FORMAT OF MODIFIED PROPOSED REGULATORY TEXT

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

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

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

Modified proposed new regulatory text for adoption in Title 8, California Code of Regulations sections 9792.27.1 – 9792.27.~~21~~<u>23</u>

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

For purposes of sections 9792.27.1 through 9792.27.~~21~~<u>23</u>, the following definitions shall apply:

(a) "Administer" means the direct application of a drug or device to the body of the patient by injection, inhalation, ingestion, or other means.

(b) "Authorization through prospective review" means authorization for proposed treatment obtained through the utilization review process set forth in section 9792.6.1 et seq.

~~(c) "Brand name drug" means an FDA-approved drug that is marketed under a proprietary, trademark-protected name.~~

<u>(c) "Brand name drug" means a drug that is produced or distributed under an FDA original New Drug Application (NDA) or Biologic License Application (BLA) approved by the FDA. It also includes a drug product marketed by any cross-licensed producers or distributors operating under the same NDA or BLA.</u>

(d) "Combination drug" means a fixed dose combination of two or more active drug ingredients into a single dosage form that is FDA-approved for marketing.

~~(e) "Compounded drug" means a drug that is created by combining one or more active pharmaceutical ingredients, and one or more inactive ingredients, to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace.~~

<u>(e) "Compounded drug" means any drug subject to:</u>

(1) Article 4.5 (commencing with section 1735) or article 7 (commencing with section 1751) of division 17 of title 16 of the California Code of Regulations, or
(2) Other regulation adopted by the State Board of Pharmacy to govern the practice of compounding, or
(3) Federal law governing compounding, including title 21, United State Code, sections 353a, 353a-1, 353b.

(f) "Dispense" means: 1) the furnishing of a drug upon a prescription from a physician or other health care provider acting within the scope of his or her practice, or 2) the furnishing of drugs directly to a patient by a physician acting within the scope of his or her practice.

(g) "Executive Medical Director" means the medical director of the Division of Workers' Compensation.

(h) "Exempt drug" means a drug on the MTUS Drug List which is designated as being a drug that does not require authorization through prospective review prior to dispensing the drug, provided that the drug is prescribed in accordance with the MTUS Treatment Guidelines. The Exempt status of a drug is designated in the column with the heading labeled "Exempt / Non-Exempt".

(~~h~~i) "Expedited review" means the expedited utilization review conducted prior to the delivery of the requested medical services, in accordance with Labor Code section 4610 and title 8, California Code of Regulations section 9792.6.1 et seq.~~, where the injured worker's condition is such that the injured worker faces an imminent and serious threat to his or her health, including, but not limited to, the potential loss of life, limb, or other major bodily function or the normal prospective review timeframe would be detrimental to the injured worker's life or health or could jeopardize the injured worker's permanent ability to regain maximum function.~~

(~~i~~j) "FDA" means the United States Food and Drug Administration within the United States Department of Health & Human Services.

(~~j~~k) "FDA-approved drug" means a prescription or nonprescription drug that has been approved by the FDA under the federal Food, Drug, and Cosmetic Act, title 21, United States Code, section 301 et seq.

~~(k) "Generic drug" means an FDA-approved drug that is therapeutically equivalent to a brand name drug as determined by the FDA's designation of the drug with the Therapeutic Equivalence Evaluation Code designation as an "A" product in the Orange Book. The FDA's therapeutic equivalency determinations are accessible through the FDA website at: http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm . ("Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations".)~~

(l) "Generic drug" means a drug that is produced or distributed under an FDA Abbreviated New Drug Application (ANDA) approved by the FDA. A generic drug may

be substituted for a therapeutic equivalent brand name drug pursuant to applicable state and federal laws and regulations.

(~~l~~m) "MTUS Drug Formulary" means the MTUS Drug List set forth in section 9792.27.~~14~~15 and the formulary rules set forth in sections 9792.27.1 through 9792.27.~~21~~23.

