SUBCHAPTER F - PHARMACEUTICAL BENEFITS
28 TAC §§134.500, 134.506, 134.510, 134.520, 134.530, 134.540, and 134.550*****

1. INTRODUCTION. The Commissioner of Workers' Compensation (Commissioner), Texas Department of Insurance, Division of Workers' Compensation (Division) adopts amendments to §134.500 concerning Definitions, and §134.506, concerning Outpatient Open Formulary for Claims with Dates of Injury Prior to September 1, 2011. The Division also adopts the addition of five new sections to this subchapter: §§134.510, 134.520, 134.530, 134.540, and 134.550 of this title concerning Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011; Outpatient Closed Formulary for Dates of Injury On or After September 1, 2011; Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks; Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks; and Medical Interlocutory Order, respectively. These amendments and new sections are adopted with changes to the proposed text published in the July 16, 2010, issue of the *Texas Register* (35 TexReg 6239). In accordance with Government Code §2001.033, the Division's reasoned justification for these amended and new sections is set out in this order, which includes the preamble, which in turn includes the rules. The preamble contains a summary of the factual basis of the rules, a summary of comments received from interested parties, names of the entities that commented and whether they were in support of, or in opposition to, the adoption of the rules, and the reasons why the Division agrees or disagrees with the comments and recommendations.

The public comment period ended on August 16, 2010. The Commissioner conducted a public hearing on August 16, 2010.

2. REASONED JUSTIFICATION. These amendments and new sections are necessary to implement provisions of House Bill 7 (HB 7), enacted by the 79th Legislature, Regular Session, and effective September 1, 2005. HB 7 added requirements to the Labor Code concerning pharmaceutical services, which provided under amended §408.028(b) that:

> The commissioner by rule shall adopt a closed formulary under Section 413.011. Rules adopted by the commissioner shall allow an appeals process for claims in which a treating doctor determines and documents that a drug not included in the formulary is necessary to treat an injured employee's compensable injury.

To fulfill the legislative requirements of Labor Code §408.028 to adopt a pharmacy closed formulary, and to be consistent with the provisions contained in §134.550 of this title regarding Medical Interlocutory Order, the Division also adopts amendments to §133.306 of this title (relating to Interlocutory Order for Medical Benefits) which are adopted elsewhere in this issue of the *Texas Register*.

Additional HB 7 legislative objectives stated in Labor Code §413.0111 provide the rules adopted for reimbursement of prescription medication must authorize pharmacies to use agents or assignees to process claims and act on behalf of pharmacists.

HB 7 defined two new terms in the Labor Code that are pertinent to these adopted sections concerning a pharmacy closed formulary. Labor Code §401.011(18-

a) defines evidence-based medicine to mean the use of current best quality scientific and medical evidence formulated from credible scientific studies, including peer-reviewed medical literature and other current scientifically based texts, and treatment and practice guidelines in making decisions about the care of individual patients. Building on the definition of evidence-based medicine, HB 7 also clarified in Labor Code §401.011(22-a) that health care reasonably required means health care that is clinically appropriate and considered effective for the injured employee's injury and provided in accordance with best practices that are consistent with evidence-based medicine or if that evidence is not available, generally accepted standards of medical practice recognized in the medical community.

Applicability to Certified Networks

The Division's pharmacy closed formulary is also applicable to claims receiving care through certified workers' compensation health care networks (certified networks) pursuant to Insurance Code §1305.101(c). Both Insurance Code Chapter 1305 and the Labor Code §408.028(b) provision, requiring the Commissioner of Workers' Compensation (Commissioner) to adopt a pharmacy closed formulary, were enacted by HB 7 during the 79th legislative session.

Changes from Proposal

The Division has changed some of the proposed language in the text of the rules as adopted in response to public comments received, or for non-substantive clarification. The changes, however, do not materially alter issues raised in the proposal, introduce new subject matter, or affect persons other than those previously on notice.

Adopted §134.500(3)(C) of this title concerning Definitions, contains non-substantive clarification from proposal that deletes the terms "in accordance with," and replaces the terminology with "as defined by." Reference to Labor Code §413.014 was changed to §413.014(a) in the adopted language to clarify and specify the subsection. This change is made to acknowledge the Labor Code citation as the source for the definition of investigational or experimental when applied in the context of the closed formulary.

Adopted §134.500(13) contains two changes from proposal made as a result of public comments. The first change is a deletion of the phrase "and supporting evidence-based documentation" from the requirements of a statement of medical necessity. The Division notes the potentially burdensome nature of providing this information, especially by an injured employee, and also notes that §134.500(13)(F) satisfies the Division's expectation that the statement of medical necessity should thoroughly provide the documentation that supports the medical necessity for the drug. The second adopted change to the rule from proposal is to change the term, "includes" to "shall include" to clarify the mandatory nature of all elements of a statement of

medical necessity. The adopted change strengthens and clarifies the requirements for a complete statement of medical necessity.

Adopted §134.506 contains changes from proposal to the title of the rule from "Outpatient Open Drug Formulary for Claims with Dates of Injury Prior to January 1, 2011" to "Outpatient Open Formulary for Claims with Dates of Injury Prior to September 1, 2011." The word "Drug" is deleted from the title as proposed for consistency of terminology used in the remainder of these adopted rules and Labor Code §408.028(b) which uses the term "formulary" and not the term "drug formulary." The dates in the title and subsection (a) are changed to September 1, 2011 in response to public comment concerning a request for delayed implementation so that system participants may change policies; develop, test, and implement programming requirements; appropriately train and educate prescribing doctors, pharmacists, insurance carriers, and other affected entities; and to allow insurance carriers to implement and refine their utilization review processes. As a result of public comment, subsection (a) is also re-worded to clarify the intent of the amendments to continue the use of the open formulary, which implements changes to Labor Code §408.028 made by HB 2600 in 2001, until such time that all claims become subject to the pharmacy closed formulary. The amended language is as follows: "For claims with dates of injury prior to September 1, 2011 (for purposes of this section, referred to as 'legacy claims'), the open formulary as described in §134.500(9) of this title (relating to Definitions) remains in effect until those claims become subject to the closed formulary in accordance with §134.510 of this title

(relating to Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011)." Subsection (f) is changed from proposal, which a commenter stated provided broad language that could potentially circumvent certified network and non-network preauthorization requirements for investigational or experimental drugs. Adopted subsection (f) now clarifies that drugs included in the open formulary that do not require preauthorization and are prescribed and dispensed for legacy claims are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier. Without the clarification to subsections (a) and (f), there would be no guidance or direction, including utilization review requirements, provided to system participants for those claims with the latter phase-in date (legacy claims). Absent a clear continuation of the open formulary, there would be confusion as to medically appropriate prescription medications, treatment guidelines, preauthorization requirements, and retrospective review considerations.

