California Workers' Compensation Institute
1333 Broadway Suite 510, Oakland, CA 94612 • Tel: (510) 251-9470 • Fax: (510) 763 -1592

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VIA E-MAIL – dwcrules@dir.ca.gov

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

Re: Written testimony on proposed Drug Formulary regulations

Dear Ms. Gray:

This written testimony on proposed Drug Formulary regulations is presented on behalf of members of the California Workers' Compensation Institute (the Institute). Institute members include insurers writing 83% of California's workers' compensation premium, and self-insured employers with $57B of annual payroll (30% of the state's total annual self-insured payroll).

Insurer members of the Institute include AIG, Alaska National Insurance Company, Allianz Global Corporate and Specialty, AmTrust North America, Berkshire Hathaway, CHUBB, CNA, CompWest Insurance Company, Crum & Forster, EMPLOYERS, Everest National Insurance Company, The Hartford, ICW Group, Liberty Mutual Insurance, Pacific Compensation Insurance Company, Preferred Employers Insurance, Republic Indemnity Company of America, Sentry Insurance, State Compensation Insurance Fund, State Farm Insurance Companies, Travelers, XL America, Zenith Insurance Company, and Zurich North America.

Self-insured employer members include Adventist Health, BETA Healthcare Group, California Joint Powers Insurance Authority, California State University Risk Management Authority, Chevron Corporation, City and County of San Francisco, City of Torrance, Contra Costa County Schools Insurance Group, Costco Wholesale, County of Alameda, County of Los Angeles, County of San Bernardino Risk Management, County of Santa Clara, Dignity Health, Foster Farms, Grimmway Enterprises Inc., Kaiser Permanente, Marriott International, Inc., Pacific Gas & Electric Company, Safeway, Inc., Schools Insurance Authority, Sempra Energy, Shasta County Risk Management, Shasta-Trinity Schools Insurance Group, Southern California Edison, Special District Risk Management Authority, Sutter Health, University of California, and The Walt Disney Company.

Recommended revisions to the proposed regulation are indicated by underscore and ~~strikeout~~. Comments and discussion by the Institute are identified by *italicized text.*

Priority Considerations

The Institute strongly recommends that the Division consider the following issues of particular priority:

1. Delay of Implementation Date: Labor Code section 5307.27 requires that a drug formulary be adopted by July 1, 2017; it does not require that the formulary be effective on that date. CWCI urges the Division to address the universally-expressed concerns of the stakeholders by delaying implementation of the Drug Formulary until January 1, 2018. Delaying implementation would provide sufficient flexibility for necessary technical compliance and allow for an educational process. The Institute's proposal for a delayed implementation is contained in our Recommendations to Section 9792.27.3 of these proposed regulations.

2. Definitive Transition Date: Recognizing that the enabling statute calls for a phased implementation period for workers injured prior to July 1, 2017, it is nevertheless imperative that the regulations specify a definitive date by which time all injured workers must be safely transitioned to medications pursuant to the formulary. Without a final deadline, it is likely that compliance will be substantially less than complete, and the formulary will not have the intended effect of providing injured employees in California with the most effective drug treatment and protection from deleterious and unnecessary drugs.

3. Supporting Information: Under the proposed regulation, payment for a drug not authorized through prospective review prior to dispensing may be denied if the drug is determined not medically necessary upon retrospective review. It is necessary to also disallow payment of the drug if an RFA with sufficient supporting information is not timely received; otherwise the unintended consequence will be that a provider who withholds sufficient information on which to base a retrospective review decision will nevertheless be assured payment.

4. Cost Containment: The proposed Drug Formulary appropriately bases Preferred and Non-Preferred status on Evidence-Based Medicine guidelines, but it does not address the costs associated with the drugs. Under the current Pharmacy Fee Schedule there is tremendous variation in the amounts paid for drugs that are pharmaceutically and therapeutically equivalent, and also for drugs that differ by dosage. Federal Upper Limits (FULs) and Average Wholesale Prices (AWPs) are factors used in Medi-Cal drug payment calculations.

   As part of a forthcoming research report to be published this summer,[1] CWCI examined the potential impact of the formulary and determined that in 2015, 29% of scripts (and 23% of payments) were for drugs identified as Preferred on the DWC's initial Formulary List; 54% of scripts (and 50% of payments) were for Non-Preferred drugs; and 17% of scripts (27% of payments) were non-Listed drugs. The Institute's original study[2] provided examples of variation in payment factors for therapeutically equivalent drugs of varying dosages: FULs for the opioid tramadol HCL ranged from a minimum of $.03 per unit to $16.49 per unit, and AWPs ranged from $0.09 to $19.87. The pharmacy fee schedule provides an example of novel doses from the same manufacturer: $0.0229 per 10 mg tablet of the muscle relaxant cyclobenzaprine when dispensed on March 1, 2017, but $3.8305 per 7.5 mg tablet, a 4,900% mark-up for the smaller dose (from the same manufacturer, dispensed on the same date).