(~~m~~n) "MTUS Drug List" means the drug list and related information in section 9792.27.~~14~~15, which sets forth the ~~preferred~~ Exempt or ~~non-preferred~~ Non-Exempt status of drugs listed by active drug ingredient(s).

(~~n~~o) "~~Non-Preferred~~ Non-Exempt drug" means a drug on the MTUS Drug List which is designated as requiring authorization through prospective review prior to dispensing the drug. The ~~Non-Preferred~~ Non-Exempt Drug status of a drug is designated in the column labeled ~~"Preferred / Non-Preferred"~~ "Exempt / Non-Exempt".

(~~o~~p) "Nonprescription drug" or "over-the-counter drug" (OTC drug) means a drug which may be sold without a prescription and which is labeled for use by the consumer without the supervision of a health care professional.

(~~p~~q) "Off-label use" means use of a drug for a condition, or in a dosage or method of administration, not listed in the drug's FDA-approved ~~FDA's~~ labeling for approved use.

~~(q) "Over-the-counter drug" (OTC drug) or "Nonprescription drug" means a drug which may be sold without a prescription and which is labeled for use by the consumer without the supervision of a health care professional.~~

(r) "OTC Monograph" means a monograph established by the FDA setting forth acceptable ingredients, doses, formulations, and labeling for a class of OTC drugs. ~~When a final OTC Monograph is adopted by the FDA for a class of drugs, OTC drugs that conform to the monograph are considered to be generally recognized as safe and effective and do not need an approved drug application in order to be marketed.~~

(s) "Perioperative Fill" means the policy set forth in section 9792.27.~~12~~13 allowing dispensing of identified ~~Non-Preferred~~ Non-Exempt drugs without prospective review where the drug is prescribed within the perioperative period and meets specified criteria.

(t) "P&T Committee" means the Pharmacy and Therapeutics Committee established by the Administrative Director pursuant to Labor Code section 5307.29 to review and consult with the administrative director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs in the updating of the evidence-based drug formulary.

(u) "Physician": Notwithstanding the definition in Labor Code section 3209.3, for purposes of the MTUS Drug Formulary, "Physician" means a medical doctor, doctor of osteopathy, or other health care provider whose scope of practice includes the prescription of drugs. However, for purposes of membership on the P&T Committee,

"physician" means a medical doctor or doctor of osteopathy licensed pursuant to the California Business and Professions Code.

~~(v) "Preferred drug" means a drug on the MTUS Drug List which is designated as being a drug that does not require authorization through prospective review prior to dispensing the drug, provided that the drug is prescribed in accordance with the MTUS Treatment Guidelines. The Preferred status of a drug is designated in the column with the heading labeled "Preferred / Non-Preferred".~~

(v) "Prescription drug" means any drug whose labeling states "Caution: Federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(w) "Prospective review" means the utilization review conducted prior to the delivery of the requested medical services, in accordance with Labor Code section 4610 and title 8, California Code of Regulations section 9792.6.1 et seq.

~~(x) "Retrospective review" means the utilization review conducted after the delivery of medical services, in accordance with Labor Code section 4610 and title 8, California Code of Regulations section 9792.6.1 et seq.~~

(~~y~~x) "Special Fill" means the policy set forth in section 9792.27.~~11~~12 allowing dispensing of identified ~~Non-Preferred~~ Non-Exempt drugs without prospective review where the drug is prescribed or dispensed ~~at the single initial treatment visit following a workplace injury, where the visit occurs within 7 days of the date of injury.~~ in accordance with the criteria set forth in subdivision (b) of section 9792.27.12.

