Gray, Maureen@DIR

From: Alex Rossi <arossi@ceo.lacounty.gov>
Sent: Monday, April 03, 2017 1:05 PM
To: DIR DWCForums
Subject: Medical Treatment Utilization Schedule – Formulary regulations

Follow Up Flag: Follow up
Flag Status: Flagged

Ms. Maureen Gray, Regulations Coordinator
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Division of Workers' Compensation
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The purpose of AB 1124 was to give the Administrative Director clear authority to establish a formulary that will control rising prescription drug costs in the California workers' compensation system, limit the over-prescribing of highly addictive opioids, and ensure injured workers get the necessary treatment needed to get them back to work. The County of Los Angeles Workers' Compensation Program (Program) applauds the Department of Industrial Relations' efforts to adopt an evidence based drug formulary that augments and expedites the provision of quality medical care, promotes improved outcomes for injured workers, and minimizes operational friction and cost. The formulary regulations (CCR 9279.27.1 through CCR 9279.27.18) lay the foundation to achieve these goals.

As indicated in the Initial Statement of Reason, Section 9792.27.8 is needed to encourage the provision of cost-effective high quality care and supported by the RAND study that outlined the higher cost of physician dispensed medication. That study noted physician dispensing of FDA approved drugs with unique dosages, which have unit costs that are significantly higher than commonly prescribed strengths of the same drug ingredient, are undermining the OMFS and may be driven by financial reasons rather than medical necessity.

Cyclobenzaprine provides an example of a physician dispensing pattern that leads to higher system costs. A comparison of the cost of the same product amount prescribed at deferent dosages follows:

Below information is supplied on 9/16/2016 for date of service 9/1/2016.				
NDC	**Label Name**	**# Units**	**Unit Price**	**Product Cost**
00591333001	Cyclobenzaprine 7.5 mg Tablet	120	3.8305	$459.66
			Dispensing	$7.25

			Total	$466.91
NDC	**Label Name**	**# Units**	**Unit Price**	**Product Cost**
00591565801	Cyclobenzaprine 10 mg Tablet	90	.0229	$2.06
			Dispensing	$7.25
			Total	$9.31

The above reflects an approximate 4,900% mark-up when cyclobenzaprine is prescribed and dispensed in the 7.5 mg dose as opposed to a 10 mg dose.

As drafted, proposed Section 9792.27.8 does not require the prescribing and dispensing physician to document why a more costly dosage is provided. Under proposed Section 9792.27.8, prospective review can be used to determine the medical necessity of a drug, but cannot be used to influence the physician's prescribing pattern. Therefore, CEO-RMB staff recommends including the following Section 9792.27.8(b) in the final regulations.

Section 9792.27.8. Physician-Dispensed Drugs.

(a) Drugs dispensed by a physician must be authorized through prospective review prior to being dispensed, except as provided in subdivision (b), section 9792.27.11 ("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 the drug is found upon retrospective review to be not medically necessary.

(b) If a physician prescribes and dispenses a drug at a specific dosage strength when a lower unit cost of the same drug at an alternate dosage strength exists, the physician must document the medical necessity for prescribing the more costly dosage strength. The documentation must include patient-specific factors that support the physician's determination that the specific dosage strength is medically necessary. The physician must obtain authorization through prospective review prior to the time the drug at the more costly dosage strength is dispensed. If required authorization through prospective review is not obtained prior to dispensing the more costly dosage strength, retrospective review may be conducted to determine if it was medically necessary to use the more costly dosage strength rather than the less costly dosage strength. If it is determined that the less costly dosage strength is medically necessary and an effective replacement for the more costly dosage strength, payment for the drug may be made at the fee schedule price for the lowest priced alternate dosage strength of the same drug.

(bc) 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 the drug was not medically necessary.

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

Sincerely,

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RE: Public Comments on the proposed Workers' Compensation – Medical Treatment Utilization Schedule – Formulary

Ms. Gray,

These comments on the modification of the proposed regulatory language for the Workers' Compensation – Medical Treatment Utilization Schedule – Formulary, Title 8, California Code of Regulations Section 9792.27.1 – 9792.27.21, are respectfully submitted on behalf of PRIUM. PRIUM is a utilization review organization that has been performing utilization review in California since 2009 (URO Plan #104).

We are in support of California's decision to adopt a drug formulary to address the overutilization of prescription drugs in workers' compensation claims in the state. The rules as proposed represent a great effort in establishing a drug formulary; however it may be more challenging to accomplish the legislature's stated goal of "providing appropriate medications expeditiously while minimizing administrative burden and associated administrative costs" may be more challenging. (Cited language from AB 1124, § 1(e)).

We have organized our comments into two categories: general and specific. Under the "general" category, there are two areas that we see as of critical importance: Prospective Review and the Transitioning of Existing Claims. The "specific" category contains several comments with specific language changes proposed. These comments are enclosed.

Again, PRIUM appreciates the time and effort that the Division and others have put into this rulemaking process.

Sincerely,

Ben Roberts
Executive Vice President and General Counsel,
PRIUM

GENERAL COMMENTS

GENERAL COMMENT #1: PROSPECTIVE REVIEW

Prospective Review of non-preferred drugs is a key component of the formulary, and it is included in the proposed rules. However, its impact is minimized by the plain language of the rules, which requires retrospective review before a payer may deny a medication.

According the report published by Rand, Implementing a Drug Formulary for California's Workers' Compensation Program, Wynn, et.al. 2016, "If the formulary is to meet its objective to provide appropriate medications expeditiously while minimizing administrative costs, the [prospective review] requirement for drugs **should be mandatory** (and initiated with a physician's RFA)" *pg. 92 (Emphasis added.)*

The Rand Report also contemplates different scenarios in which drugs should require mandatory prospective review -- the most important of which, is not contemplated in the proposed rules. The scenario presented in the Rand Report is as follows:

> *"A point-of-sale screen identifies that a prescription has not had the prerequisite PR and approval. Current UR rules do not specifically address screening occurring during a pharmacy transaction (point-of-sale edits). The rule should clarify whether the screening should trigger formal UR with or without a physician's RFA and whether a rejection of the prescription based on a condition-specific PR requirement (rather than an across the-board PR rule) constitutes a medical necessity denial." pg. 92*

As it stands, the rules do not address this scenario. The proposed rules do not permit payers to delay an unauthorized fill of a non-preferred drug while they seek prospective utilization review, nor do the proposed rules protect payers who do so from being penalized for an "improper delay" of treatment. The proposed rules do not permit payers to deny the medication for failure to obtain preauthorization, and, under existing law, such a denial would be considered a determination of medical necessity that must be performed through the utilization review process. As a result, their only option for dealing with unauthorized fills of non-preferred drugs under the proposed rules is to approve the unauthorized fill and perform a retrospective review. (It should be noted that this is already how payers deal with all unauthorized medications under the current rules.)

Essentially, as written, the preauthorization requirement is unenforceable. The offered remedy of retrospective UR is nothing new; payers can already (under the current rules) submit all medications to retrospective UR and obtain a denial that is effective for 12 months (absent a documented change in the circumstances material to the UR determination). Giving providers the option to request authorization – and giving payers the right to obtain retrospective UR for unauthorized drugs – is not a formulary.

This process offered in the proposed rules does not appear to meet "the goal of providing appropriate medications expeditiously while minimizing administrative burden and associated administrative costs".

As such, the rules should be amended to provide guidance to stakeholders attempting to implement the formulary.

GENERAL COMMENT #2: TRANSITION PERIOD

It has been noted by the DWC, the Rand Report, CWCI, stakeholders, and the legislature that a transition period for workers injured prior to the implementation of the formulary must be included in the rules. Specifically, AB 1124 amended Section 5307.27 of the Labor Code to include the following:

"(c) The drug formulary shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary."

Section 97929.27.3 of the proposed rules provides the language that supports this requirement by stating: "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."

The proposed rules do not go into detail regarding the length of time for changes to be "phased in" or even the process by which they should be "phased in". The rules simply state that there shouldn't be "an abrupt change" that causes harm and that the claims administrator shall not "unilaterally" terminate "previously approved" drug treatment.

It could be that the DWC relied on statements from the Rand Report such as "[a]n initial transition may be less important for California's WC program because the MTUS has been in effect since 2004, and UR typically occurs for all prescriptions on a prospective basis. Unlike the other states, implementation of the WC formulary should reduce the number of prescriptions that require PR." Rand Report page 68

Taken on its face, the statement by Rand indicates that a transition period is less important because "UR typically occurs for all prescriptions on a prospective basis." As a URO in the state of California this has not been PRIUM's experience. Physician generated RFA's requesting authorizations for medications are rare. According to the CWCI:

> *Of the 5.6 million medical services in the study sample, about 860,000 (or 15.3 percent) were requested in RFAs and underwent UR. That means that almost 85 percent of all 2014 medical services were paid without being requested in RFAs and without UR, either through prior authorization programs, retrospective authorization, or because no request for authorization was received and the service fell within the claims administrator's parameters for approval. Within the study sample, the percentage of treatment services in which an RFA was submitted varied by claims administrator, ranging between about 9 percent and 19 percent of services.*
>
> *David, Jones, Ramirez, and Swedlow. "Medical Review and dispute Resolution in the California Workers' Compensation System." California Workers' Compensation Institute Research Update, December 2015, pg. 10*

Based on CWCI's reporting and our own organization's experience, it is unlikely that the majority of injured workers on non-preferred drugs have already obtained an approval for those medications through the utilization review process. This means that beginning July 1, 2017, more payers are going to be subjecting medications to utilization review, thereby increasing "the administrative burden and the associated administrative costs," which is antithetical to the legislature's goal.

The transition period language should be amended to clarify or include definitions for ambiguous terms (ex.: “phased-in,” “unilaterally,” “previously approved”) and to provide guidance to stakeholders on the process and timing for transitioning existing claims, as well as the penalties associated for failing to adhere to the process.

SPECIFIC COMMENTS

Comment #1

Proposed Language:

Section 9792.27.1(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 within the perioperative period and meets specified criteria.

Issue:

The proposed definition of Perioperative Fill fails to define or identify the location of the definition for the specified criteria in the rules. A clarifying citation should be added to make the definition more clear.

Alternatively, the criteria on which the definition is based could be brought forward and included in the definition section.

Recommended Language Change:

Section 9792.27.1(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 within the perioperative period and meets specified criteria~~.~~ *, as defined in section 9792.27.12(b).*

Comment #2

Proposed language:

Section 9792.27.1(y) "Special Fill" means the policy set forth in section 9792.27.11 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed or dispensed at the single initial treatment visit following a workplace injury, where the visit occurs within 7 days of the date of injury.

Issue:

The proposed definition of Special Fill does not use the full definition as outlined in section 9792.27.11(b). Section 9792.27.11(b) not only includes a reference to the treatment visit occurring within 7 days of the date of injury, but it also includes language regarding the supply of the drug, qualifications for the type of drug (brand v. generic), and the qualification that the drug be prescribed in accordance with the MTUS Treatment Guidelines.

The incomplete definition should be removed from the section and replaced with a citation to section 9792.27.11(b) which contains the completed definition.

Alternatively, the criteria on which the definition is based could be brought forward and included in the definition section.

Recommended Language Change:

Section 9792.27.1(y) "Special Fill" means the policy set forth in section 9792.27.11 allowing dispensing of identified Non-Preferred drugs without prospective review where the drug is prescribed or dispensed ~~at the single initial treatment visit following a workplace injury, where the visit occurs within 7 days of the date of injury.~~ *in accordance with the criteria set forth in section 9792.27.11(b).*

Comment #3

Proposed Language:

Section 9792.27.1(e) "Compounded drug" means a drug that is created by combining one or more active pharmaceutical ingredients, and one or more inactive ingredients, to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace."

Issue:

The definition is overly-specific; this has the effect of creating unintended loopholes. The inclusion of the two qualifying criteria ("one or more inactive ingredients" and "to meet specific patient medical needs that cannot be met with… other drugs…") provides a clear path for compounding pharmacies to create compound medications that do not meet the regulatory definition of "compounded drug," and so evade the preauthorization requirement. If a compounded drug is alleged to contain no inactive ingredients (for example, if the topical base is alleged to have its own therapeutic benefit), then it fails to meet the definition as proposed. Additionally, if the compounded drug meets only medical needs that can be met with a different drug "available in the marketplace," then it fails to meet the definition of a "compounded drug," and so does not require preauthorization.

Both of these qualifying criteria in the regulatory definition create opportunities to evade the preauthorization requirement, for drugs that the pharmacy industry would consider to be compounded drugs —simply because they do not meet the overly-specific regulatory definition of "compounded drug."

Additionally, this dangerous level of specificity is unnecessary since the proposed rules already recognize a protected class of FDA-approved "combination drugs" as a separate defined, category.

Recommended Language Change:

Section 9792.27.1(e) "Compounded drug" means a drug that is created by combining one or more active pharmaceutical ingredients~~, and one or more inactive ingredients, to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace~~; however, this definition shall not include "Combination drugs" as defined in 9792.27.1(d).

Comment #4

Proposed Language:

Section 9792.27.3(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. 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. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.

Issue:

There are ambiguous terms used throughout this paragraph that will lead to confusion amongst stakeholders and will require litigation to resolve the ambiguity. Ambiguous terms should be either defined or eliminated to avoid confusion. Preferably, the ambiguous terms would be replaced with more instructive language that offers clear expectations to the stakeholders involved.

Recommended Language Change:

Section 9792.27.3(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. he~~ 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 request must be accompanied by a plan to wean, substitute, or discontinue the requested medication, as applicable, over a period of time in order to bring the treatment of the injured worker into compliance with the MTUS. If the provider feels that the treatment cannot be brought into compliance with the MTUS, the request shall be accompanied by an explanation and documentation demonstrating why a variance from the MTUS is appropriate for the particular patient. The claims administrator shall not withdraw authorization for an authorized fill of a medication. The claims administrator shall not deny reimbursement for any drug treatment without utilization review, except where these rules explicitly permit payers to deny reimbursement for failure to obtain authorization ~~unilaterally terminate or deny previously approved drug treatment.~~ If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, ~~the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.~~ the provider shall request authorization for future treatment, as required by this section, in order to ensure that the injured worker does not suffer an undue delay of treatment.

Comment #5

Proposed Language:

Section 9792.27.7 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 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.

Issue:

This paragraph contains mandatory steps that the physician must take in order to prescribe brand name drugs. The physician "must":

1. Include "Do Not Substitute" or "Dispense as Written" on the prescription,
2. 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.),
3. include the patient-specific factors that support the physician's determination that the brand name drug is medically necessary, and
4. obtain authorization through prospective review before the brand name drug is dispensed.

In the event that the physician fails to meet any of these mandated steps, the only available remedy is a retrospective review. The retrospective review "may be conducted to determine if it was medically necessary to use the brand name drug rather than the generic therapeutic equivalent" but the retrospective review will not determine if the above listed mandatory steps are met. The language should be amended to support the mandatory nature of paragraph.

Recommended Language Change:

Section 9792.27.7 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. <u>If any of these requirements are not met</u> ~~If required authorization through~~

~~prospective review is not obtained before dispensing the brand name drug, retrospective review may be conducted to determine if it was medically necessary to use the brand name drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand name drug is medically necessary~~, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand name drug. If it is determined through prospective or retrospective review that neither the generic drug nor the brand name drug is medically necessary, payment for the drug may be denied, pursuant to section 9792.27.10.

Comment #6

Proposed Language:

Section 9792.27.8(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 the drug is found upon retrospective review to be not medically necessary.

Issue:

A mandatory clause should not be immediately followed by a provision that entirely removes the mandatory nature of the previous clause. A requirement should either be clearly mandatory, or clearly not mandatory.

In this case, "Drugs dispensed by a physician must be authorized through prospective review prior to being dispensed" is the mandatory clause; it indicates a mandatory requirement. However, it is followed by language that suggests that the requirement is not mandatory – that it is conditional upon future action by the payer: "[i]f 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." This provision essentially removes the mandatory nature of the initial clause. The language should be amended to remove this provision.

Recommended Language Change:

Section 9792.27.8(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 the drug is found upon retrospective review to be not medically necessary.~~

Note: this language is properly reflected in Section 9792.27.9 Compounded Drugs which states:

> *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.*

Comment #7

Proposed Language:

Section 9792.27.10(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 it is determined upon retrospective review that the drug treatment is not medically necessary.

Issue:

A mandatory clause should not be immediately followed by a provision that entirely removes the mandatory nature of the previous clause. A requirement should either be clearly mandatory, or clearly not mandatory.

In this case, "authorization through prospective review must be obtained prior to the time the drug is dispensed" is the mandatory clause; it indicates a mandatory requirement. However, it is followed by language that suggests that the requirement is not mandatory – that it is conditional upon future action by the payer: "[i]f 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." This provision essentially removes the mandatory nature of the initial clause. The language should be amended to remove this provision.

Recommended Language Change:

Section 9792.27.10(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 it is determined upon retrospective review that the drug treatment is not medically necessary.~~

Note: this language is properly reflected in Section 9792.27.9 Compounded Drugs which states:

> *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.*

Comment #8

Proposed Language:

Section 9792.27.10(e) For an unlisted drug, authorization through prospective review must be obtained prior to the time the drug is dispensed. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary. A combination drug that is not on the MTUS Drug List is an unlisted drug even if the individual active ingredients are on the MTUS Drug List.

Issue:

A mandatory clause should not be immediately followed by a provision that entirely removes the mandatory nature of the previous clause. A requirement should either be clearly mandatory, or clearly not mandatory.

In this case, "authorization through prospective review must be obtained prior to the time the drug is dispensed" is the mandatory clause; it indicates a mandatory requirement. However, it is followed by language that suggests that the requirement is not mandatory – that it is conditional upon future action by the payer: "[i]f 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." This provision essentially removes the mandatory nature of the initial clause. The language should be amended to remove this provision.

Recommended Language Change:

Section 9792.27.10(e) For an unlisted drug, authorization through prospective review must be obtained prior to the time the drug is dispensed. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied. ~~if it is determined upon retrospective review that the drug treatment was not medically necessary.~~ A combination drug that is not on the MTUS Drug List is an unlisted drug even if the individual active ingredients are on the MTUS Drug List.

Note: this language is properly reflected in Section 9792.27.9 Compounded Drugs which states:

> *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.*

Comment #9

Proposed Language:

Section 9792.27.11(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.

Issue:

The use of the terms "in very limited circumstances, and for a short period of time" do not provide any additional meaning or clarity to the section and may create confusion as they are undefined terms. Clarification on the Special Fill policy and definition are provided in paragraph (b) of this section.

Recommended Language Change:

Section 9792.27.11(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.~~ *as long as it meets the requirements of this section paragraph (b).*

Comment #10

Proposed Language:

Section 9792.27.15(a) The Administrative Director may maintain and post on the DWC website a listing by NDC code of drug products that are embodied in the MTUS Drug List. If posted, the listing will be regularly updated to account for revisions to the MTUS Drug List and for changes in drug products that are marketed for outpatient use.

Issues:

The maintenance of the NDC code list will be essential to effectiveness of the Drug Formulary going forward. Stakeholders must be able to rely on the DWC to maintain this list. The language should be amended to reflect the mandatory nature of this requirement.

Recommended Language Change:

Section 9792.27.15(a) The Administrative Director ~~may~~ shall maintain and post on the DWC website a listing by NDC code of drug products that are embodied in the MTUS Drug List. If posted, the listing will be regularly updated to account for revisions to the MTUS Drug List and for changes in drug products that are marketed for outpatient use.

April 28, 2017

California Division of Workers' Compensation
Maureen Gray
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Delivered via Email

Re: Comments on MTUS Formulary Proposed Rule

Dear Ms. Gray:

We appreciate the openness of the Division throughout the rule development process and the thoughtful consideration of comments previously submitted. While we are generally supportive of the proposed MTUS Formulary rule, we offer the following comments to aid in the practical application of the rule in the marketplace. Our comments are informed by years of experience managing pharmacy benefits for claims administrators and the injured workers they serve, particularly our experience with implementing and administering state-established workers' compensation formularies.

9792.27.1: Definitions

We have only one recommendation related to the definitions outlined in the rule. The proposed definition for compounded medications could leave open a loophole for compounds that involve only active ingredients or for only altered ingredients. We recommend the following definition for compounded medications: ***A pharmaceutical product that results from the combining, mixing, or altering of one or more active or inactive ingredients, excluding flavorings, to create a customized drug (not typically produced by a manufacturer) for an individual patient in response to a licensed practitioner's prescription.***

9792.27.2: MTUS Drug Formulary, Effective Date

It is vitally important that a drug formulary is based on strong foundational treatment guidelines. We are strongly supportive of the language in the rule requiring the prescribing of preferred and other medications in accordance with the treatment guidelines. We also support responsible variations based on the unique medical needs of a particular injured worker, enabling both the treating physician and the employer/claims administrator to facilitate the safest and most effective care.

AB1124 calls for inclusion of a drug formulary in the MTUS guidelines starting on or before July 1, 2017. The short time frame between formal adoption and the proposed effective date does not allow sufficient time for adequate communication to various stakeholders, including treating physicians. Early success with other state-mandated formularies was premised on an extensive educational campaign targeted to physicians and pharmacists treating injured workers who are

most impacted by the change. Absent that educational component, the application of the formulary could create unnecessary delays in approved pharmacy care getting to injured workers. Additionally, we have some concern about the capacity of all impacted stakeholders to program and adapt to the provisions of the final rule, and meet this deadline. The combination of the new approach to a drug formulary by California and the length of time taken to release a draft rule, allows for a very short window for essential programming and testing between trading partners once the final rule is approved and published. And while we believe we will be ready on the propsed date, some of our partners are not as certain. We are also concerned that a lack of adequate testing time may add unnecessary complication and error to a formulary methodology not previously used in the country with some unique programming challenges. We therefore recommend the Division work with the legislature to extend the effective date time frame an additional 60-90 days to allow for adequate education of stakeholders and to accommodate those stakeholders who may need additional programming and testing time.

