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9792.27.1	Definitions section, suggested edits: (v) **Prescription Drug** –def. contains a potential loophole, in that some private label topical drugs are labeled with the words in the current def., but are not FDA approved Rx drugs. **Recommended Update:** "Prescription drug means any drug that has an approved NDA(new drug application) or ANDA(abbreviated new drug application) application with the FDA and labeling which specifies 'caution federal law prohibits dispensing without prescription' or 'rx only'." (l) **Generic Drug** –def. could be more specific. Suggests updating to insert the word "prescription" to clarify that it is not-intended to apply to over-the-counter drugs.	Sandy Shtab, AVP, Advocacy & Compliance **Healthesystems** -Written Comment, 9/19/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.
9792.27.2	Typographical error correction: (a): "there is an errant '7' immediately preceding 'presumption' that was not in the prior draft" – recommend removing it.	Denise Niber, Claims & Medical Director, California Workers' Compensation Institute (**CWCI**) -Written Comment, 9/21/2017	Agree.	Typographical correction will be made.
9792.27.3	MTUS Drug Formulary Transition: "We support the change to substitute the word 'safe' for the phrase 'medically appropriate'." It will help implement proven weaning protocols and give latitude to physicians for customizing weaning programs to the patients' needs	Brian Allen, VP Government Affairs, **Mitchell** --Written Comment, 9/22/2017	DWC notes the commenter's support.	No action necessary.
9793.27.3	**Issue #1**: (b)(2)(A) "We urge that the	Diane Worley,	Issue #1: Disagree. Medically	No action necessary.

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	word '**safe**' remains" , as removal to replace by 'medically necessary' omits the basic premise that "a previously prescribed drug, whether or not in the MTUS Drug Formulary List, is by definition 'medically appropriate' as it was previously recommend by the treating physician and authorized by the carrier." **Issue #2**: (b)(2)(A) "We urge that the CDC Guidelines for Tapering Opioids for Chronic Pain as set forth, be referenced in Section to best serve medical practitioners in meeting the standard of care in safely treating their patients." The rationale for the request involves a discrepancy in the recommended rate of tapering of opioids between the CDC and the ACOEM guidelines. Requester believes that the faster rate of tapering in ACOEM "may cause significant harm to many workers" The following **new language is proposed**: (b)(2)(A)"Include a treatment plan setting forth a safe medically appropriate weaning , tapering or transitioning of the worker to a drug pursuant to the MTUS in the timeframe recommended by the CDC Guidelines for Tapering Opioids for Chronic Pain https://www.cdc.gov/drugoverdose/pdf/clinical_pocket_guide_tapering-a.pdf, or " … **Issue #3:** Re-instates the previous request	Director of Policy Implementation, California Applicants' Attorneys Association (**CAAA**) --Written Comment, 9/22/2017	appropriate denotes a service which is necessary and consistent with accepted standards for the patient's condition or care that is expected to yield health benefits that exceed risk. A previously prescribed drug may be, or may not be appropriate at some point after it has been prescribed. In addition, the term "medically appropriate" is preferable; the term "safe" is too narrow as it only encompasses one aspect of a treatment plan. Issue #2: The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period. Issue #3: The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary. No action necessary.

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	presented during the 1st 15-day-comment period to replace section 9792.27.3 (b)(4) with modified language to match the 'continuity of care requirements for chronic and serious conditions' in LC4616.2(d)(3)(B) to serve as an established model for a safe transition period to formulary drugs. **Recommends following statutory language**: "Previously approved drug treatment shall not be terminated or denied for a period of time necessary to complete a course of treatment and to arrange for a safe tapering and weaning plan as recommended by the treating physician. Drug treatment approved before implementation of the MTUS drug formulary may not be terminated based on the MTUS or in accordance with applicable utilization review and independent medical review regulations until a safe tapering and weaning treatment plan has been in effect for 12 months."			
9792.27.8	Physician Dispensed Drugs: "We support this change as it better reflects the current contracting practice in the marketplace"	Brian Allen, VP Government Affairs, **Mitchell** --Written Comment, 9/22/2017	DWC notes the commenter's support.	No action necessary.
9792.27.8	Suggestion that 'regardless of the MPN contractual requirement, physicians be afforded the ability to dispense meds for the first 10 working days following the initial presentation to the occupational industry clinic. And the ability to continue	Frank Huljev, Clinic Administrator, **Palm Medical Group Inc**. -Written Comment, 9/21/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.

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	to dispense medication if a claim has not yet been filed." The stated rationale for this request: • Existing gap between occurrence of new work injury and the time it takes the employer to report the claim • Physicians are the first-responders to the injury and should have the ability to afford the patient medication in a timely manner • The physician is not allowed to file a claim on behalf of the worker, and some carriers do not allow workers to file their own; so the physician encounter might be pending the employer's claim assignment • Requested dispense ability needed to reduce pain/suffering as well as further risks to the patient (like infection)			
9792.27.8	Physician Dispensed Drugs (b)-(d)--Proposed regulation is not 'necessary' (as defined by APA) to bring into effect the authorizing statute. "CA workers suffering from industrial injuries will be deprived of essential medical if physicians can prescribe 7-day supplies of medication only if the injured worker's initial visit occurs within 7-days of the underlying injury. Because injured workers first typically see their employer's physician immediately after injury, they rarely have an opportunity to	Dario J. Frommer, **Akin Gump**-Strauss-Hauer & Feld, LLP (in representation of **Blue Oak Medical Group)** --Written Comment, 9/22/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.

