

Implementing AB 1124 Drug Formulary and update of MTUS Guidelines Forum Comments – September 2016

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Zenith supports 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 body of this letter summarizes our most significant suggestions. We have separated these further into critical comments and then other technical comments.

In addition, Appendix A includes specific examples and more detailed discussion of the points below. Appendix B provides comments, organized by section and page number, with proposed language amendments where applicable.

Critical Comments:

1. In order to streamline formulary use and maintenance, Zenith recommends that the formulary drug list include only those drugs that are "Preferred" or eligible under the "First Fill" guidelines. All drugs not specifically listed would be considered "Non-Preferred" (Please see Appendix A comment 1).
2. The following additional medications should be incorporated as "Preferred" or "First Fill Eligible": Cephalexin, Silver Sulfadiazine, Prednisone, Diclofenac Sodium, and Medrol Dose Pack.
3. We commend the significant work that has gone into this first phase of development and also recognize that there is a significant amount of work to be done prior to the implementation date of July 1, 2017. To this end, we recommend accelerated constitution of the P&T Committee. Two important operational elements should be immediately addressed by the P&T Committee: 1) Inclusion of specific NDC Codes and 2) a provision for Step Therapy (Please see Appendix A comments 2 and 3).
4. 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.
5. The definition of Compound Drugs should incorporate single active ingredients as well as compound "kits." (Please see Appendix B for suggested language).
6. We suggest clarifying additional definitions: "MTUS Preferred Drug List", "Non-Preferred Drug", and "Preferred Drug". We also recommend adding a definition for "Clinical Setting" (Please see Appendix B for suggested language).

Technical Comments:

7. We recommend that language be added requiring use of over the counter (OTC) formulations where they exist, so the most cost-effective version of a drug is dispensed. (Please see Appendix A comment 4).

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8. The time period for “First Fill” should clarify whether the date of injury is “Day 0” or “Day 1.” (Please see Appendix A comment 5).
 9. We have specific comments on improving the drug list including changes to the Formulary headers, addition of columns for “Preferred Dosage Form” (i.e., Tablet, Capsule, Topical, etc.) and “Time Release Mechanism” (i.e., Immediate Release, Extended Release, etc.) (Please see Appendix A comment 6, and Appendix B under 9792.27.12).
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Appendix A

Each item below corresponds to a recommendation made in the Zenith Comment Letter and provides examples, rationale, or a more detailed discussion.

1. In reference to streamlining the Preferred Drug List (Critical Comment 1):
 - a. Removing “Non-Preferred” drugs eliminates confusion or misconception between those drugs listed as “Non-Preferred” versus those which are unlisted. Both require the same elements for pre-authorization therefore it is unnecessary to list some but not all in §9792.27.12;
 - b. Limiting the list to “Preferred” drugs will increase ease of use and decrease the chances of internal inconsistencies or loop holes within the regulations which may create unintended consequences and increase litigation; and
 - c. Makes for more efficient updating of the drug list.
2. Regarding inclusion of specific NDC codes (Critical Comment 3):
 - a. Inclusion of NDC codes will allow for better management of off-label exclusions. An example is:
 - i. Diclofenac K+, 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.
 - b. Inclusion of NDC codes will aid in reducing price variability. An example is:
 - i. 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

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NDCs. This also allows exclusion of NDC codes that do not match to the Medical 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.

- c. NDC specificity will also distinguish different products with the same chemical ingredient. An example is:

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

3. Regarding Step Therapy (Critical Comment 3):

- a. Regarding “Step Therapy”, we would like to see stratification of preferred products into first, second, and possibly third tier categories based on potential adverse impact on the injured worker and the cost effectiveness of the drug itself. This is also an example of the need for a more specific and detailed listing of the formulary to include NDC numbers.
- b. Step Therapy and cost-effective evaluation analysis requires NDC numbers to differentiate various products made from the same chemical ingredients (therapeutic equivalents). An example of this is diclofenac which is available as a potassium or sodium salt compound; tablets as delayed or extended release form; a gel; a solution and as an eye drop.

Drug Ingredient	Drug Name	Step Status	Drug Class	Approx. Cost per Unit
Diclofenac Potassium 50mg	Cataflam 50mg	Preferred; Tier 1	Anti-inflammatory	\$0.60/pill
Ibuprofen 600mg	Motrin 600mg	Preferred; Tier 1	Anti-inflammatory	\$0.10/pill
Diclofenac Sodium 75mg	Voltaren 75mg	Preferred; Tier 1	Anti-inflammatory	\$0.16/pill
Diclofenac Sodium Gel 1%	Voltaren Gel 1%	Preferred; Tier 1	Dermatologic	\$0.50/gram
Celecoxib 200mg	Celebrex 200mg	Preferred; Tier 2	Anti-inflammatory	\$0.96/pill
Etodolac 300mg	Lodine 300mg	Preferred; Tier 2	Anti-inflammatory	\$1.14/pill
Diclofenac Sodium ER 100mg	Voltaren XR 100mg	Preferred; Tier 2	Anti-inflammatory	\$0.16/pill

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Diclofenac Sodium Gel 3%	Voltaren Gel 3%	Preferred; Tier 2	Anti-inflammatory	\$9.00/gram
Diclofenac Sodium Solution 1.5%	Pennsaid 1.5%	Preferred; Tier 2	Dermatologic	\$1.00/ml
Diclofenac Potassium 50 mg Powder	Cambia 50mg Powder	Non-Preferred	Migraine Product	\$51.64/pkt
Diclofenac Potassium 25mg	Zipsor 25mg	Non-Preferred	Anti-inflammatory	\$7.77/pill
Diclofenac Sodium Solution 2%	Pennsaid 2%	Non-Preferred	Dermatologic	\$22.00/ml
Diclofenac Sodium Solution 0.01%	Voltaren Eye Solution 0.01%	Non-Preferred	Ophthalmic	\$3.50 – 18.00/ml

- c. We believe that with a streamlined list of medications, the P&T committee will be able to detail these steps. We recommend that at least (2) tier 1 drugs must be trialed and failed prior to using a step 2 product and so forth.
 - d. NDC specificity will help to curb use of drug formulations with middle strengths that are made mostly for financial gain. An example is cyclobenzaprine; a frequently prescribed muscle relaxant mainly seen in office dispensing situations. If the formulary was NDC specific it would allow cyclobenzaprine 5 mg and 10mg (cost range \$0.03 to \$1.39/pill), which are reasonably priced, while preventing the use of cyclobenzaprine 7.5mg (\$4.00/pill) which is significantly more costly and provides no further benefit.
4. Regarding inclusion of OTC medication use (Technical Comment 7):
- a. 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 Nexium 20mg (NDC64764-0541-30; Cost \$16/pill).
 - b. In this example Prevacid 15mg OTC is the same dosage form and strength as its prescription counterparts (i.e., all therapeutic equivalents).
 - c. 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:
 - i. Where an OTC product is available, as seen in the example below, 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.

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

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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

5. Regarding timeline for First Fill Policy (Technical Comment 8):
 - a. It is important to have clarity for how to calculate the “7 days” referenced in the first fill policy. It could be the difference between automatic approval of a covered medication with no delay of care to the injured worker and a denial of the medication due to lack of pre-authorization through prospective review and a significant delay in care.
 - b. The regulations should clearly indicate whether the intent of the “7 days” is for the date of injury to be counted as Day 0 or as Day 1.
 - i. 7 days with date of injury counting as day 0: If the date of injury is 07/01/2017 then the seventh day falls on 07/08/2017.
 - ii. 7 days with date of injury counting as day 1: If the date of injury is 07/01/2017 then the seventh day falls on 07/07/2017.
6. Regarding changes to the heading titles and columns within the Preferred Drug List (Technical Comment 9):
 - a. The current Preferred Drug List identifies minimal specificity regarding each listed drug. In addition to necessary changes to existing headings with the streamlined exclusion of Non-Preferred drugs (see appendix B section 9792.12), it is crucial to add columns for Dosage Form and Time Release Mechanism. Clear identification of the dosage form and time release mechanism, as in the following examples, is important for ease of use, accuracy, and updating.
 - b. An example of the importance of Dosage Form specificity:

Drug Ingredient	Preferred Status	NDC Code	Dosage Form	Cost per Unit
Tizanidine HCL 2mg	Preferred	00878-1665-19	Capsule	\$2.25/ pill
Tizanidine HCL 2mg	Preferred	00591-2788-86	Capsule	\$2.16/ pill
Tizanidine HCL 2mg	Preferred	60505-2648-07	Capsule	\$2.25/ pill
Tizanidine HCL 2mg	Preferred	00185-0084-10	Tablet	\$0.15/ pill
Tizanidine HCL 2mg	Preferred	00185-0084-51	Tablet	\$0.15/ pill
Tizanidine HCL 4mg	Preferred	00878-1666-19	Capsule	\$2.85/ pill
Tizanidine HCL 4mg	Preferred	60505-2649-07	Capsule	\$2.85/ pill
Tizanidine HCL 4mg	Preferred	00591-2789-86	Capsule	\$2.73/ pill

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Tizanidine HCL 4mg	Preferred	68084-0013-01	Tablet	\$1.25/ pill
Tizanidine HCL 4mg	Preferred	00878-0724-19	Tablet	\$0.14/ pill

As can be seen above, capsules are priced up to 1435% and 1953% higher than their tablet counterpart. However there is no difference between these medications from an efficacy standpoint (i.e., therapeutically equivalent).

c. An example of the importance of Time Release Mechanism specificity:

Drug Ingredient	Brand Name and Strengths	Time release Mechanism IR-Immediate Release ER-Extended Release	Preferred/First Fill	First Fill Day Supply	Drug Class
Morphine Sulfate	MSIR 15mg, 30mg	IR	First Fill	4 days	Analgesic-Opioid
Morphine Sulfate	Avinza 30mg, 45mg, 60mg, 75mg, 90mg, 120mg	ER			Analgesic-Opioid
Morphine Sulfate	Kadian 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg, 80mg, 100mg 130mg, 150mg, 200mg	ER			Analgesic-Opioid
Morphine Sulfate	MS-Contin 15mg, 30mg, 60mg, 100mg, 200mg	ER			Analgesic-Opioid
Morphine Sulfate	Oramorph-SR 15mg, 30mg, 60mg, 100mg	ER			Analgesic-Opioid
Morphine Sulfate	Roxanol Sol (mg/ml) 10/5, 20/5, 100/5	IR			Analgesic-Opioid

The above example identifies multiple versions of Morphine Sulfate, some are short acting immediate release and others are long acting extended release. Because there is no specificity regarding time release mechanism, as written, the proposed regulations would allow all forms of Morphine Sulfate to be dispensed under the “First Fill” policy. The First Fill policy is intended to provide a short course of otherwise Non-Preferred medications to an injured worker at the very outset of a workplace injury and should not include medications that are intended for chronic, cancer, or end-of-life pain.

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Appendix B

Appendix to Comments submitted by Zenith regarding Proposed Regulations - Medical Treatment Utilization Schedule - Drug Formulary - Notice of Proposed Rulemaking September 2016 (California Code of Regulations, title 8, §§ 9792.27.1 through 9792.27.18)

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

1. Page 1, 9792.27.1(d)- Zenith is concerned that the definition of Compound Drug does not address drugs with only one active ingredient and does not address products that are commercially manufactured in “kits” whereby the manufacturer’s label provides instructions on how to mix or reconstitute the compounded formula. Zenith recommends this definition be amended as follows:

(d) “Compounded drug” means a product that is created by combining two or more active or inactive pharmaceutical ingredients to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace inclusive of kits designed for ease of compounding such products.

(1) Except as outlined in section (d), a “compounded drug” does not include a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.
2. Page 2, 9792.27.1(l)- Zenith feels that the drug formulary should only address those medications that are “Preferred” or are eligible under the “First Fill” policy. Zenith recommends the following amendment:

9792.27.1(l)- “MTUS Preferred Drug List” or “Preferred Drug List” means the drug list and related information in section 9792.27.12, which sets forth preferred drugs and those eligible under the “First Fill” policy ~~preferred or non-preferred status of drugs~~ listed by active drug ingredient.
3. Page 2, 9792.27.1(m)- Zenith feels that the drug formulary should only address those medications that are “Preferred” or are eligible under the “First Fill” policy. Zenith recommends the following amendment:

9792.27.1(m) “Non-Preferred Drug” means any drug not listed on the MTUS Preferred Drug List and those listed on the MTUS Preferred Drug List as “First Fill Eligible”.
4. Page 2, 9792.27.1(t)- Zenith feels that the drug formulary should only address those medications that are “Preferred” or are eligible under the “First Fill” policy. Zenith recommends the following amendment:

9792.27.1(t)-“Preferred drug” means a drug on the MTUS Preferred Drug List which is designated as “Preferred” and is thereby a drug that does not require authorization through prospective review prior to dispensing the drug, provided that the drug is prescribed in

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accordance with the MTUS Guidelines. ~~The Preferred Drug status of a drug is designated in the column with the heading labeled “Preferred / Non-Preferred”.~~

5. Zenith recommends the addition of a definition for “Clinical Setting” as follows:

“Clinical Setting” means those settings which provide emergency medical care, inpatient hospital treatment, and outpatient procedures or surgeries. The term Clinical Setting does not apply to evaluation and management appointments conducted in a physician’s office unless the injured worker presents with a condition requiring emergency intervention.

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

6. Page 4, 9792.27.2(b)(3)- Zenith notes that there is no definition for “clinical setting” as it is used in this section. We believe that the intent of this section is to ensure that medications administered in settings outside of regular office visits, for instance those in an urgent care, emergency room, or inpatient hospital setting, are not subject to the formulary. Therefore, Zenith recommends the addition of a definition for “clinical setting”, as noted above.
7. Page 4, 9792.27.2(b)(3)- Zenith notes that this section does not address retrospective review of medications that are administered to an injured worker. The language notes that “Although the MTUS Drug Formulary is not applicable to drugs administered in a clinical setting, drug treatment in those settings is subject to relevant MTUS Guidelines and rules”. In order for MTUS Guidelines to be applied to the medication administered, there must be some method for retrospective review. Therefore, Zenith recommends the addition of the following language:

9792.27.2(b)(3)(A) Medication administered to a patient in an applicable clinical setting 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.

§9792.27.3. MTUS Drug Formulary Transition

8. Page 4, 9792.27.3(b) - Zenith feels that the drug formulary should only address those medications that are “Preferred” or are eligible under the “First Fill” policy. Zenith recommends the following amendment:

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug ~~or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”)~~, the physician shall either:

- (1) Prepare a treatment plan to transition the worker to a Preferred Drug, or

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(2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug ~~or unlisted drug~~. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug ~~or unlisted drug~~ for an extended period where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

§9792.27.5. MTUS Drug Formulary - Off Label Use

9. Page 5, 9792.27.5(a) This section references off label use of Non-Preferred and Unlisted drugs.

Zenith feels that the drug formulary should only address those medications that are "Preferred" or are eligible under the "First Fill" policy. Zenith recommends the following amendment:

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

§9792.27.6. MTUS Drug Formulary – Access to Drugs Not Listed in the Preferred Drug List

10. Zenith notes that this section appears to leave open the interpretation that any drug listed on the MTUS Preferred Drug List, regardless of its status as "Preferred" or "Non-Preferred", does not require prospective review when dispensed in accordance with the MTUS Guidelines. We believe the intent is that only "Preferred" drugs would fit this criteria and therefore Zenith recommends the following amended language:

Drug treatment that is in conformity with the MTUS Guidelines is presumed correct on the issue of extent and scope of medical treatment pursuant to section 9792.21 subdivision (c), and Labor Code section 4604.5. Although the MTUS Preferred Drug List identifies "Preferred" drugs that do not require prospective review when dispensed in accordance with the MTUS Guidelines...

§9792.27.7. MTUS Drug Formulary – Brand Drugs; Generic Drugs; OTC Drugs.

11. Zenith recommends adding "OTC Drugs" to the title of this section and providing language to indicate that if an over the counter (OTC) formulation exists, it should be dispensed to the injured worker in place of either a generic or brand name product.

12. Page 5, 9792.27.7- Zenith notes that there are three separate outcomes regarding use of Brand Drugs versus Generic Drugs and either prospective or retrospective UR under this section;

1) The Brand Drug is deemed appropriate and medically necessary by either prospective or retrospective UR, 2) The Brand Drug is determined to be inappropriate and not medically necessary; however, the Generic Drug is deemed appropriate and medically necessary by either prospective or

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retrospective UR, or 3) Neither the Brand Drug nor the Generic Drug is determined to be appropriate or medically necessary by either prospective or retrospective UR. Zenith recommends each outcome be addressed in this section. Zenith also recommends that clarity be provided regarding the fee schedule used to determine the “lowest priced generic therapeutic equivalent of the brand drug”. This can be accomplished by amending the section as follows:

9792.27.7 (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 document the medical necessity for prescribing the brand drug in the patient’s medical chart and in the Doctor’s First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician’s determination that the brand drug is medically necessary.

(1) The physician must obtain authorization through prospective review prior to the time the brand drug is dispensed. Prospective review will determine whether the brand drug, the generic drug, or neither is medically necessary.

(2) If required authorization through prospective review is not obtained prior to dispensing the brand drug, retrospective review may be conducted to determine if it was medically necessary to use the brand drug rather than the generic therapeutic equivalent.

(A) If it is determined that the generic drug but not the brand drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand drug as compared across all databases .

(B) If it is determined that neither the brand drug nor the generic drug is medically necessary, payment for the drug may be denied.

§9792.27.8. Physician-Dispensed Drugs

13. Page 6, 9792.27.8(b)- Zenith believes that the intent of this section is to limit physician dispensing to a seven day supply of “Preferred” medications at the initial office visit after an injury. As written, the regulation leaves open the possibility that a physician could dispense a seven day supply of a “Preferred” medication at any office visit. We recommend the following amendment to this section:

(b) At the initial office visit after the date of injury, a physician may dispense up to a seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be

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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.

§9792.27.9. Compounded Drugs

14. Page 6, 9792.27.9(a)- For clarity purposes as well as consistency with prior sections, Zenith recommends adding the following language:

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

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

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

15. Page 7, 9792.27.10(c)- Zenith recommends striking this section and deferring to 9792.27.10(e). Zenith believes that only "Preferred" drugs should be included on the MTUS Preferred Drug List and therefore 9792.27.10(e), with a slight modification, suffices to address all other drugs- those currently listed as "Non-Preferred" as well as those which are unlisted. Zenith recommends the following amended language:

(e) For a drug not identified as "Preferred" on the MTUS Preferred Drug List, authorization through prospective review must be obtained prior to the time the drug is dispensed. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied.

16. Page 7, 9792.27.10(d)- Zenith notes that there is no language in this section that addresses situations in which a "First Fill Eligible" drug is requested or dispensed but does not meet the requirements under the "First Fill" policy. Zenith recommends the following amendment:

(d) For a drug that is identified as "First Fill Eligible"on the MTUS Preferred Drug List, the usual requirement to obtain authorization through prospective review prior to

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dispensing the drug is altered for the specified circumstances set forth in section 9792.27.11. If the requirements set forth in section 9792.27.11 are not met then the drug is considered “Non-Preferred” and is subject to the provisions set forth under 9792.27.10(e)

§9792.27.11. MTUS Preferred Drug List – First Fill

17. Page 7, 9792.27.11(b)- Zenith notes that the language in this section uses both “prescribed” and “dispensed” in the language. This could lead to confusion as well as the possibility for the interpretation that a physician may both prescribe and dispense the “First Fill Eligible” medication. For clarity purposes, Zenith recommends the following amendments to this section:

- (b) The drug identified as a First Fill drug may be prescribed ~~dispensed~~ to the injured worker without seeking prospective review if the following conditions are met:
- (1) The drug is prescribed at the initial visit following a workplace injury, provided that the initial visit is within 7 days of the date of injury. For purposes of this timeframe requirement, day 1 is considered the first day after the date of injury; and
 - (2) The prescription is for a supply of the drug not to exceed the limit set forth in the Preferred Drug List; and
 - (3) The prescription is for:
 - (A) An FDA-approved generic drug or single source brand drug; or
 - (B) A brand drug where the physician documents and substantiates the medical need for the brand drug rather than the FDA-approved generic drug; and
 - (4) The drug is prescribed in accordance with the MTUS Guidelines.

18. Page 8, 9792.27.11- Zenith notes that this section does not address retrospective review of a medication prescribed under the “First Fill” policy. In order for MTUS Guidelines to be applied to the medication prescribed as outlined in 9792.27.11(b)(4), there must be some method for retrospective review. Therefore, Zenith recommends the addition of the following language: 9792.27.11(d) Any medication prescribed under the “First 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 the drug was not medically necessary.

§9792.27.12. MTUS Preferred Drug List

19. Zenith feels that the drug formulary should only address those medications that are “Preferred” or are eligible under the “First Fill” policy. Zenith recommends the following amended headings: Drug Ingredient; *Preferred/~~Non-Preferred~~ **First Fill Eligible; First Fill Day Supply; Drug Class; Reference in Guidelines
20. Zenith notes that the Header box should be updated to reflect the deletion of the “Non-Preferred” designation. Zenith recommends the following amended language:
*Preferred/~~Non-Preferred~~ – “Preferred” indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS.

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1) Physician dispensed “Preferred” drugs limited to 7-day supply without Prospective Review. 2) Prescription/dispensing of Brand name Preferred drug where generic is available requires authorization through Prospective Review. ~~“Non-Preferred” drug requires authorization through Prospective Review prior to prescribing or dispensing.~~ (See 8CCR §9792.27.1 through 9792.27.11 for complete rules.)

**First Fill Eligible – indicates Drug may be prescribed/dispensed without Prospective Review: 1) Rx at initial visit within 7 days of injury, and 2) Supply not to exceed # days indicated under “First Fill Day Supply”, and 3) if in accord with MTUS (See 8CCR §9792.27.11)

21. Zenith recommends additional columns within the Preferred Drug List for 1) “Preferred Dosage Form” (i.e., Tablet, Capsule, Topical, etc.) and 2) “Time Release Mechanism” (i.e., Immediate Release, Extended Release, etc.). This will allow for greater specificity within the Preferred Drug List.
22. The Drug List notes a “Drug Class” of “null” in multiple instances. This should be corrected in all occurrences (lines 49, 138, 169, and 174).
23. Line item #98 for Flunisolide Anhydrous is missing a designation for “Preferred/Non-Preferred” and “First Fill”. Zenith recommends this be reviewed and updated accordingly.
24. Line item #77 lists Diclofenac Sodium solely under “dermatologicals” as a drug classification. Zenith believes that this medication has been misclassified and should be listed as both a “Dermatologicals” and “Analgesics-Anti-inflammatory”.

§9792.27.15. Pharmacy and Therapeutics Committee – Conflict of Interest

25. Page 10, 9792.27.15(c)(2)(D) - Zenith notes that the dollar value of \$2000 or more “in a publicly-traded pharmaceutical entity, not including an investment held through a diversified mutual fund” appears low for a trigger value and recommends consideration of raising this dollar value.

Edward Canavan
Sedgwick

September 16, 2016

At Sedgwick, we appreciate the opportunity to comment on the proposed updates to MTUS and Formulary, and recognize the considerable work which went into the regulations.

Sedgwick recognizes DWC is under a tight timeline to adopt an evidence-based drug formulary, consistent with MTUS, to support the delivery of high quality medical care and promote timely return-to-work, while reducing administrative burden and cost. We appreciate that DWC has determined this is also a favorable time to update MTUS clinical topics that are sorely out of date.

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We have concerns about whether the proposed Formulary meets the objectives of AB1124 which include that the formulary be evidence-based, nationally recognized and updated quarterly. Implementation of a state-specific Formulary, purportedly based on MTUS, but inconsistent with ACOEM, and far more restrictive than national, evidence-based guidelines like ODG, does not appear to meet the objectives. Implementation of a state-specific PDF Formulary lacking linkage to guidelines and medical coding will be difficult to operationalize. We rely heavily on automation, integration, and online query tools for our claims team and within the claims, clinical (utilization review/case management), and bill review systems.

As an organization offering workers' compensation, disability, liability, and professional liability administration our teams are highly engaged with evidence-based medicine and treatment guidelines. Sedgwick engaged cross function teams to extensively evaluate the guideline market and determined ODG guidelines should be used and automated inside our claims and clinical management systems. Our colleagues use ODG to assist with determining medical necessity and approval of quality care for workers' compensation. ODG provides automated, evidence-based guidelines and treatment plans for every condition and procedure in workers' comp. It is the most comprehensive, evidence-based, and up-to-date guideline available, with a proven Drug Formulary and application tools to apply the guidelines like a UR Advisor, which is coded with ICD, CPT and NDC codes for integration and automation inside systems. The claims and clinical teams work directly with treating physicians to negotiate return to work and share guidance on evidence-based treatments, as necessary, may engage a physician advisor to provide a peer outreach to the treatment provider. We have found an increasing number of physicians using ODG guidelines and the mobile tool in treating workers' compensation claims.

Sedgwick is accessing ODG's 21st edition for 2016, delivering a new and updated version every year. Like Sedgwick, ODG has become the leader in market share due to their core values that include evidence-based methodology, a comprehensive and dependable update process, and top-notch customer service. One of the major advantages of ODG over other tools is treatment; ODG provides a complete integrated treatment guidelines (medical and disability) so our nurses, claims examiners, and physician advisors can ensure injured workers have the most appropriate care across our occupational and non-occupational claims administration.

ODG is recommended in both the Rand Formulary study commissioned by DWC, and the 2004 Rand Technical Quality Evaluation. While the regulations are well written, we respectfully request that DWC strongly consider replacing the proposed formulary and MTUS clinical updates with ODG.

Joshua Prager, MD, Director
Center for the Rehabilitation of Pain Syndromes

September 16, 2016

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This letter is in response to request for comments relating to the released draft proposal to implement changes to the medical treatment utilization schedule for the State of California. These comments relate specifically to the proposal for the back disorder chapter, with the guideline eliminating spinal cord stimulation as a treatment for failed back surgery syndrome and other related pain conditions. It is with profound sadness and astonishment that I write this letter. As will be discussed below, the reasons I am astonished to see this proposal specifically because DWC previously in December 2014 put forth a similar proposal to eliminate spinal cord stimulation. After an exhaustive review of the compelling evidence supporting the therapy and a vigorous response by physicians and concerned societies as well as academic programs, this proposal was not enacted.

This letter will cover two topics.

- I. History of DWC's proposal to eliminate access for the injured workers in the State of California to receive spinal cord stimulation for treatment of failed back surgery syndrome, the reaction to this, and the ultimate result.
- II. Discussion of the ACOEM guidelines. There will be explicit discussion of the inherent bias of these guidelines and the process and why they should not be implemented in the State of California.

I.

Recent History of DWC Proposal to Eliminate Coverage for Spinal Cord Stimulation

On 12/08/2014, the DWC solicited comments regarding a new chronic pain chapter. <https://www.dir.ca.gov/DIRNews/2014/2014-114.pdf> These comments were due on 12/18/2014. The comments can be found at The proposed chronic pain chapter would eliminate access for injured workers in the State of California for spinal cord stimulation and intrathecal therapy for chronic pain. Numerous comments were received by the deadline of 12/18/2014. <http://www.dir.ca.gov/dwc/DWCWCABForum/ChronicPainMedicalTreatmentGuidelines.htm>

In response to the solicitation for comments, I provided an extensive evidence table demonstrating an extensive literature review regarding these modalities. Ultimately, a document more than 1-inch thick was provided to the DWC in several parts. An executive summary was provided that reviewed the burden of chronic pain, treatment options, and presented the evidence for spinal cord stimulation and targeted drug delivery in appropriately selected patients with chronic pain. There are appendices that supported the efficacy, safety, and cost effectiveness of these two modalities. In addition, current clinical practice guidelines were provided. This document was endorsed by a physician in an administrative capacity for every academic pain program in the State of California in addition to:

- The American Society of Anesthesiology
- American Society of Interventional Pain Physicians
- The North American Neuromodulation Society
- The California Society of Anesthesiologists
- California Society of Interventional Pain Physicians
- The California Society of Industrial Medicine

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This amount of consensus from this number of leading organizations and academic institutions is rare. The arguments made in the evidence tables were convincing so that there was an overwhelming support and commitment from these organizations to ensure that access to these modalities for injured workers in the State of California would not cease.

Immediately below is the cover letter for the document

*April 28, 2015
Division of Workers' Compensation
PO Box 420603
San Francisco, CA 94142*

We are writing on behalf of a group of professional societies representing thousands of pain treatment specialists regarding the Division of Workers' Compensation (DWC) proposed Chronic Pain Medical Treatment Guidelines posted on December 8, 2014. The proposed medical treatment utilization schedule (MTUS) language contradicts the Official Disability Guidelines (ODG) on which it is based. The current MTUS is the result of the work of the Medical Evidence Advisory Committee (MEEAC), a vetted group of professionals appointed by the state of California who worked in an iterative fashion with ODG to develop these evidence-based guidelines. The proposed new MTUS ignores this evidence-based work as well as new, high-quality, compelling evidence that supports coverage of spinal cord stimulation (SCS) for failed back surgery syndrome (FBSS) and intrathecal drug delivery (IDD) systems for noncancer pain. We respectfully request that you rescind the portions of the MTUS that remove coverage for these treatments for which there is substantial evidence published in peer-reviewed journals that supports the recommendations of the prior MTUS with regards to both the efficacy and cost-effectiveness of these therapies.

According to the recent independent and authoritative Institute of Medicine (IOM) report on Pain in America, chronic pain is a costly public health problem that requires:

“a transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain.”

To that end, our members are acutely aware that removing effective, Food and Drug Administration-approved treatment options from patients with chronic pain clashes with our professional ethics and deprives patients of therapies with decades of evidence as to their utility.

In support of our request, please consider the accompanying documents:

- An **Executive Summary** that reviews the burden of chronic pain, treatment options, and evidence for using SCS and IDD in appropriately selected patients with chronic pain.*
- **Summaries of Peer-Reviewed Literature** (Appendices II, III, VI, VII) that amply support the efficacy, safety, and cost-effectiveness of both SCS and IDD.*
- **Current Clinical Practice Guidelines** (Appendices IV, VIII) that include SCS and IDD.*

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Since the current MTUS was published, subsequent data have supported its conclusions and, absent compelling data to the contrary, there is no rationale for change. As specialists who spend every day caring for patients in pain, we thank you for the opportunity to present these data that emphasize the vital role of SCS and IDD in the treatment of chronic pain.

Sincerely,

The Executive Summary that accompanied the Evidence Table and Analysis is below.

Executive Summary in Support of Spinal Cord Stimulation for Failed Back Surgery Syndrome and Targeted Intrathecal Drug Delivery for Noncancer Pain

Chronic Pain Is a Costly Public Health Problem

- *Chronic pain that lasts beyond the expected healing time or longer than 3 monthsⁱ afflicts at least 110 million Americans, more than the total number affected by cancer, diabetes and heart disease combined.ⁱⁱ*
- *The Federal Government recognized that untreated and under-treated pain is a serious problem and mandated that the Institute of Medicine (IOM) convene a highly vetted, distinguished committee to analyze the problems caused by inadequate treatment of pain and make recommendations to improve the situation. The results were published by the Institute of Medicine (US) Committee on Advancing Pain Research, Care and Education as *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.*"³ Significant points included:*

 - *Chronic pain costs Americans up to \$635 billion annually in medical treatment and lost productivity, according to the Institute of Medicine (IOM).ⁱⁱⁱ*
 - *"To reduce the impact of pain and the resultant suffering will require a transformation in how pain is perceived and judged both by people with pain and by the health care providers who help care for them. The overarching goal of this transformation should be gaining a better understanding of pain of all types and improving efforts to prevent, assess, and treat pain."ⁱⁱⁱ*
 - *For many patients cure may be unlikely," according to IOM.ⁱⁱⁱ*

Chronic Pain Can Be "Frustratingly Difficult to Treat"ⁱⁱⁱ

- *Conventional medical management (CMM) for chronic pain consists of medications (including systemic opioids), regional anesthetic interventions, psychological therapies, rehabilitative/physical therapy, and complementary and alternative medicine.ⁱⁱⁱ*
- *"A growing, deadly epidemic" of prescription medicine overdose deaths in the U.S.^{iv} has made access to prescription systemic opioids more difficult, even for medically indicated chronic pain*

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management. Among physicians, 29% of primary care and 16% of pain specialists report they prescribe opioids less often than they think appropriate because of possible regulatory repercussions.^v

- For patients who suffer intolerable side effects from oral opioids or whose pain is not relieved, few other treatment options exist.
- Spinal cord stimulation (SCS) and targeted intrathecal drug delivery (IDD) can be evaluated before implementation during a screening trial, and offer physician-controlled pain therapy that is safe, effective, and cost-effective.
- Patient satisfaction with SCS and IDD has been consistently high (Appendices II and VII).

Spinal Cord Stimulation Is Effective and Cost-Effective in Treating Failed Back Surgery Syndrome

A new groundbreaking Level 1, pivotal, Food and Drug Administration-supervised randomized controlled trial (RCT) compared high-frequency 10 kHz SCS to traditional low-frequency SCS.^{vi} (See Appendix II)

- 10 kHz SCS produced profound and durable pain relief as well as functional improvement measured by validated instruments, such as the Oswestry Disability Index (ODI).
- The 1-year responder rate ($\geq 50\%$ pain reduction) for 10 kHz high-frequency SCS was 78.7% for both back pain and leg pain.
- Pain reduction for both traditional SCS and 10 kHz high-frequency SCS was between 44% and 69%.
- Previous RCTs that demonstrated significantly better pain relief and improvement in health-related quality of life (HRQoL) for SCS compared with CMM. (See Appendix II)
- SCS treatment of FBSS resulted in significant functional improvements over baseline in pain intensity, sex life, sitting, social life, standing, traveling, and walking at 6 months compared with CMM. These improvements were maintained at 24 months.^{vii}
- SCS was also significantly more successful than reoperation for FBSS, with 48% of SCS patients and only 12% of reoperation patients reporting $\geq 50\%$ pain relief.^{viii} Patients preferred SCS to reoperation and were less likely to require increased opioids.^{ix}
- Pain relief with SCS has proved durable, with 60% patients having pain relief after an average of 8.1 years.^x Over a 22-year period, the early success rate was 80% (328 patients), and the long-term success rate was 74% (243 patients).^x
- Numerous studies using actual costs or health economic modeling have found SCS to be cost-effective in treating FBSS (See Appendix III), with the breakeven point for SCS occurring at approximately 2.5 years after implantation.
- SCS is recommended in numerous clinical practice guidelines for treatment of FBSS. (See Appendix IV)
- **Intrathecal Drug Delivery Is Effective and Cost-Effective in Treating Chronic Noncancer Pain**
- The independent ECRI (<https://www.ecri.org/Pages/default.aspx>) found that IDD leads to clinically relevant pain relief for chronic noncancer pain, and is associated with a decrease in the amount of other drugs taken or in the proportion of patients taking other drugs.^{xi} (See Appendix VI) Additional evidence of IDD efficacy and of the therapy-limiting drawbacks of systemic opioids has continued to accumulate since the 2008 ECRI review (Appendix VI).
- Physician control of IDD has the potential to improve both safety and efficacy when opioids are prescribed.

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- *Improvements in safety, efficacy, compliance, and cost can be achieved by reducing or eliminating concomitant oral opioids in patients treated with IDD for chronic pain. (See Appendices VI and VII)*
- *IDD patients were less likely than those taking oral opioids to discontinue treatment due to adverse events (8.9% vs. 22.9%, respectively), or insufficient pain relief (7.6% vs. 10.3%, respectively), according to a Cochrane review of thousands of patients.^{xii}*
- *IDD has the potential to reduce longitudinal costs (Appendix VII) compared to other routes of opioid delivery, and compared to the costs associated with ineffective therapy, noncompliance, diversion or abuse.*
- *IDD is recommended by numerous clinical practice guidelines (Appendix VIII).*

In the spring of 2015, an appointment was made with Dr. Das, medical director for the DWC, to discuss this evidence table and analysis in her office in Oakland, California. Traveling to that meeting that was scheduled several weeks in advance were myself; Dr. Francis Riegler, president of the California Society of Interventional Pain Physicians; from Los Angeles and Dr. Lawrence Poree, director of neuromodulation at the University of California San Francisco Medical Center. Dr. Das had jury duty that day. She did not notify us that she would be absent and we travelled to Oakland without meeting with her.

On 07/28/2016, the DWC published chronic pain guidelines, which included access to the therapies that were originally proposed to be eliminated.

On 08/31/2015, I travelled again to Oakland and did have the opportunity to meet with Dr. Das to discuss the document that was endorsed by this multitude of organizations.

On 09/01/2015, public hearing on a chronic pain chapter was held. I testified at that hearing and transcript of the testimony is available on the DWC web site. <https://www.dir.ca.gov/dwc/DWCPropRegs/MTUS-Opioids-ChronicPain/Transcript.pdf> . By the time of the hearings, the proposal for change in the guidelines had been modified to include access to spinal cord stimulation and targeted drug delivery as indicated above, but there were several remaining ambiguities.

It is hard to believe that after going through this entire process over a 9-month period with resolution resulting in inclusion of access to these therapies for injured workers in the State of California, a new proposal would emerge to once again proposed to eliminate them.

II.

The Bias of the ACOEM Lower Back Chapter and why it should not be implemented as a guideline for treatment of injured workers in the State of California.

Below are listed all participants in the process for developing the lower back chapter for ACOEM. In the listing, the board certifications or other qualifications of the participants are listed. It is important to note that there is not one board certified pain physician included in developing the lower back chapter.