9792.27.3: Transition

The proposed draft rule anticipates the need for a transition period for injured workers receiving non-preferred medications prior to the effective date of this formulary. We strongly support the concept of a transition period as a critical component to aid injured workers who may be dependent on a non-preferred medication. However, the language in 9792.27.3 (b) stating, "*The claims administrator shall not unilaterally terminate or deny previously approved drug treatment*," creates a potential barrier to making a transition. Read literally, the language would allow a treating physician to avoid a transition by simply refusing to engage in a conversation with the claims administrator about a transition plan. At that point, absent the cooperation of the treating physician, the claims administrator would be placed in the untenable position of being powerless to effect a transition since the rule expressly prohibits unilateral action.

We believe the Division intends for every reasonable, cooperative effort to be made by the claims administrators and the treating physicians to transition injured workers to preferred medications wherever possible. In that light, we suggest the following language, or something similar, be amended into the rule in paragraph 9792.27.3 (b) to cure the potential loophole: "*If the injured worker is receiving a course of treatment including a Non-Preferred Drug, an unlisted drug or a compounded drug, the* ***treating physician shall submit a transitional*** ~~*existing procedures for submitting the*~~ *treatment plan in accordance with MTUS formulary rule.*~~,~~ ~~*and*~~ ***The existing procedures for submitting*** *the* ***treatment plan and*** *for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.*

9792.27.4: Pharmacy Networks, Pharmacy Benefit Managers

Pharmacy benefit managers and pharmacy networks can play a valuable role in helping to ensure medications are prescribed consistent with the MTUS treatment guidelines and the proposed MTUS drug formulary and that injured workers have access to convenient and appropriate care.

9792.27.5: Off-Label Use

We support a pre-authorization process for off-label medication use.

9792.27.6: Unlisted Medications

We support a pre-authorization process for unlisted medications.

9792.27.7: Brand Name Drugs

The use of therapeutically equivalent generic medications has, over time, proven to be a significant cost saver while still maintaining the safety, efficacy and quality of care. The provision requiring a pre-authorization process for prescribing brand-named medications balances the need to contain costs while allowing for medically necessary care adaptations based on the unique medical needs of an injured worker. We therefore support this provision.

9792.27.8: Physician-Dispensed Drugs

Physician dispensing continues to drive costs in the California workers' compensation system. We support the proposed language requiring physicians to seek pre-authorization prior to dispensing medications, with the limited exception of the seven-day fill on a one-time basis. The allowance for a retrospective review on the one-time fills creates an added protection against potential abuse of the exception.

9792.27.9: Compounded Medications

Although we recognize the therapeutic value of a compounded medications in extremely unique situations where an injured worker's condition or physiology renders traditional medications ineffective or unusable,the rapid growth of pre-packaged, mass-produced, mass-marketed, non-FDA-approved and costly compounded medications with unproven efficacy challenges the accepted practice of using a compounded medication uniquely tailored for a specific and uncommon medical need of a particular injured worker.

We support the language requiring pre-authorization of compounded medications in this section of the rule as we believe it returns the practice of compounding medications to its intended role and purpose: treating specific, unique medical needs of the individual injured worker as a second-line therapy. Such requirements will also help reduce unnecessary medication costs in California.

9792.27.10: Preferred, Non-Preferred and Unlisted Drugs, Prospective Review

We support the provision of preferred medications without prospective review when prescribed in accordance with the MTUS treatment guidelines. This allows for appropriate pharmacy care to reach the injured worker without delay. For non-preferred and unlisted medications, we support the requirement for pre-authorization to ensure medical necessity when prescribing practices vary from preferred medications.

9792.27.11: Special Fill

This is an area that will create new programming requirements not previously included in drug formularies in other states. We understand the reasoning and appreciate the limited number of medications in this category, however would like to point out that this added complexity combined with the short window of time between the approval of the final rule and the proposed

effective date is creating some concern among stakeholders regarding their ability to fully implement on July 1, 2017.

9792.27.12: Perioperative Fill

This is another area that will create new programming requirements not previously included in drug formularies in other states. Here again, we understand the reasoning. However, pharmacy benefit managers have not previously had uniform access to information about pending surgeries, requiring new programming processes to be designed and tested to automate the approval for perioperative fills. This highlights another area of concern we have heard from our partners related to meeting a July 1, 2017 implementation date.

9792.27.13: Applicable Health and Safety Regulations

Stakeholders should already be complying wth these rules and we support this provision.

9792.27.14: MTUS Drug List

It is our hope the DWC will maintain the list in an electronic, downloadable format that can be used by all stakeholders to import into automated systems.

9792.27.15: National Drug Codes

We strongly recommend this provision be changed from a “may” to a “shall”. Having the DWC assign the appropriate NDC or GPI numbers to the medications on the MTUS drug list will help eliminate any confusion that might arise if a claims administrator and a physician disagree on how an NDC or GPI for a particular drug was determined.

9792.27.16: Pharmacy and Therapeutics Committee – Composition

9792.27.17: Pharmacy and Therapeutics Committee – Application

9792.27.18: Pharmacy and Therapeutics Committee – Conflict of Interest

9792.27.19: Pharmacy and Therapeutics Committee – Conflict of Interest Disclosure Form

9792.27.20: Pharmacy and Therapeutics Committee – Meetings

We are generally supportive of these provisions related to the Pharmacy and Therapeutics Committee. We offer caution as it relates to conflicts of interest and to undue influence on the committee from outside groups who might lobby to get drug classifications changed or drugs added to the list. The Drug List should be based on sound medical evidence and not influenced by financial or political whims. Having the committee serve solely in an advisory role with the final decision resting with the Administrative Director should help guard against these risks.

9792.27.21: MTUS Drug List Updates

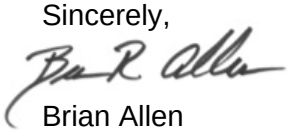
The proposed rule does not currently specify a time between the adoption of a change by the Administrative Director and when the change might become effective. It is important for any adopted change that sufficient time is allowed between the adoption and the effective date of

the change to allow for programming changes and adequate communication to stakeholders. The only exception to this requirement would be the immediate removal of a drug due to a recall or change creating a potential safety risk for injured workers.

Summary

We reiterate our appreciation to the Division for their willingness to meet with and listen to stakeholders regarding this important change. We offer our comments in an effort to be constructive and to share our insights on potential pitfalls gained from our experience with other state-established workers' compensation drug formularies, as well as our own. Should you have any questions on these comments, please feel free to contact Brian Allen at 801-661-2922 or via email at Brian.Allen@optum.com.

Sincerely,



Brian Allen
Vice President, Government Affairs
Optum Workers' Comp and Auto No-Fault

IWP
The Patient Advocate Pharmacy®

Maureen Gray, Regulations Coordinator
Department of Industrial relations
Division of Workers' Compensation
1515 Clay Street, 18th Floor
Oakland, CA 94612

April 4, 2017

For over fifteen years, Injured Workers Pharmacy (IWP) has been the industry leader in providing prescription services to workers who have been the victims of workplace accidents. In 2015, IWP acquired MH Express Pharmacy, based in San Dimas, California, which specializes in California specific workers' compensation claims. As a home delivery workers' compensation pharmacy with specific knowledge regarding California's workers' compensation system and its impact on injured workers, I write today to express some of our concerns regarding the proposed drug formulary and regulations.

IWP remains supportive of the efforts by the Department of Workers' Compensation (DWC) to develop and implement a formulary. We have seen from our work in other states that formularies can help reduce unnecessary and costly medications, support evidence based medical treatment, lessen administrative burdens, and help injured workers receive the treatment they need. However, the proposed formulary and regulations, which remain nearly identical to those put forth back in the fall, would undercut much of the progress being made in those areas within California.

The formulary remains overly restrictive and unencompassing. Categories of medications common in the treatment of injured workers are deemed almost entirely non-preferred, including muscle relaxants and anti-depressants, and sleep aides are completely absent from the formulary. Of the listed 242 prescription drugs in the formulary, only 76 are considered preferred. When the formulary is applied to our experience within California, of our 30 most dispensed medications, only 10 are preferred, 13 are non-preferred and 7 are not even listed. The fact that the list of non-covered prescriptions is so lengthy raises concerns that the draft formulary did not properly account for common workers' compensation injuries and their treatment. Although the formulary implementation would lessen the use of non-listed or non-preferred drugs, it would not entirely eliminate it. By limiting the list of covered drugs under the formulary, the state is interfering in the patient-physician relationship, limiting a physician's ability to determine and prescribe appropriate treatment for an injured worker. A restrictive formulary, such as this proposal, forces the physician to either select a preferred drug from a small list simply because of its preferred status or risk delayed treatment for the injured worker.

Injured Workers Pharmacy | P.O. Box 338, Methuen, MA 01810 | Toll Free: 888-321-7945 | www.IWPharmacy.com

Although the proposed formulary and regulations do allow for special fills of some of the non-preferred drugs common in treatment of injured workers, there remains concern about an injured workers' access to sustained treatment. If a patient receives a special four-day fill of a medication, what safeguards are in place for them to continue on their course of treatment after the four days? Even if a physician completes the appropriate pre-authorization materials are insurers required to respond in a timely manner or does the injured worker risk a disruption in their medical treatment, leading to longer recovery times or unnecessary suffering?

It is also important to keep in mind that an overly restrictive formulary undercuts the intentions behind the implementation. One reason cited in support of a drug formulary is to reduce administrative burdens, including lengthy and costly utilization review (UR) and independent medical review (IMR) appeals. However, if the Department continues forward with the current formulary, the vast majority of medications offered to injured workers on a regular basis are non-preferred or not-listed. Therefore, in order to treat the majority of patients, a physician would have to complete the pre-authorization request process. This process has no time limitations imposed by regulations, which can easily lead to delay or even abruptly stopping an injured workers' treatment. Not only does it create additional administrative work for physicians that could otherwise be avoided, but with so many common prescriptions left off the list, pharmacy benefit managers (PBMs) and payers will be inundated with prior authorization requests, creating an overwhelming administrative workload for payers, delay for injured workers, and frustrations for all stakeholders.

The regulations also fail to adequately address injured workers already subject to on-going medical treatment, which contains non-preferred or non-listed medications. The vague regulations require a physician to submit a proposed treatment plan through the normal procedures and prohibit a claims administrator from simply terminating or denying previously approved prescriptions, but provide little clarity around timelines. Specifically, as we inch closer to the implementation date, is there a timetable by which insurers need to evaluate and approve treatment plans - without one it is possible that the formulary will go into effect before a treatment plan is approved for a patient, leaving practitioners and pharmacies uncertain about what to do. The ambiguous process also creates a large administrative burden on medical providers to develop, write, submit, and defend a patient's medical treatment plan with limited time to eliminate gaps in treatment. In comparison, a staggered implementation, which has worked successfully in other states, depicts clear timelines for payers, physicians, and patients that either must be met or require the development of alternative plans. It allows physicians the opportunity to collaborate with their patients in establishing a treatment plan and it reduces administrative work for all parties. Although leaving the process more open-ended gives physicians and payers more freedom to develop their own processes, it also eliminates any guidance or protections for injured workers.

Additionally, the regulations state that the "Administrative Director may maintain and post on the DWC website a listing by NDC code of drug products . . .. ." While the Department has addressed earlier concerns about the lack of NDC coding provided within the formulary, the use of "may" raises concerns that it might not be maintained or routinely updated to reflect future changes. NDC codes ensure uniformity among providers and insurers and is a key element of a seamless administrative process. To reduce confusion and administrative delay in the treatment of injured workers, we urge you to consider amending the regulations to require an NDC code be contained within the formulary, ensuring that it is public knowledge and that providers and payers can pull the information from a single source.

Finally, we urge the Department to consider delaying implementation of the formulary to allow all parties to properly implement the new system. As it stands now, we are only two months out from the implementation date and neither the formulary nor the regulations are finalized. Medical providers, payers and even injured workers need more time to familiarize themselves with the new formulary and regulations and properly adjust their processes to comply. As a pharmacy specializing in workers' compensation, we need time to alter our internal systems and processes to fully comply with the formulary and regulations, further ensuring we are properly and efficiently serving our patients.

Thank you for your time and consideration on this matter. If you have any further questions, please do not hesitate to contact me at 888-321-7945 or djaffee@iwpharmacy.com.

Sincerely,

Danielle M. Jaffee, Esq.
Manager of Government Affairs, IWP

May 1, 2017

The California Applicants' Attorneys Association ("CAAA") appreciates the opportunity to provide written comments on the proposed MTUS Drug Formulary currently posted on the DWC website for a 45 day comment period ending May 1.

CAAA strongly supports the provision of the highest quality and most effective medical treatment for injured workers. We recognize that considerable work went into the drafting of these regulations by DWC staff and we commend them for their work and tremendous efforts. However, we continue to have concerns about whether this proposed Formulary meets the objectives of AB1124 to adopt a formulary which is based on nationally recognized evidence based guidelines. Specifically, the Preferred Drug List in the proposed formulary is restricted to only low cost, non-opioid prescriptions. While public policy considerations may include the benefit of reducing drug costs for carriers and concerns regarding opioid dependency, the Preferred Drug List should also meet the equally important standards of evidence based medicine . The current proposal is neither linked to evidence based treatment guidelines nor any scientific literature or studies recommending these preferred drugs over others as an efficacious means of treatment for a particular medical condition or injury.

While there does not seem to be any advantage to designating a very limited number of consumer-type drugs as "Preferred," there does seem to be a clear disadvantage in designating a large number of drugs as "Non- Preferred." Undoubtedly many employers would prefer not to provide the drugs on the "Non-Preferred" list, but if a drug is medically appropriate under the MTUS, what evidence based reason is there for designating that drug as "Non-Preferred?" Unfortunately assigning the "non-preferred" label to so many drugs appears to be based solely on financial considerations and will undoubtedly result in a stigmatization of those drugs by many carriers in their utilization review practices.

Our specific comments follow.

Section 9792.27.3. MTUS Drug Formulary Transition.

Labor Code section 5307.27 requires the formulary to include a phased implementation for workers injured prior to July 1, 2017.

Regulation 9792.27.3 was changed from the first draft posted on the DWC Forum to the current draft and it now contains no timeframe for a worker to be allowed to transition from a non- formulary drug to a formulary drug .

When implementing its' formulary, Texas set a two-year deadline for transitioning patients into their formulary . On one hand this gives physicians a clear timeline for weaning patients who have been on a non -formulary drug for an extended period, but it also protects workers from being abruptly cut off their medications.

While the removal of a deadline is viewed by the DWC as allowing doctors flexibility in shaping a treatment plan, it also provides little protection to workers who may need time to transition to a new drug. The language "The claims administrator shall not unilaterally terminate or deny previously

approved drug treatment" provides little to no protections to the worker because the claims administrator can send the request for a renewal of a previously authorized prescription drug to utilization review where it may be promptly denied if a non-formulary drug!

As the statute mandates a phased implementation for workers injured prior to July 1, 2017, it is recommended that a two year timeline be added to Section 9792.27.3 for "legacy" workers to be covered by the formulary.

Additionally the lack of a transition timeframe presents a risk for workers as ACOEM does not appear to have a multidisciplinary approach to weaning that is evidence-based similar to that provided for in the ODG guidelines which were incorporated into the Chronic Pain and Opioid Guidelines approved last year.

Therefore it is further recommended that until such time as ACOEM updates their Opioid Guidelines that the administrative director adopts regulations for weaning which are evidence-based which may include the weaning protocols followed by ODG and implemented last year.

Additional treatment guidelines for tapering opioids which may be used include:

CDC Guideline for Tapering Opioids for Chronic Pain

https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf

Washington State Opioid Taper Plan Calculator
www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf

Tapering Long-Term Opioid Therapy in Chronic Noncancer Pain
www.mayoclinicproceedings.org/article/S0025-6196(15)00303-1/fulltext

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

Unfortunately, as currently drafted the formulary will have minimal impact on reducing frictional costs of utilization review and Independent Medical Review because there is such a small number of preferred drugs on the list which are not subject to prospective review.

The CWCI reports that 78% of prescription drug payments in California will continue to require preauthorization under the proposed MTUS Formulary. In other words almost four out of every five medications prescribed will still be subject to pre-authorization. With such a highly restrictive formulary, there will be virtually no positive impact on or reduction of UR and IMR costs in the system. As a result, delays will continue for injured workers in accessing appropriate medications while recovering from their work injuries. While a formulary might be expected to decrease the amount of

utilization review for drug prescriptions, as providers are steered toward preferred drugs that don't require preauthorization, the amount of payer scrutiny of non-preferred drugs or medications not listed in the formulary will most likely increase when a formulary is adopted.

It is possible the adoption of the formulary, and specifically the "first fill" exception, could result in a quicker delivery of those prescriptions on the preferred list. However, if the purpose of the formulary proposal is to designate a limited number of drugs as "Preferred" this will have little to no impact on how fast injured workers receive prescribed medications. Looking at the top 20 drugs that will be in the Preferred category, the list includes a number of drugs, such as Advil, Tylenol, Prilosec, Zantac, Nexium, Prevacid, and Pepcid, that are readily available over-the-counter.

Designating these drugs as "Preferred" will speed up delivery only if requests for these drugs are currently being sent to formal Utilization Review. An earlier CWCI study found that approximately 85% of medical treatment is approved and paid without a Request for Authorization (RFA) being filed. If that is anywhere near correct, then it is likely that requests for Tylenol and Pepcid are not currently going to formal UR (or at least they shouldn't be). Consequently, designating these drugs as Preferred and exempting them from formal UR will not change anything.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

Perioperative medication management can be complicated in high risk patients. A 4 day fill following surgery is not going to be adequate for many patients in controlling pain and can ensure a trip to the emergency room if the 4th day falls on a weekend. Therefore, to avoid these risks it is recommended the length of a perioperative drug fill be 7 days. Most patients will have the ability to follow up with their doctor following surgery in a 7 day time period, which would include monitoring of the medications that have been prescribed and management of perioperative pain levels.

Conclusion: ACOEM Says Doctors Should Be Paid for Dealing With Utilization Review

As a growing number of states adopt workers' compensation drug formularies, ACOEM released a position paper on formularies in August 2016 that includes a recommendation to pay physicians for time they spend dealing with utilization review.

"Policies for the implementation of a formulary should aim to pay providers for the extra time required for documenting medical necessity, following step-care procedures, and communicating with (pharmacy benefit managers) and UR agents," according to the position paper, authored by a six-member task force.

For example, in Arizona billing codes have been approved for reimbursing doctors $75 to $100 for the time spent on discussing medical necessity issues with utilization reviewers.

ACOEM further noted in this paper that while a formulary gives greater clarification on a drug-by-drug basis resulting in fewer disputes, it can also delay the filling of prescriptions, to the detriment of the injured worker. The delay might arise because the formulary is "silent" as to whether a particular drug is recommended or not.

CAAA urges the DWC to heed ACOEM's recommendations when finalizing the regulatory process for the implementation of the MTUS drug formulary. This may include an extension beyond the July 1, 2017 statutory deadline to get the design of the formulary right.

CompPharma

April 30, 2017

Ms. Maureen Gray
Regulations Coordinator, Division of Workers' Compensation, Legal Unit
P.O. Box 420603
San Francisco, CA 94142
dwcrules@dir.ca.gov

Dear Ms. Gray:

Regarding: Title 8, California Code of Regulations sections 9792.27.1 – 9792.27.21 – Development of the MTUS Drug Formulary

CompPharma, LLC is a consortium of pharmacy benefits managers (PBMs) providing workers' compensation pharmacy benefit services in all fifty states. Our members consist of the nation's most prominent workers' compensation PBMs. These companies have years of experience in developing and applying clinical medication formularies to ensure proper utilization of prescription medications by injured workers and their treating physicians.

We strongly support the California MTUS Formulary as it brings common sense tools to the provision of pharmacy services to the state's injured workers. The formulary will help ensure injured workers receive the right drugs at the right time. We look forward to continuing to work with the Division to facilitate proper implementation of the MTUS Formulary, so that treatment of injured workers can be improved throughout the state. At the same time, as an organization that represents PBMs, we have a duty to also express our concerns regarding certain segments of the proposed rule language.

In particular, we remain concerned with the short implementation time frame (effective/implementation date of July 1, 2017), a lack of direction for physicians and payers handling the transition of existing claimants, and the lack of specific drug-identifying data included in the current proposed drug list. We believe the lack of drug-identifying data combined with the short implementation timeline may disrupt provision of pharmacy services at the retail pharmacy level, which would inevitably create access difficulties for injured workers.

Separately and regardless of the implementation time frame, we are specifically concerned that there is no clear direction regarding the transition of existing claimants. We believe the vagueness in the existing proposed language will lead to dangerous and life-threatening situations where injured workers may unnecessarily be denied needed medications.

To address these concerns, CompPharma provides the following comments and suggested changes to the proposed language. We believe these changes **will not** undermine the formulary in any way and will provide stakeholders the appropriate data and time needed to properly and effectively implement the new process with little impact to care provided to injured workers.