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[1] Swedlow, A. & Hayes, S. "*California's Proposed Workers' Compensation Formulary Part 2."* Anticipated publication July 2017. Swedlow, A. & Hayes, S.

[2] Swedlow, A. & Hayes, S. "*California's Proposed Workers' Compensation Formulary Part 1: A Review of Preferred and Non-Preferred Drugs."* CWCI Spotlight Report. August 2016.

In order to disincentivize dispensing of higher cost drugs in the same therapeutic class, or high-cost novel doses, the Institute has recommended incorporating NDCs into the Formulary Drug List, and revising the pharmacy fee schedule to more effectively address cost-issues. This would enable cost containment and would not limit injured employees' access to all reasonable and necessary drug ingredients.

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

Recommendation

(f) "Dispense" means: 1) the furnishing of a drug for outpatient use 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 a drug~~s~~ for outpatient use directly to a patient by a physician acting within the scope of his or her practice.

(s) "Perioperative Fill" means the policy set forth in section 9792.27.12 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed for outpatient use ~~within~~ during the perioperative period and meets specified criteria.

(z) "Surgery" means a surgical procedure that has "010", or 10 Global Days, listed for the reimbursable CPT code as found in the Medicare National Physician Fee Schedule Relative Value File incorporated into the Official Medical Fee Schedule.

(~~z~~aa) 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. 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~~bb) "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.

Discussion

The changes recommended in (f) are necessary to clarify that the definition of dispense relates to outpatient drugs for the purpose of these sections.

*As currently proposed in (s), the drug must be **prescribed** during the perioperative period. If, as the Institute believes, the intent is for the drug to be **prescribed for use** during the perioperative period, the recommended modification is necessary for clarification, otherwise a prescribing physician could, on the 4th day after surgery, prescribe a 90-day supply of a drug.*

Adding a definition for "surgery" is necessary to clarify under what specific conditions the "Perioperative Fill" policy is applicable. Spinal injections such as trigger points injections and epidural steroid injections, as well as diagnostic procedures such as endoscopy, are all procedures that would not normally necessitate the prescribing of drugs for outpatient use of

during the perioperative period. Without this definition, however, they could be considered surgery. Adding this definition will avoid unnecessary frictional costs.

If the definition for surgery is added, it will be necessary to renumber the subsequent definitions.

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

Recommendation

(b) Except for continuing ~~medical~~ drug 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 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 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) 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~~.~~).

Discussion

*Since ongoing **non-drug medical treatment** is not subject to the Drug Formulary, an exception is only necessary for continuing **drug treatment**. It is not necessary to apply the exception to other ongoing medical treatment.*

A listing of dispensing individuals and entities is not necessary, and creates a loophole whereby any other individual or entity dispensing drugs prescribed by physicians for outpatient use may claim exemption from the requirements of the Formulary.

Section 9792.27.3. MTUS Drug Formulary Transition

Recommendation

(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) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary ~~should~~ shall be phased in by April 1, 2018, ~~to ensure that~~ for injured workers who are receiving ongoing drug treatment to ensure that they are not harmed by an abrupt change to the course of that drug

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 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. ~~The claims administrator shall not unilaterally terminate or deny previously approved drug treatment.~~

(c) If, on January 1, 2018, the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug, or a compounded drug, the physician shall, by February 1, 2018, submit to the claims administrator a revised treatment plan for the safe weaning, tapering, or transition to a Preferred drug, and existing procedures for submitting the treatment plan and for obtaining authorization for the treatment in accordance with utilization review regulations in accordance with MTUS regulations shall apply.

(d) If a physician fails to submit the report required under section 9792.27.3(c), such failure may constitute a showing of good cause for a claims administrator's petition requesting a change of physician pursuant to Section 4603; and may serve as grounds for termination of the physician from the medical provider network or health care organization; and reports from the physician shall not be admissible and the physician's treatment bills shall not be reimbursable until the report required by 9792.27.3 is received by the claims administrator.