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Lower back problems certainly require pain treatment. **Pain medicine is an ACGME recognized specialty and this specialty was deliberately excluded.**

panel members	BOARD CERTIFICATIONS	
roger belcourt	American Board of Preventive Medicine	
ronald donelson	American Board of Orthopaedic Surgery	
marjorie eskay-auerbach	American Board of Orthopaedic Surgery	
jill glaper	physical therapist	
michael goertz	American Board of Preventive Medicine	
scott haldeman	American Board of Psychiatry & Neurology	
paul hooper	chiropractor	
james lessenger	American Board of Preventive Medicine	
tom mayer	American Board of Orthopaedic Surgery	
kathryn mueller	American Board of Preventive Medicine	
donald murphy	chiropractor	
william tellin	chiropractor	
michael weiss	American Board of Preventive Medicine	American Board of Physical Medicine & Rehabilitation
chair		
russell travis	American Board of Neurological Surgery	
editor-in-chief		
kurt hegmann	American Board of Preventive Medicine	
consultants		
cameron macdonald	physical therapist	
jeffrey harris	American Board of Preventive Medicine	American Board of Emergency Medicine
research conducted by		

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kurt hegmann	American Board of Preventive Medicine	
jeremy biggs	American Board of Preventive Medicine	
matthew hughes	American Board of Preventive Medicine	
society reviewers		
david o'gurek	American Board of Family Medicine	
j d bartleson	American Board of Psychiatry & Neurology	
ryan carter cassidy	American Board of Orthopaedic Surgery	
john o'toole	American Board of Neurological Surgery	
mohammed ranavaya	American Board of Preventive Medicine	
michele maiers	chiropractor	
joshua broder	American Board of Emergency Medicine	
stephen cantrill	American Board of Emergency Medicine	
jeff snodgrass	occupational therapist	
daniel bruns	psychologist	
vitaly napadow	acupuncturist	
claudia witt	physician, no board certification	
other reviewers		
steven hwang	American Board of Neurological Surgery	
howard king	American Board of Orthopaedic Surgery	
steven mandel	multiple listings (none pain certified)	

Please note:

- Kurt Hegmann is a preventive medicine specialist and editor in chief of the ACOEM guidelines. He does not practice pain.
- The chair of the panel is Russell Travis, a neurosurgeon.

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- The researchers for the panel consisted of three board-certified preventive medicine specialists without the inclusion of one pain specialist.
- The panel was comprised of five preventive medicine specialists, three orthopedists, one physician certified in psychology and neurology, one physical therapist, and three chiropractors.
- Consultants included one preventive medicine specialist and one physical therapist.
- Society reviewers were from family medicine, psychiatry, neurology, orthopedics, neurosurgery, preventive medicine, emergency medicine, occupational therapy, psychology, acupuncture, and chiropractic.
- One physician had no board certification.
- None of the society reviewers was a pain medicine specialist.
- There were two additional reviewers, one from neurosurgery and one from orthopedics.
- There was one physician whose specialty could not be determined who clearly was not a pain specialist.
- **Thus, participants in this process included four chiropractors, an acupuncturist, an occupational therapist, a psychologist, and a physical therapist, but not one pain specialist.**

The societies that were requested to review this included:

- Family medicine.
- Neurology.
- Orthopedics.
- Physical medicine and rehabilitation.
- Neurosurgical spine.
- The American Board of Independent Medical Examiners.
- The American Chiropractic Association.
- American College of Emergency Physicians.

There are numerous associations of physician pain specialists, but none were included. Options would have included:

- The American Academy of Pain Medicine.
- The American Society of Regional Anesthesia and Pain.
- The American Society of Interventional Pain Physicians
- The American Society of Anesthesiology, Pain Committee.
- Spinal Injection Society
- The American Association of Neurological Surgeons/Congress of Neurosurgeons Pain Section.
- The American Academy of Pain Medicine.
- The North American Neuromodulation Society.

Thus, those charged with the responsibility of researching the document were not pain specialists. The panel members did not include a pain specialist. The reviewers did not include a pain specialist. The physician societies and non-physician societies that reviewed this document did not include a pain society.

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This should be contrasted with ACOEM's published Methodology:

Methodology for ACOEM's *Occupational Medicine Practice Guidelines – 2016 Revision* – details the peer review process used in the development of ACOEM Guidelines:

ACOEM conducts external peer review of the Guidelines to: 1) assure that all relevant high quality scientific literature related to the topics has been found; 2) assure that the important evidence from the scientific literature relevant to the Guidelines has been accurately interpreted; 3) solicit opinions on whether the findings and recommendation statements are appropriate and consistent with the evidence; and 4) obtain general information on the Guidelines' conclusions and presentation from external topic experts.

Specifically, ACOEM sets forth organizations to be invited to review:

Attachment 15 (pg 51) **Professional and Patient Organizations to be Invited to Review the Updates to the *Guidelines*.**

This list includes the following pain-related Societies –which were not identified as being included in the review of the Low Back Disorders Guideline:

American Academy of Pain Management
American Academy of Pain Medicine
American Pain Association
American Pain Foundation
American Pain Society
American Society of Interventional Pain Physicians
Chronic Pain Association of Canada
International Association for the Study of Pain
The National Pain Foundation
North American Neuromodulation Society

Thus, ACOEM did not include any of the pain societies that they list as invitees in their own review protocol.

The ACOEM guidelines were specifically designed to exclude the input of pain physicians in the research, development, review, and societal review of the documents. Thus, these guidelines were created from inception to completion without the input of pain medicine an important bona fide highly relevant specialty both on the individual and society level. **Pain management is extremely important in treating the lower back and deliberately excluding this specialty resulted in excluding what the specialty would recommend.**

SUMMARY

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Access to neurostimulation should be provided to appropriately selected patients for treatment of failed back surgery in the State of California. A prior proposal to exclude this therapy was changed resulting in implementation of guidelines as recently as last year, including this therapy in the revised MTUS.

We are at a time when there is an opioid crisis in the United States. Overdose deaths involving prescription opioids have quadrupled since 1999,¹³ and so have sales of these prescription drugs.¹⁴ From 1999 to 2014, more than 165,000 people have died in the U.S. from overdoses related to prescription opioids.¹³ Opioid prescribing continues to fuel the epidemic. Today, at least half of all U.S. opioid overdose deaths involve a prescription opioid.¹³ In 2014, more than 14,000 people died from overdoses involving prescription opioids. **This is a time when therapies that are nonpharmacological and do not include opioids should be considered for treatment of pain. Both the CDC and FDA recommend that other modalities be tried first. Removing access to neurostimulation at this critical time is unconscionable and contrary to public policy promulgated to reduce opioid consumption.**

The State of California should not consider a biased document such as the ACOEM guidelines, which were created, conceived of, researched by, and reviewed with the exclusion of board certified pain specialist. ACOEM proceeded to use physical therapist and chiropractors, but did not consider the input from pain specialists. **Furthermore ACOEM violated its own procedure by excluding relevant organizations it lists as societies to invite.** This document should not be implemented in the State of California.

Given the short timeframe that was provided, at this time we did not have the opportunity to solicit the support of the multitude of organizations that supported the previous document. Since that document was created, there are additional articles in well-regarded peer review journals providing additional data supporting the use of neurostimulation for treatment of back pain.

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Jon Seymour, MD,CEO
Peers Health

September 16, 2016

I'm having a hard time figuring out why the [State of California is "partnering" with Reed Group](#) when a better avenue is so readily available.

I have extensive experience in drug information, having written the Clinical Pharmacology drug database (now owned by Elsevier) and served as CEO of Medi-Span, and in medical publishing generally, having been Chief Medical Officer at Wolters Kluwer Health. In occupational health, having worked first as President of Guidelines for Reed and now, with Peers, as a close partner of Work Loss Data Institute, I can speak to both companies' history and relevant capabilities.

For decades, Reed's MDGuidelines shied away from treatment recommendations and also had absolutely nothing to do with evidence-based medicine. (Nobody knows better than Reed that non-EBM guidelines can be very valuable.) With the 2013 acquisition of ACOEM's guidelines business, Reed added treatment and EBM to its portfolio, but ACOEM at that time had, and today still has, a very limited history of implementation in workers' compensation. And the formulary (read: drug list) is brand new to

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both ACOEM and Reed, having been developed just recently with a third-party pharmacy benefits manager.

One of the reasons for ACOEM's limited success in WC is its ivory-tower approach to EBM, which the Reed organization, relatively inexperienced with EBM, is now embracing full-throttle, claiming a competitive advantage when in fact there is a disadvantage: there's insufficient (purely academic) evidence for a wide range of common treatments. This will backfire on DWC.

Reed Group's primary business is not guidelines (content) at all, but rather absence management services, yet even there, it does not serve WC (only STD, LTD, FMLA, and ADA). Compounding the contrast, Reed is itself owned by Guardian Life Insurance Company of America, which obviously is in many lines of business outside of publishing (but not, to my knowledge, WC).

Work Loss Data Institute, on the other hand, is an evidence-based guidelines publisher, period. For 21 years, ODG has supplied EBM for WC, generating success stories across the country. ODG supplements comprehensive literature review (practical EBM) with real-world data including millions of WC cases. Its treatment and return-to-work guidelines are crafted by the same editors, providing critical internal consistency (something DWC claims to value). It answers the key questions for all WC participants in a timely, actionable way that demonstrably leads to high-quality medical care. Its formulary has been put to work benefitting states and stakeholders for 8 years. It is, beyond argument, the gold standard in WC guidelines.

As many of you know, ACOEM recognized the prominence and impact of ODG in its own journal recently, in the landmark study "A New Method of Assessing the Impact of Evidence-Based Medicine on Claim Outcomes" (Hunt et al., *JOEM* 58:5, May 2016). The article, copyrighted by ACOEM, affirms ODG's stature as a true EBM resource, its position as the most widely-adopted guideline in WC, and its dramatic positive impact on outcomes. Enough said.

Given Reed's push into the market, DWC appropriately asked Rand to assess its content options, and Rand reported mostly what I would have expected: that ODG's guidelines and formulary are more comprehensive and up-to-date and that the formulary is significantly easier to implement and operationalize. (Those points should seal the deal.) But, somewhat inexplicably, Rand muted ODG's positives by stating that "The [ACOEM] guidelines are developed through a process that is more rigorous, transparent, and evidence based than ODG's (Nuckols et al., 2014)". The Nuckols study alone was cited each time ODG was deemed "less rigorous" than ACOEM. Rand used the phrase "rigorous" five times in the report, including twice to describe itself. Yet Rand was anything but rigorous in assessing EBM quality. In the Nuckols study, which looked at only one chapter (pain) from 13 different guidelines, "rigor" was but one of six criteria in but one of two appraisal methods, and ACOEM was far from the top of the rankings for rigor. In fact, ACOEM received only a "fair" rating overall (lower than ODG) by one method and in the other, half of the appraisers voted that ACOEM could not be recommended for use at all. Not surprisingly, the study was publicly criticized by ACOEM itself, making it ironic at best to see it cited by Rand in this context!

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In clinical medicine, as opposed to academic research, EBM is a means to an end, with that end being measurable positive outcomes. It is nothing in and of itself. DWC seems intent on deviating from a very clear path forward, and it should reconsider.

Minh Q. Nguyen, D.O., President
U.S. Health Works Medical Group

September 16, 2016

On behalf of U.S. HealthWorks Medical Group, Prof. Corp. thank you for the opportunity to respond to the request by the California Division of Workers' Compensation for comments on the subject of "Implementing AB 1124 Drug Formulary and update of MTUS guidelines."

As the largest provider of occupational medicine in the state of California, with over 70 centers throughout the state, U.S. HealthWorks supports the Division's workers' compensation reform initiatives, including the new drug formulary. From our national experience with our other medical groups in states such as Washington, Texas and Ohio, we know that a properly structured occupational medicine drug formulary is consistent with sound medical practices, and can lead to systemic efficiencies and better care for injured workers.

With respect to the current proposal, we offer the following comments from the perspective of the dedicated front-line occupational medicine providers who provide care to injured California workers:

Prospective Review

It appears that the structure of the formulary contemplates a healthy and robust prospective review process. Conceptually, the use of prospective review makes a lot of sense. However, in our experience, the administrative and logistical issues inherent in occupational medicine often make seeking and obtaining timely prior authorization for a drug (or any treatment for that matter) difficult and problematic. We are concerned that the timeframe allowance for the use of the medications outlined in the proposal may result in delays that substantially harm injured workers in cases where there is a legitimate medical need for a drug that requires prospective review.

It takes significant administrative effort to get authorization to process a workers' compensation claim. Consider that in many cases it can take two or three weeks, and sometimes even longer, just to get a claim properly filed and a case number assigned. We have had a large payer tell us it takes an *average of 21 days* just to get a case number in California. Without a case number, it is extremely difficult to get any sort of referral or treatment approved. This leaves providers in the unenviable position of either having to either tell the patient to wait and go without the critical drug(s) or provide the treatment hoping that the retrospective review will allow for reimbursement.

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Lack of a case number doesn't just affect physician dispensing; it also means patients may not be able to get prescriptions filled, a problem which is exacerbated when physician dispensing is limited to a 7-day period.

We would respectfully request that the Division consider the administrative factors impacting prospective review as you work through the formulary regulations. We believe there will be many cases where we will not be able to get a timely prospective review on a medically-necessary non-preferred drug or longer first fill. As an example, an injured worker comes to our clinic late on a Friday with an injury requiring a muscle relaxant and a moderate pain reliever such as Tramadol. Under the current proposed rules, he/she would only have meds through the following Tuesday unless we managed to get a prospective review completed in less than two business days. In reality, it is most likely that this claim would not have an assigned case file during this timeframe, which means the patient would potentially go without needed meds.

Our recommendations:

- Align the formulary rules closer to those of the reduced preauthorization burdens in SB 1160, allowing greater leeway for MTUS-compliant MPN physicians.
- Implement a maximum time period of 48 hours for a payer to respond to a request for prospective review under the formulary.
- Additional rules or greater enforcement of current rules to incentivize faster claim administration and facilitate an efficient prospective review process.

Preferred vs Non-Preferred Drugs

The list of preferred medications generally includes NSAIDs, eye preparations, GI prophylaxis, and antibiotics. This list of medications appears to us to be appropriate and useful, and provides a wide array of choices. However, there are other categories of medications that we believe should be included in the preferred group to address acute occupational conditions.

Muscle Relaxants

We believe that muscle relaxants such as tizanidine, Skelaxin, Robaxin and Parafon forte should be moved to the preferred list. Acute muscular strains are very common occupational injuries. Per ODG, muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. When used in conjunction with other medications such as analgesics, they can be a helpful adjunct in the early healing process.

Topical Medications

We believe certain topical medications should be included in the preferred list, such as low and medium potency topical corticosteroids for acute dermatitis and dermatoses. These conditions best respond when topical steroids are applied early, and therefore waiting for prospective authorization would be counterproductive in these cases. Similarly, silver-sulfadiazine for severely burned patients is

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recommended per ODG. In cases where transmission of skin disorders are possible, such as with scabies, medication like permethrin cream should also be included on the preferred list to prevent further potential occupational spread.

Post Exposure Prophylaxis (PEP)

Antivirals recommended by the CDC to prevent HIV infection in blood borne pathogen exposure should also be included in the preferred list. The initiation of these medications are time sensitive, with the highest level of efficacy when started within 48 hours after the exposure. Similarly, antimicrobial chemoprophylaxis with ciprofloxacin for patients exposed to meningococcal diseases is recommended by the CDC; and therefore ciprofloxacin should be considered as a preferred medication in this setting.

First Fill Exceptions

For the reasons discussed above, we strongly recommend that the first fill period for pain medications and muscle relaxants (to the extent not included in the preferred category) be extended to at least seven business days. The four calendar day period is too short to allow for prospective review should an additional course of treatment be medically necessary,

Generic Drugs, Compound Drugs and Opioids

We support the Division's position regarding the use of generic drugs and compounded drugs. We support the Division's categorization of opioid medications as non-preferred and believe that the occasional exception for a medication such as Tramadol should be handled through the "first fill" exception as discussed above.

Brenda Ramirez, Claims & Medical Director
Stacy L. Jones, Senior Research Associate
California Workers' Compensation Institute

September 16, 2016

These 1st Forum comments on the draft Drug MTUS Formulary Regulations are presented on behalf of members of the California Workers' Compensation Institute (the Institute). Institute members include insurers writing 72% of California's workers' compensation premium, and self-insured employers with \$46B of annual payroll (28% of the state's total annual self-insured payroll).

Insurer members of the Institute include AIG, Alaska National Insurance Company, Allianz/Fireman's Fund Insurance Company, AmTrust North America, 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 Group, Republic Indemnity

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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, ALPHA Fund, California State University Risk Management Authority, Chevron Corporation, City and County of San Francisco, City of Santa Ana, City of Torrance, Contra Costa County Schools Insurance Group, Costco Wholesale, Country of Alameda, 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 indented and identified by *italicized text*.

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

Recommendation

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

Discussion

The Institute understands that the first fill is intended to apply only at a single visit per claim -- the first treatment visit. Clarification is necessary to prevent disputes over whether an employee could visit multiple clinics in the first seven days and get a first fill at each one.

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 to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician shall, within six weeks of the effective date of these regulations, either:

- (1) Prepare and submit to the claims administrator a treatment plan outlining a safe weaning, tapering, or transitioning of the worker to a Preferred Drug by January 1, 2018, or
- (2) Prepare and submit to the claims administrator a Request for Authorization and supporting documentation to substantiate the medical necessity of, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or

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unlisted drug for an extended period where that is determined to be reasonably required ~~necessary~~ for the injured worker's condition or ~~necessary~~ for safe weaning, tapering, or transition to a Preferred Drug.

Failure of a physician to submit a treatment plan under subsection (1), or to submit a Request for Authorization and supporting documentation under subsection (2), may constitute a showing of good cause for an employer's petition requesting a change of physician or provider pursuant to Labor Code Section 4603 and may serve as grounds for termination of the physician from the medical provider network or health care organization.

If a physician submits a treatment plan under subsection (1) to transition the worker to a Preferred Drug, but fails to complete that transition by January 1, 2018, such failure may constitute a showing of good cause for an employer's petition requesting a change of physician or provider pursuant to Labor Code Section 4603 and may serve as grounds for termination of the physician from the medical provider network or health care organization.

Discussion

A defined time limit applicable to the transition period is necessary to avoid abuse and provide the injured worker with safe and effective medical care. Clarification is necessary to ensure that submission of either the transition plan or the documentation substantiating medical necessity for Non-Preferred drugs is made directly to the claims administrator. A stated consequence is necessary in the event the physician fails to submit a transition plan or a Request for Authorization and supporting documentation, or fails to complete a transition to a Preferred Drug.

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 benefit manager or pharmacy network for the provision of drugs for the treatment of injured workers, the drugs available to the injured worker must be consistent with the MTUS guidelines and MTUS Drug Formulary for the injury or condition being treated and may not be further restricted pursuant to the contract.

Discussion

The term "restricted" needs to be clarified in order to avoid frictional costs of UR, IMR, or litigation. For example, where the Formulary or Guidelines are silent on a particular dosage or number of days, the regulation should be clear that a PBM can address these issues through UR without violation of the regulation.

Section 9792.27.5. MTUS Drug Formulary - Off Label Use

Recommendation

(b) When a physician believes the requests a prescription of a drug for an off label use not addressed by

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the MTUS Guidelines ~~is medically necessary~~, the permissibility of the treatment outside of the guidelines is governed by section 9792.21 subdivision (d) (condition not addressed by MTUS or seeking to rebut the MTUS), section 9792.21.1 (medical evidence search sequence), section 9792.25 (quality and strength of evidence definitions) and section 9792.25.1 (MTUS methodology for Evaluating Medical Evidence.) The physician must obtain authorization through prospective review prior to the time the drug is dispensed for the off label use. If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.

Discussion

The permissibility of treatment outside the MTUS Guidelines is governed by the section 9792.21, whether or not a physician believes the prescription of a drug for an off label use that is not addressed by the MTUS Guidelines is medically necessary, and since the question of “medically necessary” is not determined until the review, replacing that term “believes” with “requests” better reflects the process.

Section 9792.27.6. MTUS Drug Formulary – Access to Drugs Not Listed in the Preferred Drug List.

Recommendation

Drug treatment that is in conformity with the MTUS Guidelines is presumed correct on the issue of extent and scope of medical treatment pursuant to section 9792.21 subdivision (c), and Labor Code section 4604.5. Although the MTUS Preferred Drug List identifies drugs that do not require prospective review when dispensed in accordance with the MTUS Guidelines, other medically necessary drugs are available to the injured worker when authorized through prospective review. An injured worker may be prescribed any medically necessary FDA-approved prescription drug, FDA-approved nonprescription drug, or nonprescription drug that is marketed pursuant to an FDA OTC Monograph, if it is shown by a preponderance of scientific medical evidence that a variance from the guidelines is required to cure or relieve the injured worker from the effects of his or her injury. ~~Treatment outside~~ 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.)

Discussion

This change is recommended to clarify the intent of the rule, and ensure that the “preponderance of scientific evidence” is governed by these sections.

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

Recommendation

(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 document the medical necessity

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for prescribing the brand drug in the patient's medical chart and in the Doctor's First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician's determination that the brand drug is medically necessary. The physician must obtain authorization through prospective review prior to the time the brand drug is dispensed. If required authorization through prospective review is not obtained prior to dispensing the brand drug, retrospective review may be conducted to determine if it was medically necessary to use the brand drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand drug. If it is determined through prospective or retrospective review that neither the generic drug nor the brand drug is medically necessary, payment for the drug may be denied, pursuant to section 9792.27.10.

Discussion

Reference to section 9792.27.10 is necessary so that there is no doubt that payment may be denied if review determines that neither the brand name drug nor a less costly therapeutically equivalent drug is medically necessary.

Recommendation

(b) If a physician prescribes a generic drug when a less costly therapeutically equivalent generic or brand drug exists, the physician must document the medical necessity for prescribing the more costly 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 more costly drug is medically necessary. The physician must obtain authorization through prospective review prior to the time the higher-priced drug is dispensed. If required authorization through prospective review is not obtained prior to dispensing the more costly drug, retrospective review may be conducted to determine if it was medically necessary to use the more costly drug rather than the less costly therapeutic equivalent. If it is determined that the more costly drug but not the less costly drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced therapeutic equivalent drug. If it is determined through prospective or retrospective review that neither the more costly nor the less costly drug is medically necessary, payment for the drug may be denied pursuant to section 9792.27.10.

Discussion

Section 1(c) of Assembly Bill 1124 (Perea) states that it is the intent of the Legislature that the Administrative Director create an evidence-based drug formulary, and that the formulary include the "[u]se of generic or generic-equivalent drugs in the formulary pursuant to evidence-based practices, with consideration being given to use of brand name medication when its use is cost-effective, medically necessary, and evidence-based." The Institute believes that adding this proposed language will address this stated intent.

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As in subdivision (a), the final sentence is necessary to ensure there will be no doubt that payment may be denied if review determines that neither the brand name drug nor a less costly therapeutically equivalent is medically necessary.

Section 9792.27.8. Physician-Dispensed Drugs.

Recommendation

(b) A physician may dispense up to a seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List **on a one-time basis** without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.

Discussion

While it may be appropriate for a physician to dispense a seven-day supply to ensure immediate access to the drug, it would be unnecessary to do so again because the patient would have ample time for pharmacy prescription fills. Permitting repeated seven-day supplies at every office visit would create a financial incentive to unnecessarily increase the frequency of office visits for the purpose of dispensing seven-day supplies.

Section 9792.27.11. MTUS Preferred Drug List – First Fill.

Recommendation

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

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

(1) The drug is prescribed at the **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 **First Fill** limit **as** set forth in the Preferred Drug List; and

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

(4) The prescription is for:

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

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

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

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

Discussion

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

Clarification is necessary in (b)(1) to prevent disputes over whether an employee could visit multiple clinics in the first seven days and get a first fill at each one.

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.

Section 9792.27.12. MTUS Preferred Drug List

Recommendation

Add hyperlinks to the guideline references included in the Reference to Guidelines column of the MTUS Preferred Drug List document.

Discussion

The Institute recommends adding hyperlinks that enable a user to automatically link to the pertinent section of the MTUS in order to facilitate efficient use of the guidelines and to support compliance.

Recommendation

Add Opioid Treatments to the guidelines referenced for opioid drugs in the Reference to Guidelines column of the MTUS Preferred Drug List document.

Discussion

The Institute recommends adding the Opioid Treatment Guidelines as a reference for all opioids in the MTUS Drug List in addition to the body part guidelines in order to facilitate adherence to the MTUS guidelines as well as to reinforce the contraindications for opioid use at various stages in clinical treatment.

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

Recommendation

(b) Persons applying to be appointed to the P&T Committee shall not dispense drugs to injured employees for outpatient use nor have done so during the 12 months prior to the appointment, nor may drugs be dispensed for outpatient use from his or her practice location, nor have been dispensed from his or her practice location during the 12 months prior to the appointment. 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 dispensing or employment during the term of appointment shall not be eligible to continue to serve on the committee.

Discussion

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

Recommendation

(c) 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, “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

The modifications to (c) are recommended for clarity.

Priority Considerations

As issues of particular priority, the Institute strongly recommends that the Division consider incorporating the following suggestions into the MTUS Preferred Drug List:

1. Pertinent conditions and diagnoses, as well as other information such as NDCs and black box warnings, should be incorporated in order to identify drugs that have not been

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prescribed in accordance with the MTUS Guidelines. If basic factors such as pertinent conditions, diagnoses, and NDCs are not integrated into the list, efficiency will be significantly reduced because a separate review will be necessary to determine whether or not a drug is prescribed in accordance with the MTUS Guidelines. Furthermore, disputes over those determinations will arise, cause delays, and will require an as-yet-undefined dispute resolution process.

2. Providing links to pertinent MTUS Guidelines regulations and to the pharmaceutical fee calculator, and further enabling users to search and sort the Drug List would greatly facilitate appropriate drug prescription, authorization, and review.
3. 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.
4. The proposed formulary appropriately bases Preferred and Non-Preferred status on Evidence-Based Medicine guidelines, but it does not address the costs associated with drugs in the categories. There is tremendous variation in the amounts paid under the Pharmaceutical section of the Official Medical Fee Schedule based on the National Drug Code (NDC) self-assigned to the same therapeutic drugs. A recent CWCI study¹ provided examples of variation in payment values for therapeutically equivalent drugs such as Tramadol HCL ranging from a minimum of \$.03 per unit to \$16.49 per unit under the Medi-Cal Federal Upper Limit pricing structure and a range of \$0.09 to \$19.87 in Average Wholesale Price. In order to disincentivize dispensing of higher cost drugs in the same therapeutic class, the Institute recommends incorporating NDCs into the MTUS Drug List. As referenced in the RAND study, organizations such as Milliman can provide an objective cost analysis of NDCs for inclusion in the MTUS Drug List. Alternatively, PBMs could be permitted to address and incorporate the difference in dosages. Providing a method for addressing cost without impacting the therapeutic determinations would enable cost containment while protecting injured workers' access to necessary drugs.

Kristen V. Hedstrom, MPH, Director
Health Economics & Reimbursement, Neuromodulation
Boston Scientific

September 16, 2016

¹ 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.

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On behalf of Boston Scientific, which is dedicated to transforming lives through innovative medical solutions that improve the health of patients around the world, I am writing in opposition to the Division of Workers Compensation proposal to adopt the American College of Occupational and Environmental Medicine (ACOEM) for Low Back Disorders into the Medical Treatment Utilization Schedule (MTUS). Specifically, Boston Scientific strongly disagrees with the ACOEM's recommendation against Spinal Cord Stimulators (SCS) as a treatment for chronic low back pain or Failed Back Surgery Syndrome (FBSS).

Patients who are appropriate candidates for SCS have failed many, if not all possible conservative medical treatments, such as back surgery, injections, physical therapy and medications including narcotics. At times, SCS is the only treatment that provides pain relief necessary to allow a sick or injured worker to return to work. The proposed guideline is inconsistent with the Food and Drug Administration's (FDA) recognition of SCS as an "aid in the management of chronic intractable pain of the trunk or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome." In addition, both the public and private sectors widely cover SCS for FBSS, including Medicare (Noridian Local Coverage Determination L33489, Spinal Cord Stimulators for Chronic Pain) and almost every commercial insurer. SCS is a clinically effective treatment of intractable pain in FBSS patients as supported by randomized controlled trials.

The proposed adoption of the ACOEM guidelines, if implemented, would jeopardize patient access to SCS and negatively impact injured workers and employers alike. Boston Scientific urges you not to accept the flawed ACEOM guidelines in order to protect patient access to needed therapies like spinal cord stimulation for chronic low back pain and FBSS

Lisa Anne Forsythe, Director
Workers' Comp Government Relations
Coventry

September 16, 2016

Thank you for the opportunity to provide feedback on the Draft Formulary Regulation Text Promulgated in Response to AB1124 (2015) in Light of the Forthcoming SB1160 (2016). 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:

1. Section 9792.27.10(c) Language Should Be Modified to Specify the Role of the Provider/Prescriber in Obtaining Prospective Review Prior to the Dispensing of a "Non-Preferred" Drug

ISSUE: Section 9792.27.10(c) of the Draft Rules provides that for a drug that is identified as "Non-Preferred," authorization through Prospective Review must be obtained prior to the time the drug is dispensed. If authorization through Prospective Review is not obtained prior to dispensing the drug,

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payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.

The language as drafted, however, does not specify that the *provider/prescriber* must undertake the Prospective Review process. As a result, the current text leaves open the possibility that authorization in all forms may be relegated to the payers (i.e., the claims manager/adjuster).

SOLUTION: Modify the language of the proposed rules as follows:

“For a drug that is identified as “Non-Preferred,” authorization through Prospective Review must be obtained **by the prescriber** prior to the time the drug is dispensed. If authorization through Prospective Review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.”

2. The Section 9792.27.3. MTUS Drug Formulary Transition Should Specify a Transition Timeline

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.

SOLUTION: Modify the language of the proposed rules to specify a specific timeline for transition, 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”)...”

3. Updates to the Formulary Should Be Effective After a 90-Day Transition Period

ISSUE: Section 9792.27.18(a) addresses the MTUS Preferred Drug List Updates, and provides that “...the Administrative Director shall consult with the P&T Committee on updates to the MTUS Preferred Drug List, which may be adopted by the Administrative Director on a quarterly or more frequent basis in order to allow provision for all appropriate medications...”

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SOLUTION: In order to allow for injured worker treatment plan changes, discussion with prescribing doctors and systemic changes at the pharmacy level, it is recommended that the following language be appended to Section 9792.27.18(a):

“Any changes adopted by the Administrative Director will not be effective for a period of ninety (90) days or longer, at the discretion of the Administrative Director.”

Inclusion of this language will allow adequate time for stakeholders to adjust to changes as they occur.

4. The Definition of “Drug Ingredient” in the Draft Preferred Drug List (PDL) Should Be Appended to Include a Cross-Walk to Allow System Participants to Identify Drugs at the Dispensing Level

ISSUE: The term “drug ingredient”, as defined in the proposed “Preferred Drug List”, does not appear to have a clinical cross-walk that has been published that would allow prescribers, pharmacies or PBMs to accurately evaluate drugs dispensed according to national data markers (National Drug Code, Generic Product Identifier/Generic Code Number) that are used in everyday evaluation of whether or not a drug is “on formulary.” Absence a published cross-walk to allow system participants to identify drugs at the dispensing level, the current PDL is open to widely varying interpretation.

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, such as the National Drug Code (NDC).

5. The Medical Treatment Utilization Schedule (MTUS) Should Be Modified to Specify Which Sections Are Applicable to Medications

ISSUE: In its current state, the MTUS does not provide specific direction as to which sections and corresponding guidelines of its contents are applicable to a given medication. As such, to appropriately cross-reference the Preferred Drug List to the MTUS requires an evaluator to conduct extensive research when a medication is prescribed, which is time-consuming, inefficient, and can potentially result in missing applicable guidelines.

SOLUTION: Restructure the MTUS as it pertains to medications to clearly outline, for each medication, which guidelines are applicable.

6. The Definition of “Compounded Drug” Should Be Modified to Remove or Clarify the Exclusion for Mixed/Reconstituted Drugs

ISSUE: As currently proposed, Section 9792.27.1(d) defines “Compounded Drug” to mean a “...drug that is created by combining two or more active pharmaceutical ingredients to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs,

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or other drugs commercially available in the marketplace”. However, the definition goes on to specify that a “compounded drug *does not include* a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer”.

The latter statement excluding drugs “prepared by mixing, reconstituting...” *etc.* dilutes the effectiveness of requiring a higher level of scrutiny for certain compounded medications. In today’s treatment of injured workers, there are multiple examples of compounding “kits” that drug manufacturers are providing that may fall within the technical exemption wording of this clause. As such, by falling within the technical exemption language, these “kits” would thereby evade closer examination required by prospective review, notwithstanding the relative paucity of evidence supporting their preferential use for workplace injuries vs. more traditional, evidence-based medical dispensing approaches.

SOLUTION: Modify the proposed rules to either clarify the exemption language to address the issue of compounding kits, or, ideally, delete the exemption language entirely.

7. Section 9792.27.8 Addressing Physician-Dispensed Drugs Should Be Modified to Clarify that Only “First Fills” Are Permissible

ISSUE: The current draft formulary language provides that “...drugs dispensed by a physician must be authorized through prospective review prior to being dispensed. If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.”

However, the proposed rules also provide in Subsection (b) that a “...physician may dispense up to a seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary”.

The second section cited above [Section 9792.27.8(b)] which provides for the 7-day preferred drug exemption from prospective review, seems to imply that physicians are permitted to provide a limitless number of seven-day supplies of medications. As drafted, this language contradicts the stated intention to limit physician dispensing to initial “first fill” scenarios.

SOLUTION: Modify Section 9792.27.8(b) of the proposed rules to read as follows:

“...a physician may dispense up to a ***single, initial*** seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be

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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”.

Modifying the language as stated above will ensure expediency in the delivery of initial care to injured workers as outlined in the “First Fill” sections of the proposed rules, while also ensuring that subsequent medication refills will be handled through the more traditional, pharmacy-based distribution model.

David Caraway, MD, PhD, Chief Medical Officer
Nevro

September 16, 2016

I am the Chief Medical Officer for Nevro, the manufacturer of the Senza® Spinal Cord Stimulation (SCS) System, which delivers HF10TM therapy. I have been a practicing physician in the field of interventional pain management, and specifically within neuromodulation, over the last twenty years. I am board certified by the American Board of Anesthesiology and am a graduate of the University of Virginia, where I received my MD and a PhD in Biophysics, and I have been involved as a national key opinion leader in the field of neuromodulation through my extensive experience as a primary investigator in clinical research, clinical trial design, and regulatory compliance. I make the following comments not only as a representative of Nevro, but also as an expert in the field of spinal cord stimulation.

I am writing to express concern over the California Division of Workers’ Compensation (DWC) draft proposal to update its Medical Treatment Utilization Schedule (MTUS). Specifically, MTUS is now using the American College of Occupational and Environmental Medicine (ACOEM) guidelines which state that “spinal cord stimulators are not recommended for treatment of acute, subacute, chronic low back pain, radicular pain syndromes or failed back surgery syndrome.” I strongly urge you to reconsider this recommendation. SCS is an accepted, reversible, minimally-invasive therapy that provides significant relief to suffering chronic low back pain patients and it would be a disservice to limit workers’ compensation patients access to such an effective, non-opioid based treatment option.

There is significant clinical evidence and real world experience to support the effectiveness of SCS in treating chronic low back pain and failed back surgery syndrome (FBSS)

Spinal cord stimulation is an accepted therapy for treating chronic low back pain and FBSS as recognized by evidence from numerous published randomized control trials (RCTs), recognition from the Food & Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS) and numerous influential pain societies such as the American Pain Society, the American Society of Interventional Pain Physicians, and the California Society of Interventional Pain Physicians. Non-opioid options for treatment are in desperate need in light of recent CDC directives and the epidemic of tragic deaths associated with prescription opioid use for chronic pain.

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DWC must consider the most recent, peer-reviewed, published clinical evidence to support the effectiveness of SCS in treating chronic low back pain and FBSS

In issuing this recommendation it is clear that DWC has not considered the most recent evidence to support the effectiveness of SCS in the treatment of chronic low back pain. The 24 month results from the Kapural et al. study were most recently published in *Neurosurgery* and demonstrate the long-term superiority of HF10 therapy compared with traditional SCS in treating both leg and back pain.¹ These results deserve recognition as this is the largest RCT published in the SCS space and the only rigorous study directly comparing the efficacy and safety of two commercial SCS devices, providing comparative effectiveness evidence that should be of strong interest to DWC. The Kapural et al. study demonstrates how traditional SCS technology has improved in recent years, and more specifically how HF10 therapy provides long term sustained outcomes with minimal failures following a positive trial period.

Specifically related to the treatment of **chronic low back pain**, the Kapural et al. results are even more relevant. At baseline, 86.6% of subjects had previous back surgery, with 77.1% diagnosed as having failed back surgery syndrome (FBSS). For the primary outcome measure, more subjects were responders to HF10 therapy than traditional SCS at 24 months for back pain (76.5% vs 49.3%) and leg pain (72.9% vs 49.3%). Furthermore, at 24 months back pain decreased to a greater degree for HF10 therapy subjects than traditional SCS subjects (66.9% vs 41.1%). HF10 therapy patients also had a favorable distribution of (Oswestry Disability Index) ODI categorizations compared with traditional SCS subjects at 24 months, with 23.5% of subjects receiving HF10 therapy having minimal disability compared with 9.9% of subjects receiving traditional SCS. This is meaningful clinical outcome for workers' compensation patients, directly translating to increased functionality and ability to return to work.