Implementation Time Frame and Proposed Effective Date

As the proposed MTUS Formulary language recognizes, it is of utmost concern to provide timely and **clinically appropriate** medications for injured workers and to minimize disruption in delivery of pharmacy services. To this end, CompPharma remains concerned with specific implementation dates contained in the proposed rule. The proposed language leaves less than 60 days after adoption before the July 1, 2017 implementation date. While our members will try to comply as best they can, clearly this time frame could be problematic for all stakeholders in the terms of systematic programming for many of the **new** pharmacy checks and balances required by the proposed rule. We strongly believe that injured workers will benefit by modifying the proposed regulations to permit more time for doctors, insurers, pharmacies, and injured workers to become fully aware of the impact of the new MTUS Formulary and complete all processes needed to bring pharmacy claims processing into compliance. We ask the Division to consider a potential delay – not in adoption of the rules – but in the effective/implementation date on all claims. We propose these changes out of concern for injured workers and request that the effective/implementation date of the MTUS Formulary and all associated rules be modified to January 1, 2018 for the following reasons.

First, delaying mandatory effectiveness of the MTUS Formulary until January 1, 2018 will allow the formulary effective date to act in synergy with the effective date of legislatively mandated changes to the existing Utilization Review processes enacted by Senate Bill 1160. The proposed MTUS Formulary relies upon proper application of Utilization Review rules found in Labor Code section 4610. This portion of the labor code will be significantly modified, from its current state, by January 2018 by which time the administrative rules for Utilization Review standards will be significantly different than those in place on July 1, 2017. Aligning the effective date of the formulary and soon-to-be adopted Utilization Review standards will allow all treatment guidelines and requirements to work towards the same goal with the same effective date. This will cut down on confusion and duplication of processes for all system participants, and most importantly injured workers.

Second, even with a delay in the effective/implementation date, the true intent of AB 1124 will be realized as of July 1, 2017. The rule will be adopted and in-place on the legislatively required date, but application of all rule requirements will be delayed for a period of six months, during which time all stakeholders can initiate proper processes. During the delay of rule implementation, doctors, carriers and injured workers will be able to fully understand application of the new rules to not only new claims but to current claimants. This will enable and highly motivate doctors and payers to utilize this important transition time frame to address their patients' needs, modify their prescribing habits and address ongoing patients' treatment or obtain prior authorization as soon as possible, even before the January 1, 2018 date.

Third, a delay would give the Division time to publish a drug list that contains the necessary National Drug Codes (NDCs) and allow time for service providers to prepare for the change. Section 9792.27.15 gives authority to the Administrative Director to post a list of this information, but there is currently no indication of when this list will be available. Alternatively, the delay would permit PBMs and pharmacies to develop an NDC/GPI cross-walk to ensure provision of **proper** medications.

Fourth, the MTUS Formulary allows for employers to include Non-preferred drugs in a Utilization Review Plan filed with the state. Modifying these Utilization Review Plans takes

time, and less than a 60-day implementation period will lead to treatment delays and billing questions during the transition. Allowing more time will allow insurers/physicians time to permissively adopt prior to mandatory adoption and will minimize treatment and billing disputes.

Finally, if the effective/implementation date of the formulary is moved to January 1, 2018, it will allow time for the P&T Committee to be formed and for the initial list of Preferred drugs to be reviewed prior to full implementation.

Based on these reasons, we propose that the final MTUS Formulary rules be modified as follows (inserted language is indicated as underlined and removed language appears as ~~strikethrough~~):

Section 9792.27.2. MTUS Drug Formulary; MTUS Drug List; Scope of Coverage; Effective Date.
(b) Except for continuing medical treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after January 1, 2018 ~~July 1, 2017~~ for outpatient use shall be subject to the MTUS Drug Formulary, regardless of the date of injury.

Transition Period

Of particular concern – regardless of any change in the implementation date of the formulary rules – is the lack of direction regarding the handling of a "transition" period for claims with a date of injury prior to the implementation date. Specifically, we are concerned about not having a defined time period for tapering injured workers off the Non-preferred drugs and/or transitioning them to Preferred drugs. Unlike in group health and Medicaid populations, the long-term treatment of injured workers is usually related to the treatment of pain. In fact more than seventy percent of the medications provided nationally for the treatment of work related injuries are for pain or are pain-related medications. This is not like the group health and Medicaid patient population where transitioning a patient from one blood-pressure or diabetes medication to another, similar medication can be fairly easily achieved. The proposed formulary requirements will transition many injured workers **OFF** highly addictive and dangerous pain medications that they have been using for months if not years. Prescribers need time to properly taper or wean injured workers off these drugs and to stabilize them on formulary Preferred medications. Providing a transition timeline will inform prescribers of the need to start the tapering/transition process.

We do not believe it is the intent of the Division to create potentially hazardous unintended consequences in the drafting of the proposed formulary rules. Further, we support the Division in not becoming heavy handed in mandating specific communications and actions by either the physician or the claims administrator. We do believe, however, that a lack of clarity will lead to a lack of access to needed medications that may result in harm, or in some cases even death, to the injured worker.

Additionally, if we examine the evolution of drug formularies in the workers' compensation marketplace, it is clear that the special handling of long-term claimants and their drug regimens was of specific concern in other jurisdictions. Jurisdictions such as Ohio, Tennessee and Texas, provided a fully documented, minimum six-month transition period. These transition periods enabled the prescribers to become fully aware of the formulary requirements and then to fully engage with both the claims administrator and the injured

worker in a clearly defined and documented treatment plan to transition the injured worker to a pharmacy regimen that is compliant with the formulary rules.

Based on these reasons, we propose that the final MTUS Formulary rules be modified as follows (inserted language is indicated as underlined and removed language appears as ~~strikethrough~~):

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 except for those claims with a date of injury prior to July 1, 2017 as outlined in subsection (b), regardless of the date of injury.

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary shall be implemented on a schedule intended to ensure injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. No later than January 1, 2018, a treating physician shall request a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which shall at a minimum include use of a Non-Preferred drug or unlisted drug for an extended period where that is necessary for the injured worker or necessary for safe weaning, tapering or transition to a Preferred drug. If the above required documentation is submitted in a timely manner by the treating physician and is consistent with MTUS, the claims administrator shall not unilaterally terminate or deny previously approved drug treatments which are included in the request submitted by the physician

Drug List and Specific Data Needs for Implementation and Application
During the prescribing, dispensing, processing, Utilization Review, and billing of/for a medication – specifically the dispensing and processing – pharmacy stakeholders use several nationally accepted data elements that help pharmacy stakeholders understand the medications being provided. The most basic codification is the National Drug Code or NDC of the medication. The NDC provides the pharmacist, PBM and claims administrator with the Original Labeler, the drug product code, drug strength, dosage form and formulation, and packaging size. This data enables the pharmacy and PBM to properly dispense and process the medication as well as bill for the medication.

Most pharmacy and PBM systems are systematically programmed to utilize these data elements, some at the NDC level and some more ingrained and even more specific levels. The information contained in the proposed drug list does not include the basic level data element of NDC. This will require costly and time-consuming manual processes for the initial implementation and ongoing processing of medications under the California drug formulary. Additionally, many medications have different routes of administration (dosage form and formulation) that are often clarified by the NDC. Being unable to tie a specific medication and treatment back to specific information provided by the NDC could create confusion and lead to delays in the processing of medications. As an example, the lack of an NDC may lead to confusion over whether the drug is an extended release, an immediate release, or a topical compared to oral route of administration. Not having the NDC on the proposed drug list leaves many medications open to misinterpretation.

Having the Division assign the appropriate NDC data element to medications on the proposed MTUS drug list will help stakeholders avoid costly and manual work around –

both during initial implementation and at any drug list update issued by the Division – and allow the current level of pharmacy processing systems to operate effectively without interruption.

Based on these reasons, we propose that the final MTUS Formulary rules be modified as follows (inserted language is indicated as underlined and removed language appears as ~~strikethrough~~):

Section 9792.27.15 National Drug Codes – MTUS Drug List

(a) The Administrative Director ~~may~~ shall within six months of the effective date of this rule maintain and post on the DWC website a listing by NDC code of drug products that are embodied in the MTUS Drug List. ~~If posted, the listing will~~ The listing shall be regularly updated to account for revisions to the MTUS Drug list and for changes in drug products that are marketed for outpatient use.

Thank you for considering these changes.

Sincerely,

Joe Paduda
President
jpaduda@comppharma.com

Gray, Maureen@DIR

From: Joyce Ho <jho@comppartners.com>
Sent: Friday, April 14, 2017 2:13 PM
To: DIR DWCRules
Subject: written comment on proposed Medical Treatment Utilization Schedule (MTUS) – Formulary

To whom it may concern:

The proposed formulary appears to be quite limited. There are only 76 preferred drugs, and only 24 of them for pain indication.

In addition, the medications are especially inconsistent with the current Chronic Pain Guidelines. Some examples: Medications that are considered first line treatment for neuropathic pain in the Chronic Pain Guidelines (such as gabapentin) are listed as non-preferred. Pantoprazole (generic name of Protonix), on the other hand, is a preferred drug on the formulary but the Chronic Pain Guidelines indicates that "A trial of omeprazole or lansoprazole had been recommended before Nexium therapy (before it went OTC). The other PPIs, Protonix, Dexilant, and Aciphex, should be second-line."

Thank you very much.

Joyce Ho, M.D.
Medical Director
CompPartners, Inc.

May 1, 2017

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

Via e-mail: dwcrules@dir.ca.gov

Re: Notice of Proposed Regulations for Medical Treatment Utilization Schedule (MTUS) - Drug Formulary

State Compensation Insurance Fund appreciates the opportunity to provide input regarding the Division of Workers' Compensation's (DWC) proposed regulations for MTUS – Drug Formulary. State fund appreciates the DWC's efforts to provide further clarity to the regulations and submits the following comments for your consideration.

Recommended revisions to the proposed regulation are indicated by underscore and ~~strikeout~~.

Section 9792.27.3. MTUS Drug Formulary Transition.

Recommendation

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in by (insert timeframe) to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS, which may include use of a Non-Preferred 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 administer shall not unilaterally terminate or deny previously approved drug treatment.~~ If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.

Discussion

In order to be effective, a timeframe is recommended in order to provide the injured worker with appropriate and safe medical care. An inserted date will also help to avoid abuse.

The language regarding the claims administrator "shall not unilaterally terminate or deny previously approved drug treatment" should be removed. The sentence conflicts with the obligation to perform utilization review.

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

Recommendation

(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 the drug is found upon retrospective review to be not medically necessary.~~

Discussion

We recommend a clarification on whether the last sentence suggests that no prospective review was previously done, or that there was a prospective review previously done and drug treatment was denied. If drug treatment was previously denied through prospective review prior to dispensing a drug, it should be denied and not also subjected to a retrospective review.

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 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.) If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied ~~if it is determined upon retrospective review that the drug treatment was not medically necessary.~~

Discussion

We recommend a clarification on whether the last sentence suggests that no prospective review was previously done, or that there was a prospective review previously done and drug treatment was denied. If drug treatment was previously denied through prospective review prior to dispensing a drug, it should be denied and not also subjected to a retrospective review.

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

Recommendation

(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 it is determined upon retrospective review that the drug treatment is not medically necessary.~~

Discussion

We recommend a clarification on whether the last sentence suggests that no prospective review was previously done, or that there was a prospective review previously done and drug treatment was denied. If drug treatment was previously denied through prospective review prior to dispensing a drug, it should be denied and not also subjected to a retrospective review.

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 (insert timeframe)

Discussion

A timeframe will help to avoid abuse and unattended consequences. With no timeframe, it becomes subjective and interpreted differently by everyone. We recommend a timeframe of no more than 7 days.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

Recommendation

(b) For purposes of this section, the perioperative period is defined as the period from ~~2~~ 7 days prior to surgery ~~to 4~~ to 10 days after surgery, with the day of surgery as "day zero".

Discussion

4 to 7 days is not enough time. We recommend a range of 7 to 10 days is more reasonable.

We thank the DWC for the opportunity to participate in the rulemaking process and we offer our ongoing support of the DWC's proposed MTUS – Formulary.

Sincerely,

Karen Sims
Assistant Claims Operations Manager
Claims Medical and Regulatory Division

Cc: Jose Ruiz, Claims Operations Manager, Claims Medical and Regulatory Division
Elsa Tan, Director, Claims Medical and Regulatory Division
Mary Huckabaa, Assistant Chief Counsel

May 1, 2017

Division of Workers' Compensation
Maureen Gray
Regulations Coordinator
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RE: Proposed regulations for the Medical Treatment Utilization Schedule (MTUS) Drug Formulary

Express Scripts, Inc. appreciates the opportunity to submit comments regarding the proposed regulations for the Medical Treatment Utilization Schedule (MTUS) drug formulary. Our goal is to ensure clear and concise rules to avoid any confusion or misunderstanding for all participants within the workers' compensation system.

Express Scripts, Inc. is one of the largest pharmacy benefit management (PBM) companies in North America, providing PBM services to thousands of client groups, including managed-care organizations, insurance carriers, employers, third-party administrators, public sector, workers' compensation, and union-sponsored benefit plans. Express Scripts takes a strategic approach to workers' compensation, structuring customized client solutions around best-in-class core services, supported by advanced trend-management and clinical-review programs, to ensure safety for injured workers, while aggressively controlling costs.

Below we have outlined recommendations in the following sections:

Section 9792.27.2. MTUS Drug Formulary; MTUS Drug List; Scope of Coverage; Effective Date.
(b) Except for continuing medical treatment subject to section 9792.27.3, subdivision (b), a drug dispensed on or after ~~July 1, 2017~~ January 1, 2018 for outpatient use shall be subject to the MTUS Drug Formulary, regardless of the date of injury.

Express Scripts Comments: We are recommending an implementation date of January 1, 2018 to ensure all system participants are prepared and educated on the formulary drug regulations and allowing the required time for system enhancements or process changes necessary for a successful implementation.

Transition.
Section 9792.27.3. MTUS Drug Formulary Transition.

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

(b) 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. No later than January 1, 2018, 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. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.

Express Scripts comments: With an effective date of January 1, 2018, this will align with the changes to the utilization review procedure and avoid any confusion on application.

Regarding those injured workers receiving ongoing drug treatment which would be subject to prospective review, we are recommending inserting "no later than 1/1/2018" to ensure all system participants are working towards a clearly stated goal and that conversations about current treatment plans and any needed changes in treatment be clearly communicated eliminating any disruption for the injured worker.

Section 9792.27.15. National Drug Codes - MTUS Drug List.

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

Express Scripts comments: Specific NDCs will assist with general clarification of the drug listings, including clarifying dosage forms; this will close the gap on variances in interpretation.

We appreciate the opportunity to provide feedback on the proposed regulations for the MTUS drug formulary. We look forward to continued participation and are willing to offer any assistance the Division of Workers' Compensation may find helpful.

Sincerely,

Kim Ehrlich
Workers' Compensation Compliance

COVENTRY

FIRST SCRIPT®

May 1, 2017

State of California
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 17th Floor
Oakland, CA 94612

Posted Via Electronic Submission to: DWCRules@dir.ca.gov

Re: Response to Comment Period for the Draft Formulary Regulation Text as Reflected in Proposed Title 8, CA Code of Regulations, Sections 9792.27.1 – 9792.27.21

Dear Sirs:

Thank you for the opportunity to provide feedback on the Draft Formulary Regulation Text as Reflected in Proposed Title 8, CA Code of Regulations, Sections 9792.27.1 – 9792.27.21. After a review of the proposal in light of Coventry's current operational framework (including Coventry's PBM (FirstScript™), UR, and Bill Review components), we would like to offer the following comments, some of which constitute a reiteration of previously-submitted comments.

1. **The Section 9792.27.3. MTUS Drug Formulary Transition Should Specify a 6-Month Transition Timeline for "Legacy" Claimants.**

   ISSUE: Section 9792.27.3(b), as drafted in the proposed rules, provides that 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. While providing for a period for claimants to transition safely from non-preferred to preferred medications is clearly warranted and clinically appropriate, the proposed rules do not specify a timeline for the transition, creating confusion for all stakeholders in the system, as well as potential safety concerns.

   Given that one of the specific stated objectives of formulary implementation was to improve conformity and consistency in prescribing patterns for all claimants within the California Workers' Compensation system, without a definite specified transition timeframe for so-called "legacy" claimants, many of those claimants may languish on inappropriate medications, while claimants injured subsequent to 7-1-17 will benefit from the new medical "wisdom" and prescribing restrictions provided for in the formulary from the start. Hence, the lack of specificity unintentionally creates a "two-tiered" system of treatment with no specified date of conformity.

SOLUTION: Modify the language of the proposed rules to specify a suggested specific timeline for transition of 6 months for legacy claims, as follows:

> "(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. ***Accordingly, all injured worker claims with a Date of Injury prior to July 1, 2017 shall be exempt from the MTUS Drug Formulary until December 1, 2017, at which point all injured workers are incorporated by the MTUS Drug Formulary and treatment rendered by prescribers is expected to be fully in compliance with the MTUS Drug Formulary, except where a treatment plan has been documented and authorized to the contrary.*** 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")…"

2. The "Effective Date" of the Formulary Should be Extended to January 1, 2018, Due to Delayed Publishing of Finalized Rules to Allow for Smoother Transition

ISSUE: The DWC has worked tirelessly to obtain stakeholder input, revise the proposed rules several times in response to input, held multiple public meetings to solicit feedback, etc. As such, the 7-1-2017 implementation date that was originally targeted by the DWC as an effective date has become unworkable. At this juncture, there is inadequate time to properly implement the rules between the time that they may be finalized (which may be as late as some time in June, 2017, if a subsequent 15-day comment period is undertaken), and the July 1, 2017 target date. Given that the language of AB1124 only requires that rules be promulgated by July 1, 2017, but does not specify *which specific provisions must be effective as of July 1, 2017*, it follows that it would make logical sense to complete the formalized rule-making process by July 1, 2017, but delay the effective implementation date until several months thereafter in order for stakeholders to fully and correctly implement the rules that they have so painstakingly providing input into.

SOLUTION: Modify the proposed rules to specify an effective date of January 1, 2018.

3. The Formulary Should Have Specificity to the GPI or GCN/NDC Level for Accurate Implementation and Consistency

1. **ISSUE:** – In choosing to create a formulary that borrows from multiple clinical resources, the DWC has hampered pharmacy providers' collective abilities to access a single data source that specifically indicates whether a given medication is "on formulary" or "off" formulary. As a result, PBMs will be relegated to constructing interpretive formularies that approximate the status of a drug as "preferred" or "non-preferred" based upon industry coding at the GPI or GCN level. Without access to a data source that specifically maps to the DWC's formulary, this could create more debate and friction between prescriber/provider, the pharmacy and the payer, all to the delay and detriment of the injured worker. The DWC must present a Formulary that is either:
    a. More specific in what data mapping should be done
    b. Is connected to an existing data structure that allows for NDC mapping

SOLUTION: Modify the proposed rules to add a published cross-walk, clearly identifying which *specific* drugs are "preferred" vs. "non-preferred" at the dispensing level, using a standardized nomenclature. Alternatively, predefined combinations of drug names and drug classifications would also be much easier to implement and would facilitate consistency.

I thank you for your time and consideration to the aforementioned comments. Please do not hesitate to contact me if you should require any additional information and/or if you should have any questions.

Best regards always,

Lisa Anne Bickford (Forsythe)

Director, Workers' Comp Government Relations
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May 1, 2017

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 18th floor
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Subject: Medical Treatment Utilization Schedule – Formulary Regulations

Dear Ms. Gray,

The American Insurance Association, the California Coalition on Workers' Compensation, the California Chamber of Commerce, the California State Association of Counties, the League of California Cities, CSAC Excess Insurance Authority, Schools Insurance Authority, and Albertsons / Safeway are pleased to submit the attached comments for your review.

Our organizations were early supporters of AB 1124 (Perea, 2015) because our respective memberships believe that the implementation of a formulary would help speed the delivery of appropriate medication to injured workers, protect injured workers from addiction to pain medications, reduce the administrative costs associated with Utilization Review (UR) and Independent Medical Review (IMR), and ultimately reduce the cost of California's workers' compensation system.

We thank you for your efforts developing the proposed Formulary Regulations. Overall, we think these regulations move the system in the right direction. Below we have outlined some specific comments and recommendations for your review. We look forward to working with your office through the implementation process so we can achieve our common goals of improving medical care for injured workers and reducing the expense associated with proper claims administration.

Sincerely,

Jeremy Merz
American Insurance Association

Jason Schmelzer
CCWC

Section 9792.27.3. MTUS Drug Formulary Transition

Proposed Amendment:

9792.27.3. (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. The physician *shall be* 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.*~~ If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply.

Comment:

The drug formulary is part of the Medical Treatment Utilization Schedule (MTUS). It is important to emphasize that most of the substantive provisions of proposed section 9792.27.3 are more appropriately codified in various other parts of the MTUS, including but not limited to chronic pain guidelines. Labor Code Sec. 5307.27(c) states, "(t)he drug formulary shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary". To meet this statutory mandate, reference should simply be made in the formulary to MTUS provisions now existing or as may be added regarding the proper methods by which to adjust long-term medications used by injured workers prescribed and dispensed prior to July 1, 2017. Concomitant with those anticipated amendments should be guidance for use of medications from the onset of illness or injury (dates of injury on and after July 1, 2017) consistent with the MTUS and its incorporated formulary. In both cases, this includes but is not limited to the use of opioids and medications associated with opioid use for the treatment of chronic pain.