(~~z~~y) A "therapeutic equivalent" is a drug designated by the FDA as equivalent to a Reference Listed Drug if the two drugs are pharmaceutical equivalents (contain the same active ingredient(s), dosage form, route of administration and strength), and are bioequivalent (comparable availability and rate of absorption of the active ingredient(s).) Drugs that the FDA considers to be therapeutically equivalent products are assigned a Therapeutic Equivalence Evaluation Code beginning with the letter "A" in the FDA publication "Orange Book: Approved Products with Therapeutic Equivalence Evaluations" which is available on the FDA website and accessible via a link provided on the department's website. ~~The FDA's therapeutic equivalency determinations are accessible through the FDA website at: http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm . ("Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations".)~~

(~~aa~~z) "Unlisted drug" means a drug that does not appear on the MTUS Drug List and which is one of the following: an FDA-approved ~~prescription~~ drug~~; an FDA-approved nonprescription drug;~~ or a nonprescription drug that is marketed pursuant to an FDA OTC Monograph. An "unlisted drug" does not include a compounded drug but does include a combination drug.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

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

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

(b) Except for continuing ~~medical~~ drug treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after ~~July 1, 2017~~ January 1, 2018 for outpatient use shall be subject to the MTUS Drug Formulary, regardless of the date of injury.

(1) A drug is for "outpatient use" if it is 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. "Home" includes an institutional setting in which the injured worker resides, ~~such as~~ including but not limited to, an assisted living facility.

~~(2) The MTUS Drug Formulary applies to drugs prescribed by a physician and dispensed for outpatient use by any of the following:~~
~~(A) A physician;~~
~~(B) A pharmacy;~~
~~(C) An inpatient hospital;~~
~~(D) An outpatient department of a hospital;~~
~~(E) An emergency department of a hospital;~~
~~(F) An ambulatory surgery center;~~
~~(G) Any other health care provider or health care entity~~.

(~~3~~2) The MTUS Drug Formulary does not apply to drugs administered to the patient by a physician. However, the physician administered drug treatment is subject to relevant provisions of the MTUS, including the MTUS Treatment Guidelines. ~~(for example, the Shoulder Disorders Guideline contains provisions relating to steroid injections for a variety of shoulder conditions.)~~

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.3. MTUS Drug Formulary Transition.

(a) Except as provided in subdivision (b), the MTUS Drug Formulary applies to drugs dispensed on or after ~~July 1, 2017~~January 1, 2018, regardless of the date of injury.

(b) (1) For injuries occurring prior to ~~July 1, 2017~~January 1, 2018, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. 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 use of a ~~Non-Preferred~~ Non-Exempt drug or unlisted drug, ~~for an extended period~~ where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a different ~~Preferred~~ drug. ~~The claims administrator shall not unilaterally terminate or deny previously approved drug treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.~~

(2) If the injured worker with a date of injury prior to January 1, 2018 is receiving a course of treatment that includes a Non-Exempt drug, an unlisted drug, or a compounded drug, the physician shall submit a progress report issued pursuant to section 9785 and a Request for Authorization that shall address the injured worker's ongoing drug treatment plan. The report shall either:

(A) Include a treatment plan setting forth a safe weaning, tapering, or transitioning of the worker to a drug pursuant to the MTUS, or

(B) Provide supporting documentation, as appropriate, to substantiate the medical necessity of, and to obtain authorization for, the Non-Exempt drug, unlisted drug, or compounded drug, pursuant to the MTUS (via guidelines, Medical Evidence Search Sequence, and/or Methodology for Evaluating Medical Evidence.)

(3) The progress report, including the treatment plan and Request for Authorization provided under this subdivision, shall be submitted at the time the next progress report is due under section 9785(f)(8), however, if that is not feasible, no later than April 1, 2018.

(4) Previously approved drug treatment shall not be terminated or denied except as may be allowed by the MTUS and in accordance with applicable utilization review and independent medical review regulations.

(5) The claims administrator shall process the progress report, treatment plan and Request for Authorization in accordance with the standard procedures and timeframes set forth in section 9792.6.1 et seq.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

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

Where an employer or insurer contracts pursuant to Labor Code section 4600.2 with a pharmacy, a pharmacy benefit manager or pharmacy network for the provision of drugs for the treatment of injured workers, the drugs available to the injured worker must be consistent with the MTUS Treatment Guidelines and MTUS Drug Formulary for the condition or injury being treated and may not be restricted pursuant to the contract.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4600.2, 4604.5 and 5307.27, Labor Code.