Regarding the ACOEM rating for the Kapural et al. study please note the recent independent, peer-reviewed, analysis that was performed of all the available RCTs in the SCS space.² A careful literature search was performed by an independent medical panel who applied a modified Cochrane approach to force rank the quality of all RCTs that met the basic inclusion criteria. The longest duration of any of the studies was 24-month follow-up, while some were only a few weeks in duration. In fact, this study specifically defines long-term outcomes within spinal cord stimulation as those "longer than 12 months." The Kapural et al. study, for which there is now 24-month follow-up, received the highest ranking of any of the RCTs assessed per the Interventional Pain Management Techniques – Quality of Appraisal of Reliability and Risk Bias Assessment (IPM-QRB) criteria.

In addition, given the strength of the Kapural et. al study, HF10 therapy was awarded transitional pass-through status by the Centers for Medicare & Medicaid Services (CMS). CMS determined high-frequency SCS is reasonable and necessary for the treatment of Medicare beneficiaries and concluded that the published evidence demonstrates that the Senza System provides a substantial clinical improvement over low-frequency, traditional SCS. CMS specifically noted that "a high frequency spinal cord stimulator operated at 10,000 Hz and paresthesia-free provides a substantial clinical improvement in pain management versus a low-frequency spinal cord stimulator."³

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DWC should also consider prospective clinical evidence demonstrating consistent improvement in functionality and a significant reduction in opioids

The results from this pivotal RCT are consistent with the 24 month results from the multi-center, prospective study conducted in Europe.⁴ This trial was completed in two European centers, with 72 patients implanted with the Senza SCS system and 81% of patient diagnosed with FBSS. When evaluated at 24 months, HF10 patients saw sustained back and leg pain relief, accompanied by statistically and clinically significant improvement in ODI, with their baseline ODI of 55 reduced to 40 at 24 months. The results also demonstrated a significant reduction in opioid use: 38% of patients stopped taking opioids during follow-up, and the mean dosage of morphine per patient decreased from 84 mg at baseline down to 27 mg at 24 months. These meaningful efficacy results were also accompanied by a demonstration of a comparable safety profile to traditional SCS.

It is important that DWC consider the most current, published, peer-reviewed clinical evidence supporting SCS which clearly demonstrates the efficacy of the therapy in FBSS patients. SCS is a testable, reversible, minimally-invasive therapy that has superior evidence and provides a non-opioid option to relieve patients of their chronic pain. I urge you not to limit suffering chronic patient access to an effective and safe therapy that is covered for failed back surgery syndrome patients by Medicare, most commercial health insurance and worker's compensation plans in 49 states.

References

1

http://journals.lww.com/neurosurgery/Abstract/publishahead/Comparison_of_10_kHz_High_Frequency_and.97253.aspx

2 Grider et al. Effectiveness of Spinal Cord Stimulation in Chronic Spinal Pain: A Systematic Review *Pain Physician*: January 2016; 19:E33-E54

3 CMS, April 2016 Update of the Hospital Outpatient Prospective Payment System (OPPS). Transmittal # R3471CP, eff. April 4, 2016.

4 Al-Kaisy et al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Medicine*. 2013; 15(3): 347-54.

Karen L. Sims, Assistant Claims Operations Manager
Claims Medical and Regulatory Division
State Compensation Insurance Fund

September 16, 2016

State Fund appreciates the opportunity to provide the following comments regarding the proposed Drug Formulary and Updates to Medical Treatment Guidelines.

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Recommended text changes are under sections labeled *Text Changes*, and are indicated by underline for additional language and ~~strikeout~~ for deleted language. Questions and comments are as labeled.

Comments

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

Discussion

The text of section 96792.27.1 (m) is not concise to read and should be clarified. State Fund suggests the text be changes as outlined below in our recommendation.

Recommendation

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

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

Discussion

The language of 9792.27.2 section (3) could be misinterpreted as written. State Fund recommends this section be re-written for clarity. Our suggested changes are outlined below.

Recommendation

(3) The MTUS Drug Formulary does not apply to drugs administered to the patient in ~~any a~~ a clinical setting. Although the MTUS Drug Formulary is not applicable to drugs administered in a clinical setting, drug treatment in ~~those settings~~ a clinical setting is subject to relevant MTUS Guidelines and rules. 2

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Section 9792.27.3. MTUS Drug Formulary Transition.

Discussion

It is necessary to have a defined time limit to avoid potential abuse and ensure the injured worker safe, effective medical care. There should be consequences in the event a physician either fails to submit a transition plan or fails to follow through on a transition plan to a preferred drug.

Recommendation

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician shall either: within six weeks of the effective date of these regulations,

(1) Prepare a treatment plan to transition the worker to a Preferred Drug, or;

(2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug by January 1, 2018. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

If a physician fails to submit a treatment plan under subsection (1), or to submit a Request for Authorization and supporting documentation under subsection (2), this could constitute a showing of good cause for an employer’s petition to change a physician or provider pursuant to Labor Code Section 4603 and may be grounds for termination of the physician from the medical provider network.

A physician that submits a treatment plan under subsection (1) to transition the worker to a Preferred Drug, but fails to complete that transition by January 1, 2018, may constitute good cause for an employer’s petition requesting a change of physician or provider pursuant to Labor Code Section 4603 and may serve as grounds for termination of the physician from the medical provider network.

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

Discussion

The regulations should state that the PBM may address issues not covered by the MTUS guidelines or the MTUS Drug Formulary through UR.

Recommendation

Where an employer or insurer contracts pursuant to Labor Code section 4600.2 with a pharmacy benefit manager or pharmacy network for the provision of drugs for the treatment of injured workers, the drugs available to the injured worker must be consistent with the MTUS guidelines and MTUS Drug Formulary for the injury or condition being treated and may not be further restricted pursuant to the contract. Nothing in this section precludes the pharmacy benefit manager or pharmacy network from addressing issues not covered by the MTUS guidelines or the MTUS Drug Formulary through utilization review.

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Section 9792.27.5 MTUS Drug Formulary – Off Label Use

Discussion

Section 9792.27.1 provides the definition on no-preferred drugs but not unlisted drugs. The regulations refers to when a physician believes off label use is medically necessary. It would be more accurate to refer to when a physician requests an off label use for a prescription drug.

Recommendation

State Fund would like clarification of whether non-preferred and unlisted drugs are handled the same way. The word “believes” should be changed to “requests”.

Section 9792.27.8. Physician-Dispensed Drugs.

Discussion

It is important to point out if a physician prescribes an initial seven day supply it should be on a one time basis. The injured worker will have ample time to refill prescriptions after that

Recommendation

(b) A physician may dispense up to a seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List on a one-time basis without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.

Section 9792.27.9. Compounded Drugs.

Recommendation

State Fund requests additional clarification for circumstances where a compound drug has a preferred component.

Section 9792.27.11. MTUS Preferred Drug List – First Fill.

Recommendation

State Fund would like clarification if this section will also cover “unlisted Drugs”? In addition, the regulation should specify that the first fill is for a single initial visit. Otherwise an employee could visit multiple clinics to get a first fill at each one. State Fund recommends the following language added to 9792.27.11 section (b):

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

- (1) The drug is prescribed at the single initial visit for up to four days for medications dispensed out of the office following a workplace injury, provided that the initial visit is within 7 days of the date of injury;

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Section 9792.27.12. MTUS Preferred Drug List.

Discussion

State Fund is concerned that the proposed format of the MTUS Formulary is an Adobe Portable Document Format. Without hyperlinks from the formulary to medical coding systems there could be operational problems with automation and the development of tools for online queries or integration with third party vendors.

Recommendation

State Fund recommends integrating the MTUS Formulary electronically for ease of implementation.

Ben Roberts, Executive President & General Counsel
PRIUM

September 16, 2016

PRIUM appreciates the opportunity to review and provide comments on the Draft Formulary Regulations published by the Division of Workers' Compensation last month.

The report published by Rand, *Implementing a Drug Formulary for California Workers' Compensation Program*, makes the following assumptions:

1. that the DWC intends to adopt a formulary that is designed to maximize quality-of-care, health, and work-related outcomes,
2. that controlling drug spending is an important but secondary objective, and
3. that the process and policies for determining how drugs are integrated into the formulary should be transparent.

Based on PRIUM's review and interpretation of the regulations, it appears that the DWC has done a good job crafting regulations that meet the intent of AB 1124 and manage the complexity of a Drug Formulary and its implementation.

Ongoing data collection and analysis will be essential to measuring the progress and impact of the formulary to ensure that the implemented Drug Formulary meets the expectations of the DWC and California Stakeholders.

Comment #1:

Section 9792.27.2(b)(3) states, "The MTUS Drug Formulary does not apply to drugs administered to the patient in any clinical setting." The use of the phrase "any clinical setting" is overly broad and is ambiguous.

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The proposed definition below incorporates the definition for “Health Care Facility” in 8 CCR § 9792.5.0, and the definition of “clinic” found in Section 1200 of the California Health & Safety Code.

Proposed Text:

“Clinical setting” includes clinics as defined in Section 1200 of the California Health & Safety Code, any facility as defined in Section 1250 of the Health and Safety Code, any surgical facility which is licensed under subdivision (b) of Section 1204 of the Health and Safety Code, any outpatient setting as defined in Section 1248 of the Health and Safety Code, any surgical facility accredited by an accrediting agency approved by the Licensing Division of the Medical Board of California pursuant to Health and Safety Code Sections 1248.15 and 1248.4, or any ambulatory surgical center or hospital outpatient department that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.

Comment #2:

The definition for “compound drug” is confusing, as it is overly specific. The phrase, “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,” is confusing, as it incorrectly suggests that compound drugs are only prescribed when no FDA-approved prescription drug can meet the clinical need. In reality, compound drugs are often prescribed to supplement an FDA-approved medication, or they are prescribed in lieu of an available FDA-approved medication because the prescriber simply prefers the compound medication to any available FDA-approved medication. It is recommended that the above-quoted phrase be removed from § 9792.27.1(d).

Proposed Text:

“Compounded drug” means a drug that is created by combining two or more active pharmaceutical ingredients ~~to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace.~~ A “compounded drug” does not include a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product’s manufacturer.

Comment #3:

Section 9792.27.3(b)(1) creates a sizeable loophole to application of the formulary. It allows prescribers who do not wish to request authorization or modify treatment to potentially delay the need to do either by simply preparing a treatment plan that includes a reference to transitioning to a Preferred Drug. The treatment plan can be updated to perpetually postpone efforts at transitioning the patient to a Preferred Drug. Prescribers who do not wish to transition patients to a Preferred Drug or to request authorization for Non-Preferred Drugs or unlisted drugs may simply update their treatment plans each month to push back the point at which they intend to begin efforts to transition the patient to a

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Preferred Drug.

Section 9792.27.3(b)(1) also creates confusion for PBMs, pharmacies, and payers, as it only allows them to require prior authorization for a non-preferred drug or unlisted drug if the treatment plan does not include a plan to transition the worker to a preferred drug. PBMs and pharmacies typically do not have access to treatment plans, and so will not know whether a plan to transition the worker to a Preferred Drug exists (and thus, whether authorization is required before they can bill the workers' compensation payer for the dispensed Non-Preferred or unlisted drug).

Additionally, section 9792.27.3(b) will create confusion with payers and the Workers' Compensation Appeals Board, as it does not give a clear standard for transitioning patients to a Preferred Drug or when the payer may require authorization for Non-Preferred or unlisted drugs that have not yet been phased out of the treatment plan. This section states that treatment for claims originating prior to July 1, 2017 should be "phased in" to compliance with the formulary. This makes it sound like the payer is responsible for determining what amount of time is required in each of these claims before they should require the physician to comply with the requirements of (b)(1) and (2). If the WCAB disagrees with the payer as to how soon the payer should have required the prescriber to "phase in" treatment of an injured worker, the payer stands to be penalized for unreasonably delaying or denying treatment.

It's recommended that this regulation offer a clear, standard implementation ("phase-in") period of at least one year for claims with a date of injury prior to the July 1, 2017 implementation date of the formulary. It is further recommended that, during this time, workers' compensation payers be required to notify injured workers and prescribers of the medications that will be affected by the formulary in each claim so that they will be better suited to discuss how to transition from Non-Preferred or unlisted drugs to Preferred Drugs, where appropriate, or how to request and obtain authorization for Non-preferred or unlisted drugs where no Preferred Drug is appropriate. It is further recommended that the DWC provide a means for providers and payers to enter into binding agreements limiting the application of the MTUS Preferred Drug List for the purposes of weaning, substituting, or discontinuing Non-Preferred or unlisted medications, where appropriate.

Additionally, the format of Section 9792.27.3 is confusing. Subdivision (a), which applies to claims with a date of injury on July 1, 2017, does not state that the physician must request authorization for Non-Preferred or unlisted drugs. This requirement appears only in subdivision (b), which only applies to claims with a date of injury prior to July 1, 2017. It is recommended that the requirement to request authorization for Non-Preferred or unlisted drugs appear in both Subdivision (a) and (b).

Proposed text:

(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. 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

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Drug List (an “unlisted drug”), the physician shall prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary ~~should be phased~~ shall apply on July 1, 2018 in order to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician shall either:
(1) Prepare a treatment plan to transition the worker to a Preferred Drug, or
(2) Prepare prepare and submit a Request for Authorization using the DWC Form RFA and attach supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

(c) Beginning no later than January 1, 2018, the insurance carrier shall:
(1) identify all claims with a date of injury prior to July 1, 2017 that have been prescribed a drug excluded from the closed formulary after July 1, 2017; and
(2) provide written notification to the injured employee, prescribing doctor, and pharmacy, if known, that contains the following:
(i) the notice of the impending date and applicability of the MTUS Preferred Drug List for claims with a date of injury prior to July 1, 2017; and (ii) a name, phone number, and date and time to discuss ongoing pharmacological management of the injured employee's claim.

(d) Agreement.
To ensure continuity of care, an insurance carrier and a prescribing doctor may enter into an agreement, on a claim-by-claim basis, regarding the application of the MTUS Preferred Drug List for individual claims that have a date of injury prior to July 1, 2017.

(e) Agreement requirements.
(1) The insurance carrier shall document any agreement and the terms, and share a copy of the agreement with the prescribing physician and injured employee.
(2) Health care provided as a result of the agreement is not subject to retrospective review and shall not require prior authorization for the duration of the term established in the agreement. If no term is specified, it shall be presumed that one instance of the treatment is authorized by the agreement.
(3) Denial of a request for an agreement is not subject to dispute resolution.
(4) If no agreement is reached and documented by July 1, 2018, the requirements of § 9792.27.3(b)

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shall apply.

(5) Any such agreement must be documented in writing. Where no copy of the written agreement exists, it shall be presumed that no agreement exists.

Comment #4:

The steps taken in § 9792.27.8(a) to include physician dispensed medications in the formulary are essential to encouraging prospective review prior to medications being dispensed. PRIUM recommends that § 9792.27.8(a) be edited to change the language of the last sentence to be more enforceable by changing the “may deny” to “shall deny”. By making this change, physicians dispensing medications will be more likely to comply with the intent of the section which is to require physicians who dispense medications to request approval prior to dispensing.

Proposed text:

(a) Except as provided in subdivision (b), and section 9792.27.11 in relation to “First Fills”, drugs dispensed by a physician must be authorized through prospective review prior to being dispensed. If required authorization through prospective review is not obtained prior to dispensing, payment for the drug shall be ~~may be~~ denied if the drug is found upon retrospective review to be not medically necessary.

Comment #5:

In § 9792.27.8(b) the use of “seven day supply” in the first sentence is different from the “First Fill” language that has been used throughout the rules. As the intent of the sentence appears to be in reference to the “First Fill”, we recommend the term “seven day supply” be replaced by “First Fill”.

Proposed text:

(b) A physician may dispense up to a First Fill ~~seven-day supply~~ of a drug that is listed as “Preferred” in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.

Comment #6:

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In its current form, § 9792.27.11 is similar to Texas' rule regarding "first fill" or "initial pharmaceutical coverage" period for the first seven days following the date of injury. However, one key aspect is different. The Texas rule states:

(f) Initial Pharmaceutical Coverage

(1) Drugs included in the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are not subject to retrospective review of medical necessity.

(2) Drugs excluded from the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization, except as referenced in subsection (b)(1)(C) of this section, and are subject to retrospective review of medical necessity.

28 TAC 134.530

We recommend that § 9792.27.11 be amended to include a new paragraph that permits the retrospective review of Non-Preferred drugs that are identified as First Fill.

Proposed text:

(d) A drug identified as a First Fill drug that is dispensed to an injured worker is subject to retrospective review to determine if the drug treatment was within the MTUS guidelines. Payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary

Comment #7:

PRIUM agrees with the approach taken by the DWC to create the MTUS Preferred Drug List as referenced in § 9792.27.12. The simple distinction between Preferred and Non-Preferred drugs creates a formulary list that is easily interpreted and implemented by all stakeholders.

While we value the condition-based formulary, from a clinical perspective, as the preferred type of formulary for delivering evidence based treatment to injured workers, we recognize the limitations on implementing that type of formulary in the current pharmaceutical distribution value chain.

The *Implementing a Drug Formulary for California Workers' Compensation Program* report produced by RAND effectively summarized the issue. Page 51 of the report states:

"Condition-specific PR requirements complicate processing drug bills because diagnostic information is needed to distinguish between which prescriptions require PR and which do not.

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The payers and pharmacies must have condition-specific information, such as diagnosis codes, that are present at the time the prescription is dispensed. Most of the time, the condition information is not transmitted to the pharmacy when a prescription is dispensed. Assessing the information technology needed to ensure that this type of condition-based approach could be implemented at the point when the injured worker picks up the prescription from the pharmacy is beyond the scope of this review.”

Overall, the MTUS Preferred Drug List aligns well with the RAND Report and PRIUM’s own perspective. Two primary challenges remain:

First, in order to ease the implementation of the MTUS Preferred Drug List, a listing of the NDC codes that are associated with each drug listed on the MTUS PDL should be created and published by the DWC. This will allow PBMs and pharmacies to more easily implement and update the preauthorization requirements in their systems on an ongoing basis.

The second challenge will be the ongoing effort of the DWC and the Pharmacy and Therapeutics Committee to keep it updated with current evidence based medical information. As noted by RAND “[a] comprehensive formulary is feasible only if DWC has the resources to undertake these developmental activities or makes arrangements with a qualified entity to perform this task. The arrangements have import for the administrative burden of both implementing the formulary and updating it in the future”.

Rob Ward

September 16, 2016

Summary comments:

The undertaking of creating an implementing a prescription drug formulary for the California Workers' Compensation system is a complex and daunting task. Those who contributed to the proposal should be congratulated on their accomplishment.

That being said, there remain some areas of the proposed regulatory language and the Preferred Drug List that could benefit from amendment.

The discussion and recommendations below are provided in the order of presentation within the proposed formulary regulations. It is hoped that these comments will be in some manner of benefit to the DWC as the formulary development process continues.

9792.27.1

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

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A “compounded drug” does not include a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

Defining "compounded drug" as one that contains two or more active ingredients excludes the fairly common practice of creating a custom compounded preparation containing only a single active ingredient. This is particularly common with custom compounded topical medications, where a single active ingredient is compounded with an inactive carrier, with the active ingredient at a concentration that is somewhat different from commercially available products; or where a single active ingredient is custom compounded because no commercial version is available (e.g., topical anti-epileptics, muscle relaxants, opioids).

Suggested alternative definition:

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

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

The regulation as written may constitute an over-reach of authority, and may not be appropriate to the intent of the regulations. As written, the regulation states that such medications may not be dispensed without authorization. It is likely that the DWC intended that there would be limits on the compensability of such medications without authorization.

Consider adapting language like that found in the draft of 9792.27.5(b) into 9792.27.1(m) to clarify intent:

"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."

Alternatively, if the intent is to permit insurer to deny payment for Non-Preferred medications dispensed without prior authorization; even without retrospective UR; that should be indicated.

9792.27.3

9792.27.3(b) effectively exempts all continuation of medication prescribed prior to 7/1/2017 from the MTUS Drug Formulary. While the purpose of the exemption is stated to be to permit transition of the worker to a Preferred Drug (or obtaining prior authorization for a Non-Preferred or unlisted drug), there is no time frame established for such transition. Any treating physician is therefore free to continue prescribing/dispensing materials that are exempted under 9792.27.3(b) indefinitely.

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The DWC should establish a date by which such transition should be completed. Since a progress report is required every 45 days during ongoing treatment, treating physicians should be able to complete the process of transitioning to a Preferred drug, or of requesting authorization for a Non-Preferred or unlisted drug, within 45 days. A completion of transition, as described in the regulatory draft, within 45 days of the introduction of the MTUS Drug Formulary should be sufficient.

Suggested amendment:

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician shall, on or prior to August 15, 2017, either:

(1) Prepare a treatment plan to transition the worker to a Preferred Drug, or

(2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

9792.27.10

9792.27.10(b) and (c) explicitly establish that in the event that no prior authorization is obtained, that a retrospective denial requires utilization review (“may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.”).

In contrast, 9792.27.10(e) implies that in such instances, denial may be made based only on the failure to obtain prior authorization, with no UR required (“If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied.”).

The DWC may wish to consider whether and how this is likely to play out at the WCAB, when a claimant seeks an expedited hearing on the question of denial of an unlisted medication; and there is no UR denial in place. The WCAB judge would have no evidence regarding the medical necessity of the medication, and may compensate for this by seeking to inappropriately address this issue according to their own opinion.

9792.27.10(e) also poses some consistency issues. It is stated that denial may be made on the basis of lack of prior authorization. It is not clear who is authorized to issue such denial. The placement of the proposed regulation within 9792 indicates that the definition of denial would be that found within 9792.6.1; and that such denial would have to be issued by a reviewing physician. If such is to be the case, then there is no clear procedural difference between a Non-Preferred and unlisted medications.

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Additionally, if 9792.27.10(e) appears to permit the retrospective denial of unlisted medications by non physician reviewers, without any specific process, criteria or appeal process. This creates a meaningful risk that injured workers will be denied medication that is appropriate to their condition and clinical status, but which are not listed. While it is appreciated that 9792.27.6 affords the treating physician the opportunity to provide evidence that the medication is appropriate as described in 9792.21 and 9792.25. However, that opportunity is meaningless and effectively absent unless there is a utilization review process involved.

Preferred Drug List (8CCR9792.27.12)

Medications with a status of Preferred, not mentioned within the proposed MTUS

There are a number of medications listed in the Preferred Drug List, with a status of Preferred, that are not named anywhere in the current or proposed MTUS. This will create difficulty and confusion in attempting to determine if the use of these medications is consistent with the MTUS, as is required under the draft regulations and Preferred Drug List.

This observation is not intended as an opinion that these medications should not be considered as Preferred; only as an observation that the listing is inconsistent with the described regulatory process. One would reasonably anticipate that the DWC would either remove these medications from the listing; make some changes to the process requirements for medications listed as Preferred; or would add the medications to the MTUS content with recommendations for use.

Line 45: Choline Magnesium Trisali; listed as Preferred

Believed to refer to choline magnesium trisalicylate

This specific medication is not named anywhere in the current or proposed MTUS content. Intended as a member of the NSAID category?

Line 53: Clindamycin; listed as Preferred

This specific medication is not named anywhere in the current or proposed MTUS content, which may lead to significant confusion as stakeholders attempt to determine if this medication is being used in a manner consistent with the MTUS.

Line 71: Dexlansoprazole; listed as Preferred

This specific medication is not named anywhere in the current or proposed MTUS content. Intended as a member of the category of proton pump inhibitors?

Line 79: Difunisal; listed as Preferred

This specific medication is not named anywhere in the current or proposed MTUS content. Intended as a member of the NSAID category?

Line 93: Famotidine; listed as Preferred

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This specific medication is not named anywhere in the current or proposed MTUS content. Intended as a member of the category of proton pump inhibitors? [Actually a H2 receptor blocker]

Line 136: Omalizumab; listed as Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 138: Levofloxacin; listed as Preferred.

Reference in guideline given as: Hand, Wrist and Forearm Disorders; and Hip and Groin Disorders. This medication is not mentioned in either of the indicated chapters. Medication category is given as "Null"; it is an antibiotic. This medication is typically used to treat respiratory, urinary, gastrointestinal and prostatic infections; all of which are generally non-industrial.

Line 160: Metronidazole Oral; listed as Preferred

Reference in guideline given as Hand, Wrist and Forearm Disorders. This medication is not mentioned within this chapter. This medication is an anti-protozoal, typically used to treat gastrointestinal and genitourinary infections that are generally non-industrial. Given the absence of any mention in the MTUS and the likelihood that any use is non-industrial, it is recommended that this material be removed from the Preferred Drug List.

Line 168: Moxifloxacin HCl; Listed as Preferred

Reference in guideline given as Hand, Wrist and Forearm Disorders. This medication is not mentioned within this section of the MTUS. The drug class is indicated as "Null", whereas this is actually an antimicrobial. This medication is FDA-approved for treatment of respiratory infections and skin infections. It is recommended that this medication be removed entirely from the Preferred Drug List.

Line 183: Levalbuterol; listed as Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 224: Sulfamethoxazole/Trimethoprim; listed as Preferred Reference in guideline given as Hand, Wrist and Forearm disorders. Neither Sulfamethoxazole nor Trimethoprim is mentioned in the indicated chapter.

Line 225: Sulfasalazine; listed as Preferred

Reference in guidelines given as Ankle and Foot Disorders; Chronic Pain; Elbow Disorders; Hand, Wrist and Forearm Disorders; Hip and Groin Disorders; Knee Disorders; and Shoulder. This medication is not mentioned in the content of any of these chapters, and is found only in the title of singular bibliography entry in the shoulders on Hip and Groin Disorders and Knee Disorders.

Medications listed as Non-Preferred, not mentioned within the proposed MTUS

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There are some medications that are found in the Preferred Drug List, with a status of Non-Preferred; and which are named nowhere in the MTUS content (current or proposed). There would therefore be no reason to list them at all; unless the DWC intended that denial of payment based on lack of prior authorization would require retrospective UR per 9792.27.10(c)

Line 62: Cromolyn Sodium; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 98: Flunisolide Anhydrous; not listed as either Preferred or Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma. Listing should be amended to indicate whether medication is Preferred or Non-Preferred.

Line 103: Fluticasone Propionate; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 103: Fluticasone-Salmeterol; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma. *Line 108: Formoterol/Mometasone; listed as Non-Preferred* Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 116: Golimumab; listed as Non-Preferred

Reference in guidelines given as Chronic Pain; Hip and Groin Disorders; and Knee Disorders. This medication is not mentioned in any of these sources. The medication is also listed as "Analgesics - Anti-inflammatory". This is incorrect, as this is a monoclonal antibody treatment against tumor necrosis factor. This medication is a form of treatment for inflammatory arthritides (such as RA, psoriatic arthritis and ankylosing spondylitis) and ulcerative colitis. All of these conditions are by definition non-industrial. It is recommended that this medication be removed entirely from the Preferred Drug List.

Line 130: Infliximab; listed as Non-Preferred

Reference in guidelines given as Chronic Pain; Hip and Groin Disorders; Knee Disorders; and Low Back Disorders. This medication is not mentioned in any of these sources. The medication is a monoclonal antibody treatment against tumor necrosis factor. This medication is a form of treatment for inflammatory arthritides (such as RA, psoriatic arthritis and ankylosing spondylitis) and ulcerative colitis or Crohn's disease. All of these conditions are by definition non-industrial. It is recommended that this medication be removed entirely from the Preferred Drug List.

Line 140: Levomilnacipran; listed as Non-Preferred

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Also known as Fetzima. Reference in guidelines given as Chronic Pain; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. This medication is not mentioned in any of these sources.

Line 163: Mometasone Furoate; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 163: Montelukast Sodium; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 212: Reserpine; listed as Non-Preferred

Reference in guideline given as Chronic Pain. This medication is not mentioned within the Chronic Pain Medical Treatment Guidelines. This medication is also primarily used in veterinary medicine, and rarely used in humans. It is recommended that this medication be removed entirely from the Preferred Drug List.

Line 214: Risedronate Sodium; listed as Non-Preferred

Reference guidelines given as Chronic Pain; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. This medication is not mentioned at all in the Chronic Pain Medical Treatment Guidelines, or the chapters on Low Back Disorders or Shoulder. No recommendations or discussion of this medication are made within the Hip and Groin Disorders or Knee Disorders, and there is only insignificant passing mention in the bibliography. It is recommended that this medication be removed entirely from the Preferred Drug List.

Line 216: Salmeterol; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 219: Silver Sulfadiazine; listed as Non-Preferred

Reference in guideline given as Hand, Wrist and Forearm Disorders. This material is not mentioned within the referenced chapter.

Line 223: Sulfacetamide Sodium/Prednisolone; listed as Non-Preferred

Reference in guideline given as Eye. The proposed eye chapter makes no mention of a combined application of sulfacetamide and prednisolone. These medications are discussed separately, in different sections of the chapter.

Line 231: Theophylline; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

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Line 235: Tobramycin/Dexamethasone; listed as Non-Preferred

Guideline reference given as Eye. While the eye chapter does mention both of these medications, they are discussed in entirely separate sections of the chapter, and are never discussed as being co-administered.

Line 247: Vilazodone; listed as Non-Preferred

Guideline references given as Cervical and Thoracic Spine Disorders; Chronic Pain; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. Mention in Cervical and Thoracic Spine Disorders is limited to mention as a medication for which evidence was sought, but none was reported and no recommendations offered. There is no mention of this medication in Chronic Pain, Hip and Groin Disorders, Knee Disorders, Low Back Disorders or Shoulder.

Line 253: Zafirlukast; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 253: Zileuton; listed as Non-Preferred

Reference in guideline given as "Work Related Asthma". The DWC has not adopted, nor proposed adopting, the ACOEM Guidelines for occupational asthma.

Line 256: Zoledronic Acid; listed as Non-Preferred

Guideline references given as Chronic Pain; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. Mention in Hip and Groin Disorders is limited to mention within the titles of 2 bibliography articles and no recommendations were offered. There is no mention of this medication in Chronic Pain, Knee Disorders, Low Back Disorders or Shoulder.

Opioids

There are a number of medications on the Preferred Drug List that are indicated to be opioids. All are listed as Non-Preferred, which is entirely consistent with the MTUS treatment guidelines for opioids.

For each of these medications, the "Reference in Guidelines" is given as Chronic Pain, and one or more body part specific ACOEM chapters. None of these medications is referenced to the MTUS for opioids. It is recommended that the guideline information in the Preferred Drug List for all opioids be amended such that only the MTUS for opioids is indicated.

Other recommendations:

Line 73: Dextrose 70%; listed as Non-Preferred

This item refers to an injectate for prolotherapy. As written, dextrose injectate at 70% falls under 9792.27.10(c); and all other concentrations fall under 9792.27.10(d). It would be far more sensible to determine which process the DWC intends for this material, and amend the list such that process is

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consistent for all concentrations. This can be accomplished either by removing this entry (process requirement 9792.27.10(d)); or amending it to something that is not concentration specific, such as, "Dextrose, prolotherapy injectate" (process requirement 9792.27.10(c)).

Line 76: Diclofenac Potassium; listed as Preferred

Line 77: Diclofenac Sodium; listed as Non-Preferred

The preparers of the Preferred Drug List appear to have confused the anion used to stabilize the medication as a salt (e.g., potassium or sodium) with the means of delivery (oral vs. topical). It is recommended that Line 76 be amended to read as "Diclofenac, oral" and that Line 77 be amended to read as "Diclofenac, topical". Additionally, if Line 77 were to be amended to "Diclofenac, 1% topical", it may be worthy of considering changing this to a Preferred listing; as use of the 1% topical is supported in some instances by the Chronic Pain Medical Treatment Guidelines and is FDA-approved.

Line 78: Diclofenac Sodium/Misopro; listed as Preferred

If Line 76 is amended to "Diclofenac, oral" as suggested above, then Line 78 becomes redundant and unnecessary.

Line 94: Famotidine/Ibuprofen; listed as Non-Preferred

The Preferred Drug List incorrectly states that this single-tablet combination (Duexis) is discussed in 9 separate "chapters" of the MTUS. This is incorrect. It is only mentioned in the Chronic Pain Medical Treatment Guidelines. Recommend changing the entry to "Famotidine/Ibuprofen (Duexis)", and amending the "Reference in Guidelines" column to the single correct resource only.

Line 95: Fenoprofen Calcium; listed as Preferred

Fenoprofen (Nalfon) has an unfavorable risk profile as compared to other NSAIDs, and is also less effective. (Huskisson EC, Woolf DL, Balme HW, Scott J, Franklin S. Four new anti-inflammatory drugs: responses and variations. BMJ, 1976 (1):1048-9). It is also much more expensive than safer and more effective alternatives. The most common use of this medication at this time is in the context of physician dispensed medication. Because fenoprofen is less effective, has greater side effects, and costs 30 to 50 times as much as naproxen or ibuprofen, fenoprofen should not be used unless there is a sound medical basis for not using safer, more effective, and more cost effective alternative NSAIDs. Recommend changing the entry from "Preferred" to "Non-Preferred".

Line 168: Morrhuate Sodium; listed as Non-Preferred

Drug class is given as "Assorted classes". To place this medication in a class that is consistent with the MTUS content, it is recommended that the drug class be changed to "Prolotherapy injectate".

Line 174: Neomycin Sulfate; listed as Non-Preferred

Drug class is given as "Null". This should be amended to indicate that this is a topical antibiotic.

Line 179: Nitroglycerine transdermal; listed as Non-Preferred

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Guideline reference is given as: Ankle and Foot Disorders; and Shoulder. This medication is not mentioned in the chapter on Ankle and Foot Disorders. It is recommended that the guideline reference be amended to reflect the shoulder only.

Line 198: Phenol; listed as Non-Preferred

Drug class is given as "Antiseptics and Disinfectants". While technically accurate, this is not the context in which this material is discussed in the MTUS. Phenol is discussed solely as an injectate for prolotherapy. It is recommended that the drug class be amended to "Prolotherapy injectate".

Line 215: Rivaroxaban; listed as Non-Preferred

Guideline reference is given as: Ankle and Foot Disorders; and Hip and Groin Disorders. This medication is not mentioned in the chapter on Ankle and Foot Disorders. It is recommended that the guideline reference be amended to reflect the Hip and Groin Disorders only.

Line 226: Sulindac; listed as Preferred

Guideline reference given as Ankle and Foot Disorders; Cervical and Thoracic Spine Disorders; Chronic Pain; Elbow Disorders; Hand, Wrist and Forearm Disorders; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. There are no recommendations regarding this medication in the Cervical and Thoracic Spine Disorders; Elbow Disorders; or Hand, Wrist and Forearm Disorders.

Line 230: Thalidomide; listed as Non-Preferred

Guideline reference given as Chronic Pain; Low Back Disorders. There is no mention of this medication in the Chronic Pain Medical Treatment Guidelines.

Line 232: Tiagabine HCl; Listed as Non-Preferred

Guideline references given as Chronic Pain; Low Back Disorders; and Shoulder. There is no mention of this medication in Low Back Disorders.

Line 236: Tolemtin Sodium; listed as Preferred

Guideline reference given as Ankle and Foot Disorders; Cervical and Thoracic Spine Disorders; Chronic Pain; Elbow Disorders; Hand, Wrist and Forearm Disorders; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. There are no mentions of this medication in Ankle and Foot Disorders; Cervical and Thoracic Spine Disorders; Elbow Disorders; Hand, Wrist and Forearm Disorders; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; or Shoulder.

Line 240: Trazodone; listed as Non-Preferred

Guideline references given as Cervical and Thoracic Spine Disorders; Chronic Pain; Hip and Groin Disorders; Knee Disorders; Low Back Disorders; and Shoulder. There are no mentions of this medication in Hip and Groin Disorders or Knee Disorders.

Line 241: Triamcinolone Hexacetonide; listed as Non-Preferred

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Guideline references given as Cervical and Thoracic Spine Disorders; Chronic Pain; Hip and Groin Disorders; Knee Disorders; and Low Back Disorders. There are no mentions of this medication in Cervical and Thoracic Spine Disorders or Low Back Disorders.

Line 245: Valproic Acid; listed as Non-Preferred

Guideline references given as Chronic Pain; Low Back Disorders; and Shoulder. This medication is not mentioned in either the Chronic Pain or Low Back Disorders chapters.

Line 246: Venlafaxine; listed as Non-Preferred

Guideline references include the chapter on Knee Disorders. There is no mention of this medication within Knee Disorders.

Line 257: Zonisamide; listed as Non-Preferred

Guideline references given as Chronic Pain, Low Back Disorders and Shoulder. There is no mention of this medication in the chapter on Low Back Disorders.

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

No proposed draft of this form was made available for this comment period. It is probably a good idea to make this form part of the public comment process, so that the public may be reassured that none of the potential conflicts as listed in 9792.27.14 are inadvertently omitted from the form.

Miquel A. Dominquez, MD, FIPP
American Pain Institute

September 16, 2016

Medical reasoning in opposing this proposal:

The proposed adoption of ACOEM guidelines is another attempt at limiting viable treatment options for these patients who unfortunately suffer from intractable neuropathic pain. In December of 2014, I submitted a letter of objection to the adoption of these guidelines. Unfortunately, a repeat attempt is in process to limit effective interventional modalities that is non-opioid-based.