We have previously commented on the difficulties associated with the language, "(t)he claims administrator shall not unilaterally terminate or deny previously approved drug treatment." In order to bring about the best results for injured workers and to realize the highest potential of the MTUS, there needs to be a process by which a claims administrator may require a review of existing drug regimens regardless of whether these have been approved in the past. In other words, if medical providers had been appropriately implement existing MTUS requirements regarding long term use of certain medications, the urgency for developing the formulary and attendant rules would be different from what is today. Labor Code Sec. 5307.27(c) clearly sets forth how this can be accomplished: "(t)he drug formulary shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary." That "phased implementation" should be initiated by the physician, but it should be able to be initiated by the claims administrator as well. Such language should be incorporated into the next iteration of the substantive provisions in the MTUS and not the formulary.

Sections 9792.27.1. Medical Treatment Utilization Schedule (MTUS) Drug Formulary - Definitions and 9792.27.12. MTUS Drug List – Perioperative Fill

Proposed Amendments:

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

(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 within the perioperative period for a *surgical procedure that has "010" or 10 Day Post-operative Period or has "090", or 90 Day Post-operative Period, 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* and meets specified criteria.

Section 9792.27.12. MTUS Drug List – Perioperative Fill.

(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 during the perioperative period; and

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

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

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

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

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

(b) For purposes of this section, the perioperative period is defined as the period from 2 days prior to surgery to 4 days after surgery, with the day of surgery as "day zero" for a *surgical procedure that has "010" or 10 Day Post-operative Period or has "090", or 90 Day Post-operative Period, 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.*

Comments:

Our coalition urges the DWC to further define "perioperative fill" in order to avoid unintended consequences with opioid and/or other non-preferred drugs utilized in simple procedures billed. These issues can be avoided by using a "Zero Day Post-operative Period" for minor procedures - such as epidural steroid injections - as classified under the Medicare National Physician Fee Schedule Relative Value File with Zero Day Post-operative.

Section 9792.27.8. Physician Dispensed Drugs

Proposed Amendment:

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

Comment:

While we appreciate the definition of Dispense noted under Section 9792.27.1 (e) of the proposed regulation, we have concern that the definition will be lost on the providers under section 9792.21.8 (Physician Dispensed Drugs). We do appreciate that 9792.27.8 (c) reaffirms limitations imposed by MPN contracts, but have concerns that this section does not also include a paragraph accounting for limitations imposed by LC § 4600.2(a) regarding Pharmacy Benefit Networks. We believe that the lack of reference to the Pharmacy benefits is needed, in order to avoid potential misinterpretation within section 9792.27.8 by providers that will results in an increase in lien litigation.

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May 1, 2017

Maureen Gray, Regulations Coordinator
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 18th Floor
Oakland, CA 94612

RE: **Proposed Regulatory Text as of 4/27/2017**

Dear Ms. Gray:

The California Labor Federation writes to support the formulary regulation text as of April 27, 2017. This new language offers significant improvements over the prior version and continues to achieve key goals of a drug formulary as directed by AB 1124 (Perea, 2015). Nevertheless, we do believe a few sections would still benefit from greater clarification.

The strongest reform presented by this regulation remains language allowing treating physicians to prescribe "preferred" drugs on the drug list without prospective utilization review. This straightforward change will eliminate a great deal of unnecessarily expensive and cumbersome review, speeding up the process for injured workers and cutting costs for employers.

However, we do believe that this concept could be clarified in such a way as to reduce confusion and the potential for resulting litigation. For example, Section 9792.27.1 (v) states the following: *"'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…"* Given that non-preferred drugs *do* require authorization through prospective review, this section could be read as stating that prospective review is allowed but not required. To clarify this point, we would recommend changing "does not require" to "shall not require."

Section 9792.27.10 (b) similarly states that *"The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary."* We would recommend adding, between the words "review" and "to," the following phrase: *"but may not be subject to prospective review,"* in order to clarify that only retrospective review is permitted for preferred drugs.

We also appreciate new language in section (c) that recommends expedited review where warranted.

AB 1124 mandated a phase-in period for workers with injuries that predate the formulary, primarily to protect workers from abrupt cessation of drug treatment plans that may suddenly require meeting a different evidentiary standard prior to approval. Section 9792.27.3 outlines how this phase-in will work, and this language now includes language preventing claims administrators from "unilaterally" terminating or denying previously approved treatment.

This addition strengthens and improves the tapering provisions, though the word "unilaterally" could cause confusion in this context. Perhaps a different phrasing that specifically prohibits terminating or denying previously approved treatment for reasons other than a significant change in the worker's condition—and only following proper UR and IMR—would clarify this section's intent.

We also wish to express appreciation for replacing the phrase "…preponderance of scientific medical evidence" with "…in accordance with MTUS regulations" in the new draft, a change that we believe will ease compliance and reduce confusion for physicians treating those who require unlisted drugs.

Section 9792.27.11 and 9792.27.12 include much needed language to create "special fill" and "perioperative fill" policies, respectively, for certain common short-term painkillers and musculoskeletal therapy agents. This addition will, we believe, make a world of difference for those in acute pain following traumatic injuries and surgeries and is significantly improved by the latest version.

In addition, 9792.27.11(f) requires the Administrative Director to "…evaluate the impact of the provision on the use of opioids by injured workers." While we support this addition, we believe the proposed study should be expanded to include concerns such as whether or not the formulary has weakened injured workers' rights to appropriate and timely medical treatment or left physicians unable to adequately treat injured workers. This formulary is a major change, carrying some risk of denying workers needed care, and this study should be expanded to quickly assess whether or not any unintended consequences have taken place following implementation.

Overall, we believe that this formulary language offers significant benefits to both injured workers and employers, and we commend DIR and DWC for all of your work on this reform.

Sincerely,

Mitch Seaman
Legislative Advocate
ms/tng39521/afl-cio
MS: sm
OPEIU 29 AFL CIO

Additional Comments for the California Drug Formulary

The proposed regulations state if authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary. Would the carrier be able to issue an immediate denial of a bill for a non-preferred drug if no utilization review request was received by the time the bill was received? Or would the carrier have to retain the pharmaceutical bill and monitor for a retrospective utilization review request for a specified length of time?

Could the diagnosis code be required for all prescriptions, regardless of preferred/non-preferred drug status? A preferred drug may be appropriate for a shoulder according to MTUS, but not appropriate for the elbow. Without a diagnosis it is extremely difficult to know what body part the prescribing physician is treating. A decision based on MTUS guidelines cannot be made until the diagnosis is known. Pharmaceutical bills are very seldom submitted with a diagnosis code or supporting documentation. The pharmacy that is dispensing the medication to the injured worker does not have easy access to this information and may have difficulty obtaining it from the physician's office, particularly for first fills after the date of injury. Generally, the physician's documentation is not yet available from the office visit when the injured worker shows up at the pharmacy. This also creates special challenges for the medical bill review company as they will not be able to appropriately review or make recommendations on pharmaceutical bills. Additionally, for on-line processing from the pharmacy to the PBM (pharmacy benefits manager), the diagnosis code is not a required field. It is unlikely either will have the diagnosis code if it is a first fill.

There has been some discussion about adding NDC's into the Formulary Drug list to more effectively address cost-issues. However, if these high-dollar drugs (e.g., Tramadol HCL 150mg, Cyclobenzaprine 7.5mg, and Carisoprodol 250mg) are submitted for utilization review and the medication itself is appropriate to the injury, it will likely be certified by UR. Utilization review determines the medical necessity of the medication and the dose is not often reviewed or may not be taken into consideration. Rather than incorporating specific NDC's into the formulary, simply excluding those dose forms may be a more effective option.

Nina Walker
Applied Underwriters, Inc.

California Proposed Formulary Comment

From a pharmacy benefits management perspective, the California proposed formulary list of preferred/non-preferred drug will be extremely difficult to manage.

The reference guidelines provided are difficult to follow and contradictory. It does not appear to provide adequate preferred alternatives in the treatment of pain or neuropathy. Upon review, most of these medications are listed as non-preferred but they are significant in the treatment of workers' compensation injuries. A primary goal in developing the formulary is to reduce administrative burden and cost, however the proposed formulary will likely drive up the number of prospective utilization review requests immediately upon implementation.

Allowing a special fill of a seven day supply of non-preferred medications could have an adverse effect on the overall health of the injured worker. Starting a therapy and suddenly stopping that therapy if not approved through utilization review is not appropriate with some medications. Having to wait for a pain medication to go through the utilization review process could also delay any improvement in function and subsequently the return to work.

Physician dispensing should be disallowed in its entirety and pharmaceutical care directed back into the pharmacy, this includes any special fills.

For these and many other reasons, implementation of this formulary would compromise patient care, prolong disability, and ultimately drive up overall claim costs. California pharmaceutical issues in regards to cost, utilization review, opioid utilization, high number of IMR's, and extended disability time frames due to pharmaceuticals did not occur overnight, so the intended solution should also not occur overnight.

Gray, Maureen@DIR

From: Peak, Paul <Paul.Peak@sedgwickcms.com>
Sent: Thursday, March 30, 2017 12:07 PM
To: DIR DWCRules
Cc: Hargreaves, Mary
Subject: NDC Info Formulary

Follow Up Flag: Follow up
Flag Status: Flagged

Hi,

In relation to the proposed WC Formulary, is there a list that contains the NDC codes attached to these drugs or even perhaps GPI codes? Thanks in advance.

Paul Peak | AVP Clinical Pharmacy
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May 1, 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: 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

Gray, Maureen@DIR

From: Rob Ward <rob.ward@cidmcorp.com>
Sent: Friday, April 28, 2017 10:03 AM
To: DIR DWCRules
Subject: Comments on proposed drug formulary regulations

The crafting of formulary regulations is a complex and daunting task, and those who have contributed to the proposed regulations have done well with the challenges.

However, there are still some areas of the proposal that call out for improvements. There remains significant potential for unintended consequences, and some relatively minor changes could result in significant enhancements in the regulations.

Potential unintended consequence: Requirement for employer/insurer to conduct 2 reviews to issue denial based on medical necessity

The most recent version of the proposed 8CCR9792.27.1 - 9792.27.21 creates a potential unintended consequence of requiring the employer to conduct UR twice in order to dispute the medical necessity of some medications. This occurs in instances where the formulary regulations state that the provider may dispense medication without prior authorization, and that the employer may dispute the necessity of the medication on retrospective review. In some instances, it is implied that denial is only permitted on retrospective review; and in others this is explicit.

In circumstances where the formulary states that the dispensing provider need not obtain prior authorization, the dispensing provider may still elect to seek such authorization. In each instance where the dispensing provider elects to seek prior authorization via DWC Form RFA, LC4610 and 8CCR9792.9.1 require that the claims administrator respond to the request within 5 business days. Any dispute of medical necessity would require utilization review.

In the event that a denial of authorization for medication is issued through the utilization review process, the denial would appear to have no standing under the formulary regulations, and yet could still be challenged via the IMR process.

Should the treating physician elect to proceed in spite of the prospective denial through UR, under the formulary regulations, the denied medication would still effectively be authorized unless and until the claims administrator obtained a UR denial retrospectively.

This potential requirement to conduct 2 cycles of UR (and potentially 2 IMRs) to dispute the medical necessity of a medication occurs in each of the following sections of the proposed regulations:

9792.27.5(b) appears to exempt from prospective UR any off-label use of a Preferred drug if such use is supported by the MTUS.

9792.27.6(b): "If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary."

9792.27.8(a): "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."

9792.27.10(c): " The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary."

9792.27.10(e): "If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary."

9792.27.11(d): " A drug dispensed under the “Special Fill” policy may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary."

9792.27.12(c): " A drug dispensed under the “Perioperative Fill” policy may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary."

Even though it is highly doubtful that the DWC intends that there be a requirement for 2 cycles of review in these instances, it is likely that judicial interpretation of the proposed regulatory language would result in a finding that failure to provide a mandated timely response to a prospective request would permit the judge to take control of medical decision making; and that only retrospective denial has standing.

Regulatory language of undeterminable intent

Subsection 9792.27.3(b) should be substantively revised. In its current form, it is immune to sensible interpretation and cannot be operationalized.

The provider is to transition the patient from previously approved medications that are not Preferred; but no time frame for this process or this exemption from standard application of the MTUS is given. A provider could simply elect to ignore the need to transition, and to provide medication exempt from necessity determinations for the remainder of the injured worker's life.

The claims administrator is prohibited from a "unilateral" denial of such medication, possibly exempting such medication from denial for the injured worker's life span. However, there is no indication as to what party or parties, or process, would constitute an acceptable collective decision for permissible denial.

The final sentence of this subsection effectively contradicts the all of the language in 9792.27.3(b) that precedes it, by making all of the medication use discussed in 9792.27.3 subject to standard UR procedures.

It is recommended that two changes to the language of this subsection be considered:

1) "For injuries occurring prior to July 1, 2017" should be amended to "For drugs in use prior to July 1, 2017". It is not the date of injury that requires a transition to the formulary, but the ongoing treatment when the formulary goes into effect. Using the date of injury permits providers to begin treatment with Non-preferred or unlisted drugs after 7/1/2017, and to apply the exemptions in this subsection.

2) The DWC should determine, in conjunction with its medical experts, a reasonable upper limit for the time period during which such transition should have been completed; and to set that as an expiration date for any exemption in this subsection.

Inconsistency with Labor Code 4610(e)

Subsection 9792.27.9(a) may be inconsistent with the statutory requirements of Labor Code 4610(e).

The subsection includes: "If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied."

However, LC4610(e) states, " A person other than a licensed physician who is competent to evaluate the specific clinical issues involved in the medical treatment services, if these services are within the scope of the physician's practice, requested by the physician, shall not modify or deny requests for authorization of medical treatment for reasons of medical necessity to cure and relieve."

Given that the formulary regulations are a component of the MTUS (e.g., the standard for determining medical necessity), any denial consistent with a component of the MTUS is a denial based on medical necessity.

Consequently, the apparent intent of 9792.27.9(a) [denial without UR based on procedural criteria] would appear to be a violation of LC4610(e).

Drug list confusing and difficult to utilize

The current drug list is formatted to indicate whether the listed drugs are Preferred or Non-Preferred based body parts or regions, corresponding to the treatment guidelines adopted into the MTUS.

Because an individual drug may Preferred and/or Non-preferred and/or unlisted for different conditions within a guideline based on body parts, it is very difficult for a user of the formulary to be able to determine whether any specific drug is Preferred; Non-preferred; or unlisted for a treatment plan that is under consideration.

If the DWC intends to institute a formulary where a drug may be Preferred, or Non-preferred, or unlisted; depending on the specific case for which it is to be dispensed; then it is recommended that the listing indicate at minimum for which conditions each medication is Preferred or Non-preferred.

It should also be indicated that this approach creates the potential for meaningful disputes over how a specific drug should be classified for a specific case, and the proposed regulations offer no suggestion as to who, or by what mechanism, such disputes are to be settled. One anticipates that in the absence of an established dispute mechanism for this situation, such dispute resolution will require the involvement of the WCAB.

Alternatively, the DWC may wish to consider a drug list that simply indicates whether a drug is Preferred or Non-preferred, without any case-specific variance from that status. While this is less "clinically robust" than the current proposal, it is definitely more pragmatic.

It is respectfully suggested that the DWC consider taking this alternative approach, and that it classify as "Preferred" medications that have a favorable cost/risk/benefit profile for most patients (e.g., not excessively costly; unlikely to cause significant patient harm if used inappropriately; likely to be beneficial for a significant proportion of injured workers).

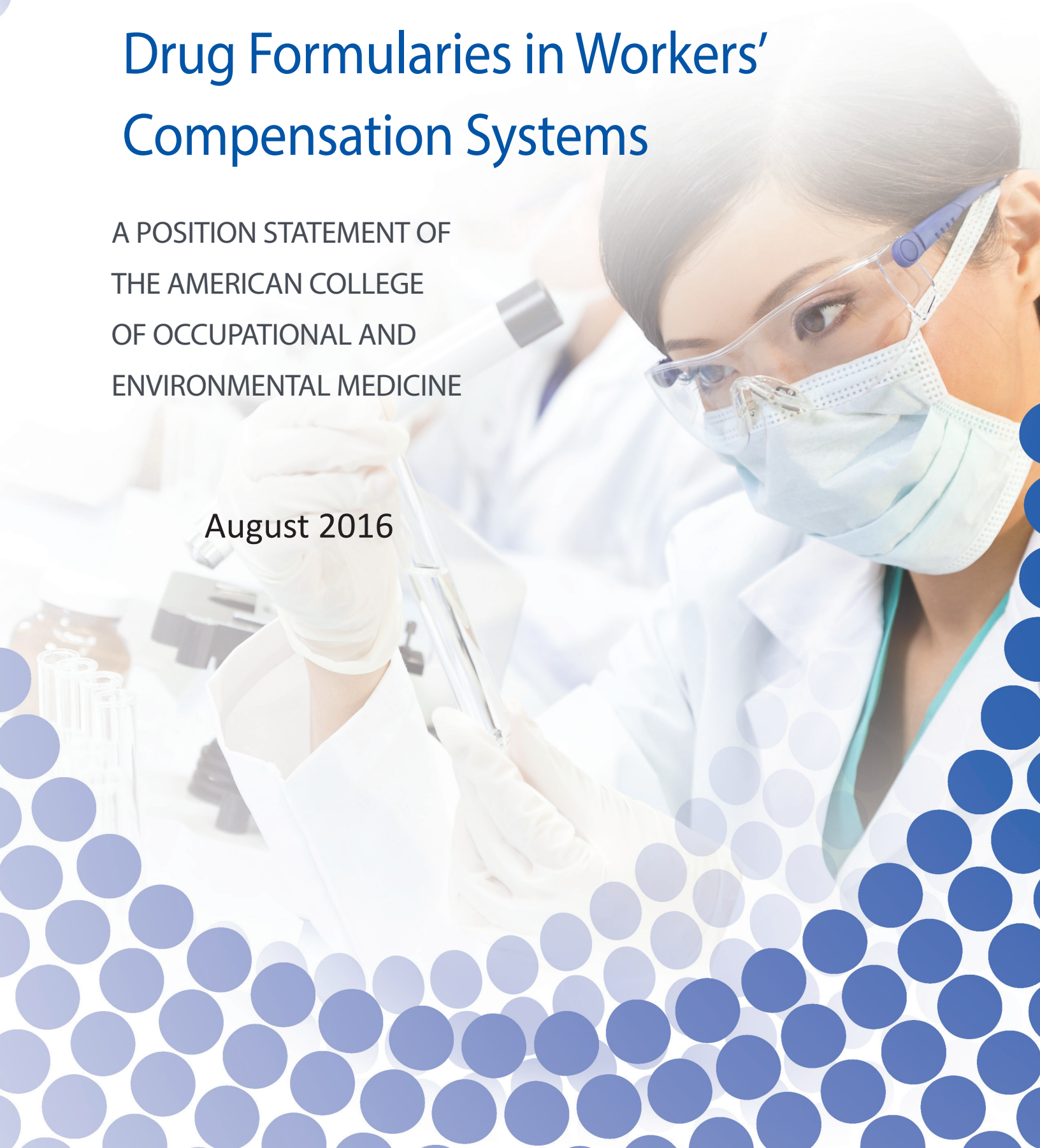
Thank you for the opportunity to comment on the evolving formulary regulations.

--
Robert Ward
Clinical Director
CID Management
"Email has no inflection."

American College of Occupational and Environmental Medicine

Drug Formularies in Workers' Compensation Systems

A POSITION STATEMENT OF THE AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE



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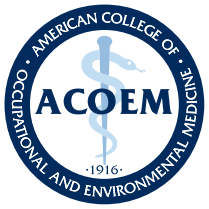

American College of Occupational and Environmental Medicine

ABOUT ACOEM

Founded in 1916, the American College of Occupational and Environmental Medicine (ACOEM) is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. The College represents more than 4,500 physicians and other health care professionals specializing in the field of occupational and environmental medicine (OEM).

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Drug Formularies in Workers' Compensation Systems

A Position Statement from the American College of Occupational and Environmental Medicine

EXECUTIVE SUMMARY AND RECOMMENDATIONS

As a number of states consider establishing workers' compensation formularies, the American College of Occupational and Environmental Medicine (ACOEM) has reviewed how formulary use might affect medical quality and cost in the care of injured workers. ACOEM recognizes that the use of drug formularies has produced significantly lower direct costs for drugs in workers' compensation cases, but also recognizes that if the details of a formulary system are not well managed, formulary use may delay care for some patients and increase administrative costs. Furthermore, ACOEM recognizes that a well-organized formulary system, founded on the principles of evidence-based medicine, can be expected to drive improvements in medical quality.

Workers' Compensation Formularies – Benefits vs Risks*

BENEFITS – proven or likely	ADVERSE CONSEQUENCES – potential
Lower total drug costs	Patients LESS compliant with treatment
Decreased opioid use	Medical decision may not be patient-focused
Diminished use of compounded topical medications	Increased burden for providers
Lower utilization review (UR) costs	Increased UR or other administrative costs

**See text for detailed discussion and references.*

At present, there are two commercially available workers' compensation formularies—the Reed Group formulary based on the ACOEM *Practice Guidelines*,[1] and the ODG® formulary published by Work Loss Data Institute. In addition, five states have adopted their own state-specific formulary systems. This document reviews the key features of formularies and discusses how the use of formularies in general might interact with existing utilization review (UR) processes. State legislators and other policy makers in state labor agencies, in deciding on the details of a workers' compensation drug formulary in their jurisdictions, should consider the following policy issues:

1) *Formulary's Evidence Base:*

ACOEM recommends that a formulary be based on well-documented evidence-based methodology (EBM). Two workers' compensation formularies in current use do so—the Reed Group formulary based on the ACOEM *Practice Guidelines*,[1] and the Washington State formulary based on the Drug Effectiveness Review Project (DERP).[2]

2) *Formulary's Format—Condition-Based:*

ACOEM sees great merit in a condition-based formulary such as the Reed Group's. However, ACOEM cautions that diagnostic categories should not be made so specific as to trigger UR disputes over the details of an ICD-9 or ICD-10 diagnostic code.