Adopted §134.510 contains conforming, non-substantive changes from proposal to the title of the rule concerning the applicability date from January 1, 2011 to September 1, 2011. Similarly, and based on public comment, subsection (a) also contains conforming applicability date changes. Adopted subsection (a) applies to claims with dates of injury prior to September 1, 2011 (for purposes of this section, referred to as "legacy claims"). These claims are subject to §§134.530, 134.540, and 134.550 on and after September 1, 2013. Subsection (b)(1) of this adopted rule also contains a conforming date change that allows at any time after September 1, 2011 and

prior to September 1, 2013, the initiation of the steps towards transition of legacy claims. Based on public comment, changes from proposal to the adopted rule at subsections (b)(1)(C) and (b)(2)(B)(i) and (ii) are modified to allow and require equal exchange of information between the prescribing doctor and the insurance carrier. New subsection (b)(1)(C) states, "When a prescribing doctor or insurance carrier is contacted by the other party regarding ongoing pharmacological management, the parties must provide each other a name, phone number, and date and time to discuss ongoing pharmacological management of the injured employee's claim." Additionally, new subsection (b)(2) states, "Beginning no later than March 1, 2013, the insurance carrier shall: (A) identify all legacy claims that have been prescribed a drug excluded from the closed formulary after September 1, 2012; and (B) 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 closed formulary for legacy claims; and (ii) the information required in subsection (b)(1)(C) of this section." As a result of public comments, the language in subsections (c) and (d) is changed from proposal to clarify that an agreement can be made between an insurance carrier and a prescribing doctor to ensure continuity of care during this transition of legacy claims. The specific reference to §134.600 of this title is not necessary, and is therefore removed because the statutory authority of Labor Code §413.014 allows for voluntary preauthorization. The adopted language now reads, "(c) Agreement. To ensure continuity of care, notwithstanding subsection (a) of this section, an insurance

carrier and a prescribing doctor may enter into an agreement regarding the application of the pharmacy closed formulary for individual legacy claims on a claim-by-claim basis." Adopted subsection (d)(3) now reads, "(3) Denial of a request for an agreement is not subject to dispute resolution." Lastly, subsection (d)(4) contains a conforming applicability date change to September 1, 2013.

Labor Code §408.028(b) requires the Commissioner to adopt a closed formulary and appeals process for drugs not included in the closed formulary. The rules adopted under Labor Code §408.028, including adopted §134.510, apply to certified networks pursuant to Insurance Code §1305.101(c). The transition provisions contained in adopted subsections (c) and (d) are intended to provide a tool of pharmacological management for use within certified networks or within the non-network system. These provisions allow and encourage a prescribing doctor and the insurance carrier to discuss the ongoing pharmacological management of legacy claims and develop appropriate transition agreements for injured employees. Under Labor Code §§402.0111, 402.00116, 402.00128 and 402.061, the Commissioner has the statutory authority to exercise executive, administrative and operational powers and duties including rulemaking and enforcement functions.

Adopted §134.520 contains conforming, non-substantive changes from proposal to the title of the rule from "Outpatient Closed Drug Formulary for Dates of Injury On or After January 1, 2011" to "Outpatient Closed Formulary for Dates of Injury On or After to September 1, 2011." The word "Drug" is deleted from the title as proposed for

consistency of terminology used in the remainder of these adopted rules and Labor Code §408.028(b) which uses the term "formulary" and not the term "drug formulary." The dates in the title and rule have changed to September 1, 2011 in response to public comments concerning delayed applicability.

Adopted §134.530 contains conforming applicability language change in subsection (a) to September 1, 2011. Adopted subsection (b) is changed from proposal to state that preauthorization for non-network claims subject to the Division's closed formulary is only required for those three instances as stated in the definition of a closed formulary as cited in §134.500(3). The proposed language only provided a reference to the definition and not the specific detail included in the adopted rule. This non-substantive clarification is included in the adopted rule because some public commenters seemed uncertain in understanding when preauthorization of a drug is necessary. A non-substantive clarification to proposed §134.530(b)(4) is made with a new subsection (c) that addresses and clarifies preauthorization of an intrathecal drug delivery system and its refills. An intrathecal drug delivery system and its refills require preauthorization in accordance with §134.600, and therefore the language, "prior to its initial use" is unnecessary and has been deleted from the adopted rule. The new subsection (c) addressing an intrathecal drug delivery system has necessitated the re-lettering of the remaining subsections of this section. Additionally, adopted subsection (f)(2) changes a proposal reference from subsection (b)(2) to reference adopted (b)(1)(C) as a result of changes made in subsection (b).

Adopted §134.540 contains conforming applicability language change in subsection (a) to September 1, 2011. Adopted subsection (b) is changed from proposal to state that preauthorization for certified network claims subject to the Division's closed formulary is only required for those three instances as stated in the definition of a closed formulary as defined in §134.500(3). This clarification is included in the adopted rule because some public commenters seemed uncertain in understanding when preauthorization of a drug is necessary. Because of public comment that recommended that intrathecal drug delivery system language for certified networks mirror provisions of non-network, the adopted language in proposed §134.540(b)(3) is changed to a new subsection (c) that addresses and clarifies preauthorization of an intrathecal drug delivery system. The new subsection (c)(2) reads, "(c)(2) Refills of an intrathecal drug delivery system with drugs excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever: (A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or (B) there is a change in prescribing doctor." The change makes the certified network intrathecal drug delivery system refill appeal "process" for drugs excluded from the closed formulary consistent with the appeal "process" applicable to non-network claims for similar intrathecal drug delivery system

refills. The closed formulary applies to certified networks and non-networks and includes an appeal process. The adopted language addresses and explains the appeal process for refills when the drug is excluded from the closed formulary. The new subsection (c) addressing intrathecal drug delivery system refills has necessitated the re-lettering of the remaining subsections of this section.

Also as a result of public comment, a new subsection (f) is added to address initial pharmaceutical coverage for claims subject to certified networks. The adopted language now reads, "(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 and are subject to retrospective review of medical necessity."

The initial pharmaceutical coverage provisions of Labor Code §413.0141 apply to both non-network and certified network claims since there is no conflict between Labor Code §413.0141 and Insurance Code Chapter 1305 and because reimbursement of pharmaceutical medication and services are governed by the Act and Division rules. Insurance Code §1305.101(c) states that: "(c) Notwithstanding any other provision of this chapter, prescription medication or services, as defined by Section 401.011(19)(E), Labor Code, may not be delivered through a workers' compensation health care

network. Prescription medication and services shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the commissioner of workers' compensation."

As a result of new subsection (f), new subsection (g) is also changed and now reads, "(g) Retrospective Review. Except as provided under subsection (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 of this title (relating to Insurance Carrier Audit of a Medical Bill), §133.240 of this title (relating to Medical Payments and Denials), the Insurance Code, Chapter 1305, applicable provisions of Chapters 10 and 19 of this title."

