California Workers' Compensation Institute
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August 2, 2017

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: 1st 15-Day comment on proposed modified Drug Formulary regulations

Dear Ms. Gray:

These comments on modifications to the proposed Drug Formulary regulations are 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 $65B 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 Farms, 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. Clarify Intent of LC §4610(i)(1): The statutory language of Labor Code section 4610(i) ("requests for treatment covered by the formulary") is ambiguous; as such, disputes over what drugs are (and are not) subject to the abbreviated (5 working day) timeframe for review determination will undoubtedly ensue. Some may contend that "covered by the formulary" means only "Exempt" and "Non-Exempt" drugs listed on the MTUS Drug List. Others, however, may take the position that "covered by the formulary" means "covered by the MTUS Drug Formulary" as defined in section 9792.27.1(m) ("MTUS Drug Formulary means the MTUS Drug List set forth in section 9792.27.15 and the formulary rules set forth in sections 9792.27.1 through 9792.27.23.").

   The latter interpretation would mean that every single drug referenced -- not only in the Drug List but also in the regulations (*i.e.*, compounded, combination, unlisted, etc.) -- would be subject to an abbreviated prospective review. If, however, the intent is to fast-track review of "Exempt" and "Non-Exempt" drugs expressly listed on the MTUS Drug List, the Institute strongly suggests amending those respective definitions to provide clarity and avoid unnecessary litigation over application of the formulary rules.

2. Address Consequences for Physician's Failure to Provide Requisite 9792.27.3 Report: The Institute applauds the additional language in section 9727.27.3 requiring that the physician submit an RFA along with either a treatment plan to safely transition patients to the MTUS Drug Formulary or, alternatively, a report justifying the continued use of Non-Exempt drugs. However, the Institute is concerned that in the absence of consequences for the physician's failure to comply, this regulatory requirement becomes merely optional. Adding consequences for the physician's failure to provide the necessary information will promote compliance with the MTUS Drug Formulary, fulfill the legislative intent of AB 1124, and promote appropriate, evidence-based, drug treatment for injured workers.

3. Prioritize Drug List Specificity for Formulary Drugs: The Institute is encouraged to see placeholders for "Dosage Form," "Strength," and "Unique Product Identifier(s)" added to the Drug List. The Institute highly recommends that the Drug List be made more specific -- with the information input for these placeholders -- for all "Exempt" drugs, as well as those eligible for Special Fill and Perioperative Fill. Providing clarity to the Drug List is necessary to avert unnecessary formulary drug rule disputes and friction costs, as well as to fulfill the intent of AB 1124 that the Drug Formulary be cost-effective while being evidence-based. Without more specificity, the Drug List could well become a "recipe book" for profiteering, as well as a source of unnecessary litigation and increased friction costs.

As previously expressed in the Institute's 5/1/17 written testimony, there is tremendous variation in the amounts paid for drugs that are pharmaceutically and therapeutically equivalent, and also for drugs that differ by dosage. The Institute recommends providing complete information (first and foremost) for all "Exempt" drugs, as well as those eligible for Special Fill and Perioperative Fill. Doing so would enable cost savings while not limiting injured employees' access to all reasonable and necessary drugs.

CWCI has issued a new Spotlight Report[1] in which the authors analyzed the potential impact of the proposed MTUS Drug Formulary. Using CWCI's Industry Research Information System (IRIS)[2] database, the authors found that more than 22 percent of workers' compensation scripts in 2016 were for anti-inflammatory analgesics -- more than 98 percent of which are designated as "Exempt" from prospective review in the proposed Drug Formulary. Thus, if left unchecked, anti-inflammatory analgesics could become a target of pricing abuse in our workers' compensation system. Completion of the Drug List placeholder categories to limit which *specific* anti-inflammatories (according to dosage form, strength, and/or unique product identifier) would be "Exempt" is critical to ensure that medically appropriate treatment is, at the same time, cost-effective.

4. Define "Surgery": The Institute urges the DWC to define "surgery" for purposes of the Perioperative Fill policy. Doing so would avoid the unnecessary initiation of opioids in the case of injured workers undergoing simple procedures such as trigger-point injections, simple laceration repairs, and the like.

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

Recommendation:

(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 and does not otherwise require prospective review under the MTUS Drug Formulary. Exempt drugs are deemed "covered by the formulary" for purposes of prospective review in accordance with Labor Code section 4610(i)(1). The Exempt status of a drug is designated in the column with the heading labeled "Exempt / Non-Exempt."~~.~~

(o) "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, and is deemed "covered by the formulary" for purposes of prospective review in accordance with Labor Code section 4610(i)(1). The Non-Exempt Drug status of a drug is designated in the column labeled "Exempt / Non-Exempt."~~.~~

[1] Swedlow, A., Hayes, S., Bullis, R. "California WC Formulary - Part II: A Review of the July 2017 Proposed Formulary Drug List of Exempt and Non-Exempt Drugs." CWCI Spotlight Report. August 2017.

[2] IRIS is CWCI's proprietary database containing data on employee and employer characteristics, medical service data, benefits, and administrative costs on approximately 5.3 million California workers' compensation claims.

(y) "Surgery" means any surgical procedure that has "010" (ten Global Days) or "090" (ninety Global Days) listed for its reimbursable CPT code as found in the Medicare National Physician Fee Schedule Relative Value File incorporated into the Official Medical Fee Schedule.

(~~y~~z) 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.

(~~z~~aa) "Unlisted drug" means a drug that does not appear on the MTUS Drug List and which is one of the following: an FDA-approved 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 initial recommended change in (h) is suggested for purposes of clarity.

The change regarding prospective review in section (h) is necessary to confirm that the rules for brand, physician-dispensed, compounded, and unlisted drugs are applicable to Exempt drugs.

A minor typographical correction is recommended at the end of (h).

As stated in our Priority Considerations above, in considering subdivisions (h) and (o), the statutory language contained in Labor Code section 4610(i)(1),"requests for treatment covered by the formulary" is ambiguous; and disputes over what drugs are (and are not) subject to the abbreviated (5 working day) timeframe for review determination will undoubtedly ensue. If the intent is to fast-track "Exempt" and "Non-Exempt" drugs expressly listed on the Drug List, the Institute strongly suggests amending the respective definitions of both "Exempt drug" (h) and "Non-Exempt drug" (o) in order to provide much-needed clarity. If there is a different intent, the Institute nevertheless suggests that "covered by the formulary" be defined in the regulations.

A minor typographical correction is recommended at the end of (o).

The Institute recommends that surgery be defined so that zero day ("000") post-operative period procedures are specifically excluded from the Perioperative Fill policy. Defining Surgery utilizing specific Global Days would avoid the use of opioids or other unnecessary drugs in the case of injured workers undergoing simple procedures such as trigger-point injections, epidural steroid injections, simple laceration repairs, or diagnostic procedures such as endoscopies (all "000" procedures).

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

Section 9792.27.3. MTUS Drug Formulary Transition.

Recommendation:
(b)(2)(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~~.~~).

Recommendation:
(b)(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. If a physician fails to submit the documents required under this subdivision, 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; further, reports from the physician shall not be admissible and the physician's treatment bills shall not be reimbursable until the documents required under this subdivision are received by the claims administrator.

Discussion
9792.27.3(b)(2)(B): A minor typographical correction is recommended.

9792.27.3(b)(3): Suggestions made are to promote compliance with the regulation, as well as the legislative mandate of AB 1124. The Institute recognizes and appreciates the additional requirements for a treatment plan with a deadline of April 1, 2018. However, without consequences for failure to submit the required documentation and revised treatment plan, the "requirements" of this subdivision might be considered to be optional, and injured workers could be subjected to continuing deleterious drug treatment outside of the Formulary and evidence-based medicine.

If the claims administrator is not provided with a treatment plan, there is no recourse through Utilization Review (either prospectively or retrospectively), because the drug protocol cannot be discontinued without a weaning or transition plan. It is necessary for the claims administrator to have the option of a change of physician in order to obtain compliance with this subdivision -- and to obtain either a workable treatment plan to transition the injured worker, or justification via documentation for continued Non-Exempt drug treatment.

In order to avoid incentivizing non-compliance with requirements for reporting and utilization review, consequences of inadmissibility and non-payment are necessary.

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

Recommendation:
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.

Discussion
Minor typographical corrections are required for clarity.

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

Recommendation:
(b) A drug that is identified as "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) Physician-dispensed drugs are subject to section 9792.27.8;
(3) Compounded drugs are subject to section 9792.27.9 even if one or more of the ingredients is listed as "Exempt" on the Drug List.

Discussion
In order to maintain consistency in the listing of brand name drugs and physician-dispensed drugs (both of which are addressed in specific subdivisions), compounded drugs should also be separately listed.

Section 9792.27.12 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-Exempt," will be allowed without prospective review as specified in subdivision (b).

(b)(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines.; and
(5) The Special Fill supply does not exceed the maximum recommended daily dose, as applicable, in the FDA-approved label and/or prescribing information.

Discussion
A minor typographic correction in (a) is required for clarity.

In subdivision (b), the provision for Special Fill drugs does not delineate how many units are included in the supply. In order to avoid unnecessary conflict over the Special Fill, the Institute recommends that (b)(5) be added, specifying that the "supply" is subject to both the limitation in the number of days and any applicable maximum daily dose.

Section 9792.27.13 MTUS Drug List – Perioperative Fill.

(a)(4) The drug is prescribed in accordance with the MTUS Treatment Guidelines~~.~~; and
(5) The Perioperative Fill supply does not exceed the maximum recommended daily dose, as applicable, in the FDA-approved label and/or prescribing information.

Discussion
In subdivision (a), the provision for Perioperative Fill drugs does not delineate how many units are included in the supply. In order to avoid unnecessary conflict over the Perioperative Fill, the Institute recommends that (a)(5) be added, specifying that the "supply" is subject to both the limitation in the number of days and any applicable maximum daily dose.

9792.27.15 DRUG LIST Document – Introduction

Recommendation:
***Perioperative Fill – Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) Rx issued during the perioperative period (~~2~~24 days before through 4 days after surgery), and 2) Supply not to exceed #days indicated (subject to any applicable maximum recommended daily dose), and 3) is a generic or single source brand, or brand where physician substantiates medical necessity, and 4) ~~if~~ is in accord with MTUS. (See 8 CCR § 9792.27.13.)

Discussion
The introduction to the Drug List needs to be updated to reflect the modified proposed regulations concerning the Perioperative Fill (9792.27.13) # days, and as noted in the actual MTUS Drug List.

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

Recommendation:
(e) The listing may include, but is not limited to, 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) Exempt or Non-Exempt status, as applicable;
(7) Any applicable Special Fill or Perioperative Fill policies;
(8) Reference Brand Name, as applicable

Discussion
The inclusion of "Reference Brand Name" in this listing maintains consistency in the Drug List as it is presently configured.

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

Sincerely,

Denise Niber
Claims & Medical Director

DN/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
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