3) *Formulary Oversight—Pharmacy and Therapeutics Committee:*

Whether a state chooses to adopt a commercial workers' compensation formulary or craft one that is state-specific, ACOEM recommends that a pharmacy and therapeutics (P&T) Committee, with occupational medicine physicians among its leaders, oversee the formulary's content. The P&T Committee should be charged

with: 1) providing guidance prior to implementation; 2) updating formulary entries at regular intervals, perhaps as often as quarterly; and 3) establishing a set of decision-making criteria for its own use. The P&T's decisions should be public and transparent.

4) Formulary Implementation and Application:

ACOEM recommends that formulary regulations be crafted to be consistent with existing UR processes and treatment guidelines. Such formulary regulations should seek to minimize delays in filling prescriptions, particularly for "early fills" or for "critical" medications. When a formulary system is first established, provision must be made for initial ramp-up, particularly for "legacy claims" where patients may already have been using non-formulary medications. In adddition, formulary entries should be readily accessible to the public.

ACOEM further recommends that state workers' compensation fee schedules should be revised if necessary, in order to reimburse providers for performing additional time-consuming tasks associated with documenting medical necessity, complying with step-care provisions, and communicating with pharmacy benefit managers (PBMs) and UR agents.

5) Procedures for Authorization and UR Appeals:

ACOEM recommends that states establishing a workers' compensation formulary also institute a means by which providers can request authorization for non-formulary medications based on medical necessity. Providers recommending such treatments should be encouraged to propose disciplined and rational clinical trials of certain non-formulary medications, using a hierarchy of medical evidence, when standard treatments have failed or are inappropriate. Additionally, states must implement a robust UR appeals process, allowing providers an additional opportunity to justify medical necessity when disputes with PBMs or UR agents arise.

6) Measuring the Formulary's Value:

ACOEM recommends that state laws and regulations establishing a workers' compensation formulary also include provisions to monitor the formulary's value. Over time, states should examine their carrier-reported claims and medical payment data in order to measure drug costs, overall drug utilization, rate of provider use of formulary-approved drugs, and the administrative costs of UR, as well as selected outcome quality metrics such as total claim cost, disability duration, patient satisfaction and compliance, and the rate of adverse effects resulting from treatment delays.

INTRODUCTION

Drug formularies, widespread in the private group health market for decades,[3] and now embedded in Medicare since the passage of Medicare Part D,[4] have only recently been adopted in certain state workers' compensation systems. In 2006, North Dakota became the first state to adopt a workers' compensation formulary, conceived as an open formulary with certain restrictions as described below. In 2011, Texas became the first state to adopt a closed formulary for its workers' compensation system.[5] Since then, eight other states (Arkansas, Delaware, Nevada, Ohio, Oklahoma, Tennessee, Washington, and Wyoming) have adopted or are in the process of adopting workers' compensation formularies. Several other states are currently considering doing so, based in part on studies demonstrating that formularies can dramatically decrease the direct cost of medications, the costs of utilization review (UR), and the inappropriate use of certain medications including opioids, non-generics, and compounded topical medications.[6]

Other studies have demonstrated that non-formulary drugs account for a disproportionate share—as much as 40%—of total drug costs, while comprising a relatively small proportion of total prescriptions.[7] However, at least one state (Colorado) has recently chosen explicitly not to adopt a workers' compensation formulary, but instead to rely on other UR processes to curtail inappropriate prescribing in workers' compensation cases.[8]

Because setting up a formulary involves multiple policy choices affecting quality, cost, and administrative complexity, the American College of Occupational and Environmental Medicine (ACOEM) has undertaken to summarize some of the clinical and policy issues which state legislative and regulatory bodies should consider if they choose to adopt a workers' compensation formulary in their jurisdictions. In a number of areas described below, ACOEM has crafted specific policy recommendations about workers' compensation formularies.

A. Drug Formularies—Typical Characteristics

SUMMARY STATEMENT: Approaches and coverage for existing workers' compensation formularies vary and the strengths and weaknesses among these approaches must be weighed to avoid gaps in coverage and to prevent prescribing restrictions from lowering patient compliance.

Drug formularies are typically constructed as lists of medications grouped according to some classification scheme, such as the classification system published by the American Hospital Formulary Service (AHFS), and used by the Centers for Medicare and Medicaid Services (CMS).[9] Formularies are sometimes classified as "open" (a simple and non-exclusive listing of drugs covered under the drug plan, frequently with various levels of cost-sharing by the patient), or "closed" (only listed drugs are covered), although considerable overlap exists.

Medicare has established drug coverage rules for pharmacy plans and formularies that can be authorized under Part-D (drug benefits), labeling certain classes of drugs as "protected classes." More specifically, CMS regards certain classes of drugs on a Medicare formulary as "protected" if those drugs meet criteria for "criticality" (the risk that a delay in filling the prescription will lead to hospitalization, death, or significant morbidity) or "non-interchangeability." A drug is said to be "non-interchangeable" if no other available drug can reasonably be substituted for it, as is the case with certain anti-viral or chemotherapeutic agents.[10] Drugs in these protected classes must be covered by Medicare Part-D plans, with a guarantee of a prompt fill without a lengthy pre-authorization process.

CMS permits Medicare drug coverage plans to attach restrictions to medications on Medicare formularies, including requirements related to prior authorization, quantity limits, and step therapy.[11] A requirement for "prior authorization" means that the patient and/or the provider must contact a pharmacy benefit manager (PBM) to demonstrate that the prescribed drug is medically necessary. "Step therapy" or the use of "preferred drug lists" (used, for example, in the workers' compensation systems of Delaware, North Dakota, and Washington) may involve a requirement that the patient must try one or more similar lower-cost drugs before the drug plan will cover the more expensive drug.

However, a recent literature review found that while such restrictions on prescribing led to significant cost reductions, it also resulted in lower patient compliance rates.[12] More research is needed on how formulary policies may impact the balance among cost, promotion of high-quality prescribing, and patient adherence to recommended treatment, in order to establish the overall value of formularies for out-patient medical care.

A comparison of seven available workers' compensation formularies—those published by Work Loss Data Institute (ODG Formulary)[13] and the Reed Group,[14] and state-specific formularies in Washington,[15] North Dakota,[16] Ohio,[17] Delaware,[18] and Wyoming,[19] illustrates some of the policy options involved in adopting a formulary for use in workers' compensation systems. Characteristics of these formularies are summarized in Appendix A.

The ODG Formulary includes drugs in 25 different categories,[13] and lists each as "Yes" (recommended) or "No" (not recommended), based on clinical guidance contained in the *ODG Guidelines*. Certain drugs include a notation about conditions for which the drug is not indicated, notably the treatment of pain or insomnia. Otherwise, the ODG formulary is silent about the specific diagnoses or conditions for which the listed drugs might be prescribed and approved.

By contrast, the Reed Group formulary is condition-based,[14] listing diagnoses or types of work-related injuries or illnesses grouped into 11 categories (eight categories of musculoskeletal problems, plus chronic pain, eye conditions, and work-related asthma). The formulary then lists those medications for which the ACOEM *Practice Guidelines* have compiled evidence of efficacy in these diagnostic categories, and labels each drug as "Yes" (recommended), "No" (not recommended), or "No Recommendation." The Reed Group formulary provides further clinical information about a drug's indications for use, and the strength of the available medical evidence for the recommendations. The formulary also includes drugs used to treat common medication side effects, such as dyspepsia caused by non-steroidal anti-inflammatory drugs (NSAIDs).

It should be noted that both the ODG and Reed Group formularies are silent about many drugs commonly used for other work-related conditions such as occupational dermatoses, dyspepsia complicating medication use, soft tissue infections, or occupational exposure to infectious agents requiring antibiotic prophylaxis. The Reed Group formulary is silent on many antibiotics and psychiatric drugs. The ODG formulary is silent about H-2 blockers.

Washington State has adopted a customized formulary based on the Drug Effectiveness Review Project (DERP),[2] with a "preferred drug list," a limited number of drug categories, and an emphasis on generic prescriptions in most categories. In the Washington formulary, each listed drug is categorized as "A" (approved), "PA" (prior authorization required), or "D" (denied).[20]

North Dakota's workers' compensation formulary lists drugs in almost all of the AHFS categories. Certain drugs are listed as "non-formulary"; others are designated as "PA" (prior authorization required). The formulary further specifies maximum daily doses for certain medications.[16] Formulary decisions are made by a pharmacy and therapeutics (P&T) committee, based on consensus.[21]

In 2011, the Ohio Bureau of Workers' Compensation adopted a proprietary formulary, listing drugs in many of the AHFS categories. In addition, the Ohio formulary includes a separate list of drugs which may be approved, but which require prior authorization using a written process mandated by the Bureau. The Ohio workers' compensation formulary was last updated in 2014.[17]

In 2012, Delaware adopted a fairly simple formulary based on drugs covered under the Delaware Medical Assistance Program, administered under its Medicaid Program, covering a limited number of analgesics and eye drugs, and categorizing them as "preferred" or "non-preferred." Non-preferred drugs may be prescribed only after at least two preferred drugs have previously been tried.[18]

Wyoming subjects all workers' compensation prescriptions to pre-authorization and in 2014 passed specific rules for documenting medical necessity for the prescription of non-generic drugs, or drugs prescribed for off-label indications.[19] In addition, authorization is to be denied for compounded topical medications. To guide UR decisions, Wyoming has published an extensive list of drugs, categorized according to the Generic Product Identifier (GPI) scheme,[22] and has identified each drug as either "included" or "excluded."[23] Certain drugs are generally to be approved during the first 42 days after a work injury. Thereafter, many drugs are to be excluded, and their continued use must be justified by a provider's discussion of medical necessity.

B. Formularies and Evidence-Based Medicine

SUMMARY STATEMENT: Formulary inclusion and exclusion decisions should follow principles of evidence-based medicine (EBM) where evidence exists. Utilization review decisions about prescription authorization should be subject to a robust appeals process, particularly where medical evidence may be lacking or where clinical practice is emerging.

A decision to include, exclude, or otherwise restrict certain medications in a formulary should optimally follow principles of evidence-based medicine (EBM), including a ranking of the strength of medical evidence about a drug's efficacy and safety.[24] ACOEM's EBM methodology,[25] which underlies the Reed Group formulary, begins with the systematic identification of high-quality research studies. Studies are then graded, taking into account the study design and results, and the highest quality studies are reviewed in detail. The evidence-based methodology used by DERP underlies the Washington state workers' compensation formulary.[26]

Decision-making by UR agents or PBMs must necessarily follow a more flexible approach in applying formulary rules to specific clinical situations. An important clinical principle is that individual variability in the responses to various medications, notwithstanding strong evidence that on average one medication may be superior to another, argues that UR and PBM agents, while still adhering to established hierarchies of evidence,[27] should be cautious in restricting the choice of medications for individual patients where the evidence may be equivocal.

C. Pharmacy and Therapeutics (P&T) Committees

SUMMARY STATEMENT: The establishment of a pharmacy and therapeutics (P&T) committee is recommended to provide guidance prior to formulary implementation and to oversee the content and operations of a workers' compensation formulary in a way that is public and transparent.

It is common practice that hospitals, health plans, or other entities establishing a drug formulary for the group health market will also establish a body of experts, often called the Pharmacy and Therapeutics (P&T) Committee, to oversee the clinical management of the formulary. The P&T Committee will make decisions about including or excluding medications, restricting their use to certain diagnoses, and specifying other conditions for UR approval based on such considerations as clinical urgency or non-interchangeability.[28] The P&T Committee will typically establish a set of guidelines for its own decision-making.[29] ACOEM recommends that a P&T Committee also oversee the content of workers' compensation formularies.

ACOEM further recommends that a workers' compensation P&T Committee include among its leaders one or more occupational medicine physicians, or other physicians with expertise in disability management and other areas of occupational medicine practice, while also including medical, nursing, and pharmacy professionals with expertise in clinical pharmacology, orthopedics, pain management, physical medicine, neurology, psychiatry, ophthalmology, medical ethics, health economics, and/or other relevant specialties. Furthermore, ACOEM recommends that all decisions of the P&T Committee be public and transparent.

The P&T Committee will provide guidance prior to formulary implementation and also reasonably oversee periodic modifications of the formulary, typically done at intervals ranging from monthly to annually. Formularies will need to be updated as new drugs are released or as new information becomes available about drug safety, drug indications, medication side effects, drug-drug interactions, and cost-effectiveness. Policy makers should further specify additional triggers for action by the P&T Committee that might include changes in the manufacturer's guidance for specific drugs, the inclusion of "black-box" or other warnings from the U.S. Food and Drug Administration, and/or petitions from practitioners in the jurisdiction.

D. Learning Lessons from Texas and Other States

SUMMARY STATEMENT: Lessons can be learned from formulary implementation in other states, including the advisability of notifying stakeholders in advance about formulary requirements.

A number of states, including Texas, Nevada, and Washington experienced dramatic cost savings after implementing formularies for their state workers' compensation systems.[30] Other states might be expected to experience similar savings.[31]

In setting up its workers' compensation formulary, Texas provided for a 2-year ramp-up interval which featured an administrative dispute-resolution process and the use of petitions by the patient or provider. These administrative processes proved to be particularly important for injured workers already under care who had been prescribed non-formulary medications. An important lesson was that for "legacy claims" injured workers, treating providers, and insurance carriers benefited from being notified about formulary requirements well in advance of the start date, with the goal of avoiding abrupt termination of non-formulary medications and resolving disputes administratively.

Texas also discovered that most change-overs from non-formulary to formulary-approved medications occurred late in the 2-year ramp-up window, suggesting that a shorter ramp-up period, perhaps 6 to 12 months, would be sufficiently long to enable legacy prescriptions to be switched to formulary-approved medications where appropriate.

Tennessee recently adopted the ODG formulary for workers' compensation prescriptions, and allowed an 8-month ramp-up for prescriptions first written after January 1, 2016, and a 14-month ramp-up for prescriptions first written before January 1, 2016.[32]

E. Workers' Compensation Formularies and the UR Process

SUMMARY STATEMENT: Processes for prescription approval using a workers' compensation formulary should be harmonized with existing utilization review processes. These processes should be fair and robust in allowing for "step care" and for disciplined clinical trials involving certain non-formulary medications when standard treatments have failed or are contra-indicated. Pre-authorization requirements and restrictions on the use of non-designated pharmacies should not delay the filling of certain prescriptions.

Successful implementation of a workers' compensation formulary will require integration with a jurisdiction's existing medical treatment guidelines, if any, and UR processes. Among the state workers' compensation programs, 15 have adopted state-specific clinical guidelines. Five states (California, Montana, Nevada, New York, and Utah) have adopted ACOEM's *Practice Guidelines* in whole or in part, while eight states have adopted the *ODG Guidelines*, which rely more heavily on consensus decision-making than do the ACOEM *Practice Guidelines*.[33]

Two states (California and Utah) have adopted a hybrid of the ACOEM, ODG, and other guidelines, which differ in some details and in their use of EBM methodologies. At this time, nearly half of the states have not adopted formal treatment guidelines.[34,35]

Where a workers' compensation formulary exists, UR agents or PBMs will use the formulary to decide whether to authorize payment for prescriptions in a workers' compensation claim. Accordingly, policy makers must determine at what point the approval of prescriptions should happen. For example, approval could occur when a dispensing pharmacist, presented with a workers' compensation prescription, contacts a PBM or other claims agent to request a guarantee of payment for the dispensed medication. Alternatively, for non-formulary medications, the medical provider might be required to send the claims administrator a "request for authorization" form at the time the prescription is written. Patients might then be instructed to wait for a designated pharmacy or PBM to notify them that an authorization decision has been reached and, if affirmative, that the medication can be picked up at a designated pharmacy or delivered to the patient. In either case, the authorization process can delay the filling of a prescription by hours or even days.

Little research has been done on the consequences of delayed prescription fills and whether such delays might contribute to delayed recovery or other adverse outcomes with costs potentially exceeding drug-cost savings. Aware of this problem, especially early in the course of care, a number of carriers and state jurisdictions have instituted specific policies for "first fill" or "early fill" prescriptions, guaranteeing payment to pharmacies filling prescriptions for "approved" medications within the first day, and sometimes up to the first month after filing a new workers' compensation claim.[36] For example, in North Dakota, a pharmacy may fill one set of prescriptions for formulary-approved drugs, provided that the provider has indicated on the prescriptions a date of injury within the past 30 days.[37]

ACOEM also recognizes that principles of patient-centered care should guide policy makers as they craft rules for how quickly workers' compensation prescriptions must be filled in order to assure prompt, courteous, and appropriate treatment of work-related injuries and illnesses. ACOEM further recognizes that the formularies used in Delaware, North Dakota, and Washington, which as previously noted include an extra drug categorization ("preferred drug" or "authorization required") may provide additional guidance for providers, carriers, and PBMs.

Of additional importance, some drugs are recognized to have "off label" efficacy before formal research or evidence-based reviews have validated such use. In cases where formulary-approved drugs or other standard treatments have failed or are contraindicated, alternative approaches should sometimes be tried. Clinicians should not be discouraged from undertaking such individual clinical trials, provided they articulate a rationale for their decisions based on external evidence and conduct the trial in a disciplined way. Accordingly, states implementing a workers' compensation formulary should also assure an accompanying fair and robust appeals process permitting occasional well-reasoned deviations from formulary rules.

ACOEM believes that a UR decision to modify or deny an injured worker's prescription must be communicated by the carrier in writing to the prescribing doctor and injured worker in a clear and prompt manner. In such cases, formulary and UR regulations should assure close communication between PBMs and clinicians. Following discussions with the PBM resulting in non-approval of previously prescribed drugs, the prescribing doctor must also discuss any planned modifications with the injured worker. There must be an adequate time period authorized to assess the clinical effectiveness and lack of adverse effects from these modifications.

Finally, as for all UR systems, where a medication dispute persists despite the above steps, UR processes should include an administrative solution to review the clinical facts and medical necessity of continuing non-formulary medications, or formulary medications for non-formulary indications, and should set the frequency of periodic reevaluations of the need for chronic medications.

Since these additional steps can be time consuming for clinicians, policies for the implementation of a formulary should aim to pay providers for the extra time required for documenting medical necessity, following step-care procedures, and communicating with PBMs and UR agents. Payment to providers may require the establishment of new workers' compensation billing codes in some jurisdictions. As an example, the Arizona Industrial Commission recently approved two new billings codes aimed at reimbursing clinicians $75 to $100 for the time required to discuss medical necessity issues with UR agents.[38]

F. Additional Quality Metrics

SUMMARY STATEMENT: ACOEM recommends that states measure a range of quality metrics as part of implementing a workers' compensation formulary in order to establish the formulary's true value.

As noted above, states that have established workers' compensation formularies have seen markedly reduced direct drug costs, related in significant part to reductions in the prescribing of opioids, compounded topical medications, and non-generics.[30] However, these cost savings, while significant, capture only part of the potential gains and losses from the adoption of a formulary system. In many cases, the benefits may also be clinical, resulting from encouraging providers to follow evidence-based guidelines and to substitute more effective drugs for less effective ones.

However, on the "loss" side there may be significant additional administrative and process-induced costs not captured by a simple tabulation of direct drug costs. As previously noted, in group health care settings certain UR practices to limit the use of expensive drugs have been shown to worsen medication compliance with treatment recommendations.[12] Furthermore, administrative efforts to align prescriptions arising in "legacy claims" with a newly established formulary can involve considerable time and effort both for claims administrators and for clinicians.

In order to establish the value of a formulary system, ACOEM recommends that states include specific provisions to measure a broad range of outcome variables in order to assess the impact, efficacy, and cost of formulary adoption, including total claim cost, rates of delayed return-to-work or delayed claim closure, the costs of UR itself, and patient and provider satisfaction. Additionally, the work of the P&T Committee can itself be time consuming and costly, with a risk of poor medical practice if the P&T Committee should fail to update the formulary in a timely manner.

In summary, failing to measure important outcome variables, in addition to direct drug costs—a limited metric—may bias the assessment of the formulary's value. Since workers' compensation systems already tend to suffer from a burden of complex rules and adversarial interactions, policy makers should strive to assure that the formulary processes are both "patient-centric" and "provider-friendly." Along these lines, states might choose to measure the frequency of delays in filling prescriptions and the frequency of administrative errors by providers or PBMs in the process of filling prescriptions. Additionally, states may wish to explore the possibility of assisting medical providers by linking formulary entries with decision-support routines in commonly used electronic health records.

G. Clinical Case Studies: Prompt Fill Challenges

SUMMARY STATEMENT: Delays in filling a workers' compensation prescription can harm the patient.

There are many clinical circumstances in which a workers' compensation prescription should be filled promptly and not delayed by UR. Where a workers' compensation formulary is in place, such delays might occur because the formulary is silent about the drug or because the drug is categorized as "non-preferred" or "pre-authorization required."

The following vignettes illustrate cases that may arise from time to time and present challenges for PBMs and claims administrators in assuring that authorization procedures will not delay the rapid filling of certain prescriptions.