Discussion

A delay in the implementation date until January 1, 2018, is necessary in order to allow for stakeholder education and system changes to ensure a successful rollout of the Drug Formulary. In the absence of a development window until January 1, 2018, technical systems will not be able to accommodate the new Drug Formulary. Likewise, a delay would allow time for educational outreach to medical providers, PBMs, pharmacists, and claims administrators.

A defined time limit applicable to the transition period is necessary to provide the injured worker with safe and effective medical care and to avoid abuse. Labor Code section 5307.27(c) ***requires*** *a phased implementation that will "ensure injured workers safely transition to medications pursuant to the formulary." If a date certain is not included, the prescribing physician may fail to transition the worker to the MTUS Drug Formulary, leaving the injured worker deprived of the protections and benefits of the MTUS Drug Formulary, contrary to Labor Code section 5327.27(c),which* ***requires*** *workers to be transitioned to medications pursuant to the drug formulary.*

According to section 1 of Assembly Bill 1124, it was a goal of the Legislature to provide "appropriate medications expeditiously while minimizing administrative burden and associated administrative costs." A three-month transition period will further that goal by ensuring that injured workers will be provided with the most appropriate drug treatment, including safe weaning, tapering, or transition to Preferred Drugs, by the end of that time frame. Furthermore, the additional administrative burden and associated administrative costs of a two-tracked implementation will be limited to that three-month period. Finally, in light of the delayed implementation recommended in subsection (a), the overall transition period is nine months.

The newly proposed language that the claims administrator "shall not unilaterally terminate or deny previously approved drug treatment" is problematic because it conflicts with the right and obligation to perform utilization review. Furthermore, it is in direct conflict with Labor Code section 4610.3(a) which states:

> *"Regardless of whether an employer has established a medical provider network pursuant to Section 4616 or entered into a contract with a health care organization pursuant to Section 4600.5, an employer that authorizes medical treatment shall not rescind or modify that authorization after the medical treatment has been provided based*

on that authorization for any reason, including, but not limited to, the employer's subsequent determination that the physician who treated the employee was not eligible to treat that injured employee. If the authorized medical treatment consists of a series of treatments or services, ***the employer may rescind or modify the authorization only for the treatments or services that have not already been provided****." (emphasis added)*

Labor Code section 4610.3(a) clearly permits rescission or modification of previous authorization for drug treatment that has not already been provided, whereas the proposed language in section 9792.27.3(b) does not.

The Institute recommends in a separate subdivision (c), additional language to clarify the specific expectations, requirements, and timeframes for physicians to address and submit revised treatment plans to safely wean, taper, or transition their industrially injured patients who are receiving Non-Preferred, unlisted, or compounded drugs on January 1, 2018. A revised treatment plan is needed for any injured worker on a non-conforming drug regimen, including those injured between the July 1, 2017, adopted date and the January 1, 2018, implementation date.

To ensure compliance with the statutory requirements, in subdivision (d) consequences are added for failing to submit the revised treatment plan that is required under subdivision (c).

Section 9792.27.4. MTUS Drug Formulary – Pharmacy Networks; PBM Contracts.

Recommendation

Where an employer or insurer contracts pursuant to Labor Code section 4600.2 with a pharmacy, 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 and MTUS Treatment Guidelines for the condition or injury being treated and may not be restricted pursuant to the contract. Pursuant to Labor Code section 4600.2(a), such contracts may limit drug attributes such as dosage, drug delivery system, frequency, or cost, but not the drug ingredient classification of medications prescribed or dispensed pursuant to the Drug Formulary.

Discussion

The Institute suggests adding "pharmacy" because Labor Code 4600.2 also specifically permits contracts with a pharmacy in addition to a pharmacy benefit manager or pharmacy network.

We also suggest reversing the order of "MTUS Treatment Guidelines" and "MTUS Drug Formulary" to keep the primary focus on the formulary.

This section needs to be clarified in order to avoid frictional costs of utilization review, independent medical review, or litigation. For example, where the Drug Formulary or Medical Treatment Guidelines are silent on a particular dosage or duration, it should be clear that these issues can be addressed by a PBM through contract, or through utilization review, without violating the regulation.