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

(a) Off-label use of a drug shall be in accordance with the MTUS Treatment Guidelines and rules and the MTUS Drug Formulary.

(b) Authorization through prospective review is not required to dispense ~~a Preferred~~ an Exempt drug for an off-label use if the MTUS Treatment Guideline recommends the off-label use of the drug to treat the condition.

(c) Authorization through prospective review is required prior to dispensing the following drugs for an off-label use:
(1) ~~Non-Preferred~~ Non-Exempt drug, or
(2) Unlisted drug, or
(3) ~~Preferred~~ Exempt drug lacking recommendation in the MTUS Treatment Guideline for the intended off-label use.
~~If required authorization through prospective review is not obtained prior to dispensing a drug for off-label use, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.~~

(d) When a physician believes it is medically necessary to prescribe a drug for an off-label use not recommended by the MTUS Treatment Guidelines or not addressed by the MTUS Treatment Guidelines, the permissibility of the treatment outside of the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical ~~Evidence.)~~Evidence).

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

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

(a) Drug treatment that is in conformity with the MTUS Treatment Guidelines is presumed correct on the issue of extent and scope of medical treatment pursuant to

section 9792.21 subdivision (c), and Labor Code section 4604.5. Although the MTUS Drug List identifies ~~Preferred~~ Exempt drugs that do not require prospective review when dispensed in accordance with the MTUS Treatment Guidelines, other medically necessary drugs are available to the injured worker when authorized through prospective review.

(b) 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 the drug ~~a variance from the guidelines~~ is required to cure or relieve the injured worker from the effects of the injury. Determination of the medical necessity of treatment based on recommendations found ~~Treatment~~ outside of the ~~guidelines~~ MTUS Treatment 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.)~~evidence). ~~If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.~~

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

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

If a physician prescribes a brand name drug when a less costly therapeutically equivalent generic drug exists, and writes “Do Not Substitute” or “Dispense as Written” on the prescription in conformity with Business and Professions Code section 4073, the physician must document the medical necessity for prescribing the brand name drug in the patient’s medical chart and in the Doctor’s First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician’s determination that the brand name drug is medically necessary. The physician must submit a Request for Authorization and obtain authorization through prospective review before the brand name drug is dispensed. ~~If required authorization through prospective review is not obtained before dispensing the brand name drug, retrospective review may be conducted to determine if it was medically necessary to use the brand name drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand name drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand name drug. If it is determined through prospective or retrospective review that neither the generic drug nor the brand name drug is medically necessary, payment for the drug may be denied, pursuant to section 9792.27.10.~~

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.8. Physician-Dispensed Drugs.

(a) Drugs dispensed by a physician must be authorized through prospective review prior to being dispensed, except as provided in subdivision (b), section 9792.27.~~11~~12 ("Special Fill"), and section 9792.27.~~12~~13 ("Perioperative Fill"). ~~If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.~~

(b) A physician may dispense up to a seven-day supply of ~~a~~ one or more drugs that ~~is listed~~ are designated as ~~"Preferred"~~ "Exempt" in the MTUS Drug List ~~on a one-time basis~~ without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Treatment Guidelines and the up-to-seven-day supply is dispensed at the time of an initial visit that occurs within 7 days of the date of injury. ~~The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.~~

(c) Nothing in this Article shall invalidate a provision in a Medical Provider Network agreement which restricts physician dispensing by medical providers within the network.

(d) Nothing in this Article shall permit physician dispensing where otherwise prohibited by a Pharmacy Benefit Network contract pursuant to subdivision (a) of Labor Code 4600.2.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.9. Compounded Drugs.

(a) Compounded drugs must be authorized through prospective review prior to being dispensed. ~~If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied.~~ When it is necessary for medical reasons to prescribe or dispense a compounded drug instead of an FDA-approved drug or over-the-counter drug that complies with an OTC Monograph, the physician must document the medical necessity in the patient's medical chart, and in the Doctor's First Report of Injury (Form 5021) or Progress Report ~~(PR-2.)~~ (PR-2) and must submit a Request for Authorization. The documentation must include the patient-specific factors that support the physician's determination that a compounded drug is medically necessary.

(b) Nothing in this Article shall invalidate a provision in a Medical Provider Network agreement which restricts physician dispensing of compounded drugs by medical providers within the network.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

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

(a) The MTUS Drug List is set forth by active drug ingredient(s).

(b) A drug that is identified as ~~"Preferred"~~ "Exempt" may be dispensed to the injured worker without obtaining authorization through prospective review if the drug treatment is in accordance with the MTUS Treatment Guidelines, except:
(1) Brand name drugs are subject to section 9792.27.7;
(2) ~~that p~~Physician-dispensed drugs are subject to section 9792.27.8. ~~The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.~~

(c) For a drug that is identified as ~~"Non-Preferred,"~~ "Non-Exempt," authorization through prospective review must be obtained prior to the time the drug is dispensed. Expedited review should be conducted where it is warranted by the injured worker's condition. ~~If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.~~

(d) For a drug that is identified as eligible for "Special Fill" or "Perioperative Fill", the usual requirement to obtain authorization through prospective review prior to dispensing the drug is altered for the specified circumstances set forth in sections 9792.27.~~11~~12 and 9792.27.~~12~~13. If the requirements set forth in section 9792.27.~~11~~12 or section 9792.27.~~12~~13 are not met, then the drug is considered ~~"Non-Preferred"~~ "Non-Exempt" and is subject to the provisions set forth under subdivision (c).

(e) For an unlisted drug, authorization through prospective review must be obtained prior to the time the drug is dispensed. ~~If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.~~ A combination drug that is not on the MTUS Drug List is an unlisted drug even if the individual active ingredients are on the MTUS Drug List.

~~(f) The prospective review requirement may be waived if the drug falls within a utilization review plan's provision of prior authorization without necessity of a request for authorization, where that provision is adopted pursuant to section 9792.7(a)(5).~~

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section 9792.27.11. Waiver of Prospective Review.

Nothing in the MTUS Drug Formulary shall prohibit waiver of the prospective review requirement for a Non-Exempt or unlisted drug if the drug falls within a utilization review plan's provision of prior authorization without necessity of a request for authorization, where that provision is adopted pursuant to section 9792.7(a)(5).

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section ~~9792.27.11.~~9792.27.12 MTUS Drug List – Special Fill.

(a) The MTUS Drug List identifies drugs that are subject to the Special Fill policy. Under this policy, a drug that usually requires prospective review because it is ~~"Non-Preferred,"~~ "Non-Exempt," will be allowed without prospective review ~~in very limited circumstances, and for a short period of time~~ as specified in subdivision (b).

(b) The drug identified as a Special Fill drug may be dispensed to the injured worker without seeking prospective review if all of the following conditions are met:

(1) The drug is prescribed at the single initial treatment visit following a workplace injury, provided that the initial visit is within 7 days of the date of injury; and

(2) The prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List; and

(3) The prescription for the Special Fill – eligible drug is for:

(A) An FDA-approved generic drug or single source brand name drug, or,

(B) A brand name drug where the physician documents and substantiates the medical need for the brand name drug rather than the FDA-approved generic drug, and

(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines.

(c) When calculating the 7-day period in subdivision (b)(1), the day after the date of injury is "day one."

~~(d) A drug dispensed under the "Special Fill" policy may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.~~

~~(e)~~(d) An employer or insurer that has a contract with a pharmacy, pharmacy network, pharmacy benefit manager, or a medical provider network (MPN) that includes a pharmacy or pharmacies within the MPN, may provide for a longer Special Fill period or

may cover additional drugs under the Special Fill policy pursuant to a pharmacy benefit contract or MPN contract.

~~(f)~~ (e) After the Special Fill provision has been in effect for one year, the Administrative Director shall evaluate the impact of the provision on the use of opioids by injured workers. As part of the evaluation process, the Administrative Director shall solicit feedback from the workers' compensation system participants.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section ~~9792.27.12.~~ 9792.27.13. MTUS Drug List – Perioperative Fill.

(a) The MTUS Drug List identifies drugs that are subject to the Perioperative Fill policy. Under this policy, the Non-Exempt drug identified as a Perioperative Fill drug may be dispensed to the injured worker without seeking prospective review if all of the following conditions are met:

(1) The drug is prescribed during the perioperative period; and

(2) The prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List; and

(3) The prescription for the Perioperative Fill - eligible drug is for:

(A) An FDA-approved generic drug or single source brand name drug, or,

(B) A brand name drug where the physician documents and substantiates the medical need for the brand name drug rather than the FDA-approved generic drug, and

(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines.

(b) For purposes of this section, the perioperative period is defined as the period from ~~2~~ 4 days prior to surgery to 4 days after surgery, with the day of surgery as "day zero".

~~(c) A drug dispensed under the "Perioperative Fill" policy may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.~~

(~~d~~c) An employer or insurer that has a contract with a pharmacy, pharmacy network, pharmacy benefit manager, or a medical provider network that includes a pharmacy or pharmacies within the MPN, may provide for a longer Perioperative Fill period or may cover additional drugs under the Perioperative Fill policy pursuant to a pharmacy benefit contract or MPN contract.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section ~~9792.27.13.~~ 9792.27.14. Treatment Provided Under Applicable Health and Safety Regulations.

The MTUS Drug Formulary and associated regulations do not relieve an employer of any responsibilities pursuant to applicable health and safety regulations such as the requirements of the California occupational Bloodborne Pathogens standard at title 8, California Code of Regulations section 5193, including the responsibility to provide urgent post-exposure prophylaxis as needed to protect the health of the employee.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section ~~9792.27.14.~~ 9792.27.15. MTUS Drug List.

[Excel Document: MTUS DRUG LIST (8 CCR §~~9792.27.14~~ §9792.27.15)]

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5 and 5307.27, Labor Code.

Section ~~9792.27.15.~~ 9792.27.16. National Drug Codes, Unique Product Identifier - MTUS Drug List.

(a) The Administrative Director may maintain and post on the DWC website a listing by NDC code, RxCUI, or other unique product identifier, of drug products that are embodied in the MTUS Drug List. If posted, the listing will be regularly updated to account for revisions to the MTUS Drug List and for changes in drug products that are marketed for outpatient use.

(b) For each active ingredient on the MTUS Drug List, the product listing shall include brand name and therapeutically equivalent generic versions of outpatient prescription drugs and non-prescription drug products. The listing shall include only drug products that can be self-administered by the patient. Injectable drug products must be packaged and identified for patient self-administration. ~~using oral routes of administration unless the drug products that are commonly prescribed for outpatient use have other routes of administration, including:~~
~~(1) Ophthalmic solutions and ointments;~~
~~(2) Dermatological topical creams, ointments, and gels;~~
~~(3) Antiasthmatic and bronchodilator inhalants;~~
~~(4) Self-administered anti-coagulant injections.~~

(c) The listing shall include combination drugs with multiple active ingredients only if the combination of active ingredients is listed on the MTUS Drug List.

(d) The listing shall exclude repackaged drugs.

(e) ~~At a minimum, the~~ The listing ~~shall~~ may include, but is not limited to, ~~for each product~~ the following data elements:
(1) National Drug Code, RxCUI, or other identifier;
(2) Drug ingredient(s);
(3) Therapeutic class;
(4) Strength;
(5) Dosage form;
~~(6) Route of administration;~~
(~~7~~6) ~~Preferred or Non-Preferred~~ Exempt or Non-Exempt status, as applicable;
(~~8~~7) Any applicable Special Fill or Perioperative Fill policies.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section 9792.27.17. Formulary – Dispute Resolution.

(a) Medical Necessity Disputes.
Disputes over the medical necessity of pharmaceutical treatment covered by the MTUS Drug Formulary are governed by the utilization review and independent medical review provisions of Labor Code sections 4610, 4610.5, and regulations at sections 9792.6.1 et seq, and section 9792.10.1 et seq.

(b) Formulary Rule Medical Treatment Disputes Other than Medical Necessity Disputes.
Disputes over failure to follow formulary rules, other than medical necessity disputes covered by subdivision (a), shall be resolved through the procedure for non-IMR/IBR disputes set forth in WCAB rules, title 8, California Code of Regulations section 10451.2, Determination of Medical Treatment Disputes.

Authority: Sections 133, 4603.5, 5307.3, 5307.1 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.1, 5307.27 and 5307.29, Labor Code.

Section ~~9792.27.16~~ 9792.27.18. Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.

(a) The Administrative Director shall create 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, for purposes of updating the MTUS Drug List.

(b) The P&T Committee shall consist of the Executive Medical Director, and six members appointed by the Administrative Director.

(1) The Executive Medical Director, or his or her designee, shall serve as chairperson of the P&T Committee. If the Executive Medical Director position becomes vacant, the Administrative Director shall appoint a competent person to temporarily assume the authority and duties of the Executive Medical Director on the P&T Committee, until such time that the Executive Medical Director position is filled.

(2) The Administrative Director shall appoint 3 pharmacists and 3 physicians (medical doctors or doctors of osteopathy) to serve on the P&T Committee. At least one of the physicians appointed shall be actively engaged in the treatment of injured workers. At least one of the pharmacists appointed shall be an actively practicing pharmacist.

(3) The members of the P&T Committee shall be appointed to serve a two-year term, but shall remain in the position until a successor is appointed. A member may apply to be reappointed when his or her two-year term ends. The Administrative Director may cancel the appointment of a committee member if a substantial conflict of interest arises, or for other reason constituting good cause.

(c) A person interested in serving on the P&T Committee shall submit an application on the form prescribed by the Administrative Director and a completed Conflict of Interest Disclosure Form. The applicant for P&T Committee appointment shall demonstrate that he or she has knowledge or expertise 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.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section ~~9792.27.17.~~ 9792.27.19. Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

[FORM: DWC MTUS PT-App (New 7/17)]

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section ~~9792.27.18.~~ 9792.27.20. Pharmacy and Therapeutics Committee – Conflict of Interest.

(a) The conflict of interest standards are intended to ensure that the members of the P&T Committee are free from financial interests or other relationships that could compromise the objectivity of the members of the committee as they perform their duties to consult with the Administrative Director on formulary updates based upon the principles of evidence-based medicine. Appointed members of the P&T Committee must impartially perform formulary update review activities, and must be free of conflicts of interest.

(b) Persons applying to be appointed to the P&T Committee 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, and shall not have been so employed for 12 months prior to the appointment. A P&T Committee member who undertakes such employment during the term of appointment shall not be eligible to continue to serve on the committee.

(c) Members of the P&T Committee shall not have a substantial financial conflict of interest in relation to a pharmaceutical entity.

(1) "Pharmaceutical entity" means a pharmaceutical manufacturer, pharmaceutical repackager, pharmaceutical relabeler, compounding pharmacy, pharmacy benefits management company, biotechnology company, or any other business entity that is involved in manufacturing, packaging, selling or distribution of prescription or non-prescription drugs, drug delivery systems, or biological agents.