Furthermore, with the anti-opioid environment that we are working with, these patients will not have options for treatment of their underlying chronic intractable pain conditions.

Most importantly, as I mentioned in December of 2014, these guidelines are in contrary to several national societies. This includes the current MTUS guidelines, the American Society of Interventional Pain Physician Guidelines (ASIPP), and the Official Disability Guidelines (ODG).

Multiple studies and experience has shown that these technologies are medically necessary and appropriate for patients with a history of nerve injury (chronic neuropathic pain) to include but not limited to post laminectomy back pain syndrome, phantom pain, and other peripheral nerve injury

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cases. Again for the patient who does not respond to the limited pharmacological approach, he/she will have extremely limited treatment options.

As an active practicing physician caring of patients with industrial related complex Pain medical conditions, these new guidelines will be detrimental to these patients. Already we have seen extreme limitations on treatment options for patients with failed back pain and associated neuropathy/radiculopathy with the current limitations on the use of pharmacological agents, opioids and non-opioids, patient will have very limited options. We may even see an increased incidence of mental disorders along with suicide.

In summary, SCS is recommended as a treatment option for FBSS in several physician society guidelines, is available to almost all commercially-insured enrollees in the U.S., is covered by a Medicare National Coverage Determination, and is covered by 49/50 Workers' Compensation state agencies. SCS is a clinically effective treatment option for patients with FBSS. I use this therapy for treating my patients with FBSS and believe it should remain a treatment option for injured workers.

I urge DWC not to adopt the proposal on the adoption of ACOEM guidelines.

In conclusion as a practicing physician with a genuine concern for the welfare of work injured patients, I object the current proposal by the DWC to adopt the ACOEM guidelines.

Ref:

SCS is an accepted therapy for FBSS symptoms. There is a long history of consistent results reported from open label studies and randomized controlled trials reflecting the efficacy of SCS for treating the painful symptoms of FBSS.

SCS for FBSS is supported by randomized controlled trials (RCTs)^{1,2} and several large post market SCS retrospectives reporting positive outcomes for over 1,000 patients.³⁻⁵

Organizations like the American Pain Society⁶, the Food & Drug Administration⁷, and the American Society of Interventional Pain Physicians⁸ all support SCS as a treatment option for FBSS.

SCS is covered by Medicare, workers' compensation plans in 49 states and most commercial health insurers.

Most patients experiencing minor or serious complications have a full recovery though permanent impairment is possible or may require additional surgery to resolve.

1. Kumar K, Taylor R, Jacques L, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicenter randomized controlled trial in patients with failed back surgery syndrome. *Pain*. 2007;132(1-2):179-88.

2. North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain; a randomized, controlled trial. *Neurosurgery*. 2005;56:98-107.

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3. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery*. 2006;58:481-96.
4. Mekhail NA, Mathews M, Nageeb F, et al. Retrospective review of 707 cases of spinal cord stimulation: Indications and complications. *Pain Practice*. 2011;11:148-53.
5. Reig E, Abejón D. Spinal cord stimulation: A 20-year retrospective analysis in 260 patients. *Neuromodulation: Technology at the Neural Interface*. 2009;12:232-9.
6. Chou Roger, Loeser John D, Owens Douglas K, et al. *Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain: An Evidence-Based Clinical Practice Guideline From the American Pain Society*. *Spine*: 1 May 2009 - Volume 34 - Issue 10 - pp 1066-1077
7. Medtronic, Spinal Cord Stimulation website, Summary of Safety and Effectiveness Data. Totally Implanted Spinal Cord Stimulator for Pain Relief. Indications for Use. <http://professional.medtronic.com/pt/neuro/scs/ind/index.htm>
8. Manchikanti L1, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician*: April 2013; 16:S49-S283
9. Shamji MF, Westwick HJ, Heary RF. Complications related to the use of spinal cord stimulation for managing persistent postoperative neuropathic pain after lumbar spinal surgery. *Neurosurg Focus*. 2015;39(4):E15.
10. Eldabe S, Buchser E, Duarte RV. Complications of Spinal Cord Stimulation and Peripheral Nerve Stimulation Techniques: A Review of the Literature. *Pain Med*. December 2015.

Kevin Smith, M.D.
Integrated Pain Specialists

September 16, 2016

I have reviewed the recently released draft proposal to implement a drug formulary and update the Medical Treatment Utilization Schedule (MTUS), and more specifically, the proposed Low Back Disorders Chapter with elimination of use of Spinal Cord Stimulation as a treatment for failed back surgery syndrome and other related chronic pain conditions. This change is based upon the recommendations as set forth in the American College of Occupational and Environmental Medicine (ACOEM) treatment guidelines per page 585 of the Low Back Disorders chapter.

This comes as very alarming news to me as I have provided evaluation and treatment of acute and chronic pain conditions for the past 30 years and consider SCS as a viable and vital treatment option for patients who suffer from chronic pain. Please allow this correspondence to serve as my official opposition to eliminating use of Spinal Cord Stimulator for treatment of the painful conditions noted above.

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Throughout my career, I have focused on providing the very best care for my patients even though some recommendations are not authorized or certified according to various medical treatment guidelines. Usually, spinal cord stimulation is a last resort type of treatment after patients have failed all other conservative and interventional treatment options.

Use of spinal cord stimulation provides multiple benefits. First and foremost, SCS provides additional relief where previous treatments and ongoing oral medications have not. SCS usually leads to increased function, allowing for participation in more social, daily living and employment related activities.

This treatment option also allows for decreased use of medications such as opiates, neurolytics, psychotropic, etc. This, in turn, allows for avoidance or, or termination of dependence / addiction issues. At a time when our country is the world's leader in narcotics, elimination of SCS as a treatment option will only place greater dependence of oral medications.

With reduced oral medications, a vast number of peripheral conditions can be reduced or eliminated. Stress placed upon bodily systems and vital organs can be greatly reduced, decreasing diagnosing and treating these consequential conditions.

Relief with SCS also improves restorative sleep leading to a return to REM sleep. REM sleep is well-documented for its importance for rehabilitation from day to day activities, cognitive improvement and recovery from injury, surgeries, other treatments and even from chronic pain.

SCS has also proven to be a psychological benefit to chronic pain sufferers. For all the reasons above, severity of psychological symptoms and the need for counseling and psychotropic medications can be greatly reduced or eliminated with successful SCS.

SCS is an accepted therapy for Failed Back Surgery Symptoms (FBSS) with a long history of consistent results reported from open label studies and randomized controlled trials reflecting the efficacy of SCS for treating the painful symptoms of FBSS.

SCS is supported by randomized controlled trials (RCTs) **1,2** and several large post market SCS retrospectives reporting positive outcomes for over 1,000 patients.**3-5**

SCS for FBSS is supported by organizations such as the American Pain Society⁶ the Food & Drug Administration⁷ and the American Society of Interventional Pain Physicians,⁸ FBSS is the number one indication for use of SCS. However, there remain a high number of surgical procedures provided on the spine each year. It has long been documented that a majority of spinal surgical procedures fail. With such a high rate of failure, and with the ever-increasing provision of additional surgeries, which are now including additional levels, with fusions, spinal surgeries continue to be recommended and authorized. Therefore, there will remain a high failure rate and a great need and demand for SCS.

There have also been documented cases where SCS has provided sufficient relief in non-operative situations, where patients cannot or will not proceed with spinal surgical intervention. SCS has also improved symptoms sufficiently enough to avoid the need for additional surgical procedures.

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With the continued number of spinal surgical procedures and their continued high failure rate, additional treatment options like SCS need to remain available to these patients and their physicians. SCS has been effective in CRPS as well.

SCS is covered by the California workers' compensation system as it is in the majority of the other states, as well as Medicare, and most commercial health insurers.

In closing, thank you for your consideration in this matter. As a very experienced pain management specialist, I again stress the importance of having SCS as a treatment option for many chronic pain conditions, not only FBSS. I would also like to point out how ACOEM guidelines inadequately address treatment of chronic pain. In retrospect, this was the main reason we began using MTUS treatment guidelines as they more thoroughly address treatment needs for chronic pain.

If SCS is eliminated as a treatment option, the pain physician is then left with continued or increased use of medications, procedures or other modalities to address chronic pain conditions that will not improve but rather worsen.

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John Bobik, Advisor, Claims Administration
ITS Group

September 16, 2016

Congratulations to the team on their design of the California formulary.

Although Phil Le Fevre, Senior VP of ODG has publicly expressed his reservations about the DWC approach recently, I believe it will work very well particularly from a technology perspective.

“The proof is in the pudding” is a term often used when there is doubt whether something will succeed or not as Phil and others have expressed. Concerns relating to the impact on current technology solutions used by claims administrators and others in approving payments for pharmaceuticals suggest the DWC formulary be based on National Drug Codes (NDCs). In order to demonstrate that the DWC approach can work without the need for NDCs for prior or pre-authorizations, I have attached two screen prints from the Minder system. Details relating to the claim and provider are fictitious and used for illustrative purposes only.

[2016,September14,Minder,California,PharmacyAuthorization.](#)

This screen illustrates entries for a specific claim and shows four pharmaceutical entries. While two entries have been automatically authorized with a dollar limit - acetaminophen for \$20 and ibuprofen for \$10, the other two entries require a review for the medications containing codeine phosphate and for medications which contain acetaminophen with codeine, prior to any payment.

For California, I’ve used the GPI (Generic Product Identifier) value for a medication in the pre-authorization process (or prior authorization process). In the pharmacy payment authorization function, a code such as the NDC is required to approve a medication. A file containing NDCs along with current pricing is available from the DIR website. Ideally the contents of this file should be integrated into the pharmacy bill review process as shown in the next screen and also into the prior or pre-authorization process for the rare occasion when specific NDCs or labelers may need to be identified. However, in the majority of cases, the GPI is a better option. Medical conditions relating to the DWC formulary need to be established in the system before the medication status of preferred or non-preferred can default. In the case of Minder, a dollar amount also defaults.

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You will note that the first line on this screen is highlighted with a right pointing orange arrow for GPI:Acetaminophen. On the far right of the screen, there is a pane titled "Item Paid Info \$2.56". This shows that \$2.56 has been paid for medications containing Acetaminophen only.

[2016,September14,Minder,California,PharmacyInquiry.](#)

This screen illustrates the pharmaceutical items submitted for payment approval along with their status. There are five entries listed. The first three are for medications containing acetaminophen only, each from a different labeler. These total \$2.56, the amount shown on the prior screen. There is also a paid amount of \$1.09 for ibuprofen. All these entries are identified with a green tick on the left-hand side of the screen, showing payment has been made. The last item shown for acetaminophen-codeine has pending, which is identified in grey print along with a grey tick. The amount shown can be paid, further reduced or not paid at all.

The Texas formulary identifies whether a medication requires authorization or not while California has taken this a step further by identifying the medical conditions the medications are generally used for. Some time in the future the DWC could further extend this as illustrated in Minder. Minder provides the opportunity to identify medications that are approved for a provider's specialty (e.g. Internal Medicine) as well as the role they have with the patient (e.g. primary treating physician). Minder also allows for medical conditions (e.g. sprained ankle), and any issues relating to those conditions (e.g. exaggerated) to be identified. In the example, the text "no issues" appears after the medical condition, indicating it has been accepted as genuine.

Although there has already been criticism about the number of medications identified as "non-preferred" or are not listed, it appears to me that the DWC has attempted to identify medications that would generally be prescribed at first physician visits or are non-habit forming. Approval of all other medications would then be made on a claim-by-claim basis and should not completely rely on lists such as the MTUS or ones produced by the ODG or ACOEM as I've discussed in two of my articles published on the website managingdisability.com. The articles available under the dialogue tab are titled "California Closed Formulary - benefit or detriment?" and "Could Employers Cite Bad Faith with the P&Cs' Work Comp Product in CA?, pages 22-26 and pages 28-29".

Per California MTUS Guidelines, medical practitioners are required to submit a report to claims administrators following the injured worker's first visit. The report which must adhere to either the 1995 or 1997 guidelines established for evaluation and management services by the Centers for Medicare and Medicaid (CMS), is then used by claims administrators for initial prospective assessment relating to medical services including medications to be provided. Using technology similar to that illustrated through the screen prints, claims administrators can identify services as well as medications approved for the claim. When an agreement cannot be reached between the medical practitioner and the claims administrator/medical director for medical services including medications, these are referred to IMR.

The DWC approach achieves the following objectives, (1) ensures the injured worker receives the necessary medical care including an initial supply of medications to treat their medical condition(s), (2)

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provides an opportunity for claims administrators and medical practitioners to agree upon ongoing medical services prior to the services being performed and (3) allows claims administrators to automate the payment approval process for medical services including medications.

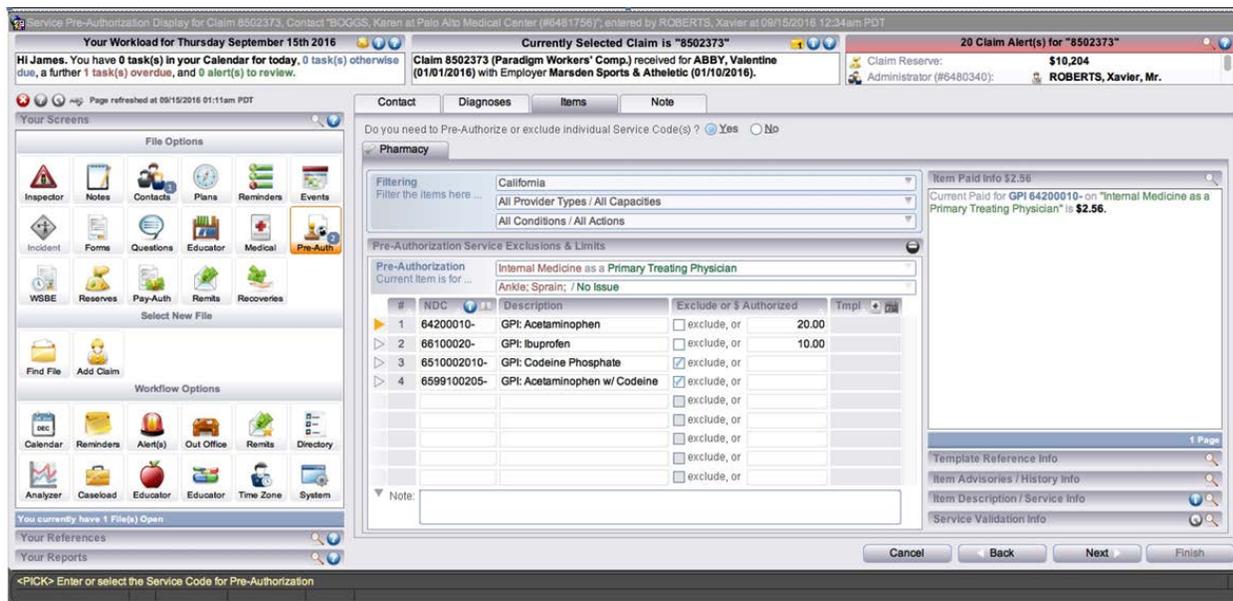
In a technology like Minder, the medical practitioner assigned to a claim has the option of either prescribing or dispensing pre-authorized (or prior authorized) medications without impacting claims administration practices or the price of medications. The DWC approach has the potential to greatly reduce the significantly high claims administrations costs currently being experienced in California.

The screenshot displays the Minder software interface for a claim inquiry. At the top, it shows the claim number 8502373 and the patient name ABBY, Valentine. A notification indicates that the claim is currently selected. The main area features a 'Pharmacy' search results table with the following data:

Pay Auth # / Line #	Reference #	Bill Date	Service Date	RX #	Code	Description	\$ Billed	\$ Allowed
211622-1	SEP-16-02110-1	09/10/2016	09/08/2016	1609-0198	49035002720	NDC: EQ Pain Reliever Ex St	5.00	0.73
211646-1	SEP-16-02111-1	09/10/2016	09/09/2016	1609-0199	10267061704	NDC: Extra Strength Acetaminophen	5.00	0.27
211651-1	SEP-16-02112-1	09/11/2016	09/10/2016	1609-0200	00615451043	NDC: Acetaminophen	10.00	1.56
211667-1	SEP-16-02111-1	09/12/2016	09/12/2016	1609-0210	24385060478	NDC: GNP Ibuprofen	5.00	1.09
211680-1	SEP-16-02111-1	09/12/2016	09/12/2016	1609-0211	000930005001	NDC: Acetaminophen-Codaine #2	10.00	3.02

Below the table, there is a section for 'Line Item Detail' for Pay Auth # / Line # 211622-1, showing 'Bill Information' for Service Provider BOGGS, Karen at Palo Alto Medical Center, and 'Service' details including Date (09/08/2016) and Drug (NDC 49035002720).

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Bryce W. A. Docherty
KP Public Affairs

September 16, 2016

Most of the statistics around the opioid epidemic are well documented, what is missing in the conversation is the information about how the current opioid based treatment of acute, post-surgical pain is feeding into the overall epidemic - **National analysis (300K patients using the Premier database): 95% of postsurgical patients received an opioid,**¹ expanding the effects to the socioeconomic stress and the overall cost of treatment and care.

The Problem:

Undertreated pain, opioid related adverse events, and prescription opioid abuse remain important public health problems. One in 15 surgical patients becomes a chronic opioid user after their procedure, and each day, 46 people die from an overdose of prescription pain killers. ^{2,3} With over 70 million surgical procedures performed annually in the United States, strategies for helping patients to achieve pain relief and minimize their use of opioids are needed now more than ever. In 2013 there were 230 million prescriptions for opioids such as Vicodin, OxyContin and Percocet, according to data from IMS Health, a drug market research firm. Dependence on these medications has risen sharply, with patients given opioids within seven days of discharge almost 50% more likely to still be on them one year after surgery and opioid related adverse drug events the most common post-discharge complication.⁴

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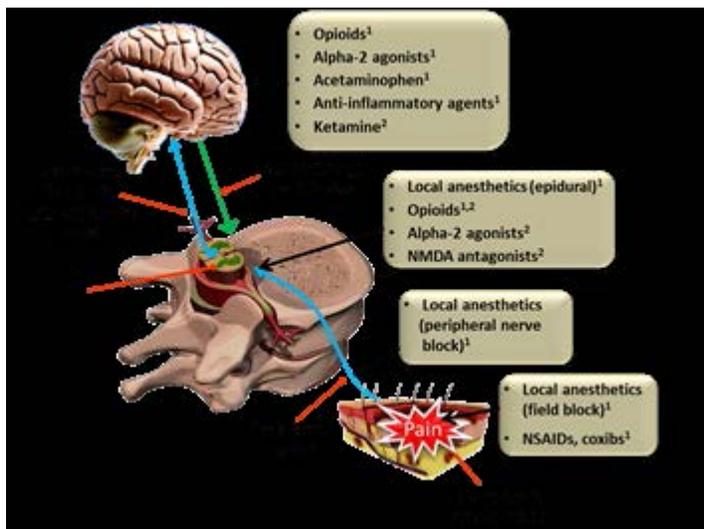
The incorporation of a multimodal strategy to treating pain is just one solution to halt the increase in the opioid epidemic.

Some Statistics:

- In patients undergoing various soft tissue or orthopedic procedures:
 - **6% of patients** continued on new opioid **150 days after surgery**
- 1 year after elective spine surgery:
 - **1/3rd** of all patients were still using opioids
 - **18%** of previously opioid-naïve patients were still using
- Insurers Spend \$446 Million on Opioid Treatment in 2015.
 - According to a Fair Health published earlier this month, insurers have seen their payments to hospitals, laboratories, treatment centers and other providers skyrocket **1,375% from 2011 to 2015** for patients diagnosed with an opioid dependence or abuse disorder. Insurers **saw treatment costs rise from \$32 million to \$446 million over the same time frame** with the average yearly cost per patient rising from \$3,435 to over \$19,000 battling opioid dependence

What is Multimodal pain control?

Multimodal pain control is the use of different medications that control pain at different receptor sites in the body, beginning with local anesthetics. This strategy reserves the use of opioid medications for breakthrough pain.



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Coxibs=cyclooxygenase inhibitors.

NE=norepinephrine.

NSAIDs=non-steroidal anti-inflammatory drugs. 1.Gottschalk A, Smith DS. *Am Fam Physician*. 2001;63:1979-84.

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We recommend the inclusion of medications like Liposomal Bupivacaine, IV acetaminophen and other non-opioid, hospital based pain medications on the formulary. In addition, the formulary committee membership should include a representative from Surgery, Nursing, Pharmacy, and Anesthesiology.

Support for change:

- **JCAHO** recommends “An individualized, multimodal treatment plan should be used to manage pain—upon assessment, the best approach may be to start with a non-narcotic”⁷
- **CDC** recommends “Health care providers should only use opioids in carefully screened and monitored patients when non-opioid treatments are insufficient to manage pain”⁸
- **ASA** recommends “a multimodal approach to pain management—often beginning with a local anesthetic where appropriate”
- **APS** recommends “clinicians consider surgical site local infiltration, which has been shown to be effective as a component of multimodal analgesia in several procedures”⁹
 - Use of local anesthetic infiltration should be on the basis of evidence showing clinical benefit for the surgical procedure in question.
 - Clinicians should be knowledgeable regarding specific local anesthetic infiltration techniques (including the use of extended-release formulations of local anesthetics such as liposomal bupivacaine), which vary depending on the procedure.

57% prefer non-opioid medications¹⁰

Patients going in for a surgical intervention deserve to be educated that the use of opioids can lead to dependency. All patients deserve to have open, unrestricted access to non-opioid medications to treat their post-surgical pain.

As a company, we are passionate about patient care. This subject is so important to us that we have an entire section of the website, www.EXPAREL.com dedicated to the opioid burden. In addition, we have partnered with The American Society of Enhanced Recovery (ASER) to launch Choices Matter, a national non-branded patient education campaign to empower patients to seek out non-opioid options—and the clinicians and institutions that offer those options—for their postsurgical recovery. The campaign website is www.PlanAgainstPain.com.

We agree with the recommendations just released by the American Pain Society that a multimodal approach to pain is the best approach and the most successful way to curb the need for narcotics.

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Doctors and nurses must have ready access to non-opioid hospital based medications to meet the needs of patients that either do not want or cannot receive opioids – especially those patients that are in recovery from addiction. These critical medications need to be included on the formulary for this to happen

There is an opioid epidemic, as recognized by national organizations and state governments. It's not just a patient problem. It's a problem for:

- Hospitals
- Physicians
- Insurers
- Businesses/employers
- Communities
- Families

The epidemic is avoidable and opioid alternatives are available today.

What are we waiting for?

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Jason Schmelzer, CCWC
Jeremy Merz, CalChamber

September 16, 2016

The California Coalition on Workers' Compensation (CCWC), the California Chamber of Commerce (CalChamber), the California State Association of Counties (CSAC), California Manufacturers and Technology Association and CSAC EIA each represent a membership that consists of a combination of public and private sector entities that employ millions of California workers. Combined, we represent a broad cross section of employers in California.

Our organizations were early supporters of AB 1124 (Perea, 2015) because we 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.

Thank you for providing our members with an opportunity to provide feedback on the Draft Formulary Regulations during this pre-rulemaking process. We believe that early stakeholder input will help the DWC craft a formulary that can be both seamlessly implemented by regulators and easily administered by claims professionals.

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.

EXPLANATION OF APPROACH

The study informing DWC's implementation, *Implementing a Drug Formulary for California's Workers' Compensation Program, Rand 2016* (Rand Report), outlines multiple options (AECOM, ODG, or CA-specific) for implementing a formulary in compliance with AB 1124. It could be helpful when the formal rulemaking process begins to have an explanation of the reasons that the CA-specific option was selected as a matter of public policy. Additionally, the Rand Report outlines some actions that should be taken if the current MTUS structure is retained (resolving conflicts with the ODG Pain Guidelines, etc.).

RECOMMENDATION: *It would be helpful for the DWC to explain the public policy reasons for their approach to the draft regulations, outline their efforts to adhere to the recommendations in the Rand Report and identify any recommendations that were not adopted.*

MTUS UPDATES

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While not technically a part of the Draft Formulary Regulations, our coalition supports the DWC's efforts to update the MTUS in conjunction with the development and implementation of the Drug Formulary. It is possible that our comments and recommendations on each proposed regulation may differ based on the totality of both regulatory proposals.

RECOMMENDATION: *We would note, for the record, that it would be quite helpful to evaluate the proposed updates to the MTUS and the proposed Drug Formulary Regulations concurrently so we can have a complete understanding of how the regulations will interact.*

SPECIALTY DRUGS

The Official Medical Fee Schedule (OMFS) is being undermined by some doctors who prescribe "specialty drugs" (unit costs are far higher than more commonly prescribed strengths of same drug), and in many cases these drugs are prescribed for the financial benefit of a medical provider instead of the medical benefit to the patient. The proposed regulations for the formulary require a physician to provide an explanation of the medical necessity for prescribing a more costly drug rather than its cheaper equivalent, but do not include anything about this unique dosage issue.

RECOMMENDATION #1: *Add (b) to §9792.27.7 as outlined below.*

(b) If a physician prescribes a drug at a specific dosage strength when a lower unit cost of the same drug at an alternative 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.

RECOMMENDATION #2: *Our coalition believes that an NDC-based formulary would help significantly in efforts to control the use of new formulations and specialty drugs and reduce price variability. The DWC should modify the regulations to ensure that a range of NDC codes are provided for each drug on the preferred drug list. While we understand that this may be an extensive undertaking, we believe that it will greatly enhance the utility of the formulary as a tool to speed appropriate care to injured workers and reduce administrative costs for employers.*

FIRST FILL DEFINITION

Our members think that this definition is slightly confusing and would propose to modify the definition as outlined below.

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RECOMMENDATION: Amend § 9792.27.1(i) as follows:

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

“DISPENSE” and “PRESCRIBE” NEED SEPARATE DEFINITIONS

We believe that the regulations need to do a better job of distinguishing between dispensing by a pharmacy, dispensing by a physician, and the act of prescribing by a physician. Our members have expressed concerns that the draft definition of “dispense” will create confusion and the regulations could contain more operational nuance if the concepts identified above were more clearly distinguishable in the definitions and text of the regulations.

ABILITY TO APPROVE NON-PREFERRED DRUGS WITHOUT UR

The regulations make it clear that a contract with a Pharmacy Benefit Manager or Pharmacy Network cannot be more restrictive than the formulary. However, we believe the regulations should also make it clear that claims administrators can choose to be more generous than the formulary if they so choose.

Phil Denniston, President
Work Loss Data Institute, Publishers of ODG

September 16, 2016

Work Loss Data Institute, publisher of ODG, respectfully submits the following comments on the Proposed Formulary Regulations. We believe this is an excellent opportunity to positively impact treatment outcomes for injured workers and expedite access to more appropriate and lower risk medications, while also lowering costs for payers and decreasing the need for prospective & retrospective review, UR, and IMR.

ODG is supportive of the Division’s efforts to update the MTUS and implement a drug formulary. However, we have several concerns and respectfully raise issues for consideration, as detailed in this submission. Our comments relative to the California Workers Compensation system are enhanced by knowledge acquired from our extensive experience with ODG Formulary & Guidelines adoptions in multiple jurisdictions.

1. The Proposed “DRAFT MTUS Preferred Drug List (8 CCR § 9792.27.12)” (herein referred to as “Proposed Formulary”) is new, untested, and state specific, apparently drafted by the DWC relative to MTUS. As posted on the DWC Forum, It is not ACOEM or ODG.
 - a. It is unclear why DWC would adopt a Formulary that lacks a proven documented track record and resultantly makes the injured workers and stakeholders of California the “test case.”

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2. The impetus behind the potential savings for AB1124 was based on CWCI Formulary Research Report (dated October 2014), which examined a Washington State Based (AMDG) formulary and Texas State Based (ODG) Formulary. Proposed Formulary has no known estimated savings at this time.
 - The Proposed DWC Formulary cannot parallel the proven, documented life-altering results in Texas over multiple years with the ODG Formulary as reported by the [Texas Division of Insurance, highlights of which include:](#)
 - The number of prescriptions for N-drugs (“non-preferred” drugs in CA terminology, requiring medical substantiation and prior authorization) fell by 85%.
 - There are no N-drugs currently in the top 10 most-prescribed medications.
 - Opioid costs decreased from 27% of the total pharmacy costs in 2009 to 18% in 2015.
 - The number of claims involving N-drug opioids with 90mg morphine equivalent doses per day decreased from almost 15,000 in 2009 to less than 500 in 2015.
 - The total opioid prescription costs for N-drugs and those on the recommended “Y” list dropped from \$43.2 million in 2009 to \$18.5 million last year.
3. The Proposed Formulary is highly restrictive, likely increasing PR, RFA, UR, and IMR, while delaying access to multiple appropriate medications.
 - a. 73% of CA work comp prescriptions and 78% of the associated payments are Non-Preferred drugs or Not on Formulary (CWCI Spotlight Report, August 2016).
 - b. Opioids account for 27% of total prescriptions; however, **there are NO opioids on the Preferred Drug List in Proposed Formulary** (CWCI Spotlight Report, August 2016).
 - c. Musculoskeletal Therapy accounts for 9.4% of total prescriptions; however, **there are NONE on the Preferred Drug List in Proposed Formulary** (CWCI Spotlight Report, August 2016)
 - d. ODG has approximately double the number of Preferred prescription drugs of Proposed Formulary
 - i. Affording injured workers increased expedited access to appropriate medications;
 - ii. Significantly decreasing the need for and cost of RFA’s, UR’s, and IMR’s.
4. The Proposed Formulary drug list is not specifically associated with evidence based studies or guidelines, recommendations with documented literature searches, or sources for evidence based recommendations for each medication. To the contrary, ODG provides the framework and evidence citations (limited sample below).

Codeine (Tylenol with Codeine®)	<p>Recommended as an option for mild to moderate pain, as indicated below. Codeine is a schedule C-II controlled substance, but codeine with acetaminophen is a C-III controlled substance. It is similar to morphine. 60 mg of codeine is similar in potency to 600 mg of acetaminophen. It is widely used as a cough suppressant. It is used as a single agent or in combination with acetaminophen (Tylenol® with Codeine) and other products for treatment of mild to moderate pain. Codeine has disadvantages in that it is a pro drug that needs to be converted by the cytochrome P450 isoenzyme 2D6 to morphine, plus there are FDA alerts of ultra-rapid metabolism. (Ray, 2013) See also Opioids for general guidelines, as well as specific Codeine (Tylenol with Codeine®) listing for more information and references</p> <p><i>Adverse effects:</i> Common effects include CNS depression and hypotension. Drowsiness and constipation occur in > 10% of cases. Codeine should be used in caution in patients with a history of drug abuse. Tolerance as well as psychological and physical dependence may occur. Abrupt discontinuation after prolonged use may result in withdrawal. (AHFS Drug Information, 2008) (Clinical Pharmacology, 2008) (Lexi-Comp, 2008)</p>
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5. The Proposed Formulary has not been documented to have been adopted, mandated or implemented in any jurisdiction in the US or abroad, raising questions of qualifying as “Nationally Recognized.” It is unproven, untested, and not operationalized, integrated, validated and/or automated by any PBM’s, Insurers, TPA’s, Employers, Medical Service Providers, software systems, or Stakeholders to date.
 - a. It would take Stakeholders considerable time, resources and money to operationalize the Proposed Formulary Drug List and updates versus using a Formulary presently in use by Stakeholders with minimal associated development and implementation costs, as reported by Rand.
 - b. It would be difficult to meet an implementation date of July 1, 2017 with time for appropriate development and testing of protocols and systems for a new Formulary which is not fully developed.
 - *ODG is already proven, tested, operationalized, integrated, validated and automated by the PBM’s, Insurers, TPA’s, Employers, Medical Service Providers, software systems, and Stakeholders.*
 - *Stakeholders report they can easily, expediently and cost effectively implement, expand, maintain, and update use of the ODG Formulary with a required overlay of California specific regulations and processes.*
 - *Other ODG state adoptions include TX, TN, NM, OK, AZ; ACOEM has none.*

6. The Proposed Formulary is not tied to NDC codes which are utilized in processing prescriptions.
 - a. This is problematic for processing and pricing prescriptions at the time of patient encounters and attempted fills.
 - b. This impedes communications and processing between Pharmacies and PBM’s.
 - c. This impedes review of appropriateness of prescriptions.
 - d. The lack of one state standard NDC coding for Formulary drugs could:
 - i. result in a wide range of interpretation and inconsistencies among the PBM’s and stakeholders as to what is actually a preferred or non-preferred medication;
 - ii. increase inconsistencies in reviews and denied authorizations across the system;
 - iii. increase disputes, UR & IMR;
 - iv. increase processes and uncompensated expenses to Pharmacies and PBMs, potentially translating to cost shifting to employers;
 - v. extend delays in fills with inconveniences for injured workers;
 - vi. impede bill review.
 - *The ODG Formulary NDC database contains over 33,000 lines of drug specific data tied to the supporting Guidelines, is updated monthly and as needed on an emergency basis, is integrated into PBM and Stakeholder systems, and is already in use nationally.*

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7. The Proposed Formulary lacks user interfaces and search/query tools for direct online use or integration into existing systems. It is not linked electronically to Evidence Based guidelines or supporting medical studies (limited example below).

	Drug Ingredient	Preferred / Non-Preferred*	First Fill**	Drug Class	Reference in Guidelines
1	Acetaminophen	Preferred		Analgesics - NonNarcotic	Ankle and Foot Disorders Cervical and Thoracic Spine Disorders Chronic Pain Elbow Disorders Eye Hand, Wrist, and Forearm Disorders Hip and Groin Disorders Knee Disorders Low Back Disorders Shoulder Chronic Pain

- The Proposed Formulary simply lists MTUS chapters (by name not section citations) addressing the medications without links to specific chapter sections or supporting evidence, making searching cumbersome and difficult.
 - The Proposed Formulary will be difficult for Medical Professionals to use at the time of patient encounters and in the PR, RFA, UR, and IMR processes.
 - The lack of simplicity with the proposed parameters and uncompensated required time, expenses and “hassle factors” for Providers and their staff may drive Medical Providers out of the system.
 - The Proposed Formulary will be difficult for injured workers and non-medical stakeholders to understand.
- *As has been documented with other states and administrative agencies, ODG provides the administrative agency with no cost monthly Formulary Updates for posting and will provide California DWC with NDC code crosswalks, tables, and automated look-up tools for posting and use by Medical Providers and Stakeholders on the DWC website at no cost (limited examples below).*

ODG Workers' Compensation Drug Formulary				
Drug Class	Generic Name	Brand Name	Gener Equiv	Status
Analgesics, narcotics	See Opioids.			
Analgesics, NSAIDs	See NSAIDs (non-steroidal anti-inflammatory drugs).			
Analgesics, OTC	See Nonprescription analgesics.			
Anticonvulsants	See Anti-epilepsy drugs (AEDs).			
Antidepressants	Am triptyline	Elavil®	Yes	Y
Antidepressants	Bupropion (mental)	Wellbutrin®	Yes	Y
Antidepressants	Bupropion (pain)	Wellbutrin®	Yes	N
Antidepressants	Citalopram	Celexa	Yes	N
Antidepressants	Desvenlafaxine	Pristiq®	Yes	Y

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**ODG Drug Formulary
NDC Advisor™**

Clear Text Print

NDC Codes: codeine

Add Claim ID and contact info (for printing/documentation)?

The National Drug Code is a unique 10-digit, 3-segment code that identifies the labeler, product, and package size. The first segment, the labeler, is 3 or 4 digits long and identifies the product. The second segment, the product, is 3 or 4 digits long and identifies the specific strength, dosage form, and package forms and sizes. The ODG lookup does the following groupings of digits into segments: 1. Labeler (first 3 or 4 digits), 2. Product (next 3 or 4 digits), and 3. Package (last 3 or 4 digits). The ODG inserts a zero in the first digit in a segment as well, ODG compiles NDC codes directly from the FDA, considering the FDA to be the official source. On June 1, 2011, the FDA changed the format they use to store NDC codes. Previous to that date, they used an asterisk to fill out segments, but now they do not, and as noted, ODG inserts a zero. In addition to formatting issues, there may be content discrepancies between what the FDA has and what third-party compilers have on file, because they both depend on accurate reporting by drug marketers and typos are possible. However, the FDA reporting requirement has the weight of law behind it, so that is the official source used by ODG.

* An asterisk in place of Y or N means that Formulary Status depends on indication. See the actual ODG Formulary listing.

68071-0073 - Acet Codeine - 300;30mg

66267-0221 - Acet Codeine Tablets - 300;15mg

66267-0002 - Acet Codeine Tablets - 300;60mg

66267-0001 - Acet Codeine Tablets - 300;30mg

68071-0481 - Acet Codeine Tablets - 300;30mg

66267-0729 - Acet With Codeine Tablets - 300;30mg

68071-0155 - Acet/Codeine Tablets - 300;30mg

**ODG Drug Formulary
NDC Advisor™**

Clear Text Print

NDC Codes: 68071-0073

Add Claim ID and contact info (for printing/documentation)?

NDC Number	68071-0073
Drug Class	Opioids
Generic Name	Codeine/acetamin.
Brand Name	Tylenol #3/4
GE (generic equivalence)	Yes
Strength	300;30mg
Trade Name	Acet Codeine
Status	Y
Effective Date	01/31/2016

Click [here](#) for Explanation of Rows.