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

Recommendation

(c) Authorization through prospective review is required prior to dispensing the following drugs for an off-label use:

(1) Non-Preferred drug, or
(2) Unlisted drug, or
(3) Preferred 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 1) the drug is found upon retrospective review to be not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

Discussion
Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if "it is determined upon retrospective review that the drug treatment was not medically necessary," there will be a perverse incentive for the provider to not submit a request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug, in which case there is no documentation upon which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

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

Recommendation
(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 a variance from the guidelines is required to cure or relieve the injured worker from the effects of the injury. ~~Treatment outside~~ Any such variance from 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~~.~~). If authorization through prospective review for a drug not listed as Preferred is not obtained prior to dispensing the drug, payment for the drug may be denied if 1) it is determined upon retrospective review that the drug treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

Discussion
Replacing "Treatment outside" with "Any such variance" is suggested to better clarify the intent of the rule. Referencing the term "variance" used in the preceding sentence clarifies that the variance from the guidelines described in the preceding sentence is governed by what follows.

We suggest adding "for a drug not listed as Preferred" for clarity. If it is not added, the sentence can be misunderstood if it is quoted out of context.

Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if "it is determined upon retrospective review that the drug treatment was not medically necessary," there will be a perverse incentive for the provider to not submit a

request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug; in which case there is no documentation on which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

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

Recommendation

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 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~~ allowance 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; or if a request for authorization with sufficient information upon which to base a prospective or retrospective review decision is not timely received, payment may be denied pursuant to Labor Code section 4610.

Discussion

"Price" generally denotes the billed amount, whereas "allowance" refers to the amount permitted under a fee schedule.

Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if it is determined through a prospective or retrospective review that a drug treatment was not medically necessary, there will be a perverse incentive for the provider to not submit a request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug; in which case there is no documentation on which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if prospective or retrospective review determines that neither the generic nor the brand name drug treatment was medically necessary, but also if sufficient information on which to base a prospective or retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

Section 9792.27.8. Physician-Dispensed Drugs.

Recommendation

(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 ("Special Fill"), and

section 9792.27.12 ("Perioperative Fill"). If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if 1) the drug is found upon retrospective review to be not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

(b) A physician may dispense up to a seven-day supply of a drug that is listed as "Preferred" 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. 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 1) the drug was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a review decision is not timely received pursuant to Labor Code section 4610.

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

(d) Nothing in this Article shall permit physician dispensing where otherwise prohibited in an agreement with a pharmacy, group of pharmacies, or pharmacy benefit network, pursuant to subdivision (a) of Labor Code 4600.2.

Discussion

Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if "it is determined upon retrospective review that the drug treatment was not medically necessary," there will be a perverse incentive for the provider to not submit a request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug; in which case there is no documentation on which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

While Section 9792.27.8(c) reaffirms limitations imposed by MPN contracts, it does not reaffirm limitations imposed by contracts with a pharmacy, pharmacy network, or pharmacy benefit network pursuant to Labor Code section 4600.2(a). As with the clarifying language in (c), the clarification in (d) is necessary to avoid disputes, liens, and other frictional costs that will otherwise arise.

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

Recommendation

(a) The MTUS 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 Treatment Guidelines, except that 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 1) it is determined upon retrospective review that the drug treatment was not medically

necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

(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. 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 1) it is determined upon retrospective review that the drug treatment is not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

(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 and 9792.27.12. If the requirements set forth in section 9792.27.11 or section 9792.27.12 are not met, then the drug is considered "Non-Preferred" 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 1) it is determined upon retrospective review that the drug treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610. 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).

(g) Nothing in sections 9792.27.1 through 9792.27.21 shall preclude a claims administrator from disputing or objecting to bills on the basis of any provisions available under the law.

Discussion

Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if "it is determined upon retrospective review that the drug treatment was not medically necessary," there will be a perverse incentive for the provider to not submit a request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug; in which case there is no documentation on which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

To avoid unnecessary disputes that will otherwise arise, it is necessary to clarify that existing statutes and regulations, such as Labor Code sections 139.3, 3208.3, and 3600; and CCR Section 9792.27.6; continue to permit claims administrators to deny, dispute, or object to payment of medical treatment, including drug treatment.

Section 9792.27.11. MTUS Drug List – Special Fill.

Recommendation

(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," will be allowed without prospective review in very limited circumstances, and for a short period of time.

(b) The drug identified as a Special 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 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 Special Fill limit as set forth in the MTUS Drug List; and

(3) The drug is prescribed in accordance with the MTUS Guidelines; and

(4) 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 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 1) it is determined upon retrospective review that the drug treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

(e) 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) 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.

Discussion

Correction of a minor typographical error is suggested in (a).

A more precise description is recommended in (b)(2).

Re-ordering the list of conditions in (b) is necessary in order to ensure that the drug is prescribed in accordance with the MTUS guidelines under all circumstances. In its current placement, the

language may be interpreted as requiring the drug to be prescribed in accordance with the MTUS Guidelines only under (4) or (4)(B). The recommended change allows no such ambiguity.

Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if "it is determined upon retrospective review that the drug treatment was not medically necessary," there will be a perverse incentive for the provider to not submit a request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug; in which case there is no documentation on which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

The Institute suggests adding "pharmacy" because Labor Code 4600.2 also specifically permits contracts with a pharmacy in addition to a pharmacy benefit manager or pharmacy network.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

Recommendation

(a) The MTUS Drug List identifies drugs that are subject to the Perioperative Fill policy. Under this policy, the 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 for outpatient use during the perioperative period; and

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

(3) The drug is prescribed in accordance with the MTUS Treatment Guidelines; and

(4) 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 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 1) it is determined upon retrospective review that the drug treatment was not medically necessary; or if 2) a request for authorization with sufficient information upon which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610.

(d) 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.

Discussion
*As currently proposed, the drug must be **prescribed** during the perioperative period. If, as the Institute believes, the intent is for the drug to be prescribed **for use** during the perioperative period, the recommended modification is necessary for clarification.*

A more precise description is suggested for (a)(2).

Re-ordering the list of conditions in (b) is necessary in order to ensure that the drug is prescribed in accordance with the MTUS guidelines under all circumstances. In its current placement some may believe that the requirement for the drug to be prescribed in accordance with the MTUS Guidelines relates only to (4) or to (4)(B). If the placement is above (4), there will be no such ambiguity.

Receipt of a request for authorization triggers the utilization review process. If payment for the drug may be denied only if "it is determined upon retrospective review that the drug treatment was not medically necessary," there will be a perverse incentive for the provider to not submit a request or supporting documentation for drug treatment. Very often a request for authorization is not received, and all that is submitted by the provider is a bill for the drug; in which case there is no documentation on which to base a decision on the medical necessity of the billed drug. If no diagnosis/ ICD-10 is provided, the medical necessity of a drug cannot be determined. It is therefore necessary not only to permit a payment denial if retrospective review determines the drug treatment was not medically necessary, but also if sufficient information on which to base a retrospective review decision is not timely received pursuant to Labor Code section 4610(i)(2).

The Institute suggests adding "pharmacy" because Labor Code 4600.2 also specifically permits contracts with a pharmacy in addition to a pharmacy benefit manager or pharmacy network.

Section 9792.27.14. MTUS Drug List.

Recommendation
The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. (See 8 CCR §9792.20 - §9792.27.21) "Reference in Guidelines" indicates guideline topic(s) which discuss the drug. In each guideline there may be one or more conditions for which the drug is Recommended (✓), Not Recommended (✕), and/or for which No Recommendation (⃠) applies. Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use.

Discussion
The additions to the explanatory language that precedes the list of drugs in this section are recommended for clarity.

Section 9792.27.15. National Drug Codes - MTUS Drug List.

Recommendation
(f) Nothing in sections 9792.27.1 through 9792.27.21 shall preclude a claims administrator from disputing the reasonableness of the amount billed for any drug.

Discussion
The addition of subsection (f) is necessary in order to permit the claims administrator to contest the reasonableness of the amount billed for any drug.

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

Recommendation

(b) Persons applying to be appointed to the P&T Committee shall not have dispensed drugs to injured employees for outpatient use, nor have dispensed drugs to injured employees for outpatient use from their practice locations during twelve months prior to the appointment. A P&T Committee member who undertakes to dispense drugs during the term of the appointment shall not be eligible to continue to serve on the committee.

(~~b~~c) 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~~d) Members of the P&T Committee shall not have a substantial financial conflict of interest in relation to a pharmaceutical entity. For purposes of this section, the following definitions apply:

(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,~~ "~~s~~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:

Discussion

Persons who dispense drugs or whose practice locations dispense drugs also have a conflict of financial interest.

The modifications to (c) are recommended for clarity.

Re-sequencing of (b) through (d) is necessary if the recommendation for prohibiting a conflict of interest for drug dispensing is accepted.

Thank you for the opportunity to comment, and please contact us if additional information would be helpful.

Sincerely,

Brenda Ramirez Claims & Medical Director	Denise Niber Claims & Medical Director	Ellen Sims Langille General Counsel

BR:DN:ESL/pm

cc: Christine Baker, DIR Director
George Parisotto, DWC Acting Administrative Director
Raymond Meister M.D., Executive Medical Director
Jackie Schauer, DIR Counsel
CWCI Claims Committee
CWCI Medical Care Committee
CWCI Legal Committee
CWCI Regular Members
CWCI Associate Members