Adopted §134.550 contains a non-substantive clarification from proposal in subsection (a) to include a reference to Insurance Code §1305.004(a)(13) in addition to §134.500(7) in the definition of "medical emergency". This reference clarifies that the medical emergency definition used in §134.550 is the same standard for both certified network and non-network claims.

3. <u>HOW THE SECTIONS WILL FUNCTION.</u>

Adopted amendment of §134.500. The adopted amendments provide definitions of new terms to the subchapter: *brand name drug*, *certified workers' compensation health care network (certified network)*, *closed formulary*, *generically*

equivalent, *pharmaceutically equivalent*, *therapeutically equivalent*, *medical emergency,* and *substitution*.

The adopted amendments also clarify the definitions of *compounding*, *open formulary*, *statement of medical necessity*, *prescribing doctor,* and *prescription*.

Under adopted new §134.500(3), a *closed formulary* is defined as, "all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes: (A) drugs identified with a status of "N" in the current edition of the Official Disability *Guidelines Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; (B) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates, and (C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined by Labor Code §413.014(a)."

In summary, the pharmacy closed formulary includes all FDA-approved drugs except drugs with status "N" in the ODG Appendix A, compounds that include drugs with status "N" and investigational or experimental drugs **as defined by** Labor Code §413.014(a).

The "N" drug designation means that a drug is not included in the drug formulary and will require preauthorization. Investigational or experimental drugs are not yet broadly accepted as the prevailing standard of care, and would require preauthorization as well.

The added definitions and clarification of the existing definitions increase the ability of system participants to understand their responsibilities.

Adopted amendment of §134.506. The adopted amendments to subsection (a) clarify that for claims with dates of injury prior to September 1, 2011 (for the purposes of §134.506 referred to as "legacy claims"), the open formulary as defined in §134.500(9) remains in effect until those claims become subject to the closed formulary in accordance with §134.510. The Division currently has an open formulary that has been in effect since 2002. The continuation of the open formulary for legacy claims until September 1, 2013 is necessary in order to provide a successful transition to the pharmacy closed formulary. The transition provides an implementation "bridge" between the two systems because of the anticipated volume of preauthorization and the time needed for system participants to prepare for the inclusion of legacy claims.

Adopted new subsection (b) provides that the prescribing of drugs for claims not subject to a certified network shall be in accordance with the Division's adopted treatment guidelines. The treatment guidelines provide evidence-based direction for the appropriate use of treatments and services, including drugs, for claims not subject to a certified network. The treatment guidelines are the standards by which medical

necessity is evaluated, including retrospective review.

Under adopted new subsection (c), the prescribing of drugs for claims subject to a certified network under the open formulary shall be in accordance with the certified network's treatment guidelines pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title (relating to Workers' Compensation Health Care Networks).

Adopted new subsection (d) sets forth that drugs included in the open formulary prescribed and dispensed for claims not subject to a certified network with dates of injury prior to September 1, 2011 do not require preauthorization, except as required by Labor Code §413.014. With this new subsection, system participants are not required to pursue preauthorization in accordance with §134.600(p)(12), and as a result, subsection (f) will require the retrospective review of these services.

Under adopted new subsection (e), drugs included in the open formulary prescribed and dispensed for legacy claims subject to a certified network shall be preauthorized pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title.

Under adopted new subsection (f), drugs included in the open formulary that do not require preauthorization under adopted new subsections (d) and (e) and are prescribed and dispensed for legacy claims are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier.

Adopted new §134.510. Adopted new §134.510 concerns the transition from an open formulary to the pharmacy closed formulary for claims with dates of injury prior to September 1, 2011, which for purposes of this section, are referred to as "legacy

claims."

Adopted new subsection (a) addresses the applicability of the section and states that the section applies to claims with dates of injury prior to September 1, 2011, which are subject to §134.530 concerning Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks, §134.540 concerning Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks, and §134.550 concerning Medical Interlocutory Order on and after September 1, 2013.

Adopted new subsection (b) provides for transition of legacy claims. Paragraph (1) sets forth the transition activities that should occur for any time after September 1, 2011 and prior to September 1, 2013. Under subparagraph (A), a prescribing doctor should include a statement of medical necessity as defined in §134.500(13) with the prescription for drugs excluded from the closed formulary. Under subparagraph (B), the prescribing doctor or the insurance carrier may contact each other for a discussion of ongoing pharmacological management of the injured employee's claim. Under subparagraph (C), when a prescribing doctor or insurance carrier is contacted by the other party regarding ongoing pharmacological management, the parties must provide each other a name, phone number, and date and time to discuss ongoing pharmacological management of the injured employee's claim. Paragraph (2) sets forth what the insurance carrier shall do beginning no later than March 1, 2013, which are: to identify all legacy claims that have been prescribed a drug excluded from the closed formulary after September 1, 2012; and provide written notification to the injured

employee, prescribing doctor, and pharmacy if known, the notice of the impending date of the applicability of the closed formulary and the information required when a prescribing doctor or insurance carrier is contacted by the other party regarding ongoing pharmacological management.

Under adopted subsection (c), prior to the applicability date of the closed formulary, an insurance carrier and prescribing doctor may enter into an agreement regarding the application of the pharmacy closed formulary for individual legacy claims on a claim-by-claim basis.

Adopted subsection (d) addresses the agreement requirements. Under paragraph (1), the insurance carrier shall document any agreement and the terms, and share a copy of the agreement with the prescribing doctor and injured employee. Under paragraph (2), the health care provided as a result of the agreement is not subject to retrospective review of medical necessity. Under paragraph (3), the denial of a request for an agreement is not subject to dispute resolution. Under paragraph (4), if no agreement is reached and documented by September 1, 2013 for a legacy claim, the requirements of §§134.530, 134.540, and 134.550 are to apply.

Adopted new §134.520. The Commissioner adopts a pharmacy closed formulary under adopted new §134.520, as defined in §134.500(3) concerning Definitions, with dates of injury on and after September 1, 2011.

Adopted new §134.530. Adopted new §134.530 concerns the requirements for the use of the pharmacy closed formulary for claims not subject to certified networks.

Adopted new subsection (a) of the section addresses applicability and provides that the closed formulary will be applicable to all drugs that are prescribed and dispensed for outpatient use on or after September 1, 2011 when the date of injury occurred on or after September 1, 2011.

Adopted new subsection (b) addresses preauthorization requirements for non-network claims subject to the Division's closed formulary. Adopted paragraph (1) sets forth that preauthorization is only required for: (A) drugs identified with a state of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / *Appendix A, ODG Workers' Compensation Drug Formulary*, and any updates; (B) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / *Appendix A, ODG Workers' Compensation Drug Formulary*, and any updates; and (C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care **as defined by** Labor Code §413.014(a). Adopted paragraph (2) provides that when §134.600(p)(12) concerning Preauthorization, Concurrent Review, and Voluntary Certification of Health Care conflicts with this section, this section prevails.