1) *Bloodborne pathogen exposure:*
An employee who has suffered a work-related needle-stick injury from a known HIV-positive source must be started on an appropriate and potentially expensive anti-retroviral drug within hours of the work exposure. Such treatment, whether covered under workers' compensation or under Occupational Safety and Health Administration mandated care paid for directly by the employer, must be managed quickly by PBMs or other UR agents. No current workers' compensation formularies include or categorize anti-retrovirals except Ohio's and Wyoming's, with the Wyoming formulary "excluding" anti-retrovirals.[17,23]

2) *Soft-tissue infection complicating a work-related wound:*
An employee who develops a serious infection some days after an initial work-related laceration or puncture wound can often be managed as an outpatient, but he or she will need to be started promptly on systemic antibiotics. Some current formularies are silent about many second- or third-generation antibiotics, which might be required in patients with co-morbidities such as diabetes or other immuno-suppressed states.

3) *Acute gout complicating a soft-tissue sprain/strain:*
Gout-prone workers who suffer lower extremity sprain and strains will occasionally develop an acute flare of gout near the affected joint. A delay in starting colchicine or other medications for gout can prolong total temporary disability and result in needless suffering in such patients. Of the seven formularies mentioned above, four are silent regarding colchicine (ODG, Delaware, Ohio, and Washington).

4) *Severe hypertension complicating a workplace violence episode:*
An employee with an accepted claim for workplace stress (e.g., following an episode of workplace violence) may be found to be dangerously hypertensive soon after the work-related assault. A rapid-acting anti-hypertensive medication may need to be started promptly in the outpatient setting. A few of the previously mentioned formularies include and categorize anti-hypertensive medications, but others do not.

5) *Nausea and vomiting complicating heat exhaustion:*
A worker who suffers a mild-to-moderate case of heat exhaustion complicated by modest dehydration can often be orally rehydrated as an outpatient, provided the patient's nausea can be quickly controlled. Most formularies are silent about drugs commonly used for nausea, such as ondansetron or trimethobenzamide, which if started promptly can forestall more expensive care such as IV treatment or hospital referral.

6) *Asthma exacerbation at work:*
An employee whose asthma suffers an exacerbation resulting from a work-related exposure to an air-borne irritant may have to be started promptly on bronchodilators and high-dose oral corticosteroids. A few of the previously mentioned formularies are silent about either or both of these treatments.

7) *Deep vein thrombosis:*
An employee with a severe soft tissue contusion or crush injury to the lower extremity may occasionally develop a deep vein thrombosis, requiring immediate hospital treatment for anticoagulation over a few days, followed by a discharge prescription for an oral anticoagulant for several weeks. The discharge prescription must be filled promptly to avoid a gap in anticoagulation. The only formularies mentioning anti-coagulants are those from North Dakota, Ohio, and Wyoming, while the Reed Group formulary includes anti-coagulants when prescribed in the peri-operative period.

H. Summary of ACOEM Recommendations:

ACOEM believes that if a workers' compensation formulary is to be established, a condition-triggered evidence-based formulary is the preferred approach. As previously discussed, policy makers must also establish other administrative processes related to UR, dispute resolution during ramp-up, assurance of non-delayed prescription fills in urgent clinical situations, robust oversight involving a P&T Committee, and careful measurement of outcome variables to assure the overall value of the formulary. To that end, ACOEM believes that state legislators and other policy makers should consider the following questions if they choose to implement a workers' compensation formulary in their jurisdiction, and recommends specific solutions.

1) *What level of evidence should underlie a state's workers' compensation formulary?*
ACOEM recommends that the formulary be based on well-documented evidence-based methods such as those embodied in the ACOEM *Practice Guidelines* and the Reed Group formulary, or in the Washington State workers' compensation formulary.

2) *What type of organizational format should the formulary follow?*
ACOEM sees great merit in a condition-based formulary such as the Reed Group formulary. However, ACOEM cautions that diagnostic categories not be made so specific as to give rise to UR disputes over the details of an ICD-9 or ICD-10 diagnostic code.

3) *How should ongoing quality oversight of formulary content be assured?*
ACOEM recommends that a P&T Committee, with occupational medicine physicians among its leaders, provide guidance prior to formulary implementation and oversee formulary content. The P&T Commit-

tee should then be charged with updating the formulary entries at regular intervals, perhaps as often as quarterly, and establishing a set of decision-making criteria for its own use. All decisions of the P&T Committee should be public and transparent and formulary entries should be readily accessible to the public.

4) *How should the use of the formulary be integrated with existing UR processes?*
ACOEM recommends that formulary regulations be crafted so as to be consistent with other UR processes, to take account of treatment guidelines in current use, and to minimize delays in filling prescriptions, particularly for "early fills" or when "critical" medications are prescribed. When a formulary system is first established, provision must be made for initial ramp-up, particularly for "legacy claims" where patients may already have been using non-formulary medications.

   ACOEM further recommends that fee schedules be properly aligned with clinical quality goals in order to incentivize providers to undertake the additional time-consuming tasks associated with documenting medical necessity, complying with step-care provisions, and communicating with PBMs and UR agents.

5) *How should appeals processes be designed related to the use of a workers' compensation formulary?*
ACOEM recommends that states establishing a workers' compensation formulary institute a robust appeals process for providers who for sound clinical reasons choose to prescribe non-formulary drugs or drugs requiring pre-authorization. Providers recommending such treatments should not be discouraged from proposing clinical rationales, based on a hierarchy of medical evidence, or from proposing disciplined and rational clinical trials of certain non-formulary medications when standard treatments have failed or are inappropriate.

6) *How should the formulary's overall value be assessed?*
ACOEM recommends that state laws and regulations establishing a workers' compensation formulary also include provisions to monitor the formulary's value. Across the time of formulary implementation, states should examine their carrier-reported claims and medical payment data in order to measure drug costs, overall drug utilization, rate of provider use of formulary-approved drugs, and the administrative costs of UR, as well as selected outcome quality metrics such as total claim cost, disability duration, patient satisfaction and compliance, and the rate of adverse effects resulting from treatment delays.

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ACOEM requires all substantive contributors to its documents to disclose any potential competing interests, which are carefully considered. ACOEM emphasizes that the judgments expressed herein represent the best available evidence at the time of publication and shall be considered the position of ACOEM and not the individual opinions of contributing authors.

APPENDIX A: FEATURES OF EXISTING WORKERS' COMPENSATION FORMULARIES

Formulary	Evidence Base	Format and Organization	Guidance on Medical Conditions?	Guidance on Pre-authorization?
ODG	*ODG Guidelines*	Detailed listing of drugs in 25 categories	None, except two exclusion types for certain drugs	Drugs are "YES" or "NO"; no additional guidance
Reed Group	ACOEM *Practice Guidelines*	Condition-triggered plus acute vs. chronic in 44 drug classes	Yes, general condition, plus ICD-9 and ICD-10 codes	Drugs are "Recommended" or "Not recommended," plus strength of evidence
Delaware	Delaware Medical Assistance Program (Medicaid)	3 drug categories, with preferred/non-preferred drugs	None	Drugs are "Preferred" or "Not preferred"; "step care" for non-preferred drugs
North Dakota	State-specific P&T consensus	AHFS listing (partial)	None	Drugs are "OK," "Non-formulary," or "Prior Authorization"
Ohio	State-specific P&T consensus	AHFS listing (partial)	None	Separate listing of drugs requiring written prior authorization
Washington	Drug Effectiveness Review Project (DERP)	19 drug categories	None	Drugs are "OK," "Non-formulary," or "Prior Authorization"
Wyoming	Unstated	64 GPI drug categories	None	Drugs are "Included" or "Excluded" with different categorization for drugs prescribed within 42 days of injury

REFERENCES

1. American College of Occupational and Environmental Medicine. ACOEM Practice Guidelines. Available at: https://www.acoem.org/PracticeGuidelines.aspx.
2. Oregon Health and Science University. Center for Evidence-based Policy: Drug Effectiveness Review Project (DERP). Background information available at: http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy- center/evidence/derp/about/index.cfm.
3. Laing R, Waring B, Gray A, Ford N, 't Hoen E. 25 years of the WHO essential medicines lists: progress and challenges. *Lancet*. 2003;361(9370):1723-9.
4. Centers for Medicare & Medicaid Services. Formulary Guidance [Web site]. Available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html. Accessed June 24, 2016.
5. Texas Division of Workers' Compensation. See https://www.tdi.state.tx.us/WC/pharmacy/index.html.
6. Swedlow A, Hayes S, David R. A report to the industry: Are Formularies a Viable Solution for Controlling Prescription Drug Utilization and Cost in California Workers' Compensation? California Workers Compensation Institute (CWCI), October 2014. Available at: www.CWCI.org/research.html.
7. North Carolina Industrial Commission. Report of the Findings and Recommendations of the North Carolina Industrial Commission Regarding the Implementation of a Drug Formulary in Workers' Compensation Claims. April 1, 2016.
8. Personal communication, Colorado Division of Workers' Compensation, May, 2016.
9. Center for Medicare and Medicaid Services. Formulary Guidance, available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html
10. Ventola CL. Biosimilars: part 2: potential concerns and challenges for P&T committees. *Pharm Therapeutics*. 2013;38(6):329-35.
11. Barlas S. Major changes for Part D drug plans scheduled for 2015: health plans and PBMs would be the chief beneficiaries. *Pharm Therapeutics*. 2014;39(3):199-202.
12. Happe LE, Clark D, Jolliday E, Young T. A systematic literature review assessing the directional impact of managed care formulary restrictions on medication adherence, clinical outcomes, economic outcomes, and health care resource utilization. *J Manag Care Pharm.* 2014;20(7):677-84.
13. WorkLoss Data Institute. Available at: http://www.worklossdata.com/drug-formulary.html.
14. ReedGroup MD Guidelines. Formulary Tool. Available at: http://www.mdguidelines.com. Accessed June 24, 2016.
15. Washington Department of Labor and Industries. 2016 Preferred Drug List. Available at: http://www.lni.wa.gov/ClaimsIns/Files/Providers/SelectedPDLforworkers.pdf
16. North Dakota Workforce Safety and Insurance. Comprehensive Preferred Drug List. 2015. Available at: https://www.usscript.com/Media/Default/docs/FORMULARY-WSI.pdf
17. Ohio Bureau of Workers Compensation: Pharmacy Benefits Program. Available at: https://www.bwc.ohio.gov/provider/services/PharmacyBenefits/.
18. Delaware Workers' Compensation Health Care Payment System. Available at: https://dowc.optum.com/docs/Pharmacy%20Formulary%202013%2009-11%20Effective.pdf.
19. Wyoming Division of Workers Compensation, Chapter 10, Sections 19 & 25. Available at: http://soswy.state.wy.us/Rules/RULES/8195.pdf.
20. Washington Department of Labor and Industries (February, 2016). Outpatient Formulary. Available at: http://www.lni.wa.gov/ClaimsIns/Files/Providers/DrugFormulary.pdf.
21. International Association of Industrial Accident Boards and Commissions: IAIABC Medical Issues Committee. A Discussion on the Use of a Formulary in Workers' Compensation. April 2016;20. Available at: http://www.iaiabc.org.
22. The Generic Products Identifier (GPI) classification system is a proprietary system developed by Medispan, a healthcare consulting firm located in Indianapolis, Indiana.
23. Wyoming Acute and Chronic Formularies. Updated March 2016. Available at: http://wyomingworkforce.org/_docs/providers/Acute-and-Chronic-Formulary.pdf.

24. Simon GE, Psaty BM, Berg-Hrachovec J, Mora M. Principles for evidence-based drug formulary policy. *J Gen Intern Med*. 2015;20(10):964-8.
25. American College of Occupational and Environmental Medicine. *Methodology for ACOEM's Occupational Medicine Practice Guidelines – 2016 Revision*. Available at: http://www.acoem.org/PracticeGuidelines.aspx. Accessed June 24, 2016.
26. McDonough MS, Jonas DE, Gartllehner G, et al. Methods for the drug effectiveness review project. *BMC Med Res Methodol*. 2012;12:140. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3532217/. Accessed June 24, 2016.
27. Guyatt GH, Haynes R, Jaeschke RZ, et al. Users' Guides to the Medical Literature: XXV. Evidence-based medicine: principles for applying the users' guides to patient care. *JAMA*. 2000;284(10):1290-1296.
28. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacy and therapeutics committee and the formulary system. *Am J Health-Syst Pharm*. 2008;65:1272-83.
29. Schiff GD, Galanter WL, Duhig J, et al. A prescription for improving drug formulary decision making. *PLoS Med*. 2012;9(5): e1001220.
30. Robinson TA. Drug Formulary: California Expects Substantial Savings But What About Cost Shifting and Provider Behavior? Lexis-Nexis Legal Newsroom, 8/20/2015, available at: http://www.lexisnexis.com/legalnewsroom/workers- compensation/b/recent-cases-news-trends-developments/archive/2015/08/20/drug-formulary-california-expects- substantial-savings-but-what-about-cost-shifting-and-provider-behavior.aspx.
31. Workers Compensation Research Institute. Impact of a Texas-like formulary in other states. WCRI Policy Paper, 2016. Available at: https://www.wcrinet.org/STUDIES/protected/exec_summaries/tx_formulary-es.html. Accessed June 24, 2016.
32. Tennessee Department of Labor and Workforce Development. https://www.tn.gov/workforce/article/wc-drug-formulary.
33. Nuckols TK, Wynn BO, Lim Y-W, et al. Evaluating Medical Treatment Guideline Sets for Injured Workers in California. Santa Monica, Calif: Rand Institute; 2005. Available at: http://www.rand.org/content/dam/rand/pubs/monographs/2005/RAND_MG400.sum.pdf. Accessed June 24, 2016.
34. International Association of Industrial Accident Boards and Commissions. State Index on Medical Treatment Guidelines. IAIABC Paper, February 2015.
35. New York Workers' Compensation Board. Medical Treatment Guidelines, 2014. Available at: http://www.wcb.ny.gov/content/main/hcpp/MedicalTreatmentGuidelines/MidandLowBackInjuryMTG2014.pdf.
36. For example, see the "First Fill" program, link - https://www.pdffiller.com/31083458-first-fill-program-benefitspdf-First-Fill-Program-Benefits--Liberty-Mutual-Group-Various-Fillable-Forms.
37. North Dakota Workforce Safety and Insurance (2015). Available at: https://www.workforcesafety.com/medical-providers/pharmacy/first-fill-program.
38. Industrial Commission of Arizona, 2016 Fee Schedule (AZ099-001 and AZ099-002). Available at http://www.ica.state.az.us/Director/FeeScheduleWorkArea_2016/2016_FS_StaffStudy_StaffRecommendations.pdf

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Western Occupational & Environmental Medical Association

A Component Society of the American College of Occupational and Environmental Medicine

April 24, 2017

George Parisotto, Administrative Director
Division of Workers' Compensation
California Dept. of Industrial Relations
1515 Clay St., 17th Floor
Oakland, CA 94612

RE: WOEMA Comment on Implementation of AB 1124 Drug Formulary

Dear Administrative Director Parisotto,

The Western Occupational and Environmental Medical Association (WOEMA) is pleased to comment on the proposed Drug Formulary regulations posted on the DWC Forum. WOEMA is a non-profit professional association representing more than 500 Occupational Medicine physicians and other health care professionals in five Western states including California, who champion workplace and environmental safety and health.

WOEMA believes that the establishment of a Workers' Compensation formulary in California has the potential to improve the quality of medical care for injured workers and to reduce pharmacy costs in a number of areas, particularly with regard to the prescribing of opioids, non-generic medications, and compounded topical medications, as has happened in other states. A carefully chosen set of "Preferred" medications and reliable guidance about their optimal use stands to benefit injured workers under medical treatment, their medical providers, and carriers. In particular, WOEMA is pleased that the chosen list of "Preferred" medications is based on the evidence-based reviews contained in the Reed Group formulary, which in turn has its foundation in the ACOEM Practice Guidelines and their evidence-based methodology.

However, WOEMA also cautions that the details of implementation are critical to ensuring that application of the formulary does not cause harm, whether through delays in filling appropriately prescribed and sometimes time-critical medications, through decreases in patient compliance, or other factors. To that end, WOEMA would draw DWC's attention to ACOEM's (American College of Occupational and Environmental Medicine) policy paper on Workers' Compensation formularies published in August, 2016, titled "Drug Formularies in Workers' Compensation Systems." WOEMA strongly supports the concerns and conclusions expressed in this ACOEM policy paper, and our comments incorporate by reference its general recommendations. The paper is available at:

http://www.acoem.org//uploadedFiles/Public_Affairs/Policies_And_Position_Statements/Guidelines/Position_Statements/DrugFormulariesinWorkersCompensationSystems.pdf

We offer the following specific comments about the proposed regulations:

1. We are concerned that designation of many medications as "Non-Preferred" may be misinterpreted by some payers as meaning "should be denied," when in fact many such drugs may be useful or even critical in some situations. The advent of the formulary should not make legitimate prescription of medications harder, and the DWC should be very clear to so state when it implements a formulary.

2. Subsections 9792.27.5, 9792.27.6, 9792.27.7, 9792.27.8, 9792.27.10, 9792.27.11 and 9792.27.12 of the proposed regulations contemplate that "retrospective review" of a prescription for a drug might find that a prescription already filled was not "medically necessary" and thus payment could be denied. For instance, it will not be a reasonable expectation that the pharmacist would know the diagnosis for which a medication is prescribed, which may determine if it is Preferred or not. In such a case, we are concerned as to how payments for the medication will be handled. If the dispensing entity is ultimately not paid despite prospective assurances, then dispensers may reasonably refuse to take part in filling any workers' compensation prescriptions, badly damaging the whole formulary enterprise. We believe that this must be avoided, and encourage the DWC to deal with this problem explicitly.

3. We believe that additional medications deserve a place on the formulary as "Preferred" in appropriate situations. In particular, those listed in ACOEM's "Drug Formularies in Workers' Compensation Systems" (August 2016), Section G, should be strongly considered for inclusion in order to protect patient health in urgent and/or non-controversial situations as described:

a) Bloodborne pathogen exposure
b) Soft-tissue infection complicating a work-related wound
c) Acute gout complicating a soft-tissue sprain/strain
d) Severe hypertension complicating a workplace violence episode
e) Nausea and vomiting complicating heat exhaustion
f) Asthma exacerbation at work
g) Deep vein thrombosis

In particular, bloodborne pathogen exposure is a relatively common problem handled under workers' compensation, where prophylactic antiviral medication must be started "as soon as practicable," and optimally within an hour or two of exposure, in order to prevent HIV infection in the exposed worker. Anti-retroviral medications present little risk of abuse, and delay in filling a prescription can be life threatening. Similar considerations apply to the prescribing of antibiotics for certain infections, including soft tissue infections following work-related lacerations and other wounds. The other scenarios on the above list also have strong arguments for their inclusion among the "Preferred" medications.

4. There will be a need for further assessment and ongoing updating of the formulary as time goes on. By the proposed implementation date of July 2017 there are likely to be significant changes in the literature already, so there should be no delay in convening the Pharmacy and Therapeutics Committee ("P&T Committee"), described in subsection Section 9792.27.1(r). In order that the panel may be convened as soon as practicable after the implementation date, we strongly recommend that the members of the P&T Committee be selected and be prepared to meet as soon as possible after the implementation date.

5. There are nine medications listed as eligible for "Special Fill," and nine listed as eligible for "Perioperative Fill" for a total of fifteen drugs eligible for one or the other category (three drugs are listed for both). In every case, those fifteen drugs are shown as not to be so prescribed for more than 4 (four) days. We would like to point out that since existing regulations require that utilization review (UR) decisions must respond to a Request for Authorization (RFA) within 5 (five) days, this leaves the fifth day uncovered for situations in which the drugs are truly necessary. We believe that the DWC should either change the maximum to five days for consistency with UR requirements, or acknowledge that in such situations an expedited review will be necessary. If a significant increase in expedited reviews are expected, preparations will be needed for an increase in such requests.

6. The only drugs listed as being eligible for “Special Fill” and “Perioperative Fill” appear to be related to musculoskeletal disorders and perioperative anticoagulation. The categories listed above under this document’s paragraph (3) should be included in Special Fill and, in the case of antibiotics, Perioperative Fill, as these may be urgently required and are not usually susceptible to abuse.

7. Very problematic is the issue of “legacy” prescriptions, or prescriptions already filled or authorized as of July 1, 2017, but which may not be “Preferred” medications. Legacy prescriptions are addressed in proposed subsection 9792.27.3. We would note that the proposed regulation would place the burden on the treating provider to identify any and all prescriptions previously written which were not “Preferred,” even if the provider had previously submitted an RFA and obtained authorization for the medications, or if they were previously covered under a Future Medical Findings and Award (“F&A”).

While we strongly support optimizing drug regimens according to evidence-based medicine concepts, in fact patients on chronic medications, including chronic pain regimens, are often difficult to manage, and reduction in morphine equivalent doses (MEDs) often requires a great deal of skill, caring, and physician time as well as risk. Efforts to initiate changes in these situations should originate with the payer, not with the treating physician. In our view, it should be up to the payer to initiate an outreach to both the provider and the patient in writing, and first to take an educational approach.
We also note that the statement, "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." seems in conflict with "The claims administrator shall not unilaterally terminate or deny previously approved drug treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug, an unlisted drug or a compounded drug, the existing procedures for submitting the treatment plan in accordance with MTUS regulations, and for obtaining authorization for the treatment in accordance with utilization review regulations, shall apply."
A reasonable solution here is to state that the MTUS Drug Formulary “**shall** 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."

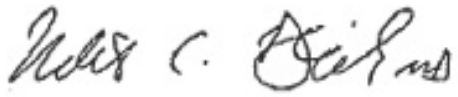
We would encourage DWC to establish administrative or other informal procedures in order to transition patients to “Preferred” medications in situations where such a transition is appropriate, rather than turning immediately to processes requiring more RFAs and UR. Because such transitions will often not be appropriate, it is imperative that there be a substantive peer-to-peer conversation between

the treating physician and the UR reviewing physician. Robust procedures must be in place to encourage such interactions as real clinical dialogue rather than as pro-forma demands for a rigid checklist.

If the treating physician is willing to discuss the case with a pharmacy benefit manager or other UR agent, then appropriate weight must be given to the provider's opinion and recommendations. The length of the transition period will be variable. For some patients on complex chronic pain regimens, a two-year transition period may sometimes be needed. But we also feel that in cases where a change in regimen is judged desirable, initiation of such transition should begin promptly and perhaps even before July 1, 2017. We certainly recognize that in many cases where the provider and patient have agreed to such a transition process, evidence of dose reduction or other optimization may need to be developed if requested in a peer-to-peer conversation, and such evidence may require 90 days or more to collect.

8. Finally, we are concerned regarding the designation of medications as being "Non-Preferred" yet both recommended and non-recommended within MTUS. For example, Cyclobenzaprine is both recommended and non-recommended in the current ACOEM Guidelines. The differentiation is the category of pain for the same condition. Since pain is a subjective experience, how will this differentiation be made? While we agree with the intent of the proposal, the mechanism for the physician to understand the formulary requires both knowledge of the formulary, and reference to the MTUS for the clinical indication. Overall it will lead to a number of challenges for prescribers.

Thank you for your consideration,



Robert Blink, MD, President

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April 27, 2017

Maureen Gray
Regulations Coordinator
Department of Industrial Relations
P.O. Box 420603
San Francisco, CA 94612
dwcrules@dir.ca.gov

Re: Zenith Insurance Company Comments on Proposed Formulary and Related Regulations

Dear Ms. Gray:

We commend the significant work that has gone into this first phase of development and fully support the DWC's efforts to develop an evidence-based formulary that can be timely updated for use in the Workers' Compensation system. We respectfully submit the following comments to the draft formulary and related regulations. The Critical Comments section below summarizes our most significant suggestions and our section-specific comments follow.

Critical Comments:

1. Zenith strongly recommends adding a provision under Section 9792.27.7 to address situations where a brand drug does not have a generic therapeutic equivalent but there are generic drugs with the same active ingredient that will effectively treat the diagnosed condition. Establishing a preference for generic drugs in this situation will allow treatment of the injured worker while simultaneously managing cost to the system. (Please see Comment 4 below under the Discussions and Comments section).
2. We recommend accelerated constitution of the P&T Committee. Three important operational elements should be immediately addressed by the P&T Committee: 1) Inclusion of specific NDC Codes; 2) a provision for Step Therapy; and 3) implementation of a Therapeutic Interchange Program. Zenith believes that any Step Therapy program must integrate with the formulary and has provided proposed language to illustrate this concept. (Please see Comment #10 below under the Discussions and Comments section).
3. The section on Physician Dispensed Drugs (§9792.27.8) should specify that physicians may dispense a seven-day supply of formulary-allowed medications only at the initial office visit following the date of injury. (Please see Comment 5 below under the Discussions and Comments section).
4. We recommend adding a definition for "Clinical Setting" to avoid disputes over what constitutes a clinical setting as that term is used in the regulations. (Please see Comment #2 below under the Discussions and Comments section).

Discussion and Comments

The following provides Zenith's detailed comments and discussion in order of the regulatory sections. Proposed language deletions are "crossed out" and proposed language additions are in red font and underlined. Finally, proposed formatting changes are double underlined, but not in red font to show that no wording change was made to the reformatted section.

1. Section 9792.27.1(a) currently states:

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

   Zenith recommends adding clarification to the word "device" to specify that it means "devices" that are used to deliver a drug to the body as follows:

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

2. There term "clinical setting" is used in Section 9792.27.2(b)(1) to describe drugs that are not considered for "outpatient use." Drugs for "outpatient use" are subject to the formulary while other drugs are not. However, the traditional definition of "outpatient" would include facilities that utilize drugs for medical treatment while the patient is obtaining treatment at the facility, even if the treatment is "outpatient" in nature. To distinguish between "outpatient treatment" and "outpatient use," it would be helpful to define "clinical setting" for purposes of this section. Therefore, Zenith recommends the following definition be added for "Clinical Setting" as follows:

   "Clinical setting" means a
   (a) physician's office;
   (b) hospital;
   (c) outpatient department of a hospital;
   (d) urgent care clinic;
   (e) emergency department of a hospital;
   (f) ambulatory surgery center;
   (g) inpatient rehabilitation centers;
   (h) any other facility, including a skilled nursing facility, that provides medical treatment to the injured worker onsite at the facility.

3. Section 9792.27.1(h) includes a definition of Expedited Review. This term is also defined in Section 9792.6.1(j). Zenith recommends only referencing the prior definition and not including any additional language. This is consistent with how other definitions are addressed such as (l) MTUS

Drug; (w) Retrospective review, etc. This approach also helps keep definitions consistent as future changes are made. The proposed modification is below:

(h) "Expedited 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., ~~where the injured worker's condition is such that the injured worker faces an imminent and serious threat to his or her health,~~ ~~including, but not limited to, the potential loss of life, limb, or other major bodily function~~ ~~or the normal prospective review timeframe would be detrimental to the injured worker's life or health or could jeopardize the injured worker's permanent ability to regain maximum function.~~

4. Section 9792.27.7 - Zenith recommends breaking the Brand Name/Generic Drug paragraph into multiple paragraphs to make it easier to follow.

Zenith strongly recommends including a provision that establishes a preference for use of generic drugs over a brand drug when the brand drug has no therapeutic equivalent but for which there are generic drugs that have the same active ingredient and would treat the diagnosed condition as effectively as the brand drug. This will allow injured workers to obtain medically necessary treatment but also manage costs within the system. It also is within the spirit of the labor code which requires dispensing of generic drugs when there is a therapeutic equivalent. Zenith recognizes that under Labor Code 4600.1(b), a pharmacy cannot be required to dispense a generic drug when there is no therapeutic equivalent. However, the approach proposed by Zenith would not require dispensing of the generic drug, but instead creates a preference for generic over brand whenever such a substitution is possible based on the drugs available in the marketplace. This allows employers the opportunity to use generics before brand when medically appropriate to do so while still providing medically necessary treatment to the injured worker. Zenith strongly recommends immediately putting this approach in place. Proposed language is provided below under new proposed subsection (b). Please see Comments 8 and 10 for additional comments related to step therapy and therapeutic interchange programs.

Zenith recommends adding language to address multiple generic drugs that may be available to treat the same condition but have a cost differential. This applies the same concept to all drugs that is applied for Brand versus Generic drugs and implements cost control mechanisms to help manage pharmacy expense while providing the injured worker medically necessary care. If a provider has a specific medical reason for requesting a particular brand-name drug, the provider would always be permitted to submit documentation showing why that drug is needed for that specific patient. Proposed language is provided below under new proposed subsection (c). Please also see comments under Comment #8 for additional comments regarding future further refinements of drug list.

Zenith also recommends that this section be modified to address over-the-counter (OTC) drugs. As drugs age in the market place, they become available OTC at generally a lower cost than the same drug dispensed from the pharmacy. In situations where this has occurred, the pharmacy should be instructed to provide the injured worker the lower cost OTC version of the drug. This allows the injured worker to obtain the treatment that is medically necessary but results in lower costs to the system. As an example of the benefits of including OTC medications, Prevacid 15mg OTC (NDC00067-6286-43; Cost $0.76/pill) dispensed over prescription generic lansoprazole 15mg (NDC00591-2448-14 and Multiple other NDCs; Cost $1.50 to $7.53/pill) before the Brand Prevacid 15mg Rx (NDC64764-0541-30; Cost $16/pill). In this example Prevacid 15mg OTC is the same dosage form and strength as its prescription counterparts (i.e., all therapeutic equivalents). In lieu of, or to supplement, this approach, OTC drugs could be included as the first line therapy in the formulary. Proposed language is provided below under new proposed subsection (c).

Zenith recommends the following modification to Section 9792.27.7 to incorporate these concepts:

Section 9792.27.7. MTUS Drug Formulary – Brand Name Drugs; Generic Drugs; Over-the-Counter Drugs.

a) 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:

i. 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.

ii. 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.

A. If it is determined that the generic drug but not the brand name drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand name drug.

B. 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.

b) If a physician prescribes a brand drug with no therapeutically equivalent generic drug but for which there are generic drugs that:
   i. have the same active ingredient as the brand drug; and
   ii. are medically appropriate to treat the diagnosed condition,

then the generic drug with the same active ingredient shall be preferred over the brand drug.

c) If a physician prescribes a generic drug when a less costly therapeutically equivalent rated generic drug alternative exists, payment for the prescribed drug shall be made at the fee schedule price for the lowest priced therapeutically equivalent generic substitute.

d) If a physician prescribes a drug when a less costly over the counter therapeutically equivalent drug alternative exists, the pharmacy must provide the over the counter drug. If the pharmacy does not provide the less expensive over the counter drug, then payment for the prescribed drug may be made at the lowest over the counter cost for the drug.

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

5. Section 9792.27.8(b) states that "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." As written, the regulation would allow a physician to office dispense a "Preferred" drug for a 7 day period at any point in time during the course of treating the injured worker. Because Section 9792.27.8 requires drugs dispensed by a physician to be preauthorized, Zenith believes dispensing without prior authorization should be limited to the first visit with the provider within 7 days of the work related injury just as in the section on Special Fill drugs under Section 9792.27.11. Therefore, Zenith suggests the following modification:

(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: (i) the drug treatment is in accordance with the MTUS Treatment Guidelines; (ii) the seven-day supply is dispensed at the time of an initial visit that occurs within 7 days of the date of injury; and (iii) the prescription is for a supply of the drug not to exceed the limit set forth in the MTUS Drug List if the MTUS Drug list recommends less than 7 days of treatment with the drug for the diagnosed medical condition. 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.

6. Section 9792.27.8(c) states that "nothing in this Article shall invalidate a provision in a Medical Provider Network that restricts physician dispensing by medical providers within the network." This provision does not address pharmacy programs or pharmacy networks that are established outside of a Medical Provider Network pursuant to Labor Code 4600.2. Therefore, Zenith recommends that the provision be modified as follows:

   (c) Nothing in this Article shall invalidate a provision that restricts physician dispensing through either a provision in a Medical Provider Network agreement, or through a pharmacy benefit program or pharmacy benefit network established pursuant to Labor Code Section 4600.2. ~~which restricts physician dispensing by medical providers within the network.~~

7. Section 9792.27.12(b) includes a definition for perioperative period. Zenith recommends removing the definition from this section and adding it to the definitions under Section 9792.27.1 for consistency.

8. Section 9792.27.14 – MTUS Drug List - Zenith has the following comments related to the MTUS Drug list and implementation.

   a. Refinement of Drug List for Increased Specificity -- Therapeutic Interchange program

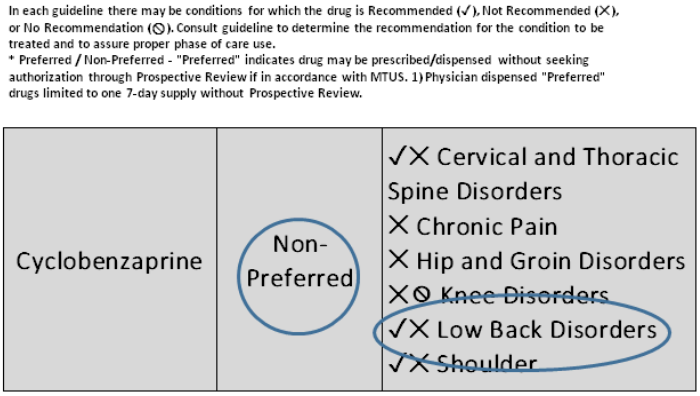
   Zenith has proposed additional language to address consideration for usage of lower cost drugs when a particular drug is prescribed but lower cost alternatives are available using the same active ingredient. Some brand name drugs will have multiple AB rated alternatives which then provides a selection of therapeutically equivalent drug choices. In that situation, if a generic is prescribed, then a lower cost generic could be used since all the generics will reference back to the same brand drug. The drug list preference should be for drug product lines that have multiple AB rated generic alternatives. Prospective review should be required for products without AB rated substitutes when a broader drug product line is available to provide the same treatment. This would be similar to requiring a physician to provide medical justification for using a brand name drug over a generic drug for a particular patient and medical condition.

   Zenith proposed language under Comment 4 above to require a generic drug over a brand drug when the brand drug has no therapeutic equivalent but for which there are generic drugs that have the same active ingredient and would treat the diagnosed condition as effectively as the brand drug. Zenith strongly recommends immediately putting this approach in place through the language proposed under Comment 4 above.

The drug list should be modified in the future to allow for this type of therapeutic interchange. Zenith encourages making this a priority for the Pharmacy and Therapeutic Committee.

b. Implementation Time Period

The current formulary list will be challenging for pharmacists. Particularly problematic are non-preferred drugs that are both recommended and not recommended for the same body part. While this may be necessary to coordinate with ACOEM, which Zenith supports, it should be noted that implementation may be complicated and require system programming for Pharmacy Benefit Managers, carriers and pharmacies. Therefore a period of time for implementation of the formulary would be beneficial to help ensure the formulary functions as intended.



In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (✕), or No Recommendation (⃠). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use.
* Preferred / Non-Preferred - "Preferred" indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS. 1) Physician dispensed "Preferred" drugs limited to one 7-day supply without Prospective Review.

Cyclobenzaprine	Non-Preferred	✓✕ Cervical and Thoracic Spine Disorders ✕ Chronic Pain ✕ Hip and Groin Disorders ✕⃠ Knee Disorders ✓✕ Low Back Disorders ✓✕ Shoulder

c. Over The Counter Drugs

Zenith recommends including OTC medications in the formulary. As noted above in Comment 4, this would allow injured workers to obtain medically necessary drugs but at less cost to the system. Use of OTC equivalents to Formulary drugs in combination with the inclusion of NDC codes and Step Therapy will allow for even greater cost containment and Step Therapy options for Tier 1 drugs meaning drugs that would be first choice above other drugs for treatment of the diagnosed medical condition.

Where an OTC product is available the specific NDC for that drug and strength would become a Tier 1 medication. The generic equivalent would be Tier 2 and the Brand drug Tier 3.

The following table shows an example of a drug class that has multiple options. Those with OTC designation would be considered Tier one in the approach outlined above.

Drug Ingredient	Preferred Status	OTC Availability	Drug Class
Cimetidine	Preferred	OTC 200mg	Ulcer Drugs

Dexlansoprazole	Preferred	n/a	Ulcer Drugs
Famotidine	Preferred	OTC 10mg, 20mg	Ulcer Drugs
Lansoprazole	Preferred	OTC 15mg	Ulcer Drugs
Misoprostol	Preferred	n/a	Ulcer Drugs
Nizatidine	Preferred	OTC 75mg	Ulcer Drugs
Omeprazole	Preferred	OTC 20mg	Ulcer Drugs
Pantoprazole Sodium	Preferred	n/a	Ulcer Drugs
Rabeprazole Sodium	Preferred	n/a	Ulcer Drugs
Ranitidine HCL	Preferred	OTC 75mg, 150mg	Ulcer Drugs
Sucralfate	Preferred	n/a	Ulcer Drugs
Esomeprazole	Preferred	OTC 20mg	Ulcer Drugs

9. Section 9792.27.21 currently states that the Administrative Director **may** maintain and post a listing of NDC codes on the web site. Zenith recommends that "**may**" be changed to "**shall**" to make sure everyone has easy access to the NDC codes. There are also important business reasons for making the NDC codes mandatory.

    a. The listing of NDC codes will make it easier to develop and establish automated rules for workflows that will be necessary to implement the various sections of the formulary rules. For example, the NDC codes would allow Zenith and its vendor partners to map Preferred Drugs to preferred drug indicators. Without the NDC codes, the ability to achieve this type of automation is questionable and more processes will be required to be manual increasing administrative expense and creating unnecessary process delays.

    b. Inclusion of NDC codes will allow for better management of off-label exclusions:
        Example: Diclofenac potassium, which is listed as a "Preferred" drug, comes in three forms (generic Cataflam, Zipsor, Cambia). Cataflam and Zipsor have a label use for management of pain. Cambia has a label use for acute migraine. Without NDC codes, Cambia is a "Preferred" drug and could be prescribed for treatment under all cited guideline sections.

    c. Inclusion of NDC codes will aid in reducing price variability:
        Example: Generic Naproxen 500mg has over 80 NDC codes representing various manufacturers. NDC codes allow matching to the Medi-Cal Pharmacy Fee Rate, a state negotiated fee schedule, which has a price range of $0.06 to $0.96 for 29 NDCs. This also allows exclusion of NDC codes that do not match to the Medi-Cal rates and therefore have greater variable Average Wholesale Pricing (AWP). Without an NDC match, AWP of generic Naproxen 500mg ranges from $0.12 to $2.79/pill.

d. NDC specificity will also distinguish different products with the same chemical ingredient:

Generic Name	Brand Name	NDC	Drug Class
Diclofenac Sodium 25mg	Voltaren 25mg	68001-0280-00; multi listings	Anti-Inflammatory
Diclofenac Sodium 50mg	Voltaren 50mg	00878-6280-10; multi listings	Anti-Inflammatory
Diclofenac Sodium 75mg	Voltaren 75mg	00781-1787-60; multi listings	Anti-Inflammatory
Diclofenac Sodium ER 100mg	Voltaren XR 100mg	00098-1041-01; multi listings	Anti-Inflammatory
Diclofenac Sodium Eye Solution 0.01%	Voltaren Eye Solution 0.01%	17478-0892-25; multi listings	Ophthalmic
Diclofenac Sodium Gel 1%	Voltaren Gel 1%	49884-0935-47; multi listings	Dermatologic
Diclofenac Sodium Gel 3%	Voltaren Gel 3%	00168-0844-01; multi listings	Dermatologic
Diclofenac Sodium Solution 1.5%	Pennsaid 1.5%	60505-0899-05; multi listings	Dermatologic
Diclofenac Sodium Solution 2%	Pennsaid 2%	75987-0040-05	Dermatologic

10. Section 9792.27.21(b)(4) should be modified to incorporate step therapy as a topic to be considered by the P&T Committee as step-therapy addresses different concerns than does a therapeutic interchange program. Both are valuable tools to help balance the need to provide appropriate cost effective treatment to injured workers. Medi-Cal has successfully implemented a step-therapy program that could be used as a model for workers' compensation. Under the Medi-Cal model, pharmacies are required to provide the ICD-10 code information to validate that the step-therapy process was followed. Under the Medi-Cal approach, protocols are used to establish first-line and second-line therapy as well as acceptable clinical exceptions. Resources for the Medi-Cal approach are available at:

Step Therapy Link
http://files.medi-cal.ca.gov/pubsdoco/publications/masters-mtp/part2/drugscdlp8_m01p00.doc

Main Medi-Cal Drug List Page
http://files.medi-cal.ca.gov/pubsdoco/manual/man_query.asp?wSearch=%28%23filename+drugscdl%2A%2Edoc+OR+%23filename+drugscdl%2A%2Ezip%29&wFLogo=Contract+Drugs+List&wFLogoH=52&wFLogoW=516&wAlt=Contract+Drugs+List&wPath=N

The following is Zenith's proposed modification to accommodate this change:

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

ADDITIONAL COMMENTS FOR STEP THERAPY WHEN IMPLEMENTED

Zenith is a strong proponent of implementing a step therapy program to work with the proposed drug formulary. Zenith recommends that this be a priority of the P&T Committee. Zenith further recommends that any step therapy program be designed to work in conjunction with the definitions and usage of Preferred, Non-Preferred, and Unlisted Drugs as defined under Section 9792.27.1. Any step-therapy program must also work seamlessly with the MTUS guidelines.

When a step therapy hierarchy is established, it would be beneficial if first line therapies aligned with the Preferred Drug category so that Preferred Drugs must be tried first, a Non-Preferred Drug second and an unlisted drug only if neither a Preferred Drug nor a Non-Preferred Drug is available or has been ineffective. An exception would also be needed to address situations where there is no alternative drug for an unlisted drug. Such an approach would correspond to the requirements to obtain utilization review that have been established for each drug category. If this approach is considered and adopted by the P&T Committee in the future, Zenith recommends the following type of language changes to accommodate this approach:

Section 9792.27.1 Definitions:

(n) "Non-Preferred drug" means a drug on the MTUS Drug List which is designated as requiring authorization through prospective review prior to dispensing the drug. The Non-Preferred Drug status of a drug is designated in the column labeled "Preferred / Non-Preferred". Non-preferred drugs are second line therapy and may be used only after available Preferred drugs subject to the exceptions set forth under 9792.27.10.

(v) "Preferred drug" means a drug on the MTUS Drug List which is designated as being a drug that does not require authorization through prospective review prior to dispensing the drug, provided that the drug is prescribed in accordance with the MTUS Treatment Guidelines. The Preferred status of a drug is designated in the column with the heading labeled "Preferred / Non-Preferred". Preferred drugs are first line therapy and may be used only as set forth under 9792.27.10.

(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 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. Unlisted drugs are third line therapy and may be used only after available Preferred and Non-Preferred drugs subject to the exceptions set forth under 9792.27.10.

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

(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. Preferred drugs, when available, are first line therapy and must be used prior to prescribing a Non-Preferred or unlisted drug. If a physician prescribes a Non-Preferred drug before prescribing an available Preferred drug, the physician must document the medical necessity for prescribing the Non-Preferred 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 Non-Preferred is medically necessary. The dispensing of the Preferred drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary.

(c) For a drug that is identified as "Non-Preferred," authorization through prospective review must be obtained prior to the time the drug is dispensed. Non-preferred drugs are second line therapy and may be used only after a Preferred drug, unless there is no Preferred drug available. If a physician prescribes an unlisted drug before prescribing an available Non-Preferred drug, the physician must document the medical necessity for prescribing the unlisted 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 Non-Preferred or unlisted drug is medically necessary. Expedited review should be conducted where it is warranted by the injured worker's condition. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.

(d) For a drug that is identified as eligible for "Special Fill" or "Perioperative Fill", the usual requirement to obtain authorization through prospective review prior to dispensing the drug is altered for the specified circumstances set forth in sections 9792.27.11 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. Unlisted drugs are third line therapy and may be used only after Preferred and Non-Preferred drugs have been utilized, unless there is no Preferred or Non-Preferred drug available. If a physician prescribes an unlisted drug before prescribing an available Preferred and Non-preferred drugs, the physician must document the medical necessity for prescribing the unlisted 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 unlisted drug is medically necessary. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment was not medically necessary. A combination drug that is not on the MTUS Drug List is an unlisted drug even if the individual active ingredients are on the MTUS Drug List.

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

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

EXTENDED RELEASE DRUGS AND IMMEDIATE RELEASE DRUG GUIDELINES

Zenith recommends that the P&T Committee also address step-therapy for the use of immediate release versus extended release drugs. Per the Centers of Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain, immediate release drugs are first-line therapy and extended release drugs are second-line therapy. A more comprehensive evidence-based step-therapy program should be implemented to address all drugs in the future through the P&T

Committee. This type of program would help ensure that medically necessary drugs are used as first line therapy but also help control costs within the workers' compensation system. Any such program must be in accordance with MTUS. The following language provides an example of the type of step-therapy Zenith is recommending for immediate release and extended release drugs:

> If a physician prescribes an extended release drug when an immediate release drug is available for treatment of the diagnosed medical condition, the physician must provide medical documentation showing that:
>
> i. first-line therapy was attempted with an immediate release drug and it is now medically necessary to prescribe a second-line therapy extended release drug; or
> ii. second-line therapy with an extended release drug is medically necessary under MTUS without attempting first-line therapy due to the nature and extent of the medical condition for which the drug is being prescribed.

11. Because Section 9792.27.21(b)(4) references a therapeutic interchange program and that term may be new to many people in the industry, Zenith recommends adding a definition for Therapeutic Interchange to 9797.27.1. Additionally, Zenith recommends adding a definition for step-therapy as well. Zenith suggests the following:

> Step-therapy means the practice of beginning drug therapy for a medical condition with the safest and most cost effective drug and progressing to other higher risk or more costly drug therapy, only if medically necessary.
>
> Therapeutic Interchange means the substitution of a drug by a pharmacist or payor with a drug that is a therapeutic alternative or equivalent, with the prescribing provider's permission.

Thank you for the opportunity to comment on the proposed regulations.

Sincerely,

Rupali Das, MD, MPH

Rupali Das, MD, MPH, FACOEM
SVP, California Medical Director

Raymond Tan, PharmD
Director of Pharmacy Benefits

California Medical Association
Physicians dedicated to the health of Californians
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May 1, 2017

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

Sent via email to: MGray@dir.ca.gov and dwcrules@dir.ca.gov

RE: Workers' Compensation - Medical Treatment Utilization Schedule –Formulary

Dear Ms. Gray:

On behalf of our more than 43,000 physician and medical student members, the California Medical Association (CMA) would like to thank you for the opportunity to provide comments on the Department of Industrial Relations, Division of Workers' Compensation (hereinafter, "DWC") proposed regulatory action to adopt the Medical Treatment Utilization Schedule (MTUS) Formulary, found in Title 8 of the California Code of Regulations. Many of our physician members are engaged in the treatment of injured workers and, consequently, in navigating the workers' compensation system in an effort to provide medically appropriate and effective care to their patients consistent with medical standards of care. Accordingly, CMA offers its considerable experience and insight regarding the potential impacts of DWC's proposed adoption of the formulary and accompanying regulations on the ability of physicians to provide care to injured workers and on the opportunity for injured workers to obtain quality medical care that will treat their injury or illness and allow them to return to work.

General Comments

CMA's primary focus in considering DWC's proposal is whether the adoption of this formulary and accompanying regulations will result in all injured workers having better access to appropriate and timely medical care or whether it will create additional barriers to the provision of this care. CMA is deeply concerned that DWC continues to adopt MTUS guidelines that focus on the treatment of workers with acute injuries, without adequate consideration of the medical needs of workers with chronic conditions or injuries. This lack of attention to the treatment of workers with chronic conditions or injuries is reflected in that DWC, in its Initial Statement of Reasons, failed to consider literature that deals with treatment of chronic injuries. Significantly, DWC failed to review or consider the Medical Board of California's opioid prescribing guidelines, which are already in effect for physicians in California and allow for appropriate flexibility in the treatment of both acute and chronic pain. Accordingly, CMA urges DWC to reconsider its adoption of the American College of Occupational and Environmental Medicine (ACOEM) formulary and accompanying regulatory scheme in favor of an approach that better serves all injured workers. Our comments below address specific aspects of the proposed regulations that are of concern.

8 C.C.R. §9792.27.3 MTUS Drug Formulary Transition

CMA is pleased to see the changes made to the language in 8 C.C.R. §9792.27.3 which will strengthen the protections for workers whose injuries occur prior to July 1, 2017 and have existing prescriptions for non-preferred drugs. While the new language, which prohibits a claims administrator from unilaterally terminating or denying a treatment plan that was previously approved provides protection from termination of existing treatment approved prior to July 1, 2017, transition treatment plans developed on or after July 1, 2017 do not appear to be afforded the same protection. Accordingly, CMA urges DWC to provide corresponding assurance that transition treatment plans developed on or after July 1, 2017 will be approved as well so that all injured workers may safely be transitioned from prescription drugs approved pursuant to the current formulary onto medications consistent with the new formulary.

8 C.C.R § 9792.27.11 MTUS Drug List - Special Fill

As indicated in our previous comments, CMA supports the concept of the special fill provisions in 8 C.C.R. §9792.27.11 which will allow physicians to prescribe the appropriate non-preferred medications to acutely injured workers without prospective utilization review. However, CMA is disappointed to see that all of the "special fill" medications are limited to a four day supply. While DWC explains in its Initial Statement of Reasons that a physician can request a longer supply of non-preferred medication through prospective utilization review in the ensuing four days, for workers injured just before or during a weekend, this may not be enough time to obtain approval for a longer fill if one is medically necessary. Accordingly, CMA urges that at least some non-preferred medications available without prospective utilization review pursuant to the "special fill" provisions be made available for an increased number of days.

With regard to the 8 C.C.R. §9792.27.11(f), which directs the Administrative Director to evaluate the impact of the special fill provisions on the use of opioids by injured workers, CMA urges DWC to clarify the parameters of this study. Specifically, DWC should indicate from which participants in the workers' compensation system the AD must solicit feedback and this list should include treating physicians from various specialties and injured workers in addition to any other system participants. A study of this provision should include not just its impact on opioids, but on health outcomes for injured workers and on the ability of injured workers to return to work. Moreover, CMA recommends that DWC conduct a comprehensive study of the impact of not just this section, but of the formulary and all of its implementing regulations as a whole, on health outcomes for injured workers and on the ability of injured workers to return to work. This would provide a more complete picture of the effect of these regulations on the workers' compensation system, and most importantly, on the ability of injured workers to receive more timely and appropriate treatment.

8 C.C.R § 9792.27.12 MTUS Drug List – Perioperative Fill

CMA supports the addition of regulatory provisions in 8 C.C.R. §9792.27.12 that allow physicians to prescribe non-preferred medications to patients without prospective utilization

review during the perioperative period. However, we are concerned that two days prior to surgery and four day after surgery may not be a long enough period to appropriately treat a surgical patient who requires non-preferred medications and may not provide sufficient time for a physician to obtain authorization for a longer fill through prospective utilization review. Accordingly, CMA recommends that at least some non-preferred medications available without prospective utilization review pursuant to the "perioperative fill" provisions be made available for an increased number of days.

8 C.C.R § 9792.27.14 MTUS Drug List

The vast experience of CMA's physician members who treat injured workers is that the ACOEM Practice Guidelines generally tend to be less appropriate and lacking the flexibility and comprehensiveness necessary for the treatment of those workers whose injuries are non-acute, such as those with work-related chronic injuries and conditions, including chronic pain. A review of the ACOEM formulary, which DWC has proposed for adoption, is consistent with this experience. The formulary, in its focus on evidence based medicine (EBM), may fail to consider a wide range of treatments that, while not necessarily meeting the rigorous standards for EBM, actually result in better outcomes for patients. In fact, CMA has concerns that, in some instances, the application of the ACOEM formulary may result a delays in the provision of appropriate, effective medications such that the ability of the injured worker to return to work is delayed. Accordingly, CMA cannot support the proposed adoption of the ACOEM formulary for use by DWC in the MTUS and urges DWC to consider whether a combination of the ACOEM formulary and the Official of Disability Guidelines (ODG) formulary might be a more effective and appropriate solution for the treatment of all injured workers, not just those with acute injuries.

8 C.C.R § 9792.27.20 Pharmacy and Therapeutics Committee – Meetings

CMA supports the changes made to the operations of the Pharmacy and Therapeutics Committee meetings in 8 C.C.R. §9792.27.20, including the new requirement that these meetings be conducted in accordance with the Badgely-Keene Open Meeting Act provisions and the requirement that notice of these meetings be given ten days in advance. CMA is confident that these changes will result in increased transparency and more robust engagement by stakeholders in these important meetings.

8 C.C.R § 9792.27.21 - MTUS Drug List Updates

CMA supports the provisions in 8 C.C.R. §9792.27.11 to the extent they require the Administrative Director to consult with the Pharmacy and Therapeutics Committee on updates to the MTUS Drug List. In order to further increase transparency, CMA urges that DWC make the recommendations made by the Pharmacy and Therapeutics Committee to the Administrative Director public and require the Administrative Director to provide a public response to any recommendation made by the Pharmacy and Therapeutics Committee that the Administrative Director does not adopt.

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Thank you again for the opportunity to provide input on these important regulations, which have the potential to have a significant impact on the ability of injured workers to access quality medical care. We look to working together with DWC and other stakeholders to ensure that the drug formulary best serves the medical needs of injured workers. I can be reached by phone at (916) 551-2552 or by email at swittorff@cmanet.org should you require any clarification or additional information regarding CMA's comments.

Respectfully submitted,

Stacey Wittorff
Legal Counsel
Center for Legal Affairs
California Medical Association

Gray, Maureen@DIR

From: Steve Cattolica <scattolica@advocal.com>
Sent: Monday, May 01, 2017 5:03 PM
To: Gray, Maureen@DIR
Subject: Formulary comments

Ms. Maureen Gray

Regulations Coordinator

Division of Workers Compensation,, Legal Unit

P.O. Box 420603

San Francisco, CA 94142

Re: Medical Treatment Utilization Schedule – Formulary

Via email only

On behalf of the California Society of Industrial Medicine and Surgery (CSIMS), the California Society of Physical Medicine and Rehabilitation (CSPM&R) and the California Neurology Society (CNS), we want to thank the Division for the opportunity to comment on the current rulemaking that will adopt Sections 9792.27.1 through 9792.27.21, the California Workers' Compensation Formulary. This regulatory package, assisted by provisions of AB 1124 (Statutes of 2015, Chapter 525) is intended to provide guidance and reduce transactional friction for both the provider and employer community with respect to prescribing and dispensing drug therapies.

It is in the spirit of smoothing the process of requesting and administering prescription drug therapies that we offer the following general comments:

1) Separate from the issue of transitioning chronically ill patients from their current therapy regimen to one more closely aligned with the formulary, it is amply clear to everyone involved in actually making the formulary work in the real world of workers compensation, that more time is needed to properly understand how the formulary is supposed to work and to put the tools into place to properly do so.

2) As added by AB 1124, Labor Code Section 5307.27 (b) mandates that the formulary "include evidence-based, peer-reviewed, nationally recognized standards of care …" Furthermore, subparagraph (c) states that the formulary "shall include a phased implementation for workers injured prior to July 1, 2017, in order to ensure injured workers safely transition to medications pursuant to the formulary."

Unfortunately, the current formulary proposal falls far short with respect to both of these critical requirements. The formulary's recommendations are not based in evidence-base medicine as defined nor does the current proposal include a phased in implementation.

Speaking to our first concern, notwithstanding the July 1, 2017 statutory date for implementation, it is unrealistic to expect the community to build, test and then operate a system that as of today has no firm rules. Even the most optimistic estimates regarding the duration of the current rulemaking process include at least one 15 day written comment period. Add to that the time needed by the Office Administrative Law and July 1 can certainly be a target, but a target only good for publishing the rules to follow, not to simultaneously expect a "go live" operation to start from scratch. Providers and employers alike do not have the resources and should not be expected to make an "educated guess" at what the final regulatory product may be and invest in systems that "might" work.

Instead, we recommend the Division target July 1 as the day for all the rules to be properly and completely established and designate the six months thereafter to building and testing systems. That would implement the formulary for dates of service on or after January 1, 2018. We should add that this does not represent the first time the Division would "miss" a statutory deadline because of the work involved and complexity of the required regulations. In this specific instance, the health and welfare of California's injured workers mandates continued care and deliberations. Time itself is immaterial in comparison to their best interests.

With respect to our second comment, the formulary will be an integral part of the Medical Treatment Utilization Schedule (MTUS). Labor Code Section 5307.27 (a) states that the MTUS addresses "the frequency, duration, intensity, and appropriateness of all treatment procedures and modalities commonly performed in workers' compensation cases…." 8CCR Section 9792.21 (c) states, "The recommended guidelines set forth in the MTUS are presumptively correct on the issue of extent and scope of medical treatment." The presumption of correctness affects the burden of proof when a provider requests an alternative to the presumed correct care or requests care for a diagnosis that the MTUS does not address.

8CCR Section 9792.8 (a)(2) requires that, "For all conditions or injuries not addressed by the ACOEM Practice Guidelines or by the official utilization schedule after adoption pursuant to Labor Code section 5307.27, authorized treatment shall be in accordance with other evidence-based medical treatment guidelines that are generally recognized by the national medical community and are scientifically based. Treatment may not be denied on the sole basis that the treatment is not addressed by the ACOEM Practice Guidelines until adoption of the medical treatment utilization schedule pursuant to Labor Code section 5307.27. After the Administrative Director adopts a medical treatment utilization schedule pursuant to Labor Code section 5307.27, treatment may not be denied on the sole basis that the treatment is not addressed by that schedule.

8CCR Section 9792.25.1, recognizes the presumption of correctness granted to all elements of the MTUS and provides a method for Utilization Review and Independent Medical Review physicians to use in weighing evidence when the MTUS does not address the condition or the treating physician is requesting an alternative therapy. Specifically, subparagraph (a) of that section instructs utilization review and Independent Medical Review physicians as follows:

> "(a) When competing recommendations are cited to guide medical care, Utilization Review and Independent Medical Review physicians shall apply the MTUS Methodology for Evaluating Medical Evidence to evaluate the quality and strength of evidence used to support the recommendations that are at variance with one another. The MTUS Methodology for Evaluating Medical Evidence provides a process to evaluate studies, not guidelines. Therefore, the reviewing physician shall evaluate the underlying study or studies used to support a recommendation found in a guideline. Medical care shall be in accordance with the recommendation supported by the best available evidence." (emphasis added).

There are no "evidence-based, peer reviewed and nationally recognized" studies upon which the DWC determined the formulary's list of preferred drug therapies. In fact, in some instances, the preferred list is in direct conflict with the underlying proposed ACOEM clinical guidelines. How is a treating physician to successfully overcome the formulary's presumption? Which "evidence-based, peer reviewed and nationally recognized" studies would he/she use to base their request? What studies would the UR and IMR physician compare?

More specifically, if the DWC does not have any "evidence-based, peer reviewed and nationally recognized" studies from which to draw its conclusions about which drugs are preferred and which are not, then the "preferred list" must be fundamentally changed or eliminated.

The option of eliminating the preferred list for lack of an evidentiary basis leaves the formulary dependent upon the clinical guidelines that are at the foundation of the MTUS in the first place. That's where the Formulary belongs.

None other than ACOEM itself has published its opinion that "while a formulary gives greater clarification on a drug-by-drug basis resulting in fewer disputes, it can also delay the filling of prescriptions, to the detriment of the injured worker. The delay might arise because the formulary is "silent" as to whether a particular drug is recommended or not."

Regarding the "phased in implementation" mandated by Labor Code Section 5307.27 (c); we do not disagree with the spirit of the currently proposed 8CCR Section 9792.27.3. However, as proposed, this section does not prescribe a transition plan as the framers of AB 1124 contemplated it. It is likewise, unrealistic to expect the employer community to go along with the status quo as it waits for the treating physician to request "a medically appropriate and safe course of treatment for the injured worker in accordance with the MTUS….."

The process can be prescriptive without being punitive.

We suggest that treating physicians be required to provide the requested plan as stated, but over a course of time that does not leave the process in limbo. To that end, we suggest that the treating physician be required to request the transition plan for only a proportion of the qualified patient population over a span of time. For example, 25% of the population each six months for 24 months – starting from oldest dates of injury to the most recent.

The total volume of patients involved may have a direct effect on a provider's ability to do so. Therefore, the process should include a way for the parties to mutually agree on an overall timeframe that varies from that suggested by the regulation. The overall transition plan must be in place within three months of implementation of the formulary and be completed within two years thereafter.

In the meantime, as the Division has proposed, the employer (claims administrator) “shall not unilaterally terminate or deny previously approved drug therapy.”

However, to assure that the process goes along as agreed and the employer not be left without some recourse, if the provider fails to submit the request as agreed, the claims administrator can submit the transition plan. However, the claims administrator’s plan must be composed of a medically appropriate weaning, tapering or transition. In this regard, we support CAAAs recommendation for the content of the transition plans in the absence of an true evidence based process such as the protocols followed by ODG.

ACOEM released a position paper on formularies in August 2016 that includes a recommendation to pay physicians for time they spend dealing with utilization review.

ACOEM states within the paper that “Policies for the implementation of a formulary should aim to pay providers for the extra time required for documenting medical necessity, following step-care procedures, and communicating with (pharmacy benefit managers) and UR agents.”

Thank you once again for the Division’s hard work under difficult conditions. We look forward to continued partnership in an effort to improve conditions for injured workers and those who are given responsibility for their care and wellbeing under the California Workers’ Compensation System.

Cordially,

Stephen J. Cattolica

Director of Government Relations

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Legislative and Administrative Agency Advocacy
Professional Association Management
Established 1983

May 1, 2017

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Cordially,

Stephen J. Cattolica

Director of Government Relations

Ms. Maureen Gray, regulations coordinator
Department of Industrial Relations
Division of Workers' Compensation
1515 Clay Street, 18th floor
Oakland, CA 94612

May 1, 2017

Dear Ms. Gray

The following are comments for the regulations related to the MTUS Formulary.

Proposed regulation 9792.27.1 (a) propose the following definitions:

"For purposes of sections 9792.27.1 through 9792.27.21, 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.

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

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

These definitions come directly from statutes, including Labor Code 5307.1 (e)(6)(A), (B) and (C). The definition of administration also matches regulation 9789.13.2.

There is no disagreement as to these definitions. There is, however, an issue related to a treatment protocol for the refilling of an implanted pain pump with either a single drug or a compounded drug product for the purposes of controlling pain. The issue comes directly from these definitions and, although it has a greater impact in medical billing and fee schedule situations, these regulations are discussing the definitions and therefore I feel it is appropriate to comment here during this rulemaking.

The process of refilling an implanted pain pump requires the physician to obtain the drugs used in the refill from a pharmacy. If a compound is being used, it is compounded by the pharmacy and then brought either to the office or an outpatient facility for the actual refill. The drug(s) are not administered to the body of the patient, but are actually inject d into a reservoir that is implanted in the body. A needle is inserted through the skin and into the reservoir. The pain pump then dispenses the medication to the patient on a schedule that has been programmed into

the devise by the physician. These refills and adjustments to the pain pump programming take place approximately monthly.

There is no clarity in any of DWC's regulations or in the underlying statutes as to whether these drugs are considered to be administered or dispensed. This process seems to fall in between the two definitions.

The reason it is an issue is really a fee schedule problem - there are two different ways to pay for the same drugs depending on whether or not they are considered to be administered or dispensed. Dispensed drugs are subject to a reimbursement limitation based on documented paid costs and administered drugs are not. This results in a disproportionately high payment for pain pump refill drugs in particular due to the lack of clarity in the definitions. In IBR determinations from Maximus Federal Services, payers and providers are receiving inconsistent answers.

I am requesting that the DWC consider identifying how pain pump refill drugs should be classified and include that in the definitions under both the Formulary regulations and eventually the Physician's Fee Schedule regulations as well. In my opinion, these drugs truly fall into the category of dispensed drugs and should be treated that way in all regulations to avoid overpayment of the drugs based on a quirk in the rules.

Thank you for your consideration.

Sincerely,

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Pacifica, CA 94044

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