124 which expresses the legislative intent that the drug formulary shall not apply to treatment provided in an emergency department or inpatient setting. Although the drug formulary adopted pursuant to Labor Code section 5307.27, subdivision (d), does not apply to physician-administered drugs, other provisions of the MTUS Treatment Guidelines do apply to physician-administered drug treatment, such as physician-administered steroid injections into joints.

In order to create a drug formulary to implement Labor Code section 5307.27, the Department of Industrial Relations contracted with the RAND Corporation, an independent research firm, to identify and evaluate options. The RAND study examined several different formulary models, including the Official Disability Guidelines (ODG) of the Work Loss Data Institute, ACOEM, published by the Reed Group, the Medi-Cal Formulary and those used in Washington, and Ohio. (Wynn, 2016.)

RAND emphasized the need for integration between the evidence-based treatment guidelines that are the core of the MTUS and the drug formulary to be adopted. Although some states examined, such as Washington and Ohio, have formularies that seem to work very well in their states, they would not translate well to California because of a lack of integration with the California treatment guidelines. The RAND study states: "While each formulary has features that might be models for the California formulary, we concluded that DWC's options are limited by the need for the formulary to be consistent with the MTUS guideline drug recommendations." (Wynn, 2016 p. xi.) Currently, almost all of the California MTUS Treatment Guidelines consist of ACOEM Guidelines adopted by the Division. Notable exceptions are the Chronic Pain guideline (based on the Official Disability Guidelines of the Work Loss Data Institute) and the Opioid Guideline (developed by the Division.) The RAND report acknowledges the difficulties of creating a unified formulary from different treatment guidelines:

> "As noted in Chapter Two, California's WC formulary should adhere to three main criteria: (1) The formulary drug list should be evidence-based and consistent with the MTUS; (2) cost considerations are important but secondary; and (3) the process and policies for determining the drug list and recommendation should be transparent….However, as discussed below in greater detail, … no existing formulary is fully consistent with the current MTUS.
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> "The rationale behind the MTUS formulary is that the MTUS guidelines should drive the formulary decisions, rather than the formulary decisions driving the MTUS guidelines….[¶] Through the rulemaking process, California has already adopted guidelines that it believes incorporate the best available evidence base for the medical care provided to injured

> workers. However, these guidelines are outdated and need to be updated for most clinical topics. Therefore, the implementation of the formulary offers an opportunity to review the sources for the treatment guidelines, ensure that they continue to be the most appropriate source for standards of care that meet the needs of California's injured workers, and determine whether additional clinical topics should be added. Ideally, DWC would implement updated guidelines before or coincident with the formulary so that the updated guideline recommendations would be reflected in the formulary drug listing." (Wynn, 2016, p. 75.)

The Administrative Director recognizes the need for updates to many of the treatment guidelines and the necessity of adoption a drug formulary that is integrated with the evidence-based guidelines. The Administrative Director has begun the process of adopting updated ACOEM treatment guidelines. In October of 2015, the ACOEM Occupational Interstitial Lung Disease and Occupational Work Related Asthma treatment guidelines were posted on the Division's Forum website for public review and comment. In addition, in August of 2016, the Division posted a public discussion Forum entitled "Implementing AB 1124 Drug Formulary and update of MTUS guidelines" which included a draft drug formulary and nine additional updated ACOEM treatment guidelines. In the near future, the Administrative Director will be commencing the process to formally adopt the updated ACOEM guidelines, moving toward an integrated set of treatment guidelines and formulary. This is necessary as pharmaceutical treatment is a component of overall treatment, and the evidence-based recommendations for drug and non-drug treatment cannot be separately compartmentalized. A unified set of treatment guidelines and formulary will improve consistency and clarity and will simplify the process of administration of medical benefits. ACOEM has indicated that updated chronic pain and opioid treatment guidelines are almost ready for publication. The Administrative Director will review them for possible inclusion in the MTUS.

The purpose of the MTUS Drug List is to set forth the status of each drug ingredient as "Preferred" or "Non-Preferred". The designation of a drug ingredient as "Preferred" or "Non-Preferred" is based on the evidence-based recommendations of the ACOEM treatment guidelines and application of the following criteria, which weigh in favor of designation as "Preferred":

1) Being noted as a first line therapy in the ACOEM guidelines;
2) Having a "Yes" recommendation for most acute or acute/chronic conditions addressed in the ACOEM guidelines;
3) Having a safer adverse effects (risk) profile;
4) Drugs listed for the treatment of more common work-related injuries and illnesses.