Adopted new subsection (c) addresses preauthorization of intrathecal drug delivery systems. Under new paragraph (1), an intrathecal drug delivery system requires preauthorization in accordance with §134.600 and the preauthorization request

must include the prescribing doctor's drug regime plan of care, and the anticipated dosage or range of dosages for the administration of pain medication. Additionally, the subsection addresses preauthorization requirements for the refilling of previously preauthorized intrathecal drug delivery system with drugs excluded from the closed formulary. Under adopted paragraph (2), refills of an intrathecal drug delivery system excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever: (A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or (B) there is a change in prescribing doctor.

Adopted new subsection (d) addresses treatment guidelines, and provides that except as provided in this subsection, the prescribing of drugs shall be in accordance with the Division's treatment guidelines. Under adopted Paragraph (1), the drugs included in the Division's closed formulary and recommended by the Division's adopted treatment guidelines may be prescribed and dispensed without preauthorization. Under adopted paragraph (2), the prescription and nonprescription drugs included in the closed formulary that exceed or are not addressed by the Division's adopted treatment guidelines may be prescribed and dispensed without preauthorization. Under adopted paragraph (3), the drugs included in the closed formulary that are prescribed and

dispensed without preauthorization are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier in accordance with subsection (g). The treatment guidelines provide evidence-based direction for the appropriate use of treatments and services, including drugs, for claims not subject to a certified network. The treatment guidelines are the standards by which medical necessity is evaluated. Treatment provided within the treatment guidelines is presumed to be health care reasonably required. Additionally, treatment may not be denied solely on the basis that the treatment for the compensable injury in question is not specifically addressed by the treatment guidelines. Where the treatment guidelines and closed formulary differ is that drugs excluded from the closed formulary require preauthorization regardless of the recommendations included in the Division's treatment guidelines.

Adopted new subsection (e) explains the appeals process for drugs excluded from the closed formulary. Adopted paragraph (1) provides that when the prescribing doctor determines and documents that a drug excluded from the pharmacy closed formulary is necessary to treat an injured employee's compensable injury and has prescribed the drug, the prescribing doctor or other requestor (which may be the pharmacist or injured employee), may request the drug in a specific case by requesting preauthorization, including reconsideration under §134.600 and under the applicable provisions of Chapter 19. Adopted paragraph (2) states that if preauthorization is being requested by an injured employee or a requestor other than the prescribing doctor, the

prescribing doctor shall provide a statement of medical necessity as set forth in current §134.502 concerning Pharmaceutical Services. Under adopted paragraph (3), if preauthorization is denied for drugs excluded from the pharmacy closed formulary, the requestor may submit a request for medical dispute resolution in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations). Adopted paragraph (4), provides that in the event of an unreasonable risk of a medical emergency, an interlocutory order may be obtained in accordance with §133.306 concerning Interlocutory Orders for Medical Benefits or §134.550 concerning Medical Interlocutory Order. The distinction in the interlocutory orders is that under §134.550 a prescribing doctor or pharmacist may request a medical interlocutory order (MIO) for drugs excluded from the closed formulary when the drug was previously prescribed and dispensed and failure to fill the prescription may result in an unreasonable risk of a medical emergency for an injured employee. However, an injured employee or any other party may pursue an interlocutory order for medical benefits, as set forth in §133.306, for continued access to health care, including pharmaceutical services excluded from the closed formulary, when the injured employee would not be able to receive medical benefits that are medically necessary and constitute health care reasonably required.

Adopted new subsection (f) addresses initial pharmaceutical coverage. Under adopted paragraph (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, except as required by Labor Code §413.014, and are not subject to retrospective review of medical necessity. Under adopted paragraph (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 required by Labor Code §413.014, and are subject to retrospective review of medical necessity.

Adopted new subsection (g) addresses retrospective review, and states that except as provided in subsection (f)(1), drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 and §133.240 of this title (relating to Insurance Carrier Audit of a Medical Bill, and Medical Payments and Denials respectively), and applicable provisions of Chapter 19. Under adopted paragraph (1), health care provided in accordance with the Division's treatment guidelines is presumed reasonable as specified in Labor Code §413.017, and is also presumed to be health care reasonably required as defined by Labor Code §401.011(22-a). Under adopted paragraph (2), in order for an insurance carrier to deny payment subject to a retrospective review for pharmaceutical services that are recommended by the Division's treatment guidelines, the denial must be supported by documentation of evidence-based medicine that outweighs the presumption of reasonableness established under Labor Code §413.017. Adopted paragraph (3) provides that a prescribing doctor who prescribes pharmaceutical services that exceed, are not recommended, or are not addressed by the Division's treatment guidelines is

required to provide documentation upon request in accordance with §134.500(13) and §134.502(e) and (f).

Adopted new §134.540. Adopted new §134.540 concerns the requirements for the use of the pharmacy closed formulary for claims subject to certified networks.

Adopted new subsection (a) of the section addresses applicability and provides that the closed formulary will be applicable to all drugs that are prescribed and dispensed for outpatient use on or after September 1, 2011 when the date of injury occurred on or after September 1, 2011.

Adopted new subsection (b) addresses preauthorization requirements for certified network claims subject to the Division's closed formulary. Adopted subsection (b) sets forth that preauthorization is only required for: (1) drugs identified with a state of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) */ Appendix A, ODG Workers' Compensation Drug Formulary*, and any updates; (2) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) */ Appendix A, ODG Workers' Compensation Drug Formulary*, and any updates; and (3) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care **as defined by** Labor Code §413.014(a).

Adopted new subsection (c) addresses preauthorization of intrathecal drug delivery systems. Under new paragraph (1), an intrathecal drug delivery system

requires preauthorization in accordance with the certified network's treatment guidelines and preauthorization requirements pursuant to Insurance Code Chapter 1305 and Chapter 10. Under adopted paragraph (2), refills of an intrathecal drug delivery system excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever: (A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or (B) there is a change in prescribing doctor.

Adopted new subsection (d) addresses treatment guidelines, and provides that the prescribing of drugs shall be in accordance with the certified network's treatment guidelines and preauthorization requirements pursuant to Insurance Code Chapter 1305 and Chapter 10. Drugs included in the closed formulary that are prescribed and dispensed without preauthorization are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier in accordance with subsection (f).