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	visit a physician of their choice within 7 – days of their injury." **Suggested revision to regulation:** (d) "Modify provision to allow physician dispensation of drugs notwithstanding any prohibition in any applicable pharmacy ~~benefit contract where such dispensation is medically necessary.~~ in the following circumstances: (1)pharmacy network does not carry the medically necessary medication; (2)the carrier or other payor has failed to provide the injured worker with medically necessary medications; or (3)emergency situations." ** If the AD declines to remedy the proposed regulations, the statement must offer supporting rationale for the limitation imposed.			
9792.27.8 9792.27.9	"The institute finds the revisions concerning physician dispensing of particular benefit. These changes provide much needed-clarification, averting unnecessary disputes and friction costs."	Denise Niber, Claims & Medical Director, California Workers' Compensation Institute (**CWCI**) -Written Comment, 9/21/2017	DWC notes the commenter's support.	No action necessary.
9792.27.9	"Prohibiting physicians from dispensing compound medications is not 'necessary' [as defined in APA]" – There is no legislative authorization to support this prohibition, and the section allow for "pharmacy benefit corporations to supplant physician expertise and make critical judgements about patient care." Suggested Revisions to the proposal:	Dario J. Frommer, **Akin Gump**-Strauss-Hauer & Feld, LLP (in representation of **Blue Oak Medical Group)** --Written Comment, 9/22/2017	Disagree. The regulation is necessary for consistency with the provisions of Labor Code §4600.2 which states in pertinent part: "…if a self-insured employer, group of self-insured employers, insurer of an employer, or group of insurers contracts with a pharmacy, group of pharmacies,	No action necessary.

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	c.) Modify provision to allow physician dispensation of compounded drugs notwithstanding any prohibition in any applicable pharmacy ~~benefit contract where such dispensation is medically necessary.~~ in the following circumstances: (1)pharmacy network does not carry the medically necessary compound drug; or (2)the carrier or other payor has failed to provide the injured worker with medically necessary compound drugs." ** If the AD declines to remedy the proposed regulations, the statement must offer supporting rationale for the limitation imposed.		or pharmacy benefit network to provide medicines and medical supplies required by this article to be provided to injured employees, those injured employees that are subject to the contract shall be provided medicines and medical supplies in the manner prescribed in the contract for as long as medicines or medical supplies are reasonably required to cure or relieve the injured employee from the effects of the injury."	
9792.27.9	Compounded Drugs: "We support the inclusion of the new paragraph (c.). The new language clarifies the rule around the dispensing of compounded medications."	Brian Allen, VP Government Affairs, **Mitchell** --Written Comment, 9/22/2017	DWC notes the commenter's support.	No action necessary.
9792.27.9 and 9792.27.10 (b)	9792.27.9 (a),(c) "We are pleased to see additional clarifying language surrounding both authorization of compounded drugs containing 'exempt' ingredients **and** the ability of pharmacy benefit contracts to prohibit physician dispensing of compounded drugs"	Kevin Tribout, Exec. Director of Government Affairs, **OPTUM** Workers' Comp and Auto No-Fault Div. -Written Comment, 9/21/2017	DWC notes the commenter's support.	No action necessary.
9792.27.9 9792.27.10	"The institute finds the revisions concerning compounded drugs of particular benefit. These changes provide much needed-clarification, averting unnecessary disputes and friction costs."	Denise Niber, Claims & Medical Director, California Workers' Compensation Institute (**CWCI**) -Written Comment,	DWC notes the commenter's support.	No action necessary.

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9792.27.10	Compounded Drugs- MTUS Drug List: "We support the additional new language strengthening the intent of this section requiring all compounds , regardless of their ingredient composition, to undergo a pre-authorization process"	Brian Allen, VP Government Affairs, **Mitchell** --Written Comment, 9/22/2017	DWC notes the commenter's support.	No action necessary.
9792.27.10	(b)(3) "We are in support of the additional working contained in section, that clarifies that all compounded drugs are subject to the compounded drug regulation, irrespective of whether one or more of the ingredients in the compound are listed as exempt in the drug list."	Joseph Paduda, President, **CompPharma** --Written Comment, 9/22/2017	DWC notes the commenter's support.	No action necessary.
9792.27.15	Drug List: "The proposed drug list format/chart is unclear, subject to interpretation, and does not contain cross-references to particular diagnosis codes." Gives example of drug with several designations, but no ICD codes attached, thus subjective use**. Proposed solution:** "either delete the chart altogether, or modify to include specific diagnosis codes that can be mapped to the appropriate drugs on the exempt list and implemented in an automated fashion."	Lisa Anne Bickford, Director, Workers' Comp Government Relations, **Coventry** --Written Comment, 9/22/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.
9792.27.16	Blue Oak notes that it has **previously submitted public** comments to the DWC on August 2, 2017. Based on the statement and current proposed regulations, however, the AD has failed to provide rationale supporting revisions to the **National Drug Code regulations**.	Dario J. Frommer, Akin Gump-Strauss-Hauer & Feld, LLP (in representation of **Blue Oak Medical Group)** --Written Comment, 9/22/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.
9792.27.16	NDC, Unique Pharmaceutical Identifiers--	Brian Allen, VP	The comment does not address	No action necessary.