8. Specific to Patient-Physician encounters, the lead time from the date of final selection of the Proposed Formulary and the effective date of July 1, 2017 is insufficient.
 - a. There is insufficient time for identification, safeguarding, and special handling of injured workers with legacy claims who are receiving opioids and medications potentially requiring tapering, weaning, or changes in medication in accordance with the proposed Formulary.
 - b. As has been demonstrated in other jurisdictional implementations of the ODG Formulary and Guidelines, sufficient lead time between the announcement of a specific Formulary and effective date has allowed for injured workers to be contacted and appropriately treated.
 - c. There is insufficient time for Medical Provider training and intervention.

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- i. A treating doctor's failure to immediately justify weaning, transition, or continued use of non-formulary or non-preferred drugs with treatment plans or an RFA with supporting documentation, could impact access to medications and patient well-being.
 - ii. In an attempt to comply with effective date, Doctors may limit prescribing while failing to provide a pathway for weaning, tapering, or detox.
 - d. The lack of a transition period does not afford sufficient time to intervene in time to comply with the effective date of 7/1/17.
 - e. There is a risk of medical providers abandoning legacy patients due to increased transactional processes and uncompensated costs.
- 9. Per AB1124, the Formulary needs to be updated quarterly, which in practice would require quarterly updates of the supporting treatment guidelines and NDC codes.
 - a. Per Rand report, the proposed Reed/ACOEM updates to MTUS have been updated every 3-5 years by Reed, which could result in a disconnect between the Formulary and MTUS.
 - b. Per Rand report, the ODG Formulary is updated monthly along with the supporting evidence and Guideline references affording consistency between the Formulary and supporting Guidelines.
 - c. The DWC process and resources to identify and review EBM for quarterly Formulary updates is undefined.
 - d. The volunteer P&T Committee cannot conceivably be responsible for comprehensively identifying evidence based studies and rationale for quarterly updates.
- 10. The entirety of the Proposed MTUS Chapter Updates and Formulary may not specifically qualify as "nationally recognized" as required by statute and regulations without documented objective "national recognition" and jurisdictional adoptions.
 - a. The current existing "ACOEM" Chapters included in MTUS were owned, authored, and published by the American College of Occupational & Environmental Medicine, a nationally recognized medical society.
 - b. The Proposed MTUS Chapter Updates using the Reed Group guidelines under the brand name of ACOEM are owned, controlled, authored, and published by Reed Group (a publisher that is also a provider of TPA services and owned by Guardian Insurance).
 - c. Proposed Reed Group Treatment Guidelines and Formulary (being branded as ACOEM and co-produced by HealthSystems, a PBM) have not been specifically named and adopted by any US jurisdictions.
- 11. The Proposed MTUS Guidelines updates are currently or will soon be out of date as listed below:
 - a. Ankle & Foot Disorders-Effective Date: September 2015
 - b. Cervical & Thoracic Spine Disorders-Effective Date: May 27 2016
 - c. Elbow Disorders-Effective Date: 2013
 - d. Eye Disorders-Effective Date: 2011

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- e. Hand-Wrist-Forearm-Effective Date: June 30, 2016
- f. **Hip & Groin Disorders-THIS IS A NEWLY ADDED MTUS CHAPTER**-Effective July 29, 2010
- g. Knee Disorders-Effective Date: October 28, 2015
- h. Low Back Disorders-Effective Date: February 24, 2016
- i. Shoulder Disorders-Effective: August 1, 2016

Although a lack of posting of a Guideline on the National Guidelines Clearinghouse (NGC) does not imply that the Guideline is not “Evidence Based,” not all of the above proposed updates are included or posted on NGC.

12. The ODG Formulary and Guidelines Copyright allows for fair use by Stakeholders. The proposed Formulary and Guidelines are copyright protected by Reed Group with no “commercial use” permitted without licensing fees. This has proven to be a problem in other jurisdictions including

ODG	ACOEM Guidelines
Most balanced	Most restrictive
Comprehensive, multidisciplinary, with unambiguous recommendations	Occupational specialty guidelines (n/a for orthopods, PT, chiro, etc.).
Updated annually	Updated every 3-5 years (6-7 historically)
Proven track record of improving outcomes	Have not demonstrably improved outcomes
Independent ownership	Owned by an insurance company and TPA
Most widely used, ready to implement	Not widely used outside of MTUS
Automatable via state of the art API	Manual look-up only
Best technical quality, with pragmatic approach to literature review	RCTs only means 70% of recommendations are “Insufficient Evidence”, paralysis by analysis
For profit, commercial product	For profit, commercial product

New York. Additional comparisons are illustrated below.

In closing, the recent Rand Report provides a review and analysis of the Formulary and MTUS to support an adoption of ODG as a solution to meet California’s Formulary and MTUS needs. Rand and other sources substantiate ODG as an as an existing proven solution that has been successfully adopted by other jurisdictions with documented results and minimal cost of implementation compared to the Proposed Formulary and MTUS updates.

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Ken Eichler, Vice President
Work Loss Data Institute, Publishers of ODG

September 16, 2016

Work Loss Data Institute, publisher of ODG, respectfully submits the following comments on the Proposed Formulary Regulations. We believe this is an excellent opportunity to positively impact treatment outcomes for injured workers and expedite access to lower risk appropriate medications, while also lowering costs for payers and decreasing the need for Prospective & Retrospective Review, UR, and IMR.

ODG is supportive of the Division's efforts to update the MTUS and implement a drug formulary. However, we have several concerns and respectfully raise issues for consideration, as detailed in this submission. Our comments relative to the California Workers Compensation system are enhanced by knowledge acquired from our extensive experience with ODG Formulary & Guidelines adoptions in multiple jurisdictions.

§ 9792.27.1. Medical Treatment Utilization Schedule Drug Formulary—Definitions

Comment:

A definition for "Unlisted Drugs" should be added.

§ 9792.27.1. Medical Treatment Utilization Schedule Drug Formulary—Definitions

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

Comment:

A similar category for first fills post-surgery, procedure, or in-patient discharge could expedite delivery of necessary medications for "outpatient use".

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

(2) The MTUS Drug Formulary applies to drugs prescribed by a physician for outpatient use or dispensed for outpatient use by any of the following:

(A) A physician;

(B) A pharmacy;

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- (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.

Comment:

This could negatively impact non-preferred or unlisted (non-“first fill”) meds that are dispensed or prescribed at the patient-physician encounter for outpatient use based on immediate or urgent medical necessity, without time to obtain prior authorization. Examples include post-procedure, ASC’s, ER, or other clinical setting and routine office visits during or beyond routine business hours.

Lack of options on the highly restrictive proposed Preferred List (lacking any opioids or musculoskeletal meds) or unlisted drugs may significantly increase unnecessary ER visits with inflated “urgent” or “emergent” care and dispensing. Control of medical care by the treating provider results in better patient outcomes than care supplemented by ER visits due to limited points of access to lower risk meds pending RFA & PR.

The negative psychosocial impact of zero “Preferred” drugs affording access to some classes of medications may further negatively impact patient attitudes and outcomes while increasing dispute resolution, legal fees, and disability durations.

Section 9792.27.3. MTUS Drug Formulary Transition.

(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician shall either:

- (1) Prepare a treatment plan to transition the worker to a Preferred Drug, or**
- (2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.**

Comment:

Noting there are no opioids on the proposed Drug Formulary “Preferred” list, a provision providing at least sixty days and no greater than a six month exemption period from the date of notice of adoption of

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regulations (not necessarily effective date) would protect patients and allow for the necessary outreach and education of medical Providers. Time is further needed to appropriately prepare and submit treatment plans and RFA, as well as allow for review, revision, and “negotiations” of the plan to safely and appropriately discontinue non-Preferred drugs and/or wean, taper, or transition patients to Preferred drugs.

Difficulties with actually getting information and responses from Medical Providers have been well documented with and by MPNs.

Perhaps the DWC could explore feasibility of mandatory prescriber training to prescribe non-formulary or unlisted drugs.

Section 9792.27.6. MTUS Drug Formulary – Access to Drugs Not Listed in the Preferred Drug List.

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.)

Comment:

Although this section is specific to “access”, to avoid confusion, consider adding the phrase used elsewhere throughout this proposed regulation: “For a drug not addressed on the MTUS Preferred Drug List, authorization through prospective review must be obtained prior to the time the drug is dispensed. If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied.”

This is far clearer in other sections.

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

Comment:

Consider adding “Unlisted Drugs” to Title.

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

(c) For a drug that is identified as “Non-Preferred,” authorization through Prospective Review must be obtained prior to the time the drug is dispensed. If authorization through Prospective Review is not

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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.

Comment:

A provision for prescribing & dispensing a limited quantity (equal to the days allowed for PR or, ideally with three day expedited PR) of substantiated immediately or urgently needed meds may be beneficial if NO opioids or musculoskeletal meds are “Preferred” drugs.

Under this suggested provision, a drug that usually requires prospective review because it is “Non-Preferred,” could be allowed without prospective review in very limited circumstances, and for a short period of time equal to the days allowed for expedited Prospective Review.

The proposed formulary effectively denies access to any such medications as dispensing will not be approved by PBMs absent PR. In practice, Patients would only have access to such medications on a cash pay basis until PR is completed.

Section 9792.27.11. MTUS Preferred Drug List – First Fill.

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

Comment:

A similar provision for first fills of meds post-surgery, procedure, or in-patient discharge could expedite delivery of necessary medications for “outpatient use” in scenarios where it may not be practical to obtain Prospective Review.

Medically speaking, surgery could be considered a new assault on the body which clinically could be equivalent to a new injury.

Section 9792.27.11. MTUS Preferred Drug List – First Fill.

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

Comment:

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Although longer first fills and additional drugs may decrease the need for Prospective Review and UR, this may eliminate safeguards for injured workers against risky or addictive medications, which is the intent of the formulary.

This provides benefits to some but not all injured workers based upon participation in an MPN, which is not an option in the control of an injured worker. It is an employer, TPA, or carrier decision that may exclude many if not initiated by employer, TPA, or carrier contracting with an MPN.

Section 9792.27.12. MTUS Preferred Drug List.

[DRUG LIST]

Comment:

No Drug List is included for review and comment as part of this document or by reference. This limits full and informed evaluation and comment by Stakeholders.

Section 9792.27.13. Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.

(a) The Administrative Director shall create an independent Pharmacy and Therapeutics Committee (P&T Committee) to review and consult with the Administrative Director on available evidence of the relative safety, efficacy, and effectiveness of drugs within a class of drugs, for purposes of updating the MTUS Preferred Drug List.

Comment:

The volunteer P&T Committee of individuals with the required qualifications will likely be otherwise employed with limited but sufficient time to successfully perform defined P&T duties. However, it could be unreasonable to anticipate or require the P&T Committee to comprehensively identify and review all evidence based studies and rationale for quarterly updates.

Section 9792.27.13. Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.

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

Comment:

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More specific definition of “actively practicing pharmacist” is needed. Practicing Pharmacists engage in very a broad scope of responsibilities and duties in various capacities and settings. Does “actively practicing” the below Sections 3(c) 1,2 & 3 qualify a Pharmacist as “an actively practicing Pharmacist?”

Section 9792.27.13. Pharmacy and Therapeutics Committee – Composition; Application for Appointment; Term of Service.

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

Comment:

Staggered terms of P&T members would have numerous advantages including but not limited to having at least three experienced Committee members every year (absent resignations or terminations) and eliminating the need for “re-training” of all Committee members every two years.

Section 9792.27.17. Pharmacy and Therapeutics Committee – Meetings.

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

Comment:

A requirement to meet with sufficient time for P&T to review proposed updates and allow for public comment per below section (3)(c) prior to the deadline for approval, adoption, and publication of quarterly update deadlines could be beneficial.

Section 9792.27.17. Pharmacy and Therapeutics Committee – Meetings.

(b) P&T Committee meetings shall be open to the public, except as provided in subdivision (e). Notice of the meetings shall be given at least one week in advance of the meeting as follows:

- (1) To persons who have requested notice of the meetings;**
- (2) To persons on the Administrative Director’s mailing list; and**
- (3) By posting notice on the division’s website.**

Comment:

Is this consistent with standard meeting notice? If members of P&T are actively employed, one week may be short notice.

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Section 9792.27.17. Pharmacy and Therapeutics Committee – Meetings.

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

Comment:

Definition of “where deemed necessary” could avoid ambiguities.

Other jurisdictions have open meetings only. The similar closed door policy of MEEAC precluded transparency and is somewhat unique to California.

Section 9792.27.18. MTUS Preferred Drug List Updates.

Comment:

Quarterly updates require adoption of treatment guidelines that are updated at the same frequency.

If Guidelines are not updated in concert with Formulary updates, application of Strength of Evidence could result in delays and increased PR, RFAs, UR, and IMR.

Rand reports that proposed Reed/ACOEM Guidelines sections are currently updated every 3-5 years. The proposed Reed/ACOEM Guidelines lack a proven track record to the contrary.

Proposed MTUS section updates are currently and/or will be outdated by the times of both the selection and effective dates of the proposed Formulary. Last updates to proposed sections span over 2010, 2011, 2103, 2015 & 2016.

Stakeholder cannot fully evaluate, understand, and provide fully informed opinions and public comment absent DWC full disclosure of the proposed update process, methodology, and qualifications of reviewers (other than P&T), including the identifying & ranking of evidence and associating the NDC codes.

Section 9792.27.18. MTUS Preferred Drug List Updates.

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

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

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

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

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

Comment:

The volunteer P&T Committee of individuals with the required qualifications will likely be otherwise employed with limited but sufficient time to successfully perform said duties.

It could be unreasonable to anticipate or require the P&T Committee to comprehensively identify and review all evidence based studies and rationale for quarterly updates.

Unrelated to specific sections of the proposed regulations, we respectfully voice concerns regarding the potential compromise of the integrity of the Forum Public Comment process by the release of a factually incorrect press release and public statements that the State of California has entered into a Partnership with Reed Group. DWC has confirmed that no such Partnership exists. The Press Release may have mislead stakeholders and potentially impacted their comments and analysis of the issues at hand.

In closing, the recent Rand Report provides a review and analysis of the Proposed Formulary and MTUS Updates to support an adoption of ODG as a solution to meet California's Formulary and MTUS needs. Rand and other sources substantiate ODG as an as an existing proven solution that has been successfully adopted by other jurisdictions with documented results and minimal cost of implementation compared to the Proposed Formulary and MTUS updates.

Lishaun Francis, Associate Director
Center for Health Policy
California Medical Association

September 16, 2016

On behalf of the California Medical Association's (CMA) over 42,000 physicians and medical students, we welcome the opportunity to respond to the Division of Workers' Compensation (DWC) recent release of the Medical Treatment Utilization Schedule Drug Formulary. AB 1124 (Perea, 2015) was intended to ensure better access to medications for injured workers and reduce delays and costs

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associated with the utilization review (UR) and independent medical review (IMR) processes. We appreciate the opportunity to provide feedback on the current formulary draft and proposed regulations and hope that our comments and recommendations will be considered throughout the finalization process to ensure that implementation of the formulary aligns with its intent. CMA is requesting the department develop these regulations to ensure they are evidenced based, transparent, and comprehensive.

Formulary not Proven to be Evidenced Based

DWC's decision to create its own formulary raises questions and concerns on whether it is evidence-based. Evidence based care has been the standard in health care and in workers' compensation for care that is known, proven and nationally recognized. The formulary DWC has proposed does not meet this standard. CMA recommends DWC provide additional information on how the proposed formulary list was developed and how it compares to those formularies that are known, proven and nationally recognized.

Formulary should be Clear and Comprehensive

- *Prohibition against Prospective Review.* CMA is concerned the proposed language does not ensure that the preferred drug list is not subject to prospective utilization review. CMA is requesting a clear statement that the prescription of preferred drugs would not be subject to prospective utilization review.
- *Clarify Expectations between Non-Preferred Drug List and all other Drugs.* CMA is requesting clarification on how those drugs on the non-preferred drug list differ from drugs that do not appear on the non-preferred drug list. For instance, are the utilization review requirements for the drugs on non-preferred drug list different from the utilization review requirements for those drugs outside of the non-preferred drug list?
- *Preponderance of Scientific Medical Evidence Standard too High.* While the proposed regulatory language seeks to guarantee injured workers access to drugs outside of the formulary, CMA is concerned about the language that requires physicians to meet a "preponderance of scientific medical evidence" before prescribing those drugs. This would require physicians to research all relevant *scientific studies and prove that a majority of them support the prescription*. CMA contends this to be time consuming, expensive and cumbersome, ultimately delaying care for patients.

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- *Expand Preferred Drug List.* The proposed drug list is not sufficient to ensure access to the injured worker. California Workers' Compensation Institute reports: "More than 73 percent of (current) prescriptions and 78 percent of the associated payments would be either Non-Preferred or Not on the Formulary." This creates a question as to whether the *formulary is in alignment* with the needs of the injured worker. Further, CMA is concerned that the top 20 non-preferred drugs account for 43.8 percent of the prescription drugs, a large portion of prescription drugs that are not part of the formulary. When choosing preferred drugs for the formulary, the state should be sure to review and consider which evidence-based prescriptions have the highest volume and therefore are most likely to be *prescribed to the average injured worker*.
- *First-Fill Provisions Fall Short.* The proposed formulary identifies seven drugs that would qualify for the first-fill policy and requires those drugs to be dispensed within the first four days from the date of injury. However, these drugs represent only 4.7 percent of all prescriptions when dispensed within seven days¹. We recommend DWC extend the day limit policy in order to increase the number of injured workers who could benefit *from the first-fill policy*. In addition, CMA requests information that would explain how the drugs and timelines were chosen.
- *Lack of Opioids Hinders Treatment.* DWC has listed all opioids as non-preferred drugs, with the exception of some first-fill prescriptions that would be subject to prospective utilization review. CMA is concerned that DWC has chosen to exclude 27 percent of all California workers' compensation prescriptions from the preferred drug list—which unfortunately will not ensure appropriate access. DWC should ensure the appropriate opioids are included in the drug formulary.
- *Strengthen Transition Provisions.* CMA recognizes the department's desire for safe drug treatment transition plans that is outlined in Section 9792.27.3. However, we are requesting DWC provide language that would prohibit an employer from denying the treating physician's transition plan for the patient.

CMA Encourages Transparency

CMA is concerned that the functioning of the Pharmacy and Therapeutics Committee outlined in Section 9729.27.14 would result in an opaque process that does not encourage stakeholder input and that this lack of transparency could potentially result in the Committee not having the necessary information to make appropriate changes to the formulary. For example, the proposed regulations allow the Administrative Director to cancel the appointment of a committee member for any reason "constituting good cause." Additionally, the section allows for the Committee to meet in closed Executive Session where deemed necessary by the Executive Medical Director. CMA is concerned these provisions could lead to an unknown overuse of power. We ask DWC to revise the structure and rules for this committee to improve access and full public participation.

Further, given the timeline for implementation (July 1, 2018), we hope DWC will enter the full and official Administrative Procedure Act process quickly, in order to allow time for robust stakeholder engagement in the finalization of the formulary.

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CMA is confident these changes will increase the transparency within the process and result in a formulary with broad stakeholder input.

Reference

1 California's Proposed Workers' Compensation Formulary. Spotlight Report. California Workers' Compensation Institute. August 2016.

Barbara Marcanti, Global Director
Reimbursement & Healthcare Economics
St. Jude Medical, Inc.

September 16, 2016

On behalf of St. Jude Medical, Inc., a manufacturer and distributor of Spinal Cord Stimulation (SCS) systems used in the treatment of patients with chronic intractable pain of the trunk and limbs, we wish to provide comment to the Division on its proposed adoption of the American College of Occupational and Environmental Medicine (ACOEM) Low Back Disorders Guideline (as published by Reed Group, Ltd.) as the new California Medical Treatment Utilization Schedule (MTUS) Low Back Disorders Medical Treatment Guidelines, per the Division's announcement published on August 26, 2016.

Introduction to St. Jude Medical:

St. Jude Medical is driven by our vision and mission to transform the treatment of expensive epidemic diseases including chronic pain, movement disorder, atrial fibrillation, cardiac dysrhythmias, heart failure, stroke, coronary artery disease, and congenital heart defects. We strive to achieve our goal by providing innovative solutions that provide improved care and that reduce the economic burden of costly diseases on health care systems worldwide.

Issue:

We are extremely concerned that the Division's decision to adopt the ACOEM Guideline for Low Back Pain will result in elimination of Spinal Cord Stimulation (SCS) as a viable non-pharmacological treatment option for injured workers in State of California with chronic intractable low back pain or failed back surgery syndrome (FBSS).

What is Spinal Cord Stimulation:

Spinal cord stimulation (SCS), also called neurostimulation or Dorsal Column Stimulation (DCS) is a proven therapy recommended by doctors to manage chronic pain and improve quality of life. Neurostimulation systems are approved or cleared by the U.S. Food and Drug Administration (FDA) for the management of chronic pain in the back, neck, arms, or legs.

Benefits of neurostimulation may include:

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- A reduction in pain by 50 percent or greater^{1,2,3}
- A reduction or elimination in the use of pain medications⁴
- Increased activity levels and an improved overall quality of life

Neurostimulation, however, is not a cure for what is causing the pain and does not treat specific diseases. Instead, it is a therapy that's designed to mask pain by blocking pain signals before they reach the brain. It has been used to manage pain that comes from failed back surgery syndrome (FBSS), post-laminectomy syndrome, and/or other neuropathies.

Spinal Cord Stimulation is a widely accepted standard-of-care treatment option among physicians when treating a broad spectrum of back pain patients across the U.S. and in other countries. Organizations like American Society of Interventional Pain Physicians (ASIPP) and American Pain Society (APS) support SCS as a treatment option for chronic low back pain.^{5,6} SCS is also covered by many major health insurance plans, Medicare^{7,8}, the Department of Defense/Veterans Administration, and the workers' compensation programs in 48 states.

SCS is also supported by numerous rigorous clinical studies including randomized controlled trials (RCT) which show SCS is a clinically effective treatment, even more so than reoperation or conventional medical management, that reduces pain among patients with FBSS.⁹⁻¹¹ There are also a number of large post-market registries which report positive outcomes for more than 1,000 SCS patients.¹² Additionally, multiple studies demonstrate a level of cost-effectiveness which, when combined with pain relief and quality of life improvement, puts therapy below the commonly accepted willingness-to-pay threshold in the U.S and other developed countries. ^{13-17, 19-21}

SCS, when used in the carefully selected patient within the context of a multi-disciplinary comprehensive pain management program, may lead to more health benefit as well as cost-savings relative to conventional medical management for FBSS, CRPS, and other types of chronic intractable neuropathic low back pain.¹⁸⁻²¹

Recommendations for Change

We strongly believe the published evidence supports California's injured workers' continued access to this important and effective treatment option for their chronic pain. We believe further clarity is needed in the new guideline regarding SCS as a treatment for specific types of chronic low back pain.

Not only is SCS widely accepted for the treatment of FBSS and other low back conditions by leading physician specialty societies, but this FDA approved treatment option continues to be available to patients covered nationally by Medicare and the Department of Defense/Veterans Administration, workers' compensation plans in 48 states, and most major commercial health insurers across the country who have evaluated much of the same evidence as ACOEM but reached a strikingly different conclusion.

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The ACOEM Guideline focused its analysis solely on three publications while dismissing the bulk of the SCS-related clinical and economic publications which provides significant evidentiary support for the use of SCS with patients suffering from certain low back disorders. A number of the publications listed in the Guideline bibliography, but not included in the ACOEM analysis, are cited by the analyses of other highly credible health technology assessment organizations¹⁹⁻²¹ as supporting the appropriate use of SCS. We contend that if the Division accepts this current guideline's limited analysis as being definitive, it may result in injured workers' being denied SCS treatment, or result in significant additional administrative burdens causing unnecessary delays to access the procedure, potentially limiting the injured worker from attaining maximum medical improvement and potentially returning to work.

The AECOM Low Back Disorders Guideline fails to consider the preponderance of published clinical evidence showing SCS as a safe and effective treatment which can reduce pain and improve injured workers' quality of life for those suffering from FBSS, neuropathic pain, and other low back disorders.

Summary:

St. Jude respectfully requests the Division clarify the MTUS guidance to better reflect a more robust and complete analysis of the SCS-related literature which considers the full body of SCS-related clinical and economic evidence and the results of that analysis be included in the Division's Medical Treatment Guidelines. We believe strongly that taking this action and retaining the use of Spinal Cord Stimulation as a treatment option, the Division will meet its objective of augmenting "the provision of high quality medical care, maximize health, and promote return to work in a timely fashion, while reducing administrative burden and cost."

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Michael K. McQuilken, Pharm.D, R.Ph
Senior Vice President of Sales
Integrated Prescription Services, Inc.

September 16, 2016

A major concern as a PBM would be to try to operationalize a very restrictive MTUS Formulary without any coding, specifically GPI and/or NDC codes. This is a major undertaking, and having individual payers and PBMs do it will not be feasible in the timeframe, and open the door to inconsistencies. Coding of Formularies to NDC is an ongoing task, as new ones are released monthly by manufacturers.

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In addition, we have concerns about implementation of a state-specific Formulary inconsistent with both ODG and ACOEM, and far more restrictive than national, evidence-based guidelines like ODG, proven effective in so many other states.

We understand DWC is under an accelerated timeline to adopt an evidence-based drug formulary, consistent with MTUS, to augment the provision of high quality medical care, maximize health, and promote return-to-work in a timely fashion, while reducing administrative burden and cost. We appreciate that DWC has determined this is also an opportune time to update MTUS clinical topics, which are sorely outdated. We respectfully request that DWC consider a system-wide adoption of the ODG guidelines and formulary.

We use ODG whenever and wherever we can today. It is comprehensive, evidence-based, easy to use, and operationalized in our systems. ODG has proven tremendously successful, improving RTW outcomes, increasing access to quality care, and decreasing costs.

ODG is recommended in both the Rand Formulary study commissioned by DWC, and the 2004 Rand Technical Quality Evaluation. While the regulations are well written, we respectfully request that DWC replace the proposed formulary and clinical updates with ODG.

Katherine Pettibone, Vice President Western Region
American Insurance Association

September 16, 2016

The American Insurance Association continues reviewing the proposed formulary rules and consulting with our members, but we wanted to apprise you of our preliminary, though general, views.

As other knowledgeable commentators on the California workers' compensation system have noted, the absence of a formulary is a gaping hole in the system's otherwise pervasive regulatory architecture governing treatment and reimbursement for work injuries. CWCI has reported repeatedly that disputes over prescription drugs comprise a major share of all medical disputes referred to IMR. A formulary is absolutely necessary, and we are strongly supportive of DWC's initiative.

We also are pleased to note that the proposal addresses two contentious issues that have bedeviled the California workers' compensation system for years: Physician-dispensed drugs and compounds. Physician-dispensed drugs would not be permitted without pre-authorization, other than a seven-day supply of a preferred drug. This approach is consistent with what other states more recently have done to stem the tide of physician dispensing, going beyond merely regulating the price – proven to be ineffective. Similarly, compound drugs would be subject to pre-authorization. This is consistent with AIA's policy, in light of the medical necessity of compound medications being rare. We urged

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California incorporate pre-authorization in lieu of a fee schedule eventually adopted in 2011, because we did not believe a fee schedule alone would stem the tide of compound drugs dispensed and would legitimize the use of compound medications. Unfortunately, we were correct, as CWCI reported two years later that the incidence and cost of compound drugs had skyrocketed in the wake of the 2011 legislation.

We also endorse the rule's tighter restrictions on use of brand name medications, requiring a physician to explain the medical justification for using a brand versus a generic.

There are many other issues to address, and we understand there is some considerable criticism over the DWC's approach, in relying heavily but not exclusively on ACOEM or, for that matter ODG. There also is concern about the DWC's ability to keep the formulary current, in contrast to adoption of an existing non-governmental formulary that is more current. We will be evaluating these and other criticisms, in concert with our members.

Nina Walker
Pharmacy Benefits Administrator
Applied Underwriters, Inc.

September 16, 2016

- The proposed California Drug Formulary is primarily designed to “reinforce” the MTUS guidelines, but according to the Rand Corporation document “Implementing a Drug Formulary for California’s Workers’ Compensation Program”, the MTUS guidelines are outdated. It should be assured all guidelines are up to date prior to establishing formularies based on these guidelines. “The formulary drug listing and prospective review (PR) requirements should be derived from the MTUS guidelines in effect as of the implementation date” and the formulary should “reduce the administrative burdens associated with utilization review and medical necessity disputes”, which can’t be accomplished when treatment guidelines provided are outdated. Perhaps the best solution due to time constraints would be to initially introduce the ODG formulary and then customize the formulary around MTUS. This allows a baseline to be established while treatment guidelines are being reviewed and updated.
- The design of the formulary and the medications listed that are “Non-Preferred” merely shifts the costs from the actual drug spend to higher utilization review and administrative costs. By making medications non-preferred, such as low cost versions of Cyclobenzaprine, Amitriptyline (for pain associated with neuropathy), Cephalexin, Tylenol #3 with Codeine, Lovenox, Duloxetine (for pain associated with neuropathy), Gabapentin, and Prednisone, patient care will be compromised. There will be delays in treatment, and higher costs will be incurred for utilization review and administrative functions. These medications are low cost and considered preferred alternatives by a number of different payers and PBM’s.

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- First fills that require no prospective utilization review can be provided in four (4) day supplies only during the first seven (7) days post injury, however this is not a sufficient supply of medication to allow for a prospective utilization review to be performed. Utilization Review guidelines allow for five (5) working days to provide a determination.
- The Rand Corporation Summary Table S.4 provides ancillary policies on cost saving measures. If the medication is appropriate to treat the injury but yet PR is required, PR will be required regardless of dispensing facility. This likely will not be a deterrent for physician dispensing.
- Therapeutic interchange is something that should take place immediately upon dispensing of the medication. A therapy should not be changed if the injured worker is experiencing success with the therapy, and implementation of therapeutic interchange over a period of time and changing medications based on therapeutic substitutes could provide for setbacks in treatment if the alternative is not effective.
- Step therapy upon an initial fill would substantially decrease costs and should be a consideration. Omeprazole is listed as a preferred medication on the proposed formulary, as is the H2RA medication Ranitidine. Currently there is no evidence to support the routine use of a proton-pump inhibitor (Omeprazole) in patients without GI risk factors such as history of ulcer or GI bleed (ODG). By implementing a step therapy process which requires trial and failure of a H2RA medication prior to authorizing a PPI such as Omeprazole, you have eliminated the dispensing of the higher cost Omeprazole without a prior approval, compared to the lower cost H2RA Ranitidine which will likely treat the condition effectively.

Christopher M. Fenno, CEO/Executive Member
HealthBASE Networks, LLC

September 16, 2016

We absolutely support the full inclusion of the Official Disability Guidelines (ODG) in the proposed California Assembly Bill 1124 and in the market. We know it is a more comprehensive, accurate and accessible set of guidelines – especially through Clinical Decision Support (CDS) tools like our solution – OrderBASESM | ProviderBASESM.

Successful and ‘appropriate’ medical management and next level cost containment returns are being driven at the Provider levels. ODG’s deeper, more educative content with simplified access via ‘e-Ordering + CDS’ and system interface (API) Platforms like ours will be crucial with Providers, while delivering new administrative efficiencies, greater savings to payers, and a better patient experience. The returns the DWC seeks for the market with AB 1124 will be compounded by including ODG and the ability to better access, track and report Guideline use and performance, and accelerate medical pre-certification when required.

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James A. Tacci, MD, JD, MPH, FACOEM, FACPM
President – ACOEM

September 16, 2016

On behalf of the American College of Occupational and Environmental Medicine (ACOEM), I am writing to express our support for the proposed drug formulary guidelines and the updated Medical Treatment Utilization Schedule (MTUS).

The Division of Workers' Compensation (DWC) is to be commended for recognizing the importance of aligning evidence-based drug recommendations with the patient's condition and phase of care. The proposed drug formulary has the potential to significantly lower direct costs for drugs in workers' compensation cases. Furthermore, a well-organized formulary system, as proposed by DWC, founded on the principles of evidence-based medicine, can be expected to drive improvements in medical quality. We are also pleased with DWC's concurrent adoption of the updated MTUS clinical topic guidelines created by ACOEM, which will align with the proposed formulary.

This is a complex topic and is not merely a question of "choosing" or supporting one proposed formulary over another. As Rand noted in its report, *Implementing a Drug Formulary for California's Workers' Compensation Program*, In addition to determining the formulary structure and ground rules, "it will be important to establish, through rulemaking, policies governing how the formulary will be implemented and integrated with the medical necessity dispute-resolution process."

Edwin Mirzabeigi, M.D.
Blue Oak Medical Group

September 16, 2016

These comments on the implementation of the AB 1124 drug formulary by way of the Draft Formulary Regulations (the **Regulations**) have been prepared by Blue Oak Medical Group.

Although we welcome some of the changes proposed by the Regulations, we have three key concerns:

(i) the proposed MTUS Preferred Drug List (the **Drug List**) is extremely limited and, in fact, does not accurately reflect all MTUS recommended drugs;

(ii) the Regulations fail to provide any consequences for insurers and claims administrators for failing to comply with utilization review (**UR**) timelines and procedure; and

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(iii) as drafted, the Regulations provide opportunity for insurers and claims administrators through abuse of the retrospective review process to avoid paying for services rendered under the guise of lack of medical necessity.

1. DRUG LIST LIMITATIONS

1.1 The proposed drug formulary is extremely limited and certain categories of medication are non-existent in the formulary or are strictly *non-preferred*. There are a number of examples: (i) there is not a single medication for the treatment of insomnia or sleep difficulty, a common complaint of injured workers; (ii) there are only two anti-anxiety medications listed on the Drug List and both are non-preferred; (iii) there is not a single preferred muscle relaxant on the Drug List, despite the large number of patients, especially those with back injuries, that experience muscle spasming; and (iv) all opioid analgesics are non-preferred and there is only one listed for first-fill, Hydrocodene/Acetaminophen. So, if it happens that a worker falls off a ladder and fractures his or her wrist and that injured worker is allergic to the aforementioned medication, then he or she would simply be out of luck.

1.2 The proposed drug formulary is not in keeping with the RAND Corporation's (**RAND**) recommendations. On page 83 of their report titled, "Implementing a Drug Formulary for California's Workers' Compensation Program", RAND recommends that the drug formulary should be derived from the MTUS. In supposed compliance with RAND's recommendations, you have compiled a drug list and named it the "MTUS Preferred Drug List". However, this appears to be a misnomer. In reality,

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the MTUS guidelines allow for many more medications and classes of medications than those provided for in the proposed drug formulary, for example, the MTUS guidelines recognize that muscle relaxants may be useful as antispasmodics and the “MTUS Preferred Drug List” does not list a single one as preferred medication. In light of the above, the Drug List should be made much broader.

1.3 It appears now that RAND did not in fact prepare the proposed drug formulary and it is otherwise not clear who did. We would ask that the DIR and DWC provide the names and credentials of those who compiled the proposed drug formulary. It is important to all stakeholders to know exactly how this Drug List was conceived. Furthermore, clarity is needed on how the Administrative Director together with the P&T Committee will, in practice, undertake the monumental task of updating the drug formulary on a quarterly basis. The P&T Committee’s terms of reference, as set out in section 9792.27.8 of the Regulations, are very vague. Given the enormity of the task, further detail explaining how the P&T Committee will go about the task of updating the drug formulary is necessary - for example, will it review the universe of advances in pharmaceutical manufacturing and make recommendations? If not, how will it choose the medications that are to be looked at and evaluated for inclusion in the formulary? Indeed, the task of scientifically evaluating the literature surrounding even one medication requires a substantial commitment of resources and we would therefore like to know what level of resources are going to be made available to the P&T Committee in terms of support staff and funding in order to enable it to properly perform this task.

2. LACK OF CONSEQUENCES FOR FAILURE BY INSURERS TO MEET UR DEADLINES AND PROCEDURES

2.1 The Regulations place onerous obligations upon providers in relation to requests for authorization (a **RFA**) and limit physicians choices for medical treatment at the risk of not getting paid or, even worse, expulsion from the MPN, yet there are absolutely no consequences for insurers for failing to comply with corresponding UR deadlines and procedures.

2.2 Insurers and claims administrators must be made to comply with UR deadlines. Currently, despite statute providing for a five working day period for an insurer to respond to a RFA, this response period is not being enforced in any way. Routinely, insurers and claims administrators either do not respond timely or do not respond at all to RFAs, yet are given an opportunity to nonetheless challenge treatment at a later date on a purported lack of medical necessity basis.

2.3 Just as providers are being held to progressively stricter standards, so should insurers and claims administrators. It is unfair for the DIR and the DWC to play favorites and allow insurance companies a second bite at the apple, while enforcing strict obligations on providers and penalizing them severely for any failures. If insurers fail to meet UR deadlines, they should not be allowed to challenge medical necessity just as if providers fail to send an RFA for their services they are not entitled to reimbursement, no matter how medically necessary their services might actually be.

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3. RETROSPECTIVE REVIEW TO AVOID PAYING FOR SERVICES

3.1 Whilst we welcome the waiver of PR for preferred drugs provided for in section 9792.27.10 of the Regulations, we are concerned that, as drafted, the Regulations allow insurers and claims administrators to undermine the waiver through abuse of the retrospective review process.