Adopted new subsection (e) explains that the preauthorization process is the appeals process for drugs excluded from the closed formulary. Under adopted paragraph (1), for situations in which the prescribing doctor determines and documents that a drug excluded from the closed formulary is necessary to treat an injured

employee's compensable injury and has prescribed the drug, the prescribing doctor, other requestor, or injured employee may request approval of the drug in a specific instance by requesting preauthorization in accordance with the certified network's preauthorization process established pursuant to Chapter 10, Subchapter F and applicable provisions of Chapter 19. Adopted paragraph (2) states that if preauthorization is pursued by an injured employee or requestor other than the prescribing doctor, and the injured employee or other requestor requests a statement of medical necessity, the prescribing doctor shall provide a statement of medical necessity to facilitate the preauthorization submission as set forth in §134.502. Under adopted paragraph (3), if preauthorization for a drug excluded from the closed formulary is denied, the requestor may submit a request for medical dispute resolution in accordance with §133.308. Under adopted paragraph (4), in the event of an unreasonable risk of a medical emergency, an interlocutory order may be obtained in accordance with §133.306 or §134.550. The distinction in the interlocutory orders is that under §134.550 a prescribing doctor or pharmacist may request an MIO for drugs excluded from the closed formulary when the drug was previously prescribed and dispensed and failure to fill the prescription may result in an unreasonable risk of a medical emergency for an injured employee. However, an injured employee or any other party may pursue a traditional interlocutory order under §133.306 for continued access to health care, including pharmaceutical services excluded from the closed

formulary, when the injured employee would not be able to receive medical benefits that are medically necessary and constitute health care reasonably required.

Adopted new subsection (f) addresses initial pharmaceutical coverage. Under adopted paragraph (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. Under adopted paragraph (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 and are subject to retrospective review of medical necessity.

Adopted new subsection (g) describes retrospective review and indicates, except as provided in subsection (f)(1), drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 and §133.240, and the Insurance Code, Chapter 1305, applicable provisions of Chapter 10 and Chapter 19. Under adopted paragraph (1), in order for an insurance carrier to deny payment subject to a retrospective review for pharmaceutical services that fall within the treatment parameters of the certified network's treatment guidelines, the denial must be supported by documentation of evidence-based medicine that outweighs the evidence-basis of the certified network's treatment guidelines. Under adopted paragraph (2), upon request, a prescribing doctor who prescribes pharmaceutical services that exceed, are not recommended, or are not addressed by the treatment parameters of certified

network's treatment guidelines, is required to provide documentation in accordance with §134.500(13) and §134.502(e) and (f).

Adopted new §134.550. Adopted new §134.550 concerns a medical interlocutory order (MIO*)*.

Adopted new subsection (a) addresses the purpose of the new section, which is to provide a system by which a prescribing doctor or pharmacy is able to obtain an MIO in cases where preauthorization denials of a previously prescribed and dispensed drug(s) excluded from the pharmacy closed formulary poses an unreasonable risk of a medical emergency to an injured employee. The adopted subsection references the definition of a medical emergency in §134.500(7) and Insurance Code §1305.004(a)(13). The definition is used in combination with "unreasonable risk" to establish the need for an MIO.

Adopted new subsection (b) states that a request for an interlocutory order that does not meet the criteria described by this section may still be requested pursuant to §133.306 of this title (relating to Interlocutory Order for Medical Benefits). To fulfill the legislative requirements of Labor Code §408.028 to adopt a pharmacy closed formulary, the Division also adopts amendments to §133.306, which are addressed elsewhere in this adoption issue of the *Texas Register*.

Adopted new subsection (c) states that an MIO will be issued if the request for an MIO contains 12 specific pieces of information. The adopted new paragraphs (1) through (12) of subsection (c) list those specific information components as: the injured

employee name; the date of birth of injured employee; the prescribing doctor's name; the name of drug and dosage; the MIO requestor's name (pharmacy or prescribing doctor); the MIO requestor's contact information; a statement that a preauthorization request for a previously prescribed and dispensed drug(s), which is excluded from the closed formulary, has been denied by the insurance carrier; a statement that an independent review request has been submitted to the insurance carrier or the insurance carrier's utilization review agent in accordance with §133.308; a statement that the preauthorization denial poses an unreasonable risk of a medical emergency; a statement that the potential medical emergency has been documented in the preauthorization process; a statement that the insurance carrier has been notified that a request for an MIO is being submitted to the Division; and a signature with a certification by the MIO requestor stating, "I hereby certify under penalty of law that the previously listed conditions have been met."

Adopted new subsection (d) notes that a complete request for an MIO under this section shall be processed and approved by the Division in accordance with this section. At the discretion of the Division, an incomplete request for an MIO under this section may be considered in accordance with this section.

Adopted new subsection (e) provides that the request for an MIO may be submitted on the designated Division form available on the Division's website, http://www.tdi.state.tx.us/wc/indexwc.html. In the event the Division form is not available, the written request must contain the provisions of subsection (c).

Adopted new subsection (f) states the MIO requestor shall provide a copy of the MIO request to the insurance carrier, prescribing doctor, injured employee, and dispensing pharmacy, if known, on the date the request for MIO is submitted to the Division.

Adopted new subsection (g) indicates that an approved MIO shall be effective retroactively to the date the complete request for an MIO is received by the Division.

Adopted new subsection (h) provides further specifications for an MIO that is notwithstanding §133.308. Under adopted paragraph (1), a request for reconsideration of a preauthorization denial is not required prior to a request for independent review when pursuing an MIO under this section. If a request for reconsideration or an MIO request is not initiated within 15 days from the initial preauthorization denial, then the opportunity for an MIO under this section does not apply. Under adopted paragraph (2), if pursuing an MIO after denial of a reconsideration request, a complete MIO request shall be submitted within five working days of the reconsideration denial.

Adopted new subsection (i) states an appeal of an independent review organization (IRO) decision relating to the medical necessity and reasonableness of the drugs contained in the MIO shall be submitted in accordance with §133.308(t).

Adopted new subsection (j) provides that the MIO is to continue in effect until the later of (1) a final adjudication of a medical dispute regarding the medical necessity and reasonableness of the drug contained in the MIO, (2) the expiration of the period for a timely appeal, or (3) an agreement of the parties.

Adopted new subsection (k) states that withdrawal by the requestor of a request for medical necessity dispute resolution constitutes acceptance of the preauthorization denial.

Under adopted new subsection (l), a party shall comply with an MIO entered in accordance with this section and the insurance carrier shall reimburse the pharmacy for prescriptions dispensed in accordance with an MIO.

Under adopted new subsection (m), the insurance carrier shall notify the prescribing doctor, injured employee, and the dispensing pharmacy once reimbursement is no longer required in accordance with subsection (j).

Under adopted new subsection (n), payments made by insurance carriers pursuant to this section may be eligible for reimbursement from the Subsequent Injury Fund in accordance with Labor Code §410.209 and §413.055, and applicable rules.

Adopted new subsection (o) states that a decision issued by an IRO is not an agency or Commissioner decision.

Under adopted new subsection (p), a party may seek to reverse or modify an MIO issued under this section if (1) a final determination of medical necessity has been rendered; and (2) the party requests a benefit contested case hearing (CCH) from the Division's chief clerk no later than 20 days after the date the IRO decision is sent to the party. A benefit review conference is not a prerequisite to a Division CCH under this subsection. Except as provided by this subsection, a Division CCH shall be conducted in accordance with Chapters 140 and 142 concerning Dispute Resolution--General

Provisions, and Dispute Resolution--Benefit Contested Case Hearing.