Under the provisions of proposed section 9792.27.10, Preferred drugs are not subject to prospective utilization review when used in accordance with the MTUS Treatment Guidelines. It is necessary to identify the Preferred drugs on the MTUS Drug List so that appropriate medication will be able to be dispensed quickly and without administrative delay for prospective utilization review. This is expected to improve the delivery of care

and incentivize the use of medications with a safer risk profile. The RAND study explained the valuable role of reduced utilization review for selected drugs:

> "Eliminating PR [Prospective Review] for MTUS-recommended drug therapies that meet specified criteria (e.g. first-line therapies indicated for the worker's condition) is an important mechanism for achieving legislative intent that appropriate drugs be provided expeditiously while minimizing administrative burden and associated costs. When drugs that do not require PR are prescribed, both point-of-sale bill-processing protocols and retrospective UR [utilization review] are safeguards to ensure that the drugs are medically appropriate for the worker's condition." (Wynn, 2016, p. 59.)

The purpose of setting forth "Non-Preferred" drugs on the list is to make it clear to the public which drugs have recommendations in the treatment guidelines. Although it would be possible to adopt a formulary that is only a "Preferred Drug List", the Division has determined that it is useful to also list "Non-Preferred" drugs as they are drugs that are addressed in the treatment guidelines. "Unlisted" drugs and Non-Preferred drugs should not be classified together. It is useful to distinguish Non-Preferred from Unlisted drugs because the MTUS Treatment Guidelines are presumed correct on what constitutes appropriate treatment for a condition. The presumption may be rebutted, but it is necessary and educational for the physician to review the treatment guideline and understand the evidence-based recommendation for use of the Non-Preferred drug for the condition being treated.

One of the major purposes of the MTUS Drug List designation of specified drugs as "Non-Preferred" is to address the overutilization of dangerous drugs, including opioid medication. The RAND study noted as follows:

> "… [T]here have been concerns over both the rising cost per claim for pharmaceuticals and the extensive use of opioids within the WC system. A Workers Compensation Research Institute (WCRI) study found that 68 percent of the claims with pain medication prescriptions received narcotics. For nonsurgical cases, the morphine equivalent amount of narcotics received by the average injured worker in California was 17 percent higher than the typical amount of the 25 study states in the study (Thumula et al., 2014).
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> These concerns have been reinforced by the experience under the medical necessity dispute resolution process. Drug treatments deemed medically unnecessary during UR account for nearly half of all IMR appeals. IMR decisions uphold 93 percent of the UR denials for medically unnecessary drug therapies, raising additional concerns about the administrative burden imposed by current prescribing practices on the UR/IMR medical necessity dispute resolutions process (RAND analysis of 2014 IMR decisions)." (Wynn, 2016, p.1.)

A recent study by the Workers' Compensation Research Institute, *Interstate Variations in Use of Opioids*, 3rd edition, Thumula, et al, June 2016, indicates that the use of opioids in California continues to be of concern, with opioid use in California at a higher level than found in the 2014 WCRI study cited by RAND. The 2016 WCRI study found that the average amount of opioids received by California injured workers was 23 percent higher than the 25-state median. (Thumula, 2016.)

The California Workers' Compensation Institute (CWCI) has also examined opioid use by California injured workers in a study entitled *Trends in the Use of Opioids in the California Workers' Compensation System*, Hayes and Swedlow, May 2016. The study examined opioid use from 2005 to 2014, and found opioid use rising over time to peak in 2009 at 31.9% of all prescriptions filled, then declining to 27.2% in 2014. CWCI described this as a "recent positive trend" but tempered the positive observation with a note of caution.

> "Despite these positive trends, opioid use is still excessive, as these drugs continue to be prescribed in situations where their use is not supported in the scientific literature. In addition, prior Institute studies of utilization review (UR) and independent medical review (IMR) have shown that medical management resources in California workers' compensation have become disproportionately dedicated to the review of requests for opioids and pain management drugs. For example, a January 2014 study found that 43% of all utilization reviews involved prescription drug requests, while a February 2016 analysis found that almost half of all IMR determinations issued in 2015 were for prescription drugs, and of those requests, opioids and pain management compounds topped the list of disputed drug requests even though about 90 percent of such requests were ultimately deemed medically unnecessary by the IMR physician."
> (Hayes and Swedlow, 2016, p. 17.)

The overutilization and abuse of opioid medication is not confined to the California workers' compensation system. The United States is faced with a growing opioid epidemic, with overuse and abuse leading to significant morbidity and mortality. The United States Centers for Disease Control (CDC) has been at the forefront of raising the opioid epidemic as a major public health concern. On December 30, 2016, the CDC's Morbidity and Mortality Weekly Report (MMWR) published the study entitled *Increases in Drug and Opioid-Involved Overdose Deaths – United States, 2010 – 2015*. The report states that the U.S. opioid epidemic is continuing, and drug overdose deaths nearly tripled during 1999-2014, reaching 47,000 deaths in 2014, 60.9% of which involved an opioid. Although many of the deaths involved illicit drugs, the CDC emphasizes the role of prescription medication in the epidemic. The MMWR report 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 United States Surgeon General has also made it a priority to address the extensive harms of drug misuse and addiction. The report, *Facing Addiction in America – The Surgeon General's Report on Alcohol, Drugs, and Health*, 2016, states:

> "Physician prescribing patterns, patient drug diversion (selling, sharing, or using medication prescribed for another person), and doctor shopping behaviors have all contributed to the ongoing opioid overdose epidemic. For example, evidence indicates that chronic pain patients with substance use disorders are prescribed opioids more often than other individuals with chronic pain, with the trend increasing over time….
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> [¶]
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> In March 2015, the U.S. Department of Health and Human Services (HHS) made addressing the opioid misuse crisis a high priority, announcing a national opioid initiative focused on … priority areas: [including] … providing training and educational resources, including updated prescriber guidelines, to assist health professionals in making informed prescribing decisions[.] … Since then, HHS has initiated many efforts to help reduce prescription opioid misuse and use disorders. Improving prescribing practices is one of these important efforts. In March 2016, the CDC released the *Guideline for Prescribing Opioids for Chronic Pain*, which provides recommendations about the appropriate prescribing of opioid pain relievers and other treatment options to improve pain management and patient safety."
> (Surgeon General: *Facing Addiction*, p. 6-10.)

In recognition of the role of prescription drugs in the opioid epidemic, the U.S. Surgeon General issued a "Dear Colleague" letter in August 2016. The letter asks physicians to "take the pledge" to turn the tide on the opioid crisis. The Surgeon General announces the "Turn the Tide" campaign, and asks physicians to educate themselves with the CDC Opioid Prescribing Guideline pocket guide. The CDC Pocket Guideline distills essential provisions, including the indication that scientific evidence is lacking for the benefits of opioids for long term pain, the recommendation to consider whether non-opioid drug and non-drug therapies are appropriate, and the recommendation that acute pain should be limited to immediate-release opioids at the lowest dose for the shortest therapeutic duration. Significantly, the Pocket Guideline states: "For acute pain: prescribe <3 day supply; more than 7 days will rarely be required."

In light of the severe potential harms of opioid use, it is necessary to classify the opioid medications on the MTUS Drug List as "Non-Preferred." Provision has been made for a 4-day fill of several opioid medications as a Special Fill and a Peri-Operative Fill so that injured workers in severe acute pain can receive appropriate medication. The 4-day fill falls within the CDC's recommendation that acute pain will normally be addressed by three days or less of opioid treatment. If the physician knows that the injured worker will need more than a three-day supply, the physician can request expedited prospective review. The utilization review regulations provide that expedited review must be conducted "in a timely fashion appropriate to the injured worker's condition, not to exceed 72 hours after the receipt of the written information reasonably necessary to make the determination." The decision to approve or deny must be communicated within 24 hours. (Title 8, Cal. Code Regs. §9796.9.1(c)(4), (d)(2), (e)(3).) In addition, the utilization review regulations explicitly address emergency care as follows:

> "Failure to obtain authorization prior to providing emergency health care services shall not be an acceptable basis for refusal to cover medical services provided to treat and stabilize an injured worker presenting for emergency health care services. Emergency health care services may be subjected to retrospective review. Documentation for emergency health care services shall be made available to the claims administrator upon request."
> (Title 8, Cal. Code Regs. §9796.9.1(e)(2).)

Non-Preferred drugs other than those falling under the Special Fill or Peri-Operative Fill, may be accessed through the normal utilization review process, which evaluates whether the use is within the MTUS Treatment Guidelines or supported by other evidence where an exception to the guidelines is applicable. (Title 8, Cal. Code Regs. §9796.9.1.)

Other features of the MTUS Drug List are intended to enhance the usefulness of the drug list. 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 and regulations. This is necessary so that the drug list promotes appropriate evidence-based care. The MTUS Treatment Guidelines contain the detailed recommendations on drug usage in light of the condition being treated and the phase of care. It is the responsibility of the doctor to consult the guidelines to ensure that the treatment falls within the recommendations. The prospective review requirements are set aside for the Preferred drugs, but only if the use is consistent with the MTUS Treatment Guideline recommendations. In addition, the doctor must be aware of the other limitations in the formulary regulations, such as limits on physician-dispensed drugs and documentation requirements for brand name drugs. The boxed material is necessary to alert those using the drug list to the need to conform to the applicable rules.

The purpose of the "Reference in Guideline" column is to provide reference to MTUS Treatment Guidelines that address each of the listed drug ingredients. Since the MTUS Drug List is not a stand-alone document, but must be used in conjunction with the guideline recommendations, it will assist physicians and others using the list to see which

topics may have applicable material. This is necessary to enhance the usefulness of the list, as it provides a quick high level overview of which guideline topics address each drug.

In addition, there are symbols to alert the public as to which type of recommendations are included. These are:

(✓) Recommended

(✕) Not Recommended

(⃠) No Recommendation

The purpose is to make the drug list more useful in identifying applicable guidelines. The boxed advisement at the top of the document states:

“"Reference in Guidelines" indicates guideline topic(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (✕), or No Recommendation (⃠). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use.”

This is necessary to inform the public what the symbols mean, and to make it clear that the symbol must be used in conjunction with the recommendation for the condition and phase of care that is contained within the guideline. For example, acetaminophen is a Preferred Drug, but its usefulness for treating an elbow disorder must be evaluated in the context of the Elbow Disorders Guideline. The symbols relating to acetaminophen and Elbow Disorders indicate that there are one or more elbow conditions for which acetaminophen is recommended, and one or more elbow disorders for which acetaminophen is not recommended. It is incumbent on the treating physician to base treatment on the evidence based MTUS Treatment Guideline.

Section 9792.27.15. National Drug Codes - MTUS Drug List.

The purpose of this section is to provide that the Administrative Director may maintain and post on the DWC website a listing of drug products embodied in the MTUS Drug List and to specify the contents of the list. The proposed regulation states that for each active ingredient on the MTUS Drug List, the product listing shall include prescription and non-prescription brand name drugs and therapeutically equivalent generic drug versions that are marketed for outpatient use. The regulation specifies that only products with oral routes of administration shall be included, except as specified. The section directs the list to include combination drugs, but only if the combination of active ingredients is listed on the MTUS Drug List. The regulation specifies that repackaged drugs are to be excluded. The data elements shall include at a minimum: National Drug Code (NDC), 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.

The regulation is necessary to enhance the usability of the MTUS Drug List by providing a crosswalk between the MTUS Drug List set forth in proposed section 9792.27.14 and the NDC-based product list to be maintained pursuant to this section. Drug products are continually entering and leaving the market, and NDC-based code sets are updated very frequently. The RAND study recommends that the formulary be operationalized by providing an NDC-based drug listing. The report states: "The ground rules and PR [Prospective Review] requirements for the formulary should be operationalized through an electronic listing of the NDCs that the formulary addresses. This listing would need to be created for either the ACOEM or MTUS formulary and would need to be updated at least quarterly to reflect changes in how drugs are being marketed." (Wynn, 2016, p. 83.)

This section implements Labor Code section 5307.29, subdivision (a) which requires the Administrative Director to make provision for no less than quarterly updates to the drug formulary to allow for the provision of all appropriate medications, including those new to the market. Further, the regulation will implement Labor Code section 5307.29, subdivision (b), which states that changes made to the list of drugs shall be made through an order exempt from the Administrative Procedure Act, with the order to be posted on the department's website, informing the public of the changes and the effective date. The posting of an NDC-based list would be a useful adjunct to the MTUS Drug List.

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

Labor Code section 5307.29, subdivision (c) 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 an evidence-based drug formulary. The statute requires the committee to be composed of six appointed members (3 physicians and 3 pharmacists) and the DWC Executive Medical Director. The purpose of the regulation is to implement the statute by setting forth additional details relating to the P&T Committee's composition.

The regulation states that the Executive Medical Director shall be the chairperson of the committee, and that the Administrative Director shall appoint a competent person to temporarily assume the committee authority and duties of the Executive Medical Director if the position becomes vacant. It is necessary for the Executive Medical Director to be the chairperson in order to facilitate the meetings, including the administrative support of the committee, and to provide continuity as public members rotate in and out of service. The regulation specifies that at least one of the physicians shall be actively engaged in the treatment of injured workers and at least one of the pharmacists shall be an actively practicing pharmacist. These provisions are necessary to ensure that some of the committee members have current, active experience which will provide a valuable perspective to the committee. The regulation provides that the P&T Committee members

shall be appointed to serve a two-year term, may apply to be reappointed, and shall continue to serve until a successor is appointed. The specification of two-year terms, with the potential to be reappointed, is necessary to encourage multi-year service in order to take advantage of experience gained and continuity of membership over time.

The regulation requires that a person interested in applying to serve on the P&T Committee submit an application form and conflict of interest statement, on forms prescribed by the Administrative Director. This is necessary in order to streamline the application process, and to make it clear how to demonstrate qualification to serve, and lack of disqualifying conflict of interest.

The regulation states that P&T Committee applicants shall demonstrate knowledge in one or more of the following:
(1) Clinically appropriate prescribing of covered drugs;
(2) Clinically appropriate dispensing and monitoring of covered drugs;
(3) Drug use review;
(4) Evidence-based medicine.

This language is taken from the statute. It is necessary to duplicate the statutory provisions in the regulation for clarity of the regulation, so that the public may be alerted to these important qualifications as they consider the requirements.

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

The purpose of this section is to set forth a form that will be used by physicians and pharmacists to apply for membership on the P&T Committee. The name of the proposed form is: DWC MTUS PT-App, and the version is designated as: "(New 7/17)". The purpose of the form is to provide an efficient way for applicants to submit the information needed to assess the applicant's qualification to serve on the committee. 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 allows attachment of other relevant supporting material at the option of the applicant. The regulation is necessary to standardize the manner of applying for appointment so that the Administrative Director will have sufficient information to assess the qualifications of the applicants. Standardization of the application also makes it easier to compare the relative qualifications of applicants if there are numerous persons applying to serve on the committee.

The form includes a notice that the form is a public document, and includes advisements pursuant to the Information Practices Act. It is necessary to include this notice so that applicants and members filling out the form are aware of its public nature. 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. This is necessary to assure accuracy of the form and enhance public confidence in the P&T Committee member selection process.

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

Labor Code section 5307.29 specifies that P&T Committee members shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or a company engaged in the development of a pharmaceutical formulary for commercial sale during his or her term, and shall not have been so employed for 12 months prior to his or her appointment. The regulation restates these provisions of Labor Code section 5307.29, subdivision (c)(2), which is necessary for the purpose of clarity since these provisions are closely related to the "substantial financial conflict of interest" standards that the statute authorizes the Administrative Director to establish. The purpose of the regulation is to set forth specific standards to define a substantial financial conflict of interest that would preclude a person from serving as a member of the P&T Committee. The regulations define substantial financial conflict of interest as a direct or indirect interest in a pharmaceutical entity that meets the following.

- Income of $500 or more within the previous 12 months, including salary, wages, speaking fees, consultant fees, expert witness fees, honoraria, gifts, loans, travel payments.
- Grants or research funding within the previous 24 months.
- Ownership interest in a pharmaceutical entity during previous 12 months
- Investment interest of $2,000 or more in a publicly-traded pharmaceutical entity.

The regulations define the following terms: "pharmaceutical entity," "direct financial interest," "indirect financial interest" and "immediate family member." It is necessary to define these terms in order to specify the kinds of interests that are considered to pose a disqualifying conflict of interest. The limits imposed are necessary so that the committee can perform its work free of vested financial interests, and to enhance public confidence in the role of the committee in advising the Administrative Director on formulary updates.

Another purpose of the regulation is to make sure that committee members continue to be free of conflicts of interest over time. To carry out this purpose it is necessary for the regulation to require the members of the P&T Committee to submit an updated Conflict of Interest Disclosure Form annually, and more frequently if there have been relevant changes in employment or financial interests.

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

This section sets forth the form that must be filed: 1) by an applicant to the P&T Committee, and 2) annually by P&T Committee members, disclosing whether there are financial interests that would be 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 purpose of the form is to provide a convenient and precise method for applicants or members of the P&T Committee to certify to adherence to the conflict of interest standards set forth in proposed section 9792.27.18. It is necessary to have a form so that there is a standard manner to disclose financial interests, to enhance the process of maintaining a conflict-free committee. The form includes a notice that the form is a public document, and includes advisements pursuant to the Information Practices Act. It is necessary to include this notice so that applicants and members filling out the form are aware of its public nature. 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. This is necessary to assure accuracy of the form and enhance public confidence in representations regarding lack of conflict of interest.

Section 9792.27.20. Pharmacy and Therapeutics Committee – Meetings.

The purpose of this regulation is to establish rules for timing, notice, and conduct of the P&T Committee meetings to maximize effectiveness of the committee as consultant to the Administrative Director and to provide for public awareness of the committee meetings and work. This supports the transparency envisioned by Assembly Bill 1124. The section states that the committee shall meet when deemed necessary by the Executive Medical Director, but no less frequently than quarterly. Meetings shall be conducted in accordance with the Bagley-Keene Open Meeting Act. The section requires notice to be given by posting on the web and directly to specified persons at least 10 days in advance of the meeting. Meetings shall include a period of public comment. Written documentation of the meeting shall be maintained, including recommendations to be made to the Administrative Director, and a record of the vote of each member for any action taken. The section is necessary to implement the Labor Code section 5307.29 which requires at least quarterly updates to the formulary, and which requires the P&T Committee to consult with the Administrative Director on updates. The regulation is also necessary to ensure that interested members of the workers' compensation system are aware that the Government Code open meeting provisions of the Bagley Keene Act apply to the functioning of the P&T Committee.

Section 9792.27.21. MTUS Drug List Updates.

The purpose of the section is to set forth topics the P&T Committee may address in carrying out the statutory duty pursuant to Labor Code section 5307.29, subdivision (c), to "consult with the administrative director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs." The topics that may be addressed include: 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, and for 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.

It is necessary to set forth the topics to be addressed by the P&T Committee in order to establish a framework that will allow the committee to focus on issues that will provide the most useful consultation to the Administrative Director.

Another purpose of the regulation is to make it clear that the P&T Committee recommendations are advisory only, and are not binding on the Administrative Director. This is necessary in order to implement the statutory provision that the committee shall "review and consult" with the Administrative Director. The section makes it clear that the consultant role of the committee does not override the Administrative Director's authority to adopt updates to the formulary.

The regulation states that the Administrative Director may update the MTUS Drug List on a quarterly or more frequent basis. It states that the updates will be adopted by the Administrative Director by issuance of an order that will specify the changes and effective date, which will be posted on the division's website. It is necessary to include these provisions, which parallel the statutory language, in the regulatory text as it improves the clarity of the update process for the regulated public.

TECHNICAL, THEORETICAL, OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS RELIED UPON – GOVERNMENT CODE § 11346.2(b)(3)

The Administrative Director relies on the following documents in proposing the regulation. They are available for public review and comment in the rulemaking file.

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

DOCUMENTS INCORPORATED BY REFERENCE

None

SPECIFIC TECHNOLOGIES OR EQUIPMENT, SPECIFIC ACTIONS OR PROCEDURES

The proposed regulations do not prescribe specific technologies or equipment.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATIONS AND REASONS FOR REJECTING THOSE ALTERNATIVES

The Administrative Director has not identified any effective alternative, or any equally effective and less burdensome alternative to the regulation at this time. The public is invited to submit such alternatives during the public comment process.

REGULATION MANDATED BY FEDERAL LAW OR REGULATION

The regulatory action does not adopt a regulation mandated by federal law or regulation.

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, 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 workers' compensation premiums is estimated to be approximately $23.0 million. This translates into an increase in California Gross State Product (GSP) of approximately $12.5 million for total economic benefits of $35.4 million (note the subtotals do not sum to the overall impacts due to rounding). There are three reasons why the increase in GSP is less than the full amount of the reduction. 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. These estimates of increases in California GSP translate into increased employment of approximately 140 jobs.

Similarly, the change in provider net revenue is estimated to be a decrease of approximately $6.8 million. This translates into a decrease in the California GSP of approximately $3.8 million for total economic costs of $10.4 million (note the subtotals do not sum to the overall impacts due to rounding). In total, the net increase in California GSP from both the change in workers' compensation premiums together with the decrease in provider net revenue is approximately $8.7 million. These estimates of decreases in California GSP translate into decreased employment of approximately 41 jobs.

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 140 jobs will be created and 41 jobs will be eliminated across the state. Costs and benefits and resulting changes in employment 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 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 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. 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.

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