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	While in support of this section of the rule, offers the following suggestion: "**We recommend** the inclusion of the GPI/GSN number along with the NDC/RxCUI. The GPI/GSN provides information about a generic drug's therapeutic class that is lacking in an NDC number. The NDC number would be our second choice of identifier. Both GPI/GSN number and the NDC are widely used in the WC systems throughout the country. The RxCUI number is not commonly used in WC and would add another layer of programming complexity to an already programmatically complex rule."	Government Affairs, **Mitchell** --Written Comment, 9/22/2017	the substantive changes made to the proposed regulations during the 2nd 15-day comment period	
9792.27.16	"Use of the NDC is necessary to ensure clean implementation of the formulary" –strongly feel that the NDC should be included as the chose identifier, as it is "generally regarded as 'industry standard' drug identifier, most commonly used by stakeholders to pinpoint correct ID of specific drugs" …and "used in nearly every jurisdiction to cross-reference to AWP lists such as RedBook and MediSpan." States that failure to include NDCs will result in • confusion and inaccuracies throughout the system • increase administrative burdens to the state in the form of increased medical disputes (IBRs) • will have negative clinical implications for UR/IMR	Joseph Paduda, President, **CompPharma** --Written Comment, 9/22/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.

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	• will greatly impact ability of stakeholders to implement the formulary in the relative short time-frame of regulations			
9792.27.16	Recommendations for this section: "NDCs will assist with general clarification of the drug listings, including clarifying dosage forms; this will close the gap on variances in interpretation, and NDCs are well known and utilized by industry participants."	Kim Erlich, Workers' Compensation Compliance, **myMatrixx**, an **Express Scripts** Company -Written Comment, 9/22/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.
9792.27.16	"We urge the DWC to reconsider its approach to using the RxCUI or other pharmaceutical identifier" on grounds: • -investigated complexity as published by NIH • difficult to load/not readily available for commercial PBM system "NDC remains the most universally recognized standard of the identifiers proposed by the DWC. If a unique identifier were to be selected, we would support NDC over RxCUI."	Sandy Shtab, AVP, Advocacy & Compliance **Healthesystems** -Written Comment, 9/19/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.
9792.27.16	**Issue #1:** (d) "we support the proposed removal of irrelevant language concerning repackaged drugs and other less substantive modifications made" **Issue #2**: Concerns on the Issue of **NDC vs. RxCUI** and the AD's discretion for selection: "We continue to recommend that such an	Kevin Tribout, Exec. Director of Government Affairs, **OPTUM** Workers' Comp and Auto No-Fault Div. -Written Comment, 9/21/2017	Issue #1: DWC notes the commenter's support. Issue #2: The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	(1) No action necessary. (2) No action necessary.

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	identifier be mandatory to eliminate confusion and potential conflict between treating prescribers and claims administrators, and to eliminate potential loopholes that could be exploited for unjust enrichment."			
9792.27.16	NDC/Unique Pharmaceutical Identifiers: "The Unique Pharmaceutical Identifier should be the relatively more static GPI or GCN codes, cross-walked to NDC, to avoid clinical misinterpretations, costly and time consuming IT development efforts and to facility accurate reimbursements" –offers analysis to support this suggestion **GPI/GPN or NDC, would:** • facilitate cross-referencing the exempt drug list to nationally recognized and commonly used drug pricing lists (Redbook and MediSpan) • as well as assist in therapeutic determinations **Choosing RxCUI or Other Pharmaceutical identifier would:** • require costly and time-consuming information technology investment • implementation of the formulary would be greatly delayed **Proposed solution:** " Add a <u>mandated</u> published cross-walk, clearly identifying which specific drugs are exempt at the dispensing level, using GPI/GCN and/or cross-walking to the corresponding NDC"	Lisa Anne Bickford, Director, Workers' Comp Government Relations, **Coventry** --Written Comment, 9/22/2017	The comment does not address the substantive changes made to the proposed regulations during the 2nd 15-day comment period.	No action necessary.

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9792.27.1-9792.27.23	General Comment: "After review of the latest proposed modifications, we again offer our support of the proposal as currently drafted, with one minor recommendation for change [see 9792.27.16}"	Kevin Tribout, Exec. Director of Government Affairs, **OPTUM** Workers' Comp and Auto No-Fault Div. -Written Comment, 9/21/2017	DWC notes the commenter's support.	No action necessary.
9792.27.1-9792.27.23	"Overall, we are in support of the proposed changes, as many areas of previous concern have been addressed in the current version of the formulary"	Joseph Paduda, President, **CompPharma** --Written Comment, 9/22/2017	DWC notes the commenter's support.	No action necessary.