Under adopted new subsection (q), the insurance carrier may dispute an interlocutory order entered under this title by filing a written request for a hearing in accordance with Labor Code §413.055 and §148.3 concerning Requesting a Hearing.

4. SUMMARY OF COMMENTS AND AGENCY'S RESPONSE TO COMMENTS.

The Division notes that in responding to public comments, the numbering of certain subsections may have changed from proposal. In order to avoid confusion concerning the written comments as received, the Division has maintained the commenter's numerical references to the proposed sections.

General: Commenters acknowledge and express appreciation for the Division's deliberative approach and close involvement with system participants while developing the closed formulary rules. Several of the commenters additionally recognize that the intensive stakeholder meetings and informal working draft rules processes have resulted in a vastly improved proposal product.

Agency Response: The Division appreciates the supportive comments.

General: A commenter requests that all stakeholders have continuous password access to the ODG link to the drugs identified in Appendix A.

Agency Response: The Division clarifies that information concerning how to obtain full access to *ODG Treatment in Workers' Comp* is currently available on the Division's

website. Additionally, the Division anticipates separately listing drugs with an "N" status on Appendix A on the Division's website as a convenience for system participants.

General: A commenter opines that the proposed rules provide no evidence that addresses a process or system of reviewing the ODG and evaluating on an ongoing basis to allow for refinements of inclusion/exclusion (formulary maintenance) that reflects the ever-changing new drug information, nor the intent to employ a drug review process to target and refine drug therapy that has become problematic regarding effectiveness, safety and/or cost.

Agency Response: The Division disagrees. As required by Labor Code §413.011(e), the Commissioner has adopted *ODG Treatment in Workers' Comp* as the Division's treatment guidelines. The Division's treatment guidelines are evidence-based and reviewed and updated by the Work Loss Data Institute (WLDI). The details of the review process for new evidence, which employs the Appraisal of Guidelines Research and Evaluation (AGREE) Instrument and the open invitation to submit new evidence regarding treatments and services, is available on the WLDI website. Labor Code §413.011(e) further states treatment may not be denied solely on the basis that treatment for the compensable injury in question is not specifically addressed by the treatment guidelines. Consequently, evidence that is not included in the treatment guidelines may be presented in a statement of medical necessity to substantiate the need for the use of a pharmaceutical that is not recommended or addressed by the

guidelines. The guidelines in ODG Appendix D also provide suggestions for documenting instances regarding the medical necessity of treatments and services that are not recommended, not included in, or exceed the recommendations of the treatment guidelines.

General: A commenter states that the proposed rules provide no evidence of the system's intent to employ any utilization management process, other than preauthorization, to address inappropriate prescribing and suggests much can be accomplished through simpler and easier processes, such as quantity of prescription limits and step therapy edits as an integral part of the formulary utilization management process.

Agency Response: The Division disagrees. Injured employees in the Texas workers' compensation system are entitled to all health care reasonably required that relieves or cures the compensable injury or facilitates an injured employee's return-to-work. Although preauthorization is a component of reviewing the medical necessity of specific services, other services not requiring preauthorization are subject to either concurrent or retrospective review. These medical necessity reviews are primarily based upon the recommendations included in either the Division's or a certified network's adopted treatment guidelines. Step therapy and quantity limits may be adequately addressed through the medical necessity reviews of the preauthorization and retrospective review processes.

General: A commenter states there is no evidence of what, if any, clinical, drug-specific, preauthorization criteria would be employed for each drug requiring preauthorization, and without specific criteria for approving or disapproving a preauthorization request for a specific drug, subjectivity and approval rates will be higher than necessary or appropriate.

Agency Response: The Division disagrees. The preauthorization process for drugs not included in the closed formulary is subject to the utilization review requirements as outlined in Chapters 10, 19, 134, and 137 of this title (relating to Workers' Compensation Health Care Networks, Utilization Review, Benefits--Guidelines for Medical Services, Charges and Payments, and Disability Management, respectively). Utilization review requires determinations to be made on a case-by-case basis; however, preauthorization determinations of all treatments and services, including pharmaceutical services, are required to consider recommendations included in either the Division's or a certified network's adopted treatment guidelines. Consequently, approvals will be appropriate and only for medically necessary services.

General: A commenter seeks further information regarding the proposal preamble's estimates of the increased costs to be incurred by insurers. The commenter states, "According to the Division, the costs of each prospective review will range from $60 to $120." If the costs of each prospective review will range from $60 to $120, then the question is whether $60 to $120 is a reasonable estimate of a cost of a prospective

review. When there is a denial of a claim, usually a physician is involved in the process. If a licensed medical provider is typically involved in the process of a denial, the projected cost would likely be somewhat significantly greater than $60 to $120.

Agency Response: The Division clarifies that the estimate provided in the proposal preamble is a range based on ongoing conversations and stakeholder meetings with insurance carrier representatives in Texas. This range is not intended to illustrate the actual cost of any particular utilization review activity. It is, however, an attempt to quantify a range of average costs as communicated to the Division throughout this and other rule development processes. Since each insurance carrier develops and implements its own review process within the structure required by Chapter 19 of this title, the actual costs for each insurance carrier varies and are best estimated by each insurance carrier. System participants have not provided more specific information to the Division regarding their cost structures for the Division to provide a more definitive estimate of the net impact of preauthorization costs.

General: A commenter states that overall the new closed formulary will complicate care for injured employees and many physicians who currently provide care for injured employees will decide to stop treating injured employees when they find that their prescriptions are not filled. This simply adds another "hassle" and the detrimental side effects of the requirements will outweigh any beneficial effects to the system.

Agency Response: The Division agrees in part. The Division agrees that there may be additional work for some health care providers in some circumstances. However,

the additional review will help to ensure the medical necessity of drugs prescribed to injured employees. The Division disagrees in part. The Commissioner's adoption of the closed formulary is required under Labor Code §408.028(b). Its adoption and use is consistent with the existing recommendations included in the Division's treatment guidelines. The Division's treatment guidelines have been in effect since May 1, 2007 and prescribing doctors may already be prescribing in a manner consistent with the adopted closed formulary. Further, the Division reconfirmed the applicability of the ODG Treatment Guideline pharmaceutical recommendations as found in the treatment summaries when the Division issued an August 29, 2008 memo titled "Use of Pharmaceuticals in the Texas Workers' Compensation System." Preauthorization of drugs excluded from the closed formulary assures that these drugs are medically necessary and increases surety of payment for the providers of pharmaceutical services. Additionally, these concepts extend to pharmaceutical services provided for claims subject to a certified network when the certified network's treatment guidelines are applicable.

General: A commenter seeks clarification on several jurisdictional issues, such as whether the closed formulary rules apply to an injured employee: (1) who is receiving pharmaceutical benefits from a retail pharmacy located out of state; (2) with a jurisdiction from another state, but receiving pharmaceutical benefits from a retail pharmacy located in the state of Texas; (3) with Texas jurisdiction, living in the state of

Texas but receiving medications from a mail order pharmacy located out of state; and (4) with Texas jurisdiction, living out of state, but receiving medications from a mail order pharmacy located in Texas.