(2) For purposes of this section, "substantial financial conflict of interest" means that the applicant or committee member, or his or her immediate family member, has a direct or indirect financial interest in a pharmaceutical entity, including:

(A) Receipt of income within the previous 12 months, amounting to a total of $500 or more from the pharmaceutical entity, including but not limited to salary, wages, speaking fees, consultant fees, expert witness fees, honoraria, gifts, loans, and travel payments;

(B) Receipt of grants or research funding from the pharmaceutical entity within the previous 24 months;

(C) Has had ownership interest in the pharmaceutical entity at any time during the previous 12 ~~months;~~months, including but not limited to, a sole proprietorship, partnership, limited liability company, or stock ownership in a corporation that is not publicly traded;

(D) Investment interest worth $2,000 or more in a publicly-traded pharmaceutical entity, not including an investment held through a diversified mutual fund;

(3) "Immediate family member" means spouse, domestic partner, child, son-in-law, daughter-in-law, parent, mother-in-law, father-in-law, brother or sister;

(4) (A) “Direct financial interest” means an interest held by the applicant or committee member.
(B) “Indirect financial interest” means an interest held by the applicant or committee member’s immediate family member, or held by a business entity or trust in which the applicant or committee member owns directly or indirectly, or beneficially, a 10-percent interest or greater.

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

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section ~~9792.27.19.~~ 9792.27.21. Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form.

[FORM: DWC MTUS PT-COI (New 7/17)]

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section ~~9792.27.20.~~ 9792.27.22. Pharmacy and Therapeutics Committee – Meetings.

(a) The P&T Committee shall meet when deemed necessary by the Executive Medical Director, but no less frequently than quarterly.

(b) P&T Committee meetings shall be conducted in accordance with the Bagley-Keene Open Meeting Act, California Government Code sections 11120 through 11132.

(c) Notice of the regularly scheduled meetings shall be given at least ten days in advance of the meeting as follows:

(1) To persons who have requested notice of the meetings;

(2) To persons on the Administrative Director’s mailing list; and

(3) By posting notice on the division’s website.

(d) The Executive Medical Director shall include a period to receive public comment during the P&T Committee meetings, in a manner consistent with the orderly and efficient conduct of the business of the committee. Members of the public addressing the P&T Committee shall be limited to three minutes per speaker.

(e) The Executive Medical Director shall maintain a written ~~documentation~~ summary of the meetings and the recommendations made to the Administrative Director in a format determined by the Administrative Director. The ~~documentation~~ written summary shall be posted on the Division's website. It shall include a description of any action taken and the vote or abstention of each P&T Committee member present.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 11120 – 11132, Government Code, 4600, 4604.5, 5307.27 and 5307.29, Labor Code.

Section ~~9792.27.21.~~ 9792.27.23. MTUS Drug List Updates.

(a) The Administrative Director shall consult with the P&T Committee as needed on updates to the MTUS Drug List, which may be adopted by the Administrative Director on a quarterly or more frequent basis in order to allow provision for all appropriate medications.

(b) The P&T Committee is responsible for reviewing and consulting with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs. In carrying out these duties the P&T Committee may provide consultation on a variety of relevant issues, including but not limited to the following:

(1) Recommendations on prospective review requirements for ~~new~~ drugs~~, and for existing drugs based upon newly available evidence~~;

(2) Recommendations on Special Fill and Perioperative Fill designation and policies ~~for new drugs, and for existing drugs based upon newly available evidence~~;

(3) Review of drug treatment changes adopted into the MTUS Treatment Guidelines to identify needed additions or deletions of drugs from the MTUS Drug List;

(4) Recommendations on establishing a therapeutic interchange program in order to promote safe and appropriate cost effective care.

(c) The P&T Committee serves in an advisory role only. P&T Committee recommendations are not binding on the Administrative Director.

(d) Updates to the MTUS Drug List will be adopted by issuance of an Administrative Director's order specifying the changes and the effective date, and shall be posted on the division's website pursuant to Labor Code section 5307.29.

Authority: Sections 133, 4603.5, 5307.3 and 5307.27, Labor Code.
Reference: Sections 4600, 4604.5, 5307.27 and 5307.29, Labor Code.