3.2 As stated above, RAND recommends that the Drug List be based upon MTUS guidelines and that retrospective review be limited to assessing whether the treatments is consistent with MTUS guidelines. The DWC changed that provision in the Regulations by substituting the term “medical necessity” for “MTUS guidelines”. That simple substitution has grave consequences to providers because, whilst the MTUS guidelines are scientific, and make it much harder for insurers and claims administrators to question treatment given in line with them, “medical necessity” is a much vaguer term and open to a wider interpretation and debate. For this reason, we ask that the Regulations be amended to reflect exactly what the RAND report recommended i.e. that any treatment that is to be reviewed retrospectively should be on the limited grounds of consistency with MTUS guidelines, and that references to medical necessity as a ground for retrospective review be deleted.

3.3 The Regulations should make clear, as is the case with Medicare which you have been trying to emulate, that where providers are dispensing preferred drugs in accordance with MTUS guidelines, they should be paid for those medications timely, even if the insurer or claims administrator intends to apply retrospective review. When retrospective review is applied, and the treatment is found to be inconsistent with MTUS guidelines, then the insurer or claims administrator is entitled to seek reimbursement from the provider, or off-set any reimbursement against any future amounts due to the provider. Without this amendment, the Regulations as drafted will give insurance companies license to routinely not pay for medications that are both preferred and in line with MTUS guidelines for indefinite periods of time. This in turn will place severe economic pressure on providers and will result in diminishing levels of care for workers’ compensation patients.

Christopher J. Wolfkiel, Ph.D.

September 16, 2016

As the former Director of ACOEM Practice Guidelines I take some satisfaction that an idea that Dr. Kurt Hegmann and I proposed 4 years ago has come to fruition – use the ACOEM 3rd Edition drug recommendations as the basis for an MTUS formulary. At that time, we had prototyped linking drug informatics (class, brand, generic, NDC numbers) to ACOEM recommendations, supporting text and evidence. With ACOEM’s clearly defined condition structure we felt that we had the potential for a valuable decision support tool. Reed has completed the product and I believe it fulfills the concept we started with.

Deriving a formulary from ACOEM evidence based recommendations is not as straightforward as it might appear. As the Rand study confirmed in order to get to an “apples to apples” comparison to other

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workers' compensation formularies certain assumptions with the ACOEM drug recommendations had to be made. Amongst them includes generalizing across conditions and that only drugs identified as a first option would be exempt from prior authorization. While unclear, the proposed MTUS formulary appears to be the result of that process. There are some indications that that whatever additional decisions that went into this version may not have been well thought out.

As others have pointed out, the proposed MTUS formulary is restrictive when compared to other nationally recognized formularies. By using the same structure as the as the ODG formulary, essentially a list of approved drugs that do not need pre-authorization, comparisons are relatively easy and offers some insights. ODG has 132 approved drugs, MTUS 73, but MTUS includes 17 preferred Ophthalmic agents, a drug class that ODG does not cover. Also MTUS has a 4 day Non-preferred exception for 7 opioids and 2 muscle relaxants, calling them Preferred gets to "apples to apples" comparison is 132 Y ODG drugs for vs 67 Preferred MTUS drugs. Good to be a UR vendor in California!

Some thoughts. While there is great merit in limiting opioids utilization, requiring pre-auth after 4 days is impractical perhaps immoral. CWCI estimated that 80% of opioid prescriptions would require pre-auth under the 4 day exemption – but how could any third party deny medication that a treating physician ordered for an injured worker in pain? While there is no doubt that there is poor opioid prescribing, the majority of prescriptions are needed and any delay to injured workers receiving them is disconcerting to say the least. Preauthorization is a very blunt tool and injured workers needing pain relief in California deserve better than a poorly thought out policy detail. Extending the exemption period for up 3 refills where there's documentation of shared decision making and an opioid contract is worth considering. After that, proof of satisfying the opioid contract i.e. urine testing may be an exemptible circumstance. These details should not be left up to vendors, they should be standardized.

When comparing ODG and MTUS for anti-infectives there is a disturbing finding. Almost all anti-infectives are Y drugs in ODG (19/20) whereas MTUS has (6/11) Preferred. Most of the MTUS anti-infective recommendations come from the Hand, Wrist and Forearm chapter and appear to derive from bite (dog, cat human) evidence but hardly transparently. For example, when searching the Hand, Wrist and Forearm document for "azithromycin" or "macrolides" nothing is found, yet the drug is non-preferred in MTUS ("Y" in ODG, "A" in Washington state). There is something going on here but it's not evidence based and certainly not transparent. And to generalize to other infective situations such as lacerations or post-surgery? Antibiotic resistance is real, macrolides have risks and may not be a first choice, but should injured workers in California be the only group in the US to be subject to UR for their use?

It's these situations that leads to the conclusion that this version of the MTUS formulary has not been adequately reviewed and has no track record. It is contradictory to the intent of the law that it be based on a nationally recognized evidenced based formulary. Evidenced based, perhaps. Nationally recognized, no. Injured workers in California deserve better than an untested formulary and to propagate one without a P&T committee in place to provide the obviously needed oversight is a questionable decision.

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

September 16, 2016

The Optum Workers' Comp and Auto No-Fault Division (formerly Helios and Healthcare Solutions) appreciates the opportunity to comment on the draft MTUS formulary and related rules posted for public comment by the Division of Workers' Compensation. We applaud the Division for its progress and engagement with stakeholders up to this point, including the RAND report commissioned to assist with the formulary rule development process.

We support adoption of an evidenced-based formulary for the California workers' compensation system. Our experience shows that state-specific and PBM formularies working together can have a significant, positive influence on the cost and utilization of workers' compensation pharmacy benefits. We believe this system of state and marketplace collaboration is the intent of the Division and the proposed rules will reinforce the benefits PBMs provide to the system.

Along with our support, we respectfully submit several recommendations for your consideration which we believe will better clarify and add certainty to the process to ensure consistent and universal stakeholder acceptance. These recommendations are informed by our knowledge of common pitfalls and challenges observed from previous experience in implementing state formularies in states like Texas, Oklahoma and Tennessee, coupled with marketplace experience in managing formularies and overall pharmacy benefit management programs for payers in the workers' compensation market. Where we suggest new language it will be underlined, and where we suggest removal of proposed language it will be indicated with ~~strikethrough~~.

Section 9792.27.3

This section creates a transition period for claims with a date of injury occurring before the effective date of the formulary that involves ongoing drug treatment with a non-preferred drug. We believe the underlying intent is to provide a reasonable time-frame during which the carrier and treating physician can work together to ensure for the proper future treatment of an injured worker who may be taking non-preferred medications. While we support the intent of the proposed language, we remain concerned that without a specific time frame to evaluate and modify or document the current medication treatment plan, the transition of injured workers to preferred medications, or justification for their current or modified treatment, could languish indefinitely. To encourage payers and providers to work together to ensure injured workers have access to appropriate medically necessary pharmacy care, and to ensure that planning is completed in a timely fashion, we respectfully submit the following proposed language:

(b) For injuries occurring prior to July 1, 2017, treating physicians and payers should work in accordance with the MTUS Drug Formulary ~~should be phased in~~ to ensure that injured workers who are receiving

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ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician and payer shall, no later than one year from the date of enactment, either:

- (1) Prepare a mutually agreed upon treatment plan to transition the worker to a Preferred Drug, or
- (2) Prepare a mutually agreed upon treatment plan that includes ~~and submit~~ a Request for Authorization and supporting documentation to substantiate medical necessity, ~~and~~ to obtain authorization, for the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or for safe weaning, tapering, or transition to a Preferred Drug.

Section 9792.27.6

This section addresses access to medications not included on the preferred drug list which under the proposed rule(s) require authorization through prospective review. We support this provision as we believe it necessary to subject these unlisted medications to review for medical necessity to ensure appropriate treatment for an injured worker at the onset, rather than after the fact.

Section 9792.27.7

We strongly support the use of generic medications where available and also support policies which require the prescriber to clearly document patient-specific factors of medical necessity that support the dispensing of a brand drug. However, the proposed language of this section, addressing usage of brand and generic drugs, in our interpretation, may increase the administrative and financial burden on pharmacies.

The language, as currently drafted, may increase the administrative burden on pharmacy stakeholders and payers due to the appearance of a **mandated** prospective authorization. As drafted, the language may force pharmacies and PBMs (concerned about retrospectively being denied payment on costly brand medications) to go beyond a simple prior authorization and ask payers to provide approved prospective utilization review on these medications. From a processor point of view, we believe this **may** be the only way to ensure that these expensive brand drugs – though authorized by the adjuster – are not denied retrospectively when they are sent to retrospective utilization review.

To ensure continued dispensing of generic equivalent drugs when less costly and available, unless the prescribing doctor justifies the medical necessity of the brand medication and obtains prior authorization through prospective review, and to reduce the administrative burden and financial risk to pharmacies and PBMs, we submit the following proposed change:

~~If a physician prescribes a brand name drug when a less costly therapeutically equivalent generic drug exists, and~~ Where a therapeutically equivalent generic drug is available and less costly than the prescribed brand drug, the generic drug shall be dispensed, unless the physician writes “Do Not Substitute” or “Dispense as Written” in conformity with Business and Professions Code section 4073.2

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~~The physician must document the medical necessity for prescribing the brand drug in the patient's medical chart . . . The physician must obtain Prior authorization must be obtained through prospective review prior to the time the brand drug is dispensed. If required prior authorization through prospective review is not obtained prior to dispensing the brand drug, retrospective review . . .~~

Additionally, the rule appears to be silent on situations where a brand drug is requested by the injured worker or the pharmacy. Will these situations be permitted, and how would pharmacies and PBMs process these requests in accordance with the prior authorization process of the MTUS drug formulary? We urge the Division to clarify if these types of requests are allowed, and if so, how they should be handled.

Section 9792.27.8

This section requires a physician to obtain authorization through prospective review before dispensing a medication to an injured worker, with some exceptions. We support this language, as physician dispensing has long been a cost driver in the California workers' compensation system.

However, we request clarification from the Division on the dispensing time-frame(s) for the initial seven day-supply. As proposed, the language in (b), states a physician may dispense up to a seven-day supply of a drug listed as "preferred" in the MTUS PDL without obtaining authorization through prospective review. As written, the language appears to allow multiple seven-day consecutive supplies of a medication, or a seven-day supply of medication with each office visit. We recommend the authorization for dispensing a seven-day supply be limited to **only** the initial supply provided to an injured worker during an **initial** office visit which takes place within the first seven days from the date of injury.

Section 9792.27.9

This section addresses compound medications and requires them to be authorized through prospective review. We support this language as compound medications have also been another source of over-utilization and cost within the system.

Section 9792.27.10

This section establishes the MTUS Preferred Drug List and outlines the approval process. We support the language in this section.

The inclusion of the phrase "in accordance with the MTUS guidelines" under (b) in this section is an important component that will promote positive results. Just because a drug is listed as preferred does not mean that it is appropriate or warranted in the treatment of a particular injury, condition or injury stage. These drugs should still be prescribed in accordance with the Division's adopted treatment guidelines for the particular injury or condition. The inclusion of this provision will ensure that PBMs are still able to continue using tools they have developed over many years to pre-screen medications for appropriateness and relevance to the workplace injury, while complying with established MTUS guidelines.

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We also support the inclusion of a provision acknowledging the ability of a claims administrator to waive prospective review requirements if the drug falls within a UR plan's provision of prior authorization. Reaffirmation of this provision will ensure avoidance of costly UR when it may not be necessary, as previously outlined in our comments on various sections, particularly for lower cost medications where the UR may cost more than the actual medication. The ability to approve medications for an extended period of time should also help reduce administrative burden and smooth out the refill process for injured workers.

Section 9792.27.11

This section addresses the first fill policy, and it permits certain non-preferred drugs to be prescribed and dispensed in very limited circumstances without prospective review. We generally support the notion of a "first fill," including the acknowledged ability of a claims administrator and their PBM to provide for a longer first fill period or to cover additional drugs pursuant to a pharmacy benefit or MPN contract. However, we encourage the Division to remember that the first fill provision, as outlined, could require some additional programming on the part of PBMs since the preferred drug list identifies only a limited number of non-preferred drugs that are subject to the first fill policy and, while the non-preferred drugs identified on the initially proposed list all have a 4-day limit, those limits could vary by medication over time. This will likely create some unique programming challenges. As the first fill list changes, we strongly recommend that the Division provide adequate programming time for PBMs and payers to adjust their systems and limit the potential confusion at the pharmacy level and possible delays in care during those critical first seven days following the date of injury.

Section 9792.27.12

This section is the actual preferred drug list. As for the layout of the PDL itself, we support the clear indication as to whether a drug is preferred versus non-preferred. The Division's extra step in clearly outlining whether a drug is considered preferred or not preferred should go a long way to ease the compliance burden on prescribers, pharmacies and PBMs when determining which drugs will require prospective review under the California workers' compensation system.

While we are supportive of the PDL provisions, there are a few concerns from a clinical perspective that we feel obligated to share with the Division for their consideration. We noticed that medications such as levofloxacin and moxifloxacin are included on the preferred drug list even though there have been recent concerns issued by the Food and Drug Administration (FDA) regarding the use of fluoroquinolones. Sucralfate has several drug-drug interactions and is thus not as widely prescribed. Ranitidine is a popular medication used for the treatment of ulcers and may be used for purposes unrelated to work place injuries. Sulfasalazine is another type of medication that may be used for purposes unrelated to work place injuries. We believe these medications may be best subject to prior review to determine applicability for the workers' compensation injury. Additionally, we noticed that the PDL includes medications that are often used for ophthalmic treatment and other specialty treatments, but in workers' compensation, they often require prior authorization to determine relatedness. We believe these medications, such as artificial tears, carboxymethylcellulose, cyclopentolate and tropicamide should not be included on the PDL and should require prior authorization. Finally, we

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noticed that the PDL does not include first-line antidepressant therapy for the treatment of depressive symptoms and neuropathic pain. It also does not include first-line treatment of anticonvulsant therapies used for the treatment of acute neuropathic pain. In these two instances, we urge the Division (or the P&T Committee later) to review their initial recommendations.

Section 9792.27.18

This section details how updates are to be made to the PDL. The P&T Committee can serve a useful function in reviewing recommendations proposed by ACOEM and adopting changes unique to California. While we support this process which will better tailor the PDL and the formulary to the unique needs of California, there are three areas of concern which we request the Division address during the rule-making process.

First, upon review, the proposed language does not consider the need for an expedited or emergency process to address situations such as (but not limited to) a drug recall. The Division should consider a process whereby they can immediately address emergency changes in a drug status or availability on the market.

Second, while we are supportive of the ability of the Administrative Director to issue orders specifying changes to the list without a formal rule-making, we encourage the Division to ensure (by rule language if deemed necessary) these orders are posted with sufficient lead time (prior to their effective date) to provide stakeholders with the necessary time to update their systems and processes to ensure compliance and eliminate potential delays in delivering care to injured workers.

Third, we do not find addressed in the proposed language an appropriate and consistent time-frame for implementing changes related to the ongoing adoption and publication of PDL updates. An appropriate and consistent time frame will allow PBMs and payers to adequately plan programming resources and provide a definitive time frame to implement non-emergency changes. Considering the P&T Committee will recommend changes and the Director will be able to revise, update and publish the PDL based upon a structure outlined in these rules, we suggest the Division also insert an appropriate and consistent time frame for revisions to the PDL to apply to the prescribing and dispensing of a medication. To address this issue, we recommend the Division insert the following language:

(e) Modifications of the MTUS Drug Formulary shall apply to prescriptions written on or after the 30th day following the last day of the month in which a revised PDL was published by the Division.

Joseph Paduda, President
CompPharma

September 16, 2016

CompPharma, LLC is a consortium of pharmacy benefits managers (PBMs) managing workers' compensation pharmacy benefits in all fifty states. We appreciate the opportunity to provide the

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following comments on the Division's proposed Medical Treatment Utilization Schedule Drug Formulary draft regulations.

Throughout this document, we express concerns with the formulary itself, the proposed draft regulations and ask the Division to provide injured workers and all California workers' compensation stakeholders much-needed clarifications necessary to implement and comply with the multitude of formulary requirements.

General Recommendations

In reviewing the entirety of the text of the Formulary's draft regulations, the associated draft Prescription Drug List (PDL), the associated segments of the California Medical Treatment Utilization Schedule (MTUS) and the current Utilization Review (UR) rules and those proposed under SB 1160, CompPharma has the following observations and suggestions for overall improvement of the Formulary regulations:

1. MTUS Custom Formulary vs. Standardized Formulary

As currently proposed, the Prescription Drug List, while rooted in a nationally-recognized set of treatment guidelines, is a significant departure from other state-mandated formularies currently in existence. CompPharma salutes the Division's concept of moving towards a mechanism which supports safer and more efficient injured worker care by going beyond the binary construct of considering a medication to be de facto appropriate simply because it exists on a drug list. Considering the long-held PBM tenet of getting the best possible medication to the injured worker for the specific injury as quickly as possible, CompPharma commends the Division's decision to implement an injury-specific formulary. However, the proposed PDL is problematic for multiple reasons, including:

- **Programming** – As constructed, the PDL requires the development, testing, programming, and on-going maintenance of pharmacy logic that considers both drug name and injury condition. While PBMs provide this service for their clients, other stakeholders (particularly injured workers, prescribers and billers) are ill-prepared to address what is a complex undertaking.
- **Clinical Updates** – Acknowledging that the draft rules call for the creation of a P&T committee, there is real concern that the speed at which the committee will address issues such as new drugs coming to market, drug recalls, new guidance from the FDA (e.g., black box warnings), or the incorporation of other standard reasons for which PBMs routinely update formularies, will be insufficient to protect injured workers and enhance patient safety.
- **Interpretation by Stakeholders** – As currently written, the draft PDL lacks the infrastructure to tie-back drug names to specific national drug code numbers (NDCs). It is highly likely stakeholders will have widely disparate interpretations of appropriateness for the same drug for the same injured worker, leading to disputes, confusion, and delays in delivering care, in addition to significantly increased administrative costs.

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Given these concerns, CompPharma recommends that the Division reconsider the development of its own unique PDL at this time and, instead, consider the full adoption of one of the already existing national formularies. Doing so would significantly reduce the potential for implementation and maintenance issues with the formulary, which will directly result in enhanced patient safety, improved service to injured workers, and less confusion and frustration on the part of prescribers and pharmacists treating those injured workers.

2. Prospective Review vs. Preauthorization

In constructing the Drug Formulary, the Division has elected to use prospective review (as defined in Section 9792.27.1. and the associated UR sections of the Labor Code) as the default mechanism for reviewing the following medications and medication types prior to dispensing:

- Non-preferred drugs on the PDL
- Drugs written for off-label use
- Compounded drugs
- Prescriber-dispensed drugs
- Drugs not incorporated by the PDL

Given that the entirety of the draft PDL contains 276 medications, with only 54 of those medications listed as “preferred,” the rules as currently constructed suggest that there are two potentially troublesome consequences stemming from the draft rules:

- Issue #1 – EVERY drug may get approved. Section 9792.27.4 of the draft regulations gives payers (via PBM/PBN) the right to have a more expansive formulary and multiple sections of the draft regulations also empower those same payers to review virtually every medication filled retrospectively and refuse payments made to providers for those drugs deemed medically unnecessary retrospectively. In a real-world application, this presents a model where claims handlers are presented prescriptions (even for highly addictive and problematic non-preferred drugs) that have a fulfillment cost which is a fraction of what it costs to evaluate the medical necessity for that same drug through prospective review under the current (and SB1160 proposed) utilization review rules. It is highly likely that claims handlers will globally approve ALL medications and only utilize prospective review for those claims in which the fulfillment of the non-preferred medications is less costly than the use of utilization review. This would seem to run directly contrary to the Division’s goal of creating a workers’ compensation ecosphere where less dangerous drugs are provided to injured workers. It also, in essence, renders the PDL advisory only. Given the great progress made by PBMs and payers in reducing the use of opioids and other dangerous, potentially harmful, and readily diverted drugs by injured workers, the proposed formulary and attendant rules could well result in a return to the days of rampant over-use of these harmful drugs.
- Issue #2 – Utilization Review Skyrockets. Assuming prescribers and payers do follow the intended path to medication authorization, even in an expedited or truncated format, the number of drugs that will go through prospective review according to the draft rules will

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substantially increase. In fact, the number of medications that, on the current draft PDL are marked as “preferred” is extremely small in comparison to the percentage of medications that are routinely used in workers’ compensation care today. As the stated goals of the Division include a reduction in the use of utilization review and reduction in delay of service provided to injured works, the proposed rules would have the opposite effect.

It is therefore strongly suggested that the Division revisit the draft regulations’ use of prospective review via the established utilization review process. While we understand RAND’s recommendation and the Division’s desire to not create a new mechanism specifically for the evaluation of medication appropriateness because of the perceived administrative cost or hassle, the use of a pharmacy preauthorization process separate from medical utilization review has been documented as administratively effective and efficient in other state-mandated formulary models, including Texas and Oklahoma. In fact, should the Division be firm on the position that utilization review be the sole mechanism for evaluation of whether a medication is medically necessary, it does not prohibit the Division from amending the rules to require that prescribers attempt to **preauthorize** any of the PDL’s non-preferred medications for their injured worker, and then allow utilization review to serve as a conduit for resolving those instances where prescriber and payer are not in alignment. Requiring prescribers to **preauthorize** medications (via the use of a standardized electronic, faxed or mailed form) would substantially reduce the need for utilization review, reduce the wait time for injured workers to obtain medications and dramatically improve the prescriber/payer interaction. This would benefit the entire California work comp system. Moreover the installation of a required, standard preauthorization form is of negligible cost and effort to the Division and the State.

3. Transition Period for Claimant Current Receiving Non-Preferred Medications

- Current Text: Section 9792.27.3. MTUS Drug Formulary Transition.
 - “(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.”
- Recommendation – CompPharma is firmly in support of the concept of allowing injured workers and their prescribers to safely and appropriately transition from non-preferred drugs to preferred drugs. However, leaving an open-ended time period for the transition of injured workers to preferred drugs is troublesome from an injured worker safety perspective and potentially highly problematic from both administrative and adjudication perspectives as it could well lead to ongoing disputes between the injured worker and employer. Accordingly we suggest the following language change:
 - “(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 July 1, 2018, at which time all injured workers are incorporated by the MTUS Drug Formulary and treatment rendered by prescribers is**

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expected to be fully compliant with the MTUS Drug Formulary. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”), the physician shall either...”

4. Updates to the Formulary

- Current text: Section 9792.27.18. MTUS Preferred Drug List Updates.
 - “The Administrative Director shall consult with the P&T Committee on updates to the MTUS Preferred Drug List, which may be adopted by the Administrative Director on a quarterly or more frequent basis in order to allow provision for all appropriate medications.”
- Recommendation – In order to allow for the safe transition of injured worker treatment plan changes, discussion with prescribing doctors and systemic changes at the pharmacy level, it is recommended that the following language be added to the end of the current text:
 - ***(e) Updates to the MTUS Preferred Drug List shall not apply until 30 days from the last day of the month in which an updated PDL was published by the Division.***
 - ***(f) The date the prescription was written shall control application of the MTUS Drug Formulary and Preferred Drug List requirements***
 - ***(g) In those instances where the United States Food & Drug Administration (FDA) issues mandatory recall notices, black-box warning updates or other warning notices, the Committee must take immediate action to incorporate those changes in the PDL.***

5. Prescriber Accountability

- Current Text: 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. 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.”
- Recommendation –Section 9792.27.10(c) should be amended to mandate that the *prescriber* is the entity that must obtain prospective review prior to the dispensing of a “Non-Preferred” drug. Without this change in language, the current text leaves open the possibility that authorization in all forms will be left entirely to the efforts of claims managers or adjusters, and shifts a significant financial burden to PBMs as part of retrospective review. As such, the following amended language is suggested:
 - “For a drug that is identified as “Non-Preferred,” authorization through Prospective Review must be obtained ***by the prescriber*** prior to the time the drug is dispensed.” ~~If authorization through Prospective Review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.”~~

6. Timing of Rule Adoption

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In deference to the injured worker population of California, the medical community and other workers' compensation stakeholders, CompPharma urges the Division to consider either extending the effective date of the Drug Formulary or expediting its final rules adoption. Understanding that there is wisdom in measuring twice but cutting only once, CompPharma also recognizes that the shorter the timeline to implement any new formulary, the more risk there is for injured workers, the greater the burden on DWC and DIR to address and resolve general and specific issues related to confusion over the formulary and implementation thereof and the more strain we put on healthcare providers.

Clarification Questions

To allow for the most effective implementation of the Drug Formulary draft regulations, CompPharma is seeking responses to the following:

1. Compounded Drugs

- Current Language - Section 9792.27.1. (d) "Compounded drug" means a drug that is created by combining two or more active pharmaceutical ingredients to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace. **A "compounded drug" does not include a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.**
- Question- Is there a reason why the Division has created an exception clause to the definition of a compound? In today's treatment of injured workers there are multiple examples of compounding kits that drug manufacturers are providing that would be exempted by this clause but still have no documented evidence of medical efficacy in the treatment of workplace injuries. The proposed language seems to allow these "compounding kits," thereby opening a large loophole.

2. Physician Dispensed Drugs

- Current Language - Section 9792.27.8. Physician-Dispensed Drugs.
“(a) Except as provided in subdivision (b), and section 9792.27.11 in relation to “First Fills,” drugs dispensed by a physician must be authorized through prospective review prior to being dispensed. If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied if the drug is found upon retrospective review to be not medically necessary.”
“(b) A physician may dispense up to a seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.”
- Question - When read in its entirety, the section on physician-dispensed drugs appears to allow for physicians to provide a limitless number of seven-day supplies of medications. Is there a

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reason why the language in section (b) should not be amended to read, “(b) A physician may dispense up to a **single initial seven**-day supply of a drug that is listed as “Preferred” in...”? Prescriber dispensing has not been proven to provide more effective or positive care to the injured worker population, while research published by CWCI has demonstrated the practice is associated with extended disability duration, higher medical costs, and higher indemnity expenses. For the sake of expediency in the delivery of initial care to injured workers, this minimal change would provide a more equitable compromise.

Mitch Seaman, Legislative Advocate
California Labor Federation, AFL-CIO

September 16, 2016

The California Labor Federation writes to commend the work of the Division of Workers’ Compensation in preparing the draft formulary regulation text as of August 26th, 2016. As written, the regulation protects the drug treatment needs of injured workers while offering significant improvements in key areas, though we do believe a few sections could be clarified, certain questions should be asked, and additional review should be conducted.

The strongest reform presented by this regulation lies in language that allows treating physicians to prescribe “preferred” drugs on the “preferred” 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 (t) 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 *“[t]he dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was within the MTUS guidelines.* 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.

Also, additional language in this section could help clarify that an employer’s right to review for appropriateness under MTUS guidelines may only be retrospective, not prospective.

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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, but language suggested doesn't require employers to respect a treating physician's transition plan. As a result, nothing in this language would prevent an employer from immediately UR'ing an injured worker's treatment on July 1st and arguing, likely successfully, that it should be denied for not meeting new evidentiary burdens. This section should include some sort of language that requires the system to defer to the treating physician's recommended transition or tapering plan.

We also appreciate language guaranteeing, as required by AB 1124, that injured workers may still access drugs not on the list. However, the draft language requires that physicians meet a "preponderance of scientific medical evidence" standard in order to dispense unlisted drugs. Given that this standard essentially means that the majority of scientific evidence must support the prescription, this phrasing could be interpreted to mean that a treating physician would be required to track down all relevant scientific studies and prove that a majority of them support the prescription. This could be prohibitively time consuming, expensive and cumbersome, and such a reading could harm a physician's ability to care for workers with complex claims. We would recommend further defining this phrase, either in 9792.27.6 or in the definitions sections, to ease compliance for treating physicians.

Section 9792.27.11 includes much needed language to create a "first fill" policy 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. However, workers do often need immediate pain relief in circumstances not allowed by this section as currently written.

For example, post-surgical pain relief taken at home would not appear to be covered by this section if needed more than seven days after the initial date of injury. It would seem inappropriate to subject workers in such acute pain to mandatory prospective review, not to mention that such UR or prior authorization would generate additional unnecessary costs for employers. Other circumstances likely exist in which a first fill policy makes sense; we urge DWC to conduct a thorough review of other circumstances that might warrant inclusion under this first fill policy.

It would also seem prudent to conduct a review of any potential conflicts between Cal/OSHA regulations or other safety standards and this new formulary. Some such standards may require or suggest immediate drug treatment following certain types of exposure or trauma, with one example being prophylactic drugs following needlestick injuries in order to minimize risk of contracting hepatitis or HIV. We should be extremely careful to not in any way reduce, limit or even slow down access to such critically important prescriptions, and as a result, DWC should ensure that such drugs are readily and quickly available when needed.

Finally, we would recommend changing the name of the "preferred drug list," perhaps to just the "drug list" or the "formulary drug list," to avoid problems and uncertainty stemming from the fact that both preferred and non-preferred drugs are included. We can see a great deal of confusion and potentially

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even litigation and denied treatment over a physician or injured worker not understanding that the “preferred drug list” includes non-preferred drugs.

Overall, however, we strongly believe that this formulary language offers significant benefits to both injured workers and employers, and we commend the Department for all of your work and look forward to continuing the discussion.

Theodore Blatt, M.D.
Medical Director, Harbor Health Systems

September 16, 2016

I am submitting these comments on behalf of Harbor Health Systems

ACOEM was never meant to be a decision support tool, but rather a “best practice” guideline. The indications for treatment modalities in ACOEM are vague at best. We struggled with this in U.R. and I fear that just citing chapters as reference for the formulary will only continue this problematic issue. I also believe that it will make decisions very challengeable.

I believe that it will be much more defensible to be using a non propriety guideline that is not only a commercial one but used in other states. I believe that CA will once again be subject to challenges regarding medications which will be difficult to defend.

I disagree with the absence of opioids in the formulary. This will severely restrict the ability to control these drugs for which there are some appropriate indications for this class of drugs. We will have little evidence based direction to dispense the most problematic class of medications.

Based on the above, I strongly recommend the use of ODG as opposed to referencing ACOEM

Christel Schoenfelder, Esq., President
California Applicants’ Attorneys Association 2016-17

September 16, 2016

The California Applicants’ Attorneys Association (“CAAA”) appreciates the opportunity to provide comments on the DWC Forum regarding the Implementation of the AB 1124 Drug Formulary and the update of the MTUS Guidelines.

The stated goal of AB 1124 is to adopt an evidence-based drug formulary, consistent with California’s Medical Treatment Utilization Schedule (MTUS), by July 1, 2017. The formulary should be designed to

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assist in the provision of high-quality medical care, while promoting return to work in a timely fashion, and reducing the administrative burden and cost of utilization review and medical necessity disputes. The proposed updated guidelines posted on the forum are created by the American College of Occupational and Environmental Medicine (ACOEM), published by Reed Group, Ltd. The preferred drug list proposed in the draft regulations was created by the DWC.

THRESHOLD QUESTIONS TO BE ANSWERED

Is the proposed MTUS Drug Formulary evidence-based?

Unfortunately, the answer to this question is it is not.

Evidence-based medicine requires a systematic review of the medical literature, ranking and weighting studies on their design and quality. In creating the preferred and non-preferred drug list for the Formulary the DWC created a list not linked to any medical literature or studies as to the efficacy of the medications in treating work injuries.

The drugs listed in the preferred category on the proposed formulary constitute a very limited group. In a recent CWCI spotlight report the top 20 drug therapeutic groups were listed which represent over 93% of all drugs dispensed in workers' compensation cases. Of these 20 therapeutic groups, only 4 have drugs in the Preferred category on the formulary: (1) Anti-inflammatory Analgesics, (2) Ulcer Drugs, (3) Non-Narcotic Analgesics, and (4) Ophthalmic Agents. Of these four groups, the last two have very little volume in the system.

While there is no advantage to designating a very limited number of consumer-type drugs as "Preferred," there is a disadvantage to designating a large number of drugs as "Non-Preferred." The question is who decided that certain drugs are non-preferred and was this evidence based? Many employers may prefer not to provide the drugs on the "Non-Preferred" list but this should not be the basis to refuse to provide reasonable and necessary medical treatment to workers to cure or relieve their injuries.

There is NO basis for designating a drug as Non-Preferred if it is appropriately necessary per the MTUS. This serves to undermine the MTUS both practically, and legally and violates the Labor Code. Designating drugs as "Non-Preferred" is not a medical necessity determination – the determination of medical necessity must be made according to the standards in the MTUS.

While there are legitimate concerns over the misuse of opioids in society in general, there are also legitimate medical uses for opioid drugs. There is no medical basis for blindly categorizing all opioids as "Non-Preferred." It appears that the main purpose of assigning drugs to a preferred or non-preferred list on the proposed formulary is to try to influence physicians' prescribing practices, based not on medical considerations but solely on financial considerations. The rules for authorizing these and all other drugs should be taken from the MTUS, and not from an arbitrary, non evidence based determination of what is "preferred".

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Is the proposed MTUS Formulary designed to assist in the provision of high-quality medical care, while promoting return to work in a timely fashion, and reducing the administrative burden and cost of utilization review and medical necessity disputes?

Unfortunately, again the answer to that question is it is not.

The CWCI reports that 78% of prescription drug payments in California will require preauthorization under the proposed MTUS Formulary. In other words three of every four medications prescribed will still be subject to pre-authorization. With such a highly restrictive formulary, there will be 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.

Why did the DWC choose to update the MTUS using the ACOEM treatment guidelines when the overriding consideration is implementation of the formulary?

Unfortunately, unlike our earlier answers, we just don't know!

The Rand study on *Implementing a Drug Formulary for California's Workers Compensation Program* states on page 31: "While the Reed Group markets its final product as a drug formulary, it is not a formulary in the traditional sense. A traditional formulary is a list of covered drugs with rules on how the drugs may be accessed and under which conditions." On page 77 of its' report Rand further states: "For several reasons, the ODG formulary would be easier to implement. It is already in use by several WC programs and has been operationalized through NDC codes. The 'Y/N' structure of the formulary

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preauthorization rules makes it easier to operationalize because it does not require diagnostic information when processing most pharmacy bills.” RAND further notes that ACOEM’s treatment guidelines do not cover mental health conditions and many clinical topics have not been updated since 2011. Also the MTUS guidelines recently updated for chronic pain and post surgical physical medicine are based on the ODG treatment guidelines, not ACOEM.

Based on these findings, it is strongly recommended that the Rand Study’s recommendation that the “ODG formulary would be easiest to implement” be revisited as it has been tried and tested in other states, is regularly updated (unlike ACOEM), and will save a lot of frustration and unnecessary delays and friction anticipated with the untested and restrictive formulary currently being proposed.

In conclusion, we offer the following specific comments to the designated sections of the proposed regulations.

Definitions

First and foremost, as written the proposed regulations do not reference the method for an expedited review of a Non-Preferred Drug . This may lead some parties to be unaware of the need to respect those timelines when appropriate as set forth in Labor Code section 4610(g) and regulation 9792.9.1(c) (4). The proposed regulations reference prospective review in 9792.27.1(m), (t), (u), 9792.27.5(b), 9792.27.8(a), 9792.27.9, 9792.27.10(c), (d), (e), (f) & 9792.27.18(b) (1) and concurrent review is permitted per 9792.27.2(b). As outpatient use is defined to include an ambulatory surgery center, inpatient hospital or emergency room if the medication is to be taken outside of the clinical setting(see 9792.27.2(b) (1) & (2)) expedited review of medications should be referenced as part of the formulary due to unanticipated complications or other urgent issues which can occur in these or other settings. Therefore we recommend that 9792.27.1 subdivision (w) provide for a definition of “expedited review”, and current subdivision (w) be re-lettered to (x).

9792.27.1(a) –“Administer” includes the term "or device." This exceeds the authority of the enabling statute Labor Code section 5307.27 which provides only for a medical treatment utilization schedule adopted by the administrative director which includes a *drug formulary using evidence-based medicine*. Devices are not drugs. For example, if the drug formulary allows for the use of Sumatriptan for treatment of migraines, whether it should be administered orally or as an injection with a “device” should not be a consideration of the drug formulary.

9792.27.1 (d) -The definition of “compound drug” does not take into consideration that a compound drug may be determined by evidence based medicine to be more effective than one or more FDA approved prescription drugs. Labor Code section 5307.27 provides that the formulary is to be based on evidence based medicine. We also recommend that the word “FDA” be added to 9792.27.1 (d) as follows “with directions contained in FDA approved labeling provided by the product's manufacturer.”

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9792.27.1(e) - The term "health care provider" includes ambulatory surgery centers, emergency rooms, and hospitals. Therefore, as stated above, expedited review of medications should be referenced as part of the formulary.

9792.27.1 (i) - Given that surgeries sometime have complications that are unexpected or not anticipated we recommend that this section be rewritten to "First Fill" means the policy relating to the drug prescription issued or drug dispensed at the initial visit following a workplace injury, where the visit occurs within 7 days of the date of injury or surgery." (amendment in bold)

Further we recommend that the period be extended from 7 days to 30 days for the first fill of a medication. The reasoning for this is that the proposed amendments to Labor Code section 4610 (b) and (c) in Senate Bill 1160(which will hopefully be signed by the Governor later this month) exempt certain treatments from prospective UR in the first 30 days after an injury. This change would achieve uniformity between the statute and regulation.

9792.27.1 (k),(l) and (m) – There is no description of how the preferred and non-preferred lists are based on evidence based medicine and no analysis of the evidence based medicine basis for the inclusion of each medication on each list.