Agency Response: The Division clarifies that these adopted rules apply to all drugs that are prescribed and dispensed for outpatient use for Texas workers' compensation injury claims and that without knowledge of all pertinent facts concerning conflict-of-law issues related to any particular medical bill processing, the Division cannot provide an advisory opinion to a disagreement on reimbursement that may be later presented in the dispute processes of the Division or other out of state dispute resolution forums. While the Division may not be able to resolve such out of state disputes due to the Division's potential lack of jurisdiction over out of state health care providers, the Division does clarify, however, that Texas workers' compensation injury claims generally are subject to Texas laws and rules. Additionally, the Department has the responsibility to regulate Texas insurance carriers and expects insurance carriers to work with out of state health care providers to ensure that Texas injured employees receive medically necessary health care services. Further, the Division clarifies that the insurance carrier should communicate with the jurisdiction responsible for the injured employee to provide direction regarding the processing of the claim.

For resource purposes only, the Division notes three Texas Supreme Court opinions that may be helpful to system participants in examining conflict-of law issues. In summary, those cases held that the basic rule is that a court need not enforce a

[worker's compensation] foreign law if enforcement would be contrary to Texas public policy; that the "most significant relationship" test applied by the court requires the court to consider which state's laws has the most significant relationship to the particular issue to be resolved and that the contacts with a state must be evaluated in light of the state's policies underlying the particular substantive issue. See *Larchmont Farms, Inc. v. Parra*, 941 S.W. 2d 93, 95 (Tex.1997), *Hughes Wood Products, Inc. v. Wagner*, 18 S.W.3d 202, 205(Tex. 2000) and *The Torrington Co. v. Stutzman*, 46 S.W.3d 829, 848 (Tex.2000) An additional resource is Lawson's Workers' Compensation Law, Volume 9, Conflict of Laws, a Matthew Bender & Company, Inc. publication. The Division further clarifies that the preceding information provided does not constitute legal advice or legal opinion and any system participant with a conflict-of law legal issue is encouraged to seek legal counsel of their choice.

General: A commenter recommends inserting the term, "or their agent or assignee" throughout the closed formulary rules whenever referencing pharmacy or pharmacists, and to include a definition of "pharmacy processing agent."

Agency Response: The Division declines to make the change. Rules adopted by the Commissioner concerning prescription medications and services, authorize pharmacies to use agents or assignees to process claims and act on the behalf of the pharmacies under terms and conditions agreed on by the pharmacies. These rules are §§133.2, 133.10, and 133.240 concerning Definitions, Required Billing Forms/ Formats, and

Medical Payments and Denials, respectively. Pharmacies and their agents are best suited to coordinate their communication activities and there is no need for the Division to insert a requirement directing that communication in these rules.

General: A commenter requests clarification if the Department or Division will be going into and inspecting pharmacies to see if drugs are properly mixed, and if so what expertise exists in the Department or Division to undertake such oversight. The commenter requests further clarification if there will be a partnership between the state and federal agencies that already provide such oversight, and if so, where the rules are that govern this type of activity by the agency, including type of penalties the Department or Division will administer, and where the penalties are listed.

Agency Response: The Division notes that pharmacies and pharmacists are regulated through the Occupations Code and rules established by the Texas State Board of Pharmacy. The Division does not have jurisdiction over the formulation of drugs or compounds and does not intend to interfere with the regulatory authority of the Texas State Board of Pharmacy, but may refer complaints to them if necessary.

General: A commenter inquires why insurance carriers have been allowing the prescription medications to be prescribed for such extended periods of time and why the prescribing doctors that have been prescribing the medications for so long have been given a free pass on responsibility.

Agency Response: The Division clarifies that HB 7 required the adoption of treatment guidelines, the adoption of a closed formulary, and allowed certified networks as components of the Texas workers' compensation system. Certified networks were implemented in early 2006, Division treatment guidelines became effective in May 2007, and these rules adopt a closed formulary. The use of these tools is intended to provide injured employees with appropriate medical services when needed to assure appropriate utilization of those services. Additionally, prescribing doctors are subject to review by the Division, the Texas Medical Board or other appropriate licensing boards if they are prescribing in a manner inconsistent with their licensure.

General: A commenter requests clarification why there is a comparison between the prescription rates for "legacy" claims between California and Texas as noted in the proposal preamble. The commenter states it makes no sense, causing the remainder of the research to be questionable, and requests an explanation.

Agency Response: The Division notes that the research comparisons between California and Texas are not specifically related to legacy claims, but are based only on prescription years 2005 and 2006 since at the time the research was conducted; this was the most current data available. Additionally, comparisons between California and Texas are relevant because both are large states with comparable pharmaceutical utilization and industry mixes.

General: A commenter inquires within the context of the proposed rules, whether a payor can choose to be more or less restrictive than the proposed formulary, and if there would be any considerations regarding the application of different utilization review standards, based on a more restrictive formulary.

Agency Response: Regarding the commenter's inquiry as to whether a payor can choose to be more or less restrictive than the proposed formulary, the Division notes the closed formulary applies to both certified network and non-network claims, and may not be amended by system participants. Drugs excluded from the closed formulary require preauthorization in both the network and non-network settings. For non-network claims prescribing doctors are subject to the recommendations included in the Division's adopted treatment guidelines, while for certified network claims, prescribing doctors are subject to the recommendations included in treatment guidelines and treatment protocols as approved during the network certification process. Regarding the commenter's inquiry as to any considerations regarding the application of different utilization review standards, the Division further notes, in both claims subject to certified network and non-networks, the preauthorization process must conform to the utilization review requirements of Chapters 10, 19, 134, and 137 of this title (relating to Workers' Compensation Health Care Networks, Utilization Review, Benefits--Guidelines for Medical Services, Charges and Payments, and Disability Management, respectively). Since certified networks may adopt their own treatment guidelines and protocols, in certain instances a drug included in the closed formulary may not be recommended by

the certified network's treatment guidelines. In this instance, the prescribing doctor should conform to the network's instructions for processing prescriptions for that drug, including preauthorization, if required, and may be subject to retrospective review based on the certified network's treatment guidelines.

General: A commenter requests clarification if the application of the closed formulary will be different for subscribers vs. non-subscribers.

Agency Response: The Division clarifies that these adopted rules do not apply to employers who do not subscribe to the workers' compensation system.

General: A commenter notes that the rules do not address off-label use. The commenter states removing the protection for off-label prescribing could hinder patient/injured employee access to many commonly used medicines.

Agency Response: The Division clarifies that there have been no changes concerning the off-label use of prescriptions by adoption of these rules.

General: A commenter recommends consideration beyond ODG status "N" to restrain medical and pharmaceutical practices in areas that are subject to abuse. If practicable, a list of non-status "N" and non-experimental drugs that are subject to abuse should be researched, compiled and excluded from the formulary or require additional scrutiny.

Agency Response: The Division declines to make the change. Drugs not included in

the closed formulary are excluded based on the medical evidence contained in the Division's adopted treatment guidelines. Experimental and investigational drugs are not included in the closed formulary in order to comport with the requirements of Labor Code §413.014 concerning Preauthorization Requirements; Concurrent Review and Certification of Health Care. It is not practicable for the Division to create a sub-formulary or a system where system participants must use a section of the ODG methodology and not use other sections of the ODG. This approach would complicate the use of the closed formulary and would be confusing for system participants. Any evidence supporting a change in the treatment guidelines should be submitted to the WLDI for evaluation and potential inclusion in the treatment guidelines based on the AGREE Instrument.

General: A commenter states the closed formulary rules should mandate that all physicians and other health care practitioners who are prescribing drugs in the Texas workers' compensation system must complete training in the safe use of narcotics in order to prevent over-use of narcotics.

Agency Response: The Division disagrees. Prescribing doctors are subject to review by the Division, the Texas Medical Board and other appropriate licensing boards if they are prescribing in a manner inconsistent with their licensure. Further, prescribing doctors suspected of unsafe, improper prescription of narcotics for specific claims may be referred to either the Texas Medical Board or the Division's Office of the Medical

Advisor. System participants may file complaints to the Medical Advisor through the Division's complaint resolution process.

General: Commenters recommend the Division's Medical Advisor and the Medical Quality Review Panel should identify and review physicians who have a high number of injured employees who may be addicted to prescription drugs or may have an inappropriate habituation wherein they use unnecessary and/or an excessive amount of prescription drugs.

Agency Response: The Division recognizes the commenters' recommendations regarding review of prescribing physicians, but notes that recommendations regarding the duties of the Office of the Medical Advisor and the Medical Quality Review Panel are outside the scope of these proposed rules. The Division will forward the comments to the Office of the Medical Advisor for consideration in the development of the Medical Quality Review Panel audit plan. System participants may file complaints to the Medical Advisor for over-utilization through the Division's complaint resolution process. The Division recognizes that insurance carriers, through the utilization review process, are able to identify physicians who have a high number of injured employees who may be addicted to prescription drugs or may have an inappropriate habituation. When identified and appropriate, insurance carriers should file complaints with the Division. If there is a danger to the public, the insurance carrier should make an appropriate referral to the Texas Medical Board. Additionally, prescribing doctors are subject to review by

the Division, the Texas Medical Board and other appropriate licensing boards if they are prescribing in a manner inconsistent with their licensure.

General: A commenter observes that it is critical that formulary changes and development are made not only with scientific evidence and medical review in mind, but also with input from those directly providing care, and those directly receiving care. This requires knowledge of the available and clear process by which to provide comment and information and to whom those comments must be directed. As the ODG is developed by a private organization, there appears to be no clear, transparent process for providing information on products or to have products added to or removed from the closed formulary. The general public, patients, providers, and interested product manufacturers are not only unable to access the closed formulary without providing payment, but also are unable to determine how to provide evidence-based relevant research information to WLDI for review for potential formulary inclusion. The process by which input can be provided is not readily available or accessible to the public, nor is it established in the TDI rules process, and therefore is subject to change at the discretion of WLDI or an entity responsible for implementing future formularies for workers' compensation. The commenter further states it is unclear from both the rule proposals and the vendor's website if and how factors are taken into consideration in the process of making formulary recommendations.

Agency Response: The Division clarifies that the Division's adopted treatment guidelines, required by statute, are evidence-based, scientifically valid, and outcome-focused. The evidence included in the Division's adopted treatment guidelines is based on the AGREE Instrument and is described in detail in the hard copy and electronic version of *ODG Treatment in Workers' Comp* and on the WLDI website. Instructions are also provided in WLDI/ODG for the submission of new evidence relating to treatments and services. Further, instructions are available in Appendix D of ODG for providers attempting to overcome the evidence basis of treatments and services included in the guidelines. Access to the electronic version of *ODG Treatment in Workers' Comp* is available at a nominal cost. A list of drugs excluded from the closed formulary will be added to the Division's website and will be available to system participants at no cost. The adoption of treatment guidelines and a closed formulary is a statutory requirement of HB 7, 79th Legislature, Regular Session.

General: A commenter objects to the fact that no measurements have been implemented to determine the success of these outside guidelines in improving outcomes. A benchmark review or finite timeline for reviewing the effectiveness and health outcomes of the guidelines implementing a closed formulary to determine if such action is in the best interests from a health and successful work integration perspective to the patients covered under workers' compensation insurance should be conducted. Another commenter recommends the Division provide a study and/or review within 18-

24 months from initial implementation of the closed formulary to determine if the program has been effective in controlling utilization of dangerous, and often addictive, medications and thwarting drug spend cost increases and pharmacy access.

Agency Response: The Division declines to make any specific additions to the rule. The Division is interested in return-to-work outcomes and the effectiveness of return to work guidelines, treatment guidelines, and the closed formulary in both the certified network and non-network settings, and may pursue research concerning these topics without additional rule language. Further, the Department's Workers' Compensation Research and Evaluation Group (REG) completes a network report card on an annual basis and conducts research on the non-network system as well, including the production of a biennial report required by Labor Code §405.0025, which analyzes the impact of HB 7 reforms. Additionally, the REG produces an annual research agenda and solicits input from system stakeholders regarding the projects included in the final research agenda. For example, in 2007, the REG conducted and published research and analysis concerning the use of pharmaceutical services in the Texas workers' compensation system.

General: Regarding injured employees treated in emergency rooms, a commenter recommends if a prescription is written, such an acute circumstance should merit the dispensing and payment of the medication as emergency room doctors have too much to worry about besides complying with the Division's closed formulary. The commenter

requests clarification how an emergency room doctor is expected to stay informed as to which medications are approved under the Texas workers' compensation system.

Agency Response: The Division declines to make the recommended change. All prescribing doctors are required to prescribe only medically necessary treatments and services. The Division's adopted treatment guidelines and certified network treatment guidelines provide recommendations that are consistent with the evidence-based medicine requirements of the Labor Code and the Insurance Code as they relate to the Texas workers' compensation system. The drugs excluded from the closed formulary are noted in Appendix A of the *ODG Treatment in Workers' Comp*, and a list of those drugs is anticipated to be posted on the Division's website. Additional evidence-based treatment recommendations for the use of pharmaceuticals are included in *ODG Treatment in Workers' Comp* and in each certified network's treatment guidelines. Drugs excluded from the closed formulary, but dispensed for use during the first seven days post-injury, including prescriptions written as a result of an emergency room visit, do not require preauthorization, but are subject to retrospective review of medical necessity. While drugs excluded from the closