Section 9792.27.1. Medical Treatment Utilization Schedule Drug Formulary – Definitions.

For purposes of sections 9792.27.1 through 9792.27.18, 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.

(d) "Compounded drug" means a drug that is created by combining two or more active pharmaceutical 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. A "compounded drug" does not include a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

(e) "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 or other health care provider acting within the scope of his or her practice.

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

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

(h) "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.

(i) "First Fill" means the policy relating to the drug prescription issued or drug dispensed at the initial visit following a workplace injury, where the visit occurs within 7 days of the date of injury.

(j) "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.

(k) "MTUS Drug Formulary" means the Preferred Drug List set forth in section 9792.27.12 and the formulary rules set forth in sections 9792.27.1 through 9792.27.18.

(l) "MTUS Preferred Drug List" or "Preferred Drug List" means the drug list and related information in section 9792.27.12, which sets forth the preferred or non-preferred status of drugs listed by active drug ingredient.

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

(n) "Nonprescription Drug" or "Over-the-Counter 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.

(o) "Off-label use" is use of a drug for a condition, or in a dosage or method of administration, not listed in the Food and Drug Administration's labeling for approved use.

(p) "Orange Book" means the FDA's publication "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations," which sets forth the FDA's generic drug equivalency determinations. It is accessible through the FDA website at: http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm.

(q) "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.

(r) "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.

(s) "Physician" means a medical doctor, doctor of osteopathy, or other health care provider whose scope of practice includes the prescription of drugs.

(t) "Preferred drug" means a drug on the MTUS Preferred 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 Guidelines. The Preferred Drug status of a drug is designated in the column with the heading labeled "Preferred / Non-Preferred".

(u) "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.

(v) "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.

(w) 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 Orange Book.

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 Preferred 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 MTUS Guidelines and rules, including the provisions relating to the presumption of correctness, the methods for rebutting the presumption and for substantiating medical necessity where the MTUS Guidelines do not address the injury or illness.

(b) Except for continuing medical treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after July 1, 2017 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 prescribed or dispensed to be taken, applied, or self-administered by the patient at home or outside of a clinical setting. "Home" includes an institutional setting in which the injured worker resides, such as an assisted living facility.

(2) The MTUS Drug Formulary applies to drugs prescribed by a physician for outpatient use or 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) The MTUS Drug Formulary does not apply to drugs administered to the patient in any clinical setting. Although the MTUS Drug Formulary is not applicable to drugs administered in a clinical setting, drug treatment in those settings is subject to relevant MTUS Guidelines and rules.

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, regardless of the date of injury.

(b) For injuries occurring prior to July 1, 2017, 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. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an "unlisted drug"), the physician shall either:
(1) Prepare a treatment plan to transition the worker to a Preferred Drug, or
(2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

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 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 guidelines and MTUS Drug Formulary and may not be restricted pursuant to the contract.

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

Section 9792.27.5. MTUS Drug Formulary - Off Label Use.

(a) Off label use of a drug shall be in accordance with the MTUS Guidelines and MTUS Drug Formulary, including the prospective review requirement if the drug is identified on the Preferred Drug List as Non-Preferred or is an unlisted drug.

(b) When a physician believes the prescription of a drug for an off label use not addressed by the MTUS Guidelines is medically necessary, 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.) The physician must obtain authorization through prospective review prior to the time the drug is dispensed for the off label use. 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.

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 in the Preferred Drug List.

Drug treatment that is in conformity with the MTUS 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 Preferred Drug List identifies drugs that do not require prospective review when dispensed in accordance with the MTUS Guidelines, other medically necessary drugs are available to the injured worker when authorized through prospective review. An injured worker may be prescribed any medically necessary FDA-approved prescription drug, FDA-approved nonprescription drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, if it is shown by a preponderance of scientific medical evidence that a variance from the guidelines is required to cure or relieve the injured worker from the effects of his or her injury. 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.)

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 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 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 drug is medically necessary. The physician must obtain authorization through prospective review prior to the time the brand drug is dispensed. If required authorization through prospective review is not obtained prior to dispensing the brand drug, retrospective review may be conducted to determine if it was medically necessary to use the brand drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand 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 drug.

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) Except as provided in subdivision (b), and section 9792.27.11 in relation to "First Fills", drugs dispensed by a physician 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 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 drug that is listed as "Preferred" in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. 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.

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.

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.) The documentation must include the patient-specific factors that support the physician's determination that a compounded drug is 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 9792.27.10. MTUS Preferred Drug List; Preferred Drugs, Non-Preferred Drugs, Prospective Review.

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

(b) A drug that is identified as "Preferred" may be dispensed to the injured worker without obtaining authorization through prospective review if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was within the MTUS guidelines. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.

(c) For a drug that is identified as "Non-Preferred," 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 is not medically necessary.

(d) For a drug that is identified as "First Fill", the usual requirement to obtain authorization through prospective review prior to dispensing the drug is altered for the specified circumstances set forth in section 9792.27.11.

(e) For a drug not addressed on the MTUS Preferred Drug List, 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.

(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. MTUS Preferred Drug List – First Fill.

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

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

(1) The drug is prescribed at the initial 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 Preferred Drug List; and

(3) The prescription is for:

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

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

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

(c) An employer or insurer that has a contract with a pharmacy network, pharmacy benefit manager, or a medical provider network that includes pharmacies within the MPN, may provide for a longer first fill period or may cover additional drugs under the first 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 9792.27.12. MTUS Preferred Drug List.

[DRUG LIST]

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. 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 Preferred 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 9792.27.14. Pharmacy and Therapeutics Committee – Application for Appointment to Committee Form.

[FORM]

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 9792.27.15. 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; including but not limited to, a sole proprietorship, partnership, limited liability company, 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;

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

(7) (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 9792.27.16. Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form.

[FORM]

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. 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 open to the public, except as provided in subdivision (e). Notice of the meetings shall be given at least one week 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.

(c) 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.

(d) The Executive Medical Director shall maintain written documentation of the meetings and the recommendations made to the Administrative Director in a format determined by the Executive Medical Director. The documentation shall be posted on the Division's website.

(e) The P&T Committee may meet in closed Executive Session where deemed necessary by the Executive Medical Director.

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. MTUS Preferred Drug List Updates.

(a) The Administrative Director shall consult with the P&T Committee on updates to the MTUS Preferred 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 First 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 Guidelines to identify needed additions or deletions of drugs from the MTUS Preferred 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 Preferred 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.