9792.27.1 (t) – There is no mention of expedited review of a non-preferred drug. As stated above, the drugs listed in the preferred category on the proposed formulary constitute a very limited group. As an example, in heart attack cases it is very common that the individual will be sent home with several medications to take every day on a precautionary basis to avoid blood clotting, among other life threatening conditions. As currently written, the formulary does not reference expedited review of these "non-preferred" medications.

MTUS Drug Formulary Transition

9792.27.3(b) should be rewritten to be consistent with current statutory law including Labor Code sections 4600 (a) and 4610.3 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. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an "unlisted drug"), the physician may shall either:

(1) Prepare a treatment plan to transition the worker to a Preferred Drug, or if they can document a change in the employee's circumstances or condition which would render the treatment previously authorized no longer reasonably required to cure or relieve the employee from the effects of the industrial injury.

(2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period

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where that is necessary for the injured worker's condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

Pharmacy Networks; Pharmacy Benefit Manager Contracts.

9792.27.4 – Many pharmacies will not provide an injured worker medication without a written or oral approval from the employer/claims examiner. We anticipate this will continue even with a “preferred” drug list on the formulary. Therefore, we recommend that 9792.27.4 be amended with the following sentence at the end, "Medications on the preferred drug list shall be automatically deemed approved for immediate dispensing by the pharmacy without further written or oral authorization from the employer."

In the alternative, language should be added to 9792.27.4 to place an affirmative duty on the claims administrator to provide written or oral authorization to the pharmacy within 24 hours of receipt of a prescription for a drug on the preferred list.

Access to Drugs Not Listed in the Preferred Drug List.

9792.27.6 – As stated above, the preferred drug list developed by the DWC appears arbitrary and not based on evidence based medicine. It provides for a very limited group of medications on the preferred list, unlike formularies developed in other states. The end result if reasonable and necessary medical treatment is not delivered to injured workers is an increase in loss adjustment expenses , frictional costs and delays which have been steadily increasing in the last ten years since the introduction of utilization review. The formulary as currently written does nothing to reduce these expenses and chronic delays.

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

9792.27.10(b) - As noted above for 9792.27.4 , many pharmacies will not provide an injured worker medication without a written or oral approval from the employer/claims examiner , whether the drug is on the Preferred Drug list or not.

Therefore, the same language needs to be added here "Medications on the preferred drug list shall be automatically deemed approved for immediate dispensing by the pharmacy without further written or oral authorization from the employer."

First fill

9792.27.11(b) (1) – To be consistent with our recommended amendment to 9792.27.1 (i) we also recommend that "or surgery" be added after "workplace injury" in 9792.27.11(b)(1).

Further we recommend that the period be extended from 7 days to 30 days for the first fill of a medication to be exempt from prospective UR after the initial injury or surgery .The reasoning for this is that the proposed amendments to Labor Code section 4610 (b) and (c) in Senate Bill 1160(which will hopefully be signed by the Governor later this month) exempt certain treatments from prospective UR in the first 30 days after an injury. This change would achieve uniformity between the statute and regulation.

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Conflict of Interest

9792.27.14(c) – This regulation only provides that members of the P&T Committee shall not have a substantial financial conflict of interest in relation to a pharmaceutical entity. However the enabling statute, Labor Code 5703.29(c)(3) is much broader. The statute reads, "[a] committee member *shall not have a substantial financial conflict of interest pursuant to standards established by the administrative director.*" Conflicts of interest may exist with utilization review entities, other cost containment entities (bill review companies), employers, insurance companies, MPN entities, even applicants (although highly unlikely given the financial incentives). For example, a physician that has a financial interest (employee, officer or stock holder) in a utilization review entity, may have a financial interest in limiting the list of Preferred Drugs so more drugs go through Prospective UR which would be an inherent conflict.

Therefore, we believe at the end of 9792.27.14(c) the following language, "a utilization review entity, cost containment entity, employer entity, medical provider network entity and insurance carrier entity" should be added. Subsequently, each category noted should have a definition listed.

The conflict-of-interest policies for the P and T committee must be strengthened to further guard against unforeseen conflicts of interest. The Center for Medicare Services requires its P&T committees to have clear policies for how they meet the conflict-of-interest requirements, requires these policies to incorporate objective third-party reviews of reported conflicts of interest, and requires a procedure for managing the recusal process in the event a conflict of interest is identified (42 Code of Federal Regulations 423.120(b)(1)). We recommend that these policies be incorporated into the proposed MTUS Formulary.

There should also be transparency in the appointment of members to the P and T committee. 9792.27.13 provides for the Administrative Director to create a P and T committee but there should be oversight in the appointment of members perhaps from medical organizations such as CMA and CSIMS assisting in the selection of the six committee members.

Pharmacy and Therapeutics Committee – Meetings.

9792.27.17(e) - It is not discretionary to allow closed executive sessions without meeting one of the requirements for holding such a meeting under the Bagley-Keene Open Meeting Act set forth in Government Code sections 11120-111321. Although, as a general rule, all items placed on an agenda must be addressed in open session, closed sessions in very limited circumstances will be allowed but only if the body complies with certain procedural requirements. (Govt. Code § 11126.3)

http://www.dca.ca.gov/publications/bagleykeene_meetingact.pdf

As the Executive Medical Director does not have the authority or independent discretion to circumvent the mandate of open meetings in the Bagley Keene Open Meeting Act it is strongly recommended that paragraph (e) be deleted from 9792.27.17.

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Dan Bodin
PM& R Specialist of Texas
Medical Liaison

September 16, 2016

The information provided in the ODG Formulary is centered in studies from the CDC which reinforce the current formulary and reinforce the necessity of the current formulary.

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

September 16, 2016

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, who also specializes in California workers' compensation claims. As a home delivery workers' compensation pharmacy, licensed in all fifty states, please accept IWP's comments in regards to the Division of Workers' Compensation's (DWC) draft formulary regulations.

IWP supports the intent of Assembly Bill 1124 and the creation of a drug formulary in the workers' compensation system. We believe that a drug formulary, if developed and implemented properly, can benefit all parties in the workers' compensation system by encouraging appropriate use of prescription medications, bolstering the use of the state's Medical Treatment Utilization Schedule (MTUS), and help reduce the administrative burden of workers' compensation claims. However, IWP believes the draft formulary, in its current form, is overly restrictive, to the detriment of injured workers and their physicians.

Formularies work best when they are broad enough to acknowledge that patient needs vary by individuals and allow physicians to exercise their medical judgment, while also encouraging appropriate, cost effective use of prescription drugs. However, the current draft formulary is overly restrictive, leaving only 73 of the 257 drugs listed as preferred. Formularies help provide guidance and a clear picture to all parties involved about what is likely covered and what will require further consideration, but when a list is too restrictive, guidance is all but eliminated.

The current preferred list contains no anti-depressants or anticonvulsants, both common medications in the treatment of injured workers. A recent report by the California Workers' Compensation Institute (CWCI) found that "[m]ore than 73 percent of prescriptions and 78 percent of the associated payments would be either Non-preferred or Not on the Formulary Drug List." The fact that the percentage of non-covered prescriptions is so high raises concerns that the draft formulary did not properly take into account all workers' compensation injuries and their medical treatment. While the formulary

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implementation would lessen that percentage, it would not entirely eliminate it, and likely still leave a large portion of commonly prescribed drugs in the workers' compensation system subject to prior authorization requirements.

By limiting the list of covered drugs under the formulary, the state is severely hindering the ability of physicians to determine and prescribe an appropriate and timely medical treatment plan for injured workers. A restrictive formulary forces the doctor to either select a preferred drug from a small list simply because of its preferred status or risk delayed treatment for the injured worker until the prescription can be authorized or denied.

This process also creates a significant administrative burden on insurers, pharmacy benefit managers (PBMs), and medical provider networks (MPNs), to evaluate all authorization requests in a timely manner. The more restrictive the formulary is, the more likely administrative costs to authorize the medical necessity of non-preferred or unlisted prescriptions will increase. Insurers, PBMs, and employers, would all likely face a large increase in authorization requests for prescriptions that had been commonly used and covered in the past. This not only creates additional work for the payers and networks, but almost guarantees that a patient will face delays in their treatment as the administrative process proceeds. Additionally, if a patient's prescription is denied under the restrictive formulary, there is an increase in the likelihood that an injured worker would obtain the prescription through their private healthcare, ultimately shifting costs, not savings.

This is not to say that the formulary should not place any limitations on access to medications. A comprehensive formulary, evidence-based, and tailored to the workers' compensation system, can provide options for doctors and injured workers while still requiring authorization for less commonly used or less medically effective prescription drugs.

The Division has noted that the formulary should be designed to work alongside MTUS and to be consistent with treatment guidelines. The Division specifically notes that they will be working concurrently to update the MTUS and recently the Division updated the MTUS to incorporate treatment guidelines from ACOEM and ODG. The Rand Corporation's report, *Implementing a Drug Formulary for California's Workers' Compensation Program*, issued just last month, specifically warned, "[a]dopting one of the other formularies we examined (Washington State L&I, Ohio, or Medi-Cal) would rise major issues of making the adopted formulary consistent with the MTUS." If the Division intends to have the formulary consistent with medical treatment guidelines, the proposed formulary would pose significant problems for the Division and all parties to the workers' compensation system.

Further, AB 1124 which authorizes the creation of the formulary states, "[t]he administrative director shall make provisions for no less than quarterly updates to the drug formulary to allow for the provision of all appropriate medications, including those new to the market." If the Division intends to maintain their own unique formulary, a quarterly update may prove unmanageable. To meet the requirements, the Division and its independent pharmacy and therapeutics committee would have to constantly monitor and examine medical research, drug development, and any updates to nationally recognized

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treatment guidelines to ensure they can update the state's formulary as frequently as required by law. Additionally, the formulary regulations note the Division's intention to develop the formulary in tandem with treatment guidelines, however, the treatment guidelines are often only updated every three to five years, creating substantial lag time. In comparison, the adoption of a more nationally established formulary, such as ODG which updates monthly, would allow the Division and its committee to consider all monthly updates and adopt/reject updates it deems necessary for California's system.

IWP encourages the development of a drug formulary for the state's workers' compensation system but believes a more comprehensive formulary that works within the MTUS, such as the ODG, would better suit the needs of the system and all its participants. The ODG formulary, which has been successfully implemented in Texas, and is currently being implemented in Tennessee and Arizona, provides a more inclusive list of medications and is evidence-based and developed in accordance with treatment guidelines specific to workers' compensation, as acknowledged by the Division with the adoption of the ODG guidelines in regards to opioids. As the Rand Corporation's report notes, "the ODG formulary would be easier to implement." The ODG formulary would provide the DWC with the ability to control prescription drug spending while ensuring that treatment options remain available for injured workers, and that physicians retain the ability to exercise medical judgment.

Although the ODG formulary is comprehensive, IWP acknowledges it is not a one-size fits all formulary for every state and that California may be well-advised to make alterations to best suit their state-specific needs. For example, the ODG formulary includes several compound medications as Y-drugs, however, California may consider placing all compounds on the N-list, requiring prior authorization, a tactic implemented by Oklahoma. The Division may also consider amending ODG to further limit access to opioids, as the national opioid epidemic continues to grow. Under the draft formulary, the Division has listed all opioids as non-preferred, and limited the first fills of opioids to 4-days. A similar approach to opioids could be implemented within the ODG formulary, which already places limits on opioids.

A final note in regards to the proposed legislation, under Section 9792.27.11(C) employers and insurers who contract with PBMs or MPNs may provide longer first fill periods or cover additional drugs under their first fill designation. Although an admirable policy to help lessen the restrictions of the formulary, a treating physician and an injured worker would not necessarily be aware of the deviations that would allow them to provide a different treatment plan without the need for prior authorization. Therefore, the physician would still have to make a choice of limiting care to fit within the formulary prescribed terms or unnecessarily seek authorization, creating additional unnecessary administrative work for the networks.

A drug formulary only works to optimize care, save costs, and produce better outcomes when it is designed in a way that allows doctors, payers, and patients to work easily within its boundaries. The current draft formulary creates a restrictive system that will only add to the administrative burden and costs, create greater confusion, and place cumbersome regulations on medical providers and injured workers. IWP remains supportive of the Division's efforts to develop and implement a drug formulary but urges the Division to develop a more inclusive and flexible formulary for California's injured workers.

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Kim Ehrlich, Director
Express Scripts

September 16, 2016

Express Scripts, Inc. appreciates the opportunity to submit comments regarding the proposed amendments to the Workers' Compensation Rules of Procedure. 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, which are supported by advanced trend-management and clinical-review programs, to ensure safety for injured workers, while aggressively controlling costs.

We support adoption of a nationally recognized, worker's compensation-specific drug list as the foundation for formulary development with a set interval for updates and easy access for all system stakeholders. In addition, we have outlined requests for clarification and/or recommendations in the following sections:

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

(c) For a drug that is identified as "Non-Preferred," authorization through Prospective Review must be obtained prior to the time the drug is dispensed. ~~If authorization through Prospective Review is not obtained prior to dispensing the drug, payment for the drug may be denied if it is determined upon retrospective review that the drug treatment is not medically necessary.~~

Express Scripts comments: The allowance of retrospective review in this section does not align with the language for "not listed" medications but also would seem to allow one to circumvent the intent and potentially impact the safety of the injured worker. The following is recommended to replace the above stricken language: If authorization through prospective review is not obtained prior to dispensing the drug, payment for the drug may be denied.

Section 9792.27.3. MTUS Drug Formulary Transition.

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(b) For injuries occurring prior to July 1, 2017, the MTUS Drug Formulary should be phased in to ensure that injured workers who are receiving ongoing drug treatment are not harmed by an abrupt change to the course of treatment. If the injured worker is receiving a course of treatment that includes a Non-Preferred Drug or a drug that is not addressed by the MTUS Preferred Drug List (an “unlisted drug”) by 7/1/2018, the physician shall either:

- (1) Prepare a treatment plan to transition the worker to a Preferred Drug, or
- (2) Prepare and submit a Request for Authorization and supporting documentation to substantiate the medical necessity, and to obtain authorization for, the Non-Preferred Drug or unlisted drug. The physician is responsible for requesting a medically appropriate and safe course of treatment for the injured worker, which may include use of a Non-Preferred Drug or unlisted drug for an extended period where that is necessary for the injured worker’s condition or necessary for safe weaning, tapering, or transition to a Preferred Drug.

Express Scripts comments: To ensure that all parties involved in the claim are engaged and focused on addressing the required actions, we are recommending that a time frame for completion be included in the language above. As such, we are recommended inserting a 1 year transition period by inserting “by 7/1/2018” as outlined in the draft language above.

Section 9792.27.8. Physician-Dispensed Drugs.

(a) Except as provided in subdivision (b), and section 9792.27.11 in relation to “First Fills”, drugs dispensed by a physician must be authorized through prospective review prior to being dispensed. If required authorization through prospective review is not obtained prior to dispensing, payment for the drug may be denied ~~if the drug is found upon retrospective review to be not medically necessary.~~

(b) A physician may dispense up to a single initial seven-day supply of a drug that is listed as “Preferred” in the MTUS Preferred Drug List without obtaining authorization through prospective review, if the drug treatment is in accordance with the MTUS Guidelines. The dispensing of the Preferred Drug may be subject to retrospective review to determine if the drug treatment was medically necessary. Payment for the drug may be denied if the drug was not medically necessary.

Express Scripts Comments: In an effort to be consistent with comments provided around prospective review, Express Scripts recommends the following language replace the portion stricken above: In section (a), remove the stricken language to remain consistent with other sections, and; in section (b), it is recommended the following be inserted as underlined above: “a single initial”.

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

(d) “Compounded drug” means a drug that is created by combining two or more active pharmaceutical ingredients to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace. A “compounded drug” does not include a drug prepared by mixing, reconstituting, or other such acts

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that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

Express Scripts comments: Express Scripts seeks clarification on whether the intent was to specifically remove items such as drug kits from the compound definition. This is certainly an area of concern regarding efficacy and the safety of the injured worker in the industry and hope that the opportunity to address this concern is not overlooked within the formulary regulations. We respectfully request that the definition include compound kits.

We appreciate the opportunity to provide feedback on the proposed regulations for a Drug Formulary and update of MTUS guidelines.

Jason Miller, MD

September 16, 2016

I am writing this email to make sure lives are not ruined by the terribly flawed idea of using ACOEM guidelines for SCS coverage determinations. This is especially true since Nevro has introduced a quantum leap forward for this therapy.

I have been performing spinal cord stimulation trials and implantations for over a decade, nearly 40 cases this year using Nevro Senza/HF 10 technology. With HF10, I have been able to treat my most difficult patients with remarkable success.

I have relieved pain from failed back, spinal stenosis, discogenic pathologies including huge annular tears, severe endplate degeneration, dural scarring, postsurgical neuropathies including root insult, as well as diabetic neuropathies. Several of the trialed patients had many of these conditions combined. A great many of these patients have predominantly axial back pain. Despite these severe and diverse etiologies, **more than 90% of my patients want to proceed with an implant!** The **average pain relief my patient's experience is 80%**. The *kicker* -- 10% of my trialed patients **have HAD COMPLETE pain relief.**

WTF - These numbers are astounding given the very modest risk and complete reversibility of the treatment. Importantly, I am not the only one getting great results. While impressive, my results are consistent with level 1 studies already published. Take a look at the 24-month data just published in the journal Neurosurgery. HF10 therapy vs traditional low-frequency SCS findings:

- Superior back pain responder rate with HF10 therapy: 76.5% versus 49.3%; P<0.001
- Superior leg pain responder rate with HF10 therapy: 72.9% versus 49.3%; P=0.003
- Superior and durable pain relief with HF10 therapy: average VAS scores for back and leg pain of 2.4 cm with HF10 therapy versus 4.5 cm and 3.9 cm with traditional SCS; P<0.001 and P=0.027
- HF10 therapy delivered pain relief with no paresthesia or paresthesia-related discomfort

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This is level 1 data that should not be ignored by ACOEM or DWC. Improving access to HF10 will save money and lives.

John Gurskis, MD

September 15, 2016

I am a Board Certified Anesthesiologist and Pain Management physician. In the past I was 50% of the teaching staff at UC Irvine fellowship program for Pain Management.

I have been working with spinal cord stimulators (SCS) for nearly 30 years.

I must oppose the ACOEM guidelines that paint with a broad brush by stating that use of SCS is not recommended for treatment of low back pain. In my own practice, the use of SCS for low back pain and radicular pain has seen long term (>5 year) significant benefit for my patients exceeding 75%. This is based on the ethical choice of patients and successful trial implantations with greater than 50% pain reduction before permanent implantation.

The ACOEM guidelines are outdated and apparently do not take into account the following study: (published on line ahead of print) from the prestigious journal NEUROSURGERY 9/6/2016.

Pain reduction at	12 months	24 months
Back pain	78.7%	76.5%
Leg pain	80.9%	72.9%

All physicians trained in this country make decisions about their patients on an individual basis concerning treatment choices. No physicians would choose to abandon a very useful technique for pain control based on "guidelines" based on outdated information.

We practice in an age where workers compensation insurance company "experts" routinely recommend denial of nearly all use of opioids and many adjuvant drugs for the treatment of chronic pain. Now we are faced with the potential ban of proven NON-DRUG treatment alternatives. This would place many of my patients in the category of "helpless and hopeless."

I would recommend that DWC publish the names of the ACOEM "experts" with their credentials along with those making decisions for the DWC. This would provide an informed public ethical transparency in government.

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A multitude of patients who are denied care would then have the opportunity to contact those involved in government decision making.

Marc D. Wolfsohn MD

September 15, 2016

I am writing to comment upon the direction the Workers' Comp system is moving regarding spinal cord stimulation and evidence based studies regarding its use for Failed Back Syndrome and other related axial and radicular back syndromes. Spinal cord stimulation has been invaluable in my practice to treat these syndromes, prevent further spinal surgery, and to provide an alternative to narcotic based therapy. There are at least three RCT studies supporting its use including the Kapural et al study regarding use of high frequency stimulation 2015/2016, Kumar et al Process study 2007, and the Richard North et al study comparing spinal cord stimulation to reoperation in 2005. All are supportive of spinal cord stimulation. There have been wonderful advances in this field that represent the future of care for spinal pain. My opinion is that many surgeries could have been avoided if this modality was offered earlier in the patient, care. I am a board certified pain specialist and have been practicing in this field since 1990. Please do not limit the use of this valuable tool.

Susan Lowe RN BS CCM CPDM
Manager, AMC Case Management

September 15, 2016

I support the proposed regulations regarding pharmacy in California and specifically regarding opiates and addicting medications.

For too long the pharmaceutical companies and medical community in general has put the nation's residents at risk and ignored the very real dangers of addicting medication without fully educating patients as to the risks. It is also a known fact that the pharmaceutical companies and their stockholders have put profits before patients as evidenced by the many lawsuits against Purdue Pharma and the past settlement. Yet, the medical community does not seem to have gotten that message, that these are dangerous products.

I personally have experienced loss in my family due to prescription drugs and as an RN and Case Manager, have witnessed for years the escalating use of opiates without a corresponding improvement in patients' lives. I have also listened to concerns voiced by their family members regarding their "drug" use. Yet, when I speak with prescribers with my concerns, most of the time, nothing changes.

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As the state with the largest population in the nation, we need to take a stand along with other states to protect our inhabitants especially when those that are charged with protecting us cannot or will not.

Please do not bow to pressures from outside influences to the detriment of California residents. Please move forward with the proposed regulations and give the medical community added support to do move away from the current path of destruction.

Robert Goldberg, MD, FACOEM
Chief Medical Officer, SVP

September 15, 2016

Sandy Shtab
AVP, Advocacy & Compliance
Health Systems

Please accept these comments on behalf of Health Systems, in regard to the proposed rules which would implement AB1124. The law requires the DWC to adopt a drug formulary based on a nationally recognized, evidence based medical treatment guidelines. First, we must acknowledge the significant time and efforts from the DIR and DWC staff and leadership as they worked to develop this proposal. There were many moving parts to consider and we appreciate the work which went into the first draft. Our remarks will focus primarily on the formulary component of the rule, although we do support the updates to several of the MTUS sections, and we recognize these were needed updates and are complimentary to the formulary itself. Further we endorse the continued use of ACOEM Guidelines as the basis of the MTUS and the formulary.

Our first impression of the draft formulary rule and drug list is very positive. We support the path being taken, which is to supply physicians and payers with a list of medications, and tying that list to the applicable sections of the updated MTUS. The drug list is simple and straightforward and PBMs are experienced in using lists like these to implement a drug formulary. NDCs are not necessary to implement or maintain a formulary; there are other product identifiers that are used by PBMs that fulfill the same purpose and capture drug class for the same drug by multiple manufacturers. PBMs have mature automated systems that can easily apply the formulary by drug class and notify the pharmacist in real time if the drug is not preferred or requires prospective review. This is common industry practice for physicians, pharmacists and for PBMs.

We recognize there may be some criticism of the number of non-preferred drugs which includes all opioids, some muscle relaxants and psychotropic medications often prescribed for injured workers. We do not perceive this as a bad thing. An additional “checkpoint” on these types of medications may initially result in an uptick in the number of UR requests; however our

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experience is that physicians are used to dealing with formularies in workers' compensation claims, in group health and other payer programs and eventually this UR uptick should level off. The Texas and Oklahoma formulary implementation experience showed us that physicians begin to modify their prescribing behaviors well before the formulary effective date if they are aware that a state formulary will be coming. In these two states, physicians started to prescribe fewer drugs which required pre-authorization. Patients were still able to get needed drugs that required preauthorization, but more patients were treated with medications that were on the approved list. California physicians will soon adapt to this change, and patient outcomes will improve as we have seen in other states. More importantly, injured workers will still be able to get the right medications at the right time, with an extra set of eyes to ensure more appropriate prescribing.

One area which we think requires additional consideration and clarity is Section 9792.27.3, which discusses the transition period for workers injured prior to July 1, 2017. We think this section could better define the timeframe for transitioning to non-preferred drugs or substantiation of the medical need for a non-preferred or "other" drug. It is our belief that all injured workers, regardless of the date of injury should be protected from inappropriate prescribing as soon as the rule becomes effective. If this modification to the rule is adopted, this would mean the transition period would only be applicable to those workers who have already received a non-preferred drug or an "other" drug prior to the effective date of the rule. In other words, if the rule is effective on July 1, 2017 and a worker sustains an injury prior to the effective date, but has never been prescribed a non-preferred drug before the rule went into effect; those cases should be subject to the MTUS formulary immediately. For those patients who have been taking a non-preferred or "other" drug, many of these patients can be weaned within a 90 day period; however we realize there can be more complex cases where patients may need extra attention. Stakeholders need adequate time to perform the administrative tasks associated with communication between the claims administrator, physician and the injured worker. In many cases RFAs or UR processes will be needed to address these cases. For this reason, we would suggest a 6 month period, ending on December 31, 2017 as the maximum timeframe to complete the transition.

We also support the language requiring the same prospective review process for physician dispensed medications, as well as compounded medications, especially topical formulations. We support taking this one step further (as proposed in comments previously submitted by Los Angeles County CEO Alex Rossi). There is a growing need to address the prescribing and dispensing of novel or uncommon doses such as those reported by RAND, CWCI and WCRI. We would support more definition and restrictions around the approval of drugs prescribed in a novel dose. If it is medically appropriate to dispense a novel dose, the most common lower cost doses can be "pill split" if truly needed. This is common practice in the medical community, and was done long before the advent of these high cost novel doses, which are primarily being dispensed at a very high cost only to workers' compensation patients. Some final thoughts on the formulary; physician and other stakeholder outreach are important to ensure all system participants are ready for this change. We recommend that the DWC offer both in-

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person training throughout the state, and on-demand webinar training which could be accessed remotely. This will allow everyone to better understand the moving parts of the formulary rule including how it fits into the MTUS and UR regulations. It cannot be over-emphasized that the success of the formulary is dependent on all parties understanding how it works and setting clear expectations for the physician, the injured worker, their employer, the claims administrator and other stakeholders in the system.

We appreciate the DIR-DWC is faced with a difficult task of balancing competing stakeholder perspectives. Some of these perspectives may be rooted in the “status quo” rather than looking forward to a more progressive method of managing drug utilization. This formulary is the most aggressive step taken by any workers’ compensation agency in recent years and we fully support it as a mechanism for positive change. With a few adjustments, we believe it will be instrumental in driving better patient outcomes, decreasing pharmacy related costs and increasing accountability of physicians, all to the betterment of the system as a whole.

Roman Kownacki, MD, MPH
Medical Director, Regional Occupational Health – Northern California
The Permanente Medical Group

September 15, 2016

After a review of the draft regulations, "Implementing AB 1124 Drug Formulary and update of MTUS guidelines," posted on the Division of Workers' Compensation website Forum, I would like to offer my support for the proposed changes to the MTUS. The proposal has accomplished what I believe are critical aspects of a robust formulary. First, it is evidence based. High quality health care must but be rooted in evidence-based medicine, so I applaud making this a priority. Second, the proposal aligns the formulary with an updated MTUS. As a result, the MTUS is made current, and the formulary is not a silo; rather it is embedded into the MTUS. Lastly, the proposal is simple. The use of preferred/not preferred will simplify the process and still not preclude non-preferred requests to be handled through the UR process.

I feel these are the most important elements of the formulary goals and this proposal has met those requirements. I recognize the Division is in the pre-regulatory phase and the proposal is subject to change. I feel this is a great foundation that will continue to evolve and improve the medical treatment for patients with work related injuries.

Glenda Garrard RN MBA
GSG Associates, Inc.

September 15, 2016

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I have reviewed the formulary and am very concerned about the development of same. There are so many drugs not on the preferred list that we regularly approve through UR. If the intent was to lessen UR and allow the injured worker quick access to necessary medications, it is not going to work.

The task that the DWC is taking on by developing its own formulary is huge, and the DWC is already a very busy organization, making quarterly review impossible. It would be so much easier to adopt an existing formulary, one that is truly evidence based and updated as new drugs reach the market, such as ODG, for example. The DWC is already faced with challenges keeping the MTUS up to date, I question how you can keep the formulary up to date.

Marc T. Taylor, M.D.

September 15, 2016

As one of a few physicians that helped to design, develop, implement, and teach the Designated Doctor courses in the past in the Texas workers' compensation system, I read with interest the proposed Drug Formulary. Having been involved with and having served as president of the Bexar County (San Antonio, Texas) medical Society, the eighth largest in the United States, and of AADEP, I am well aware that many different political issues can invariably affect the implementation of any proposed Drug Formulary or medical guidelines.

Regardless of the reasons why or how this proposed Drug Formulary was developed, it is a step back in time, especially in terms of thinking it will save money.

- Many of the most commonly used and needed drugs in the system are not even listed. This line of thinking is similar to thinking that by closing down the OB/GYN floor in a hospital, no more babies will be born.
- It is mind-boggling to think that in this day and age that the Proposed Formulary is not tied to NDC codes, lacks user interfaces and search/query tools for direct online use or integration into existing systems, and is not operationalized, integrated or automated by any PBM's, Insurers, TPA's, Employers, Medical Service Providers, software systems or Stakeholders to date.
- The millions and millions of dollars that will have to be spent by all those involved in the system to make this formulary even reasonably functional and then to maintain any functionality will certainly eat up any "savings" in the system.
- And, most importantly, it is also mind-boggling to think that in this day and age that the Proposed Formulary drug list is not evidence based.

Kasra Amirdelfan, MD

September 15, 2016

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Interventional Spine & Pain Medicine
IPM Medical Group, Inc.

I am a fellowship trained, board certified pain management physician with a practice based in Walnut Creek; IPM Medical Group, Inc. I have served this community for over 16 years and I have been treating workers compensation patients for the duration of this time. My expertise is in the field of interventional pain management and Spinal Cord Stimulation (SCS) and I have extensively lectured and continue to be actively involved in conducting research on the most advanced technologies in this field. These efforts have empowered me to help pain patients in our area, in the United States and around the world.

I appreciate the opportunity to provide my comments to the DWC regarding the proposed MTUS Chronic Pain Guidelines. I realize that the MTUS guidelines are now proposing to utilize the American College of Occupational and Environmental Medicine (ACOEM) guidelines that include guidance for Low Back Disorders and specifically, a designation of “Not Recommended” for SCS. Specifically, ACOEM states that “spinal cord stimulators are not recommended for treatment of acute, subacute, chronic low back pain, radicular pain syndromes or failed back surgery syndrome.” It is extremely disappointing to know that the DWC plans to limit SCS access for appropriate patients as indicated in the literature. As a physician who is passionate about maintaining the ability to offer my patients the most effective opioid free therapies for pain control, I would like to voice my extreme dissatisfaction regarding the proposed treatment guidelines as referenced on the DWC website¹. If these proposed guidelines are implemented as drafted, they will significantly limit my ability to effectively treat Worker’s Compensation patients with established and well-studied effective therapies such as SCS.

I note that the ACOEM guidelines were updated in April, 2016 and do not include the most recent clinical evidence supporting the effectiveness of SCS therapy, which should be immediately addressed by DWC. For reference, the most current, Level 1 clinical SCS data is not included in the current ACOEM guidelines as it was recently published this month (September, 2016) in the prestigious journal Neurosurgery². The SENZA-RCT is the only rigorous study directly comparing the efficacy and safety of two commercially available SCS devices (HF10 therapy as delivered by the SENZA SCS system and traditional SCS.) Also, this is the largest RCT (Randomized Controlled Trial) that has been published in the SCS space with durable 24-month data uniquely demonstrating safety and efficacy in the treatment of both back and leg pain, which should be of interest to DWC. A significantly higher proportion of subjects treated with the SENZA SCS System were considered study “successes” as defined by the composite primary endpoint, which consisted of the following:

- A decrease in back pain by at least 50% at 3 months compared to baseline;
- No increase in any pain medication two weeks prior to scheduled follow-up visits compared to baseline;
- No increase from baseline in pain medication for duration of greater than 5 days; and No stimulation-related clinically meaningful neurological deficit at 3 months compared to baseline neurological status.

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Subjects treated with the SENZA System had statistically significant greater mean reductions from baseline in reported back and leg pain scores, the percentage change from baseline in back and leg pain scores, and in the Oswestry Disability Index (ODI). There were no stimulation-related neurological deficits observed for either treatment group. This RCT demonstrated clear superiority of HF10 therapy over traditional SCS and as a result garnered a superiority label from FDA on May 8, 2015. Additionally, the Centers of Medicare and Medicaid Services (CMS) has stated that the device met the CMS requirement of “substantial clinical improvement” as compared to traditional SCS, and therefore created an additional pass through payment code for high frequency stimulation (C1822).

The SENZA-RCT study provides Level 1 clinical evidence available for HF10 therapy that should be specifically considered by the DWC prior to finalizing the MTUS Chronic Pain Guidelines. This study included 241 participants from 10 centers around the country. **It is noteworthy that over 70% of the study subjects presented with the diagnosis of FBSS (Failed Back Surgery Syndrome).** Alternatively, the SENZA-EU study³, which was published in 2013, also had a large proportion of patients with FBSS at 81%. Each of these studies reported significant and compelling reductions in patient’s back and leg pain for a prolonged period of time.

For context, the results from this pivotal SENZA-RCT are consistent with the 24-month results from the multicenter, prospective study conducted in Europe (SENZA-EU). This trial was completed in two European centers, with 72 patients implanted with the Senza SCS system. When evaluated at 24 months, HF10 patients saw sustained back and leg pain relief, accompanied by statistically and clinically significant improvement in ODI, with their baseline ODI of 55 reduced to 40 at 24 months. The results also demonstrated a significant reduction in opioid use: 38% of patients stopped taking opioids during follow-up, and the mean dosage of morphine per patient decreased from 84 mg at baseline down to 27 mg at 24 months.

In summary, it is in the best interest of all stakeholders to consider the most current, high quality, published peer-reviewed, evidence that is available prior to limiting the DWC treatment options for chronic low back pain patients in the state of California. I am fully supportive of utilizing interventional therapies, such as SCS for the most appropriate patients such as those who were clearly studied in both of the referenced studies. I welcome any questions or comments you may have and I look forward to having the continued ability to treat injured workers with the most appropriate therapies that are available to effectively treat their chronic pain.

Footnotes

¹ <http://www.dir.ca.gov/dwc/ForumDocs/Implementing-AB-1124-Drug-Formularyand-update-of-MTUS-Guideline/Implementing-AB-1124-Drug-Formularyand-update-of-MTUS-Guidelines.htm>

² http://journals.lww.com/neurosurgery/Abstract/publishahead/Comparison_of_10_kHz_High_Frequency_and.97253.aspx

³ Al-Kaisy et al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Medicine*. 2013; 15(3): 347-54.

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Robert P. Nickell, Pharmacist

September 15, 2016

Section 9792.27.9. Compounded Drugs.

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

Rather than state instead of a FDA approved drug or over –the-counter drug that complies with an OTC monograph, there appears there could be more "instead of" options than how it is stated, therefore, I would make the following suggestion:

Use this sentence:

Instead of a "preferred or non-preferred drug as per MTUS guidelines"

** limiting the response to FDA approved or OTC, will end up bottlenecking the system, as the FDA has many various categories of commercially available FDA drugs outside of the definition listed in this formulary.

Therefore, limiting the response to previously defined categories of "preferred or non-preferred formulary drugs" allows the physician and prospective review agent to have one document in which to refer, rather than the entire FDA database to debate.

Robert P. Nickell, Pharmacist

September 15, 2016

This response is in regards to the definition of a compounded drug, it is currently listed as the following:

(d) "Compounded drug" means a drug that is created by combining two or more active pharmaceutical ingredients to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace. A "compounded drug" does not include a drug prepared by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer.

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My suggestion is to further strengthen the definition and follow FDA guidelines for compounding. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469119.pdf>

(d) “Compounded Drug” means a drug that is created in *accordance with FDA Compounding Guidelines for 503A pharmacy or physician office compounding, as well as compounding regulations as put forth by the California State Board of Pharmacy which consists in combining two or more active pharmaceutical ingredients to meet specific patient medical needs that cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs **prepared in FDA Registered Facilities that are lawfully and commercially available in the marketplace. A “compounded drug” does not include a drug prepared by ***FDA registered facilities or by mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the products manufacturer.

*adding the sentence to define compounding as FDA 503A for pharmacy, and also adding physician office compounding, serves to further clarify to require a compounder to follow not only FDA but also California BOP regulations with regards to compounding. This will cover out of state and in-state compounders.

** adding the words FDA Registered Facilities further clarifies the “other commercially available” statement, as the FDA is constantly changing the rules, categories and types of products that can be lawfully sold in the USA, which also include, packaging, labeling, and indications, with the suggested wording. Therefore, if the FDA makes a change to the guidelines, the new formulary definition is able to still remain effective.

***again by adding FDA registered it clarifies and strengthens the message as to the delineation between compounding and manufacturing.

Steven J. Miller, M.S. Pharm, B.S. Pharm, D. Ph., R. Ph.
Chairman and President
PharmacyMSA.com

September 15, 2016

I understand DWC is under a lot of pressure to implement something to address both the opioid crisis and the financial burden the cost of medicines in workers compensation is having. The adoption of an evidence-based formulary is certainly a step in the right direction, using the Medical Treatment Utilization Schedule (MTUS) treatment guidelines, and will no doubt result in the continuation of high quality care for injured California workers in a timely manner while addressing cost and safety issues. Updating those MTUS treatment guidelines will play a big part in those overall improvement efforts, as

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they are in need of some updating due to their age and the constantly changing medical treatment landscape.

After reviewing the information provided by DWC, I believe that the adoption of the guidelines and formulary of the Official Disability Guidelines (ODG) would best serve the injured workers, their employers, and the payers into the DWC system. Everybody wins!

I have used the ODG compendia for many years in my roles as a pharmacist that 1) develops Medicare Set Aside submissions to CMS, 2) works with payers, prescribers, and patients to provide cost-effective medical and pharmaceutical care, and 3) frequently dispenses medications to injured workers at a retail pharmacy. I believe that the proposed state-specific formulary, said to be based on MTUS, but inconsistent with component formularies from ODG and ACOEM, and far more restrictive than national, evidence-based guidelines like those mentioned, will not show improved safety, efficacy, or savings. The approaches taken by ODG and ACOEM have been proven effective in many other states.

I use ODG whenever and wherever I can [today](#) and my customers, clients, and patients, have benefitted from that decision. It is comprehensive, evidence-based, easy to use, and operationalized in our systems. ODG has proven tremendously successful in this area, improving RTW outcomes, increasing access to quality care, and decreasing costs. We have found that the linkage of the information in ODG (guidelines, medical coding, costs, and others) allows quicker and smoother automation and integration of criteria, as well as easier inclusion of outcome data in final reports.

ODG is recommended in both the Rand Formulary study commissioned by DWC, and the 2004 Rand Technical Quality Evaluation. While the proposed regulations are well written, as a medical professional I believe that it would be in everyone's best interest that DWC replace the proposed formulary and clinical updates with ODG.

Mary E. Ryan, Senior Program Manager
Medtronic

September 15, 2016

This letter is in response to the Division of Workers' Compensation (DWC) notice dated August 26, 2016 to update the Medical Treatment Utilization Schedule (MTUS). We appreciate the opportunity to provide our perspective on these important rules that provide injured workers with access to medical treatment. Our comments focus on the proposal to adopt the low back disorder guidelines produced by the American College of Occupational and Environmental Medicine (ACOEM)

Medtronic, Inc. is a global medical technology and services company with a comprehensive product portfolio. Medtronic's Restorative Therapies Group manufactures spinal cord stimulators for the

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treatment of chronic, intractable pain. For this patient population with inadequate pain relief or intolerable side effects from medication, Spinal Cord Stimulation (SCS) is an important treatment option.

The ACOEM guideline, in its low back disorder chapter, does not recommend SCS. Page 585 of the guideline states: “spinal cord stimulators are not recommended for the treatment of acute, subacute, chronic low back pain, radicular pain syndromes, or failed back surgery syndrome”. We believe that the ACOEM evidence review misses a key point: while low back pain alone is not strongly supported by the body of evidence, there is a long history of consistent results reported from open label studies and randomized controlled trials reflecting the efficacy of SCS for treating the painful symptoms of failed back surgery syndrome (FBSS). Chronic back and leg pain (CBLP) includes chronic low back (axial) pain, persistent hip, buttock, and leg (radicular) pain syndromes, and combinations of back and leg pain such as FBSS and complex regional pain syndrome (CRPS).¹ We strongly disagree with ACOEM’s spinal cord stimulator recommendation.

ACOEM’s list of contributors to the February 24, 2016 edition of its Low Back Disorders guideline does not include a pain society or known interventional pain physician. Although there is a disclaimer that organizations listed do not necessarily support or endorse the guideline, and that some organizations wish to remain anonymous, it is disconcerting that the very physicians who are trained in this procedure do not appear to have been consulted.

SCS FBSS clinical and economic evidence

SCS is a clinically effective and cost-effective treatment option for patients with FBSS that is refractory to conventional medical management (CMM), supported by randomized controlled trials (RCTs). The level 1 clinical studies demonstrate that SCS is an effective therapy in significantly reducing pain in patients with FBSS as compared to best medical therapy or reoperation on the lumbosacral spine, 47-48% for SCS compared to 12% for reoperation and 9% for conventional medical management.^{2,3} The PROCESS study found patients reported significantly improved leg pain relief ($P<0.0001$), quality of life ($P<0.01$), and functional capacity ($P=0.0002$) at 24 months after SCS implant as compared to baseline.⁴

There are also several large post market SCS retrospective analyses reporting positive outcomes for 1,129 patients.^{5,6,7} One retrospective analysis including the experience of SCS in 410 patients over a 22-year period reports an early success rate of 80% (328 patients), and a long-term success rate of 74% (243 patients) after the mean follow-up period of 97.6 months (approximately 8 years).⁵

A recent systematic review and meta-analysis of patients examined the effectiveness of SCS for failed back surgery syndrome patients with chronic back and leg pain (CBLP), following previous back surgery. The article performs a meta-analysis to determine whether SCS is effective for FBSS presenting with both back pain and/or leg pain, and concludes that SCS is effective for FBSS patients “irrespective of back or leg pain location.”⁸ This study also found that pain relief from SCS was associated with duration of pain, with each additional 12-month increase in the duration of pain resulting in a -2% impact on pain relief. There are also recent economic articles demonstrating that using SCS to treat FBSS and CRPS is

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cost-effective, confirming previous research on cost-effectiveness. SCS for FBSS is cost-effective compared with medical management^{9,10,11} and is less costly and more effective than reoperation.¹² SCS for CRPS is cost-effective compared with medical management. ^{11, 13,14} In addition, this economic evidence supports that failed reoperation followed by SCS was more expensive than starting with SCS and later choosing reoperation.¹² A description of the cost associated with SCS in the US and Canada included the additional costs of complications. ¹⁵ While this is an important part of assessing the financial impact to healthcare budgets, most patients experiencing minor or serious complications have a full recovery though permanent impairment is possible or may require additional surgery to resolve.^{16,17}

SCS has been recommended for both FBSS and CRPS by many internationally-recognized health technology assessment organizations, including the UK's National Institutes for Health and Care Excellence ¹⁸ and Health Quality Ontario ¹⁹, along with clinician society consortiums such as the International Neuromodulation Society – Neuromodulation Appropriateness Consensus Committee.²⁰

Additionally, in the United States, there is widespread acceptance of SCS as a treatment option. The top fifteen commercial payers in the US, representing 60% of the US commercial population (table 1), either have an affirmative coverage policy or, at a minimum, provide coverage to SCS for chronic pain. SCS is covered by Medicare and the Department of Defense/Department of Veterans Affairs (DOD/VA). CMS issued a national coverage decision for SCS in 07/14/1988.²¹ Finally, the Official Disability Guidelines, in its low back chapter, recommends SCS for FBSS.²²

Again, thank you for this opportunity to comment during the forum so that we may substantiate our support of SCS as a viable alternative for chronic pain patients and to oppose the adoption of ACOEM low back disorders chapters. If the DWC has not done so, we strongly encourage the Medical Director to engage the Medical Evidence Evaluation Advisory Committee to advise the division about incorporating evidence based guidelines into the MTUS. The regulations concerning the MEEAC are can be found in [§ 9792.26](#) of Title 8, California Code of Regulations.

Footnotes

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Enclosed Table

Company	Total Health Plan Enrollment	Medical Policy link
UnitedHealth Group	34,675,651	https://www.myuhc.com/content/myuhc/Member/Assets/Pdfs/Intrathecal%20Pump%20for%20Chronic%20Nonmalignant%20Pain.pdf https://www.unitedhealthcareonline.com/ccmcontent/ProvideRII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFileSPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/Implanted_Electrical_Stimulator_for_Spinal_Cord.pdf
WellPoint, Inc./ now Anthem	29,576,763	https://www.anthem.com/medicalpolicies/policies/mp_pw_a053357.htm
Aetna, Inc.	18,636,285	http://www.aetna.com/cpb/medical/data/100_199/0194.html
Health Care Service Corporation	12,783,198	No published medical policy available but claims evidence supports positive coverage.
CIGNA HealthCare, Inc.	11,499,083	http://www.medsolutions.com/cignaguidelines/guideline_downloads/eviCore%20Final%20CMM-211%20Spinal%20Cord%20and%20Implantable%20Peripheral%20Nerve%20Stimulators.pdf
Kaiser Permanente	8,959,294	No published medical policy available but claims evidence supports positive coverage.
Humana, Inc.	6,805,447	http://apps.humana.com/tad/tad_new/Search.aspx?criteria=spinal+cord+stimul&searchtype=free text&policyType=both
Blue Cross Blue Shield of Michigan	4,436,836	http://www.bcbsm.com/mprApp/MedicalPolicyDocument?fileId=91845
Highmark, Inc.	4,387,427	https://secure.highmark.com/ldap/medicalpolicy/wpa-highmark/Z-7-035.html
Coventry Health Care, Inc.	3,609,930	No published medical policy available but claims evidence supports positive coverage.
Independence Blue Cross	3,528,574	http://medpolicy.ibx.com/policies/mpi.nsf/6eeddf656d983ec98525695e0068df68/85256aa800623d7a85257f1b00743523!OpenDocument&Highlight=0,spinal,cord,stimulation
BlueCross BlueShield of Tennessee	3,499,743	http://www.bcbst.com/mpmanual/Spinal_Cord_Stimulation_for_Treatment_of_Pain.htm
CareFirst BlueCross BlueShield	3,496,446	http://notesnet.carefirst.com/ecommerce/medicalpolicy.nsf/vwWebTableX/AFE4AD588AC025E785257D8F006AA642?OpenDocument
Blue Cross and Blue Shield of Alabama	3,043,985	https://www.bcbsal.org/providers/policies/final/328.pdf
Medical Mutual of Ohio	2,811,059	https://provider.medmutual.com/tools_and_resources/Care_Management/MedPolicies/PDF/200602.pdf?t=9/14/2016%2011:11:36%20AM
Total Enrollment Top 15	151,749,721	
Total Enrollment all Commercial payers percentage of covered lives	253,418,610 60%	
	AIS 2012 Directory of Health Plans -	
Data source: Medicare	53000000 Approx.	National Coverage Determination for Electrical

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Veterans Administration

8570000 Approx.

Nerve Stimulators, NCD #160.7. Centers for Medicare and Medicaid Services website. <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=240&ncdver=1&DocID=160.7&SearchType=Advanced&bc=IAAABAAAAA> A&. Accessed Sept 14, 2016
CHAMPVA.CENTRAL NERVOUS SYSTEM STIMULATION. VA website. <http://www.va.gov/PURCHASEDCARE/docs/pubfiles/policymanuals/champva/chapter2/1c2s20-9.htm>. Accessed Sept 14, 2016

Richard Shinaman, MD
Minimally Invasive Spine Care and Comprehensive Pain Medicine
Chief Medical Officer – WellBrain Psychological Testing & Mindfulness Training

September 15, 2016

The data you are using to deny coverage for SCS systems for radicular pain is flawed and biased. This appears to be yet another case of undue industry influence. It is simply unethical to deny a therapy to patients that IS MUCH BETTER PROVEN than many other things that you approve. Over the long term I suppose we should simply tell all patients with failed back surgery to take Tylenol and "grin and bear it."

It is very, very frustrating to have to tell patients I could help you, but big business runs the show and they don't want to pay for this effective therapy for you.

My partners and I were already approached by NBC about the corrupt WC system and it appears that we may have to pass along the data to them and let the public know how broken the system is.

[Redacted]

Scott C. Levy, MD, MPH, FACOEM
President, WOEMA

September 15, 2016

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.

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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 in 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 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 being "Non-Preferred" may be misinterpreted by some payors 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. Subsection 9792.27.10 of the proposed regulations contemplates that "retrospective review" of a prescription for a "Preferred" drug or a "first fill" drug" might find that a prescription already filled was not "medically necessary." In such cases, it would appear that the next step would be that the payer would not have to pay the pharmacy. 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:
 - 1) *Bloodborne pathogen exposure*

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- 2) *Soft-tissue infection complicating a work-related wound*
- 3) *Acute gout complicating a soft-tissue sprain/strain*
- 4) *Severe hypertension complicating a workplace violence episode*
- 5) *Nausea and vomiting complicating heat exhaustion*
- 6) *Asthma exacerbation at work*
- 7) *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 seven medications listed as "First Fill," defined as "*First Fill - Indicates Drug may be prescribed/dispensed without Prospective Review: 1) Rx at initial visit within 7 days of injury, and 2) Supply not to exceed #days indicated, and 3) if in accord MTUS.*" In every case, those seven 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. Finally, and most 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").

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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 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.

Matthew D. Johson, DO
PM&R
Pain Management

September 15, 2016

I strongly disagree with the proposed changes to guidelines to limit use of spinal cord stimulators. These devices, in particular the new HF devices, have been game changers for a substantial amount of my patients and have allowed reduction and cessation of medications and return to work in some circumstances. We use these devices in the worst case scenarios for injured workers and can be the rescue intervention that allows these patients to return to some semblance of a normal life. There is substantial data to support use of these devices and any change in the guidelines will ultimately push these patients to more medication and more unsuccessful surgery.

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Carlos Luna, Director of Government Affairs
Reed Group

September 14, 2016

The State of California set a precedent for the nation by updating their treatment guidelines and creating a proposed formulary that is based on the highest degree of quality evidence available. Two key events amplify aspects of this precedent setting decision.

Aug. 26: California Makes Crucial Decision

On August 26, the Department of Industrial Relations Division of Workers' Compensation (DIR/DWC) in the State of California announced that they plan to implement a workers' compensation drug formulary by July of next year as required by State Assembly Bill 1124. The State of California also announced that the foundation of the Medical Treatment Utilization Schedule (MTUS) Formulary is the evidence-based content of ReedGroup's formulary which is based on the ACOEM Practice Guidelines.

The basis of California's decision to utilize ReedGroup's ACOEM based formulary, reinforces the fact that the administration of any drug should take into consideration both the patient's condition and phase of care. A binary yes/no list of drugs may appear to be a simple approach, but in fact, it is not the best medicine.

The DIR/DWC also felt strongly that their drug formulary must be tied to high quality, transparent evidence-based guidelines. The quality and transparency of the underlying practice guidelines are what makes the State's decision not only the right one, but one that is bound to have a ripple effect that positively impacts the nation's workers' compensation industry as it will place the well-being of the patient at the top of every stakeholder's priority list.

June 23: Official Disability Guidelines (ODG) Delisted from National Guideline Clearinghouse

What occurred on June 23, 2016, is equally significant and should propel the national workers' compensation industry to do the hard work of understanding the true meaning of evidence-based medicine. On June 23, the media website *WorkComp Central* reported that the ODG, widely used in the workers' compensation industry, was being removed from the National Guideline Clearinghouse run by the federal Agency for Healthcare Research and Quality (AHRQ). The reason given by the clearinghouse for the removal was that the ODG failed to meet the criteria for high quality, transparent evidence-based guidelines as defined by the National Academy of Medicine (NAM), formerly the Institute of Medicine. [Click here](#) to view these standards.

Subsequent conversations regarding whether the ODG was dropped or whether they withdrew is of little consequence. What is of consequence is why the ODG has been unable and unwilling to meet the high standards set by the National Academy of Medicine. If there is now consensus that practice guidelines are the foundation for both treatment recommendations and drug formularies, then

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concerns about rigor, methodology and quality are of the utmost importance. Medical treatment decisions are being informed by this information. If the quality of the guidelines is in question, then every treatment or drug recommendation stemming from the guidelines must also be in question.

Inaccurate Public Commentary

This past Friday, September 9, the ODG published an email commentary which was highly critical of the State of California's formulary decision. There are numerous inaccuracies in the ODG email. Below we address five of the major inaccuracies published by ODG. [Click here](#) to find a document detailing the National Academy of Medicine's criteria for high quality, reliable, trustworthy guidelines and how the ACOEM Practice Guidelines meet each criteria.

Workers' compensation professionals should trust the National Academy of Medicine and the Agency for Healthcare Research and Quality. Combined, these organizations consist of thousands of professional members devoted to bettering health, medicine and policy. Together they set a direction consistent with ReedGroup's approach of placing the patient at the top of every stakeholder's priority list.

Misleading and Inaccurate ODG Email: "ODG Analysis on Proposed Formulary in California"

1. ODG Inaccuracy: California's MTUS formulary is a state-specific formulary with significant differences from ReedGroup's ACOEM-based formulary.

FACT: The MTUS formulary is based on the ReedGroup formulary built on the ACOEM Practice Guidelines.

According to the recently published California Workers' Compensation Institute (CWCI) report, "California's Proposed Workers' Compensation Formulary: Part 1 – A Review of Preferred and Non-Preferred Drugs" (Page 3), the State of California developed its MTUS formulary Preferred Drug List (PDL) utilizing ReedGroup's ACOEM-based formulary as the basis.

ODG states that the MTUS formulary "is significantly different from the ACOEM formulary" and "there are many approved drugs on the ACOEM formulary that are non-preferred on the MTUS formulary." In fact, the California MTUS formulary is based solely on ReedGroup's formulary based on the ACOEM Practice Guidelines. The MTUS Preferred Drug List even includes a category of "First Fill" medications to allow clinicians to provide certain medications to injured workers as long as the use is in accordance with the ReedGroup/ACOEM MTUS guidelines.

2. ODG Obfuscation: "A pharmacist should not be expected to apply evidence-based treatment guidelines and patient criteria at the counter at Walgreens."

FACT: ODG is purposely confusing the medical provider's role with the role of the pharmacist. It

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goes without saying that a pharmacist should not be expected to apply evidence-based treatment guidelines and patient selection criteria at the pharmacy counter. This is the responsibility of the treating physician, physician assistant or nurse practitioner. The California MTUS formulary will allow the pharmacist to quickly determine which drugs can be filled without prospective review (PR) and which drugs are subject to prospective review (PR). In addition, the pharmacist will have clear guidance on the select non-preferred drugs that may be prescribed under the first-fill policy.

3. ODG Inaccuracy: California's MTUS formulary is not evidence-based.

FACT: The state of California's MTUS formulary is 100 percent evidence-based. The MTUS formulary is based on ReedGroup's formulary which is based on the ACOEM Practice Guidelines. Reference: RAND Report: Implementing a Drug Formulary for California's Workers' Compensation, pages 11, 12. – "The [ACOEM] guidelines are developed through a process that is more rigorous, transparent, and evidence-based than ODG's (Nuckols et al., 2014)." The ACOEM Practice Guidelines meet the criteria for transparent, high quality, reproducible guidelines set by the NAM (formerly, IOM), AGREE, GRADE and AMSTAR).

4. ODG Inaccuracy: More "preferred drugs" are better for California's workers' compensation system.

FACT: ODG's assertion that more preferred drugs are better is misguided and not aligned with responsible medical rationale. While ODG's formulary is considered to be "more comprehensive," meaning it includes more preferred drugs, the RAND Corporation has identified concerns with ODG's lack of transparency for the development and evidence-based medical support of its guidelines and formulary: "The ODG guidelines are more comprehensive than the ACOEM guidelines, but the methods used to develop them have been less rigorous (Nuckols et al., 2014), and the methodology used to derive the PR requirements when there are condition-specific variations in the guideline recommendations is not transparent." (RAND Report: Implementing a Drug Formulary for California's Workers' Compensation Program, pages 11, 12)

RAND also outlines that ODG classifies several opioid drugs as preferred drugs without appropriate evidence-based medical support: "ODG treats several opioids, including acetaminophen-hydrocodone bitartrate and tramadol hydrochloride as preferred therapies, while ACOEM does not." (RAND Report: Implementing a Drug Formulary for California's Workers' Compensation Program, page 51)

The California MTUS formulary, based on ReedGroup's ACOEM-based formulary is more appropriate for injured workers. Drug recommendations directly link to the treatment guidelines and the evidence: "ACOEM creates a more direct link between the treatment guidelines and recommendations by making condition-specific recommendations. This

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reinforces the treatment guidelines for the prescribing physician and reduces the likelihood that medically inappropriate drugs are dispensed...” (RAND Report: Implementing a Drug Formulary for California’s Workers’ Compensation Program, page 54)

5. ODG Sales, Marketing and Lobbyist Wish: California should consider “wholesale change” (guidelines and formulary) to ODG.

FACT: The idea of a wholesale change to ODG in California would be a significant step back for the improvement of care of injured workers in two major areas:

- At present the ACOEM Practice Guidelines make up the overwhelming majority of the MTUS guidelines. The ACOEM Practice Guidelines meet the high criteria set forth by the National Academy of Medicine, GRADE, AGREE and AMSTAR. Moving to guidelines that do not meet these high standards would expose California residents to unnecessary risk.
- Making wholesale changes would create the tremendous burden of increased cost due to the transition from one standard of care to another.

Conclusion

ReedGroup agrees with the State of California’s decision and the Department of Industrial Relations statement that this decision will “provide the best evidence-based care for injured workers while reducing delays in their treatment and administrative burden.” (News Release No.: 2016-82, Aug. 26, 2016)

Additionally, we concur with the California Workers’ Compensation Institute’s assessment of the state’s decision: “Based on the preliminary analysis summarized in this report, the proposed formulary represents a significant step forward in achieving the legislative intent of AB 1124.” AB 1124 is the actual legislation calling for the creation of “an evidence-based drug formulary, with the maximum transparency possible, for use in the workers’ compensation system” (CWCI Report: California’s Proposed Workers’ Compensation Formulary: Part 1 – A Review of Preferred and Non-Preferred Drugs, page 11).

Alex Rossi, Chief Executive Office RMB
County of Los Angeles

September 14, 2016

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The County of Los Angeles Workers' Compensation Program (Program) applauds the Division of Workers' Compensation's 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.

After review, it appears the regulations do not address the dispensing of drugs with unique dosages or formulations. The RAND (August 2016) research found such products "have unit costs that are much higher than those for the commonly prescribed strengths of the same drug ingredient and appear to be prescribed for financial, rather than medical, reasons." These findings are consistent with reports from the WCRI and CWCI. County Program staff believes the following addition to CCR 9792.27.7 will allow workers' compensation stakeholders to ensure medications are dispensed for medical, rather than financial, reasons.

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

(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 document the medical necessity for prescribing the brand drug in the patient's medical chart and in the Doctor's First Report of Injury (Form 5021) or Progress Report (PR-2.) The documentation must include the patient-specific factors that support the physician's determination that the brand drug is medically necessary. The physician must obtain authorization through prospective review prior to the time the brand drug is dispensed. If required authorization through prospective review is not obtained prior to dispensing the brand drug, retrospective review may be conducted to determine if it was medically necessary to use the brand drug rather than the generic therapeutic equivalent. If it is determined that the generic drug but not the brand drug is medically necessary, payment for the drug may be made at the fee schedule price for the lowest priced generic therapeutic equivalent of the brand drug.

(b) If a physician prescribes 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.

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Samuel I. Miles, MD, Ph.D.

September 13, 2016

The proposed implementation of a drug formulary as published on the web is fatally flawed. It must be modified before it can be implemented.

Other than analgesics, no psychotropic agent is listed as being “preferred.” This is puzzling, since the MTUS Guidelines for chronic pain include recommendations for antidepressants, anticonvulsants, and other psychotropic agents. Treatment Guidelines for PTSD include recommendations for various agents including SSRI’s, prazosin, SNRI’s, and topiramate.

Failure to include some psychotropic agents in the “preferred” category is contrary to statutory authority. It will harm injured workers, and only benefit Utilization Review Organizations.

Don Balzano, Chief Legal Counsel
MEDEX

September 13, 2016

On behalf of Medex Healthcare, Inc., I am providing comments to DWC’s Forum on the proposed drug formulary, MTUS formulary and the Chapter Updates that you are considering for adoption. We are concerned about implementation of a state-specific Formulary, purportedly based on MTUS, but inconsistent with component chapters in many areas, and far more restrictive than national, evidence-based guidelines such those in the Work Loss Data Institutes’ Official Disability Guidelines (ODG), proven effective in so many other states. Implementation of a state-specific PDF Formulary without linkage to guidelines and medical coding would be an operationally and administratively problematic, without automation, integration, and query tools for use online and in third party systems.

We appreciate that DWC is under a tight timeline to adopt an evidence-based drug formulary, consistent with MTUS, to augment the provision of high quality medical care, maximize health, and promote return-to-work in a timely fashion, while reducing administrative burden and cost. We understand that DWC has determined this is also an opportune time to update MTUS clinical topics, which are really outdated. We respectfully request that DWC consider a system-wide adoption of the ODG guidelines and formulary.

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The use of a comprehensive, evidence-based, easy to use, fully operationalized, updated monthly guidelines is so important to providers our workers' compensation system. ODG has proven tremendously successful, improving RTW outcomes, increasing access to quality care, and decreasing costs. Developing a state-specific Formulary and mixing pieces from different guidelines has not been successful in other states and presents major implementation challenges, which will further add to the IMR backlog, frustrating doctors and delaying the delivery of evidence-based care. Operationally, we need guidelines and formulary that are fully integrated and deliverable both online, and via an Application Programming Interface.

We believe full adoption of ODG is necessary as it has outperformed its peers in both the Rand Formulary study commissioned by DWC, and the 2004 Rand guideline study.

For example, the proposed draft looks at updating ACOEM, new for Reed Group, untested, and is neither ACOEM nor ODG. It is our understanding that the states that have adopted ODG have seen the number of N-drug (Non-Formulary) prescriptions fall by 85%. These are the top 10 for most-prescribed medications.

Other "like California" states, such as Texas, have seen Opioid costs decreased from 27% of the total pharmacy costs in 2009 to 18% in 2015. The number of claims receiving N-drug opioids with 90 morphine milligram equivalent doses per day decreased from almost 15,000 in 2009 to less than 500 in 2015. The total opioid prescription costs for N-drugs and those on the recommended list dropped from \$43.2 million in 2009 to \$18.5 million last year.

The proposed Formulary drug list is not evidence based, meaning the authors did not perform literature searches for each medication, review and weight the studies, and source them to the Proposed Formulary. The Proposed Formulary is highly restrictive, likely increasing RFA, UR and IMR, while delaying access to multiple appropriate medications.

The proposed Formulary is unproven, untested, and not operationalized, integrated or automated by any PBM's, Insurers, TPA's, Employers, Medical Service Providers, software systems or Stakeholders to date. It would take PBMs and Stakeholders considerable time, resources and money to operationalize the Proposed Formulary Drug List and updates. It would be difficult to meet an implementation date of July 1, 2017 with time for appropriate development and testing of protocols and systems. All that would need to be done is to simply "flip on the switch" with a California specific process minimizing implementation and update time, resources and cost. Other ODG state adoptions include TX, TN, NM, OK, AZ. There are zero states, to our knowledge, that have adopted ACOEM as their formulary guideline.

Most importantly, the proposed Formulary is not tied to NDC codes which are required for processing prescriptions. This is highly problematic for processing and pricing prescriptions at the time of patient encounters and attempted fills; impedes communications and processing between Pharmacies and PBM's; and impedes review of appropriateness of prescriptions.

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Specifically, the lack of one state standard NDC coding for Formulary drugs could, among other things, result in a wide range of interpretation and inconsistencies among the PBMs and stakeholders as to what is actually a preferred or non-preferred medication; increase inconsistencies in reviews and denied authorizations across the system; and increase disputes with UR & IMR; increase processes and uncompensated expenses to Pharmacies and PBMs; extend delays in fills with inconveniences for injured workers; and impede bill review. The ODG Formulary NDC database contains over 33,000 lines of drug specific data tied to the supporting Guidelines, is integrated into PBM and Stakeholder systems, and is already in use nationally.

For these reasons, we respectfully request that you revise the proposed Formulary regulations to provide for the full adoption of the Official Disability Guidelines (ODG) that is a highly-regarded and a well-known tool used among the workers' compensation community; updated monthly and as needed; much less restrictive when compared to Reed Group in authorized opioids; and is current in its technology and compatibility.

Jake Kelly, Workers' Compensation Program Manager
Electric Insurance Company

September 13, 2016

The approach in Texas has been very effective. Why try to modify the basis for the model that is working so well? Please keep special interests out of the formulary design.

Nathan Miller, MD

September 13, 2016

I am a Pain Medicine Physician in the State of California. I have been recently made aware of the proposal in front of the DWC to adopt the language from ACOEM which would remove FBSS as an indication for Spinal Cord Stimulation (SCS) therapy.

Please be aware that injured workers are a difficult group of patients to treat due to a variety of reasons. For this population SCS therapy is one of the few effective modalities to treat these patients. A recent review by Dr. Grider* in Pain Physician listed the evidence in favor of SCS therapy as Level I and Level II. As you are aware Level I evidence is the strongest proof of effectiveness for FBSS.

I urge you to continue to observing FBSS as an indication for this treatment.

*Grider, J et al, Pain Physician: January 2016; 19: E33-E54.

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Gregory M. Gilbert
SVP Reimbursement and Governmental Relations
Concentra

September 13, 2016

Please let this letter serve as our official written comments as it relates to the proposed regulation on the Medical Treatment Utilization Schedule (MTUS) Preferred Drug List.

Concentra's medical leadership team has reviewed the draft Medical Treatment Utilization Schedule (MTUS) Preferred Drug List that was released by the California Division of Workers' Compensation (DWC) in late August 2016.

We commend the DWC for creating the MTUS Preferred Drug List and for taking strides towards smarter medication utilization practices in the California workers' compensation environment.

We appreciate the opportunity to provide feedback on the current draft of this list and hope that our recommendations will be considered in concert with our background and expertise as the largest primary care occupational medical provider in the country.

Below are our suggestions and recommendations relating to the current draft of the MTUS Preferred Drug List:

Recommend an increase from a 7-day supply to a 10-day supply without Prospective Review for physician dispensed "Preferred" drugs. Recommend an increase from a 4-day supply to a 7-day supply without Prospective Review for physician dispensed "first-fill non-preferred" drugs.

- These recommendations are based on Concentra's experience treating over 480,000 initial injuries every year and the associated time it often takes for the carrier or employer to accept the compensable injury.
- CDC opioid recommendations for use of opiates in the acute setting has been considered in this recommendation¹
- There is concern a patient, on both first fills and preferred, will need to return sooner than warranted for the physician recheck, thus driving up costs with additional physician visits and time away from the job site for the employee. WCRI data shows that patients who feel their employer/payer care about them get better faster. When injured workers perceive the system as adversarial, and have to deal with delays in getting what they need as part of their treatment plan (e.g. prescription meds), it results in ill will, anger, and increased attorney involvement. All of these serve to increase the duration and cost of care.

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As it relates to the actual list of preferred and non-preferred drugs. We have serious concerns with the unknown and unproven formulary approach. Given our multi state experience (39), we have seen success with the use of the ODG formulary and recommend the DWC take the advice given in the RAND study to use ODG.

The recent CWCI study reports that 78% of prescription drug payments in California will require preauthorization under the MTUS Formulary. Obviously there is concern related to delaying access to care on three of every four medications prescribed, which goes too far. ODG has twice as many preferred drugs, which we know have proven safe and effective when coupled with ODG guidelines, and thus do not need pre-authorization. Given the recent move to reduce pre authorization burdens by the DWC, it is odd that with the formulary a different approach is being taken without a solid reasoning behind it. Ultimately, this high burden of preauthorization will result in additional access burdens for injured workers in California

Regardless of approach, we strongly recommend the drugs below need to be listed as preferred drugs.

Recommended additions to the draft MTUS Preferred Drug List:

- ***Cyclobenzaprine:***
 - Recommended based on high prevalence of muscle related injuries in workers' compensation, lack of adequate muscle relaxant class coverage on current MTUS preferred list, cost-effectiveness, and long term physician experience with this medication.

- ***Cephalexin:***
 - Recommended based on Infectious Disease treatment guidelines for skin/soft tissue infections².
 - Also, recommended because of better patient tolerability compared to other antibiotics and cost-effectiveness.

- ***Silver-Sulfadiazine:***
 - Recommended based on its usefulness for painful second degree burns thus allowing less necessity for use of oral pain medications.

- ***Diphenhydramine:***
 - Recommended due to its effectiveness to relieve itching caused by contact dermatitis.

- ***Prednisone and/or Methylprednisolone:***
 - Recommended due to its effectiveness to relieve inflammation caused by contact dermatitis.

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- **Amitriptyline:**
 - Recommended based on long term physician experience with this medication, cost effectiveness, and its usefulness in patients with long term pain, especially those who are experiencing insomnia due to inadequate pain coverage at night.

References:

- 1) CDC Opioid Recommendations; https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf
- 2) Stevens DL, Bisno AL, Chambers HF, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America. Clin Infect Dis 2014; CID 1-43.

Jacob Lazarovic, MD, FAAFP
SVP/Chief Medical Officer
Medical Department
Broadspire

September 12, 2016

I would respectfully request that you consider the ODG as a comprehensive solution for clinical guidelines as well as the drug formulary. Of the various state and national guidelines available, I find that ODG, while not perfect, is the best available option. It is user-friendly, well-referenced, regularly updated with current evidence-based information, and can be integrated with our proprietary systems.

Alvaro Liceaga, MD
Regional Pain Treatment Medical Center

September 11, 2016

Spinal Cord Stimulation should remain as is currently practiced in CA.

DWCs flawed proposal is to update several chapters of MTUS guidelines by adopting Guidelines produced by the flawed American College of Occupational and Environmental Medicine (ACOEM) Guidelines. Page 585 of the Low Back Disorders Chapter states: “spinal cord stimulators are not recommended for the treatment of acute, subacute, chronic low back pain, radicular pain

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syndromes, or failed back surgery syndrome”. It is critically important that the DWC support maintaining SCS as a treatment option for injured workers.

Spinal Cord Stimulation is an intervention for chronic back and/or extremity pain. Spinal cord stimulation can be an effective alternative or adjunct treatment to other interventions that have failed to manage pain on their own. Spinal cord stimulation alleviates pain by electrically activating pain-inhibiting neuronal circuits in the dorsal horn and inducing a tingling sensation (paresthesia) that masks the sensations of pain.

SCS is an accepted therapy for FBSS symptoms. There is a long history of consistent results reported from open label studies and randomized controlled trials reflecting the efficacy of SCS for treating the painful symptoms of FBSS. SCS for FBSS is supported by randomized controlled trials (RCTs) 1,2 and several large post market SCS retrospectives reporting positive outcomes for over 1,000 patients. Organizations like the American Pain Society, the Food & Drug Administration, and the American Society of Interventional Pain Physicians all support SCS as a treatment option for FBSS. SCS is covered by Medicare, Workers’ Compensation plans in 49 states and most Commercial Health Insurers.

Most patients experience Good to Excellent results with SCS Implants. It would be a great loss to the working citizens of California to remove a valuable treatment modality.

The DWCs flawed proposal is not in keeping with the spirit of CA Workers’ Compensation Legislation that now favors denial of care to the citizens of California.

Spinal Cord Stimulation should remain as is currently practiced in CA and as is covered by Medicare, Workers’ Compensation plans throughout the United States and most Commercial Health Insurers.

Edgar Celis, MD

September 11, 2016

I am writing to voice my support for SCS as a valid therapy for injured workers with failed back surgery and persistent radiculopathy, I have helped many patients with this treatment and not covering this will limit significantly the options for many injured workers. This measure would push them to use more Opioids as last resource with all the significant deleterious effects this therapy has. There is a great body of evidence that clearly shows that SCS is a good therapy for this type of patients. It is approved by Medicare and the FDA and is paid by W Comp insurance in 49 states. Please do what is right for the injured workers not what is right for the insurance companies bottom line.

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2. North RB, Kidd DH, Farrokhi F, Piantadosi SA. Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain; a randomized, controlled trial. *Neurosurgery*. 2005;56:98-107.
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Standiford Helm, II, MD

September 9, 2016

I am writing to oppose the use of the ACOEM guidelines to determine the appropriateness of care provided to injured workers in California. The ACOEM Guidelines are flawed documents that do not adequately assess the literature.

I will provide two examples, spinal cord stimulation and percutaneous adhesiolysis.

Regarding spinal cord stimulation, ACOEM states that spinal cord stimulators are not recommended for treatment of failed back surgery syndrome. The guidelines state that there is no high-quality evidence supporting the use of spinal cord stimulation. The authors do not appear to be aware of Kapural's high-quality randomized controlled trial of 10 kHz high-frequency stimulation for intractable back and leg pain, which showed superiority of this therapy over conventional spinal cord stimulation.(1)

Percutaneous adhesiolysis is given the recommendation of no recommendation for insufficient evidence. The rationale is that there are no sham controlled studies. Again, the authors are unaware of Gerdesmeyer's high-quality 2012 study, in which he compared adhesiolysis to a sham procedure, with a catheter buried in the subcutaneous tissues.(2) This study showed efficacy.

Adhesiolysis is also criticized for having serious complications. The list of serious complications provided shows a lack of familiarity with interventional procedures and confuses complications associated with procedures other than adhesiolysis. The first complication is dural puncture, which is a complication of any epidural procedure, including labor epidurals. Spinal cord compression is the second complication listed. In that the procedure is done most commonly below the cauda equina, the cord itself cannot be compressed. Further, there have been no reports of hematoma after adhesiolysis.(3) The third purported serious complication, infection, is a complication of any procedure which violates the skin. The fourth complication, catheter shearing, does not occur if RK needles are not used. The final complications, cardiac dysrhythmias, myelopathy, paralysis and blindness can be associated with epiduroscopy, but not with percutaneous adhesiolysis. The final criticism is that the procedure is costly. It is in fact marginally more expensive than an epidural.

In 2004, I wrote a review of the ACOEM Guidelines.(4) The Guidelines were wanting at that time. The current edition is an improvement in form, but not in content. They do not warrant application for injured workers in California.

A better solution would be to adopt the Official Disability Guidelines.

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Daniel Madeiros, Operations Manager – Network Dispensing
St Mary's Managed Pharmacy Programs

August 30, 2016

On the proposed formulary there does not appear to be a “preferred: Musculoskeletal Therapy Agent. Will there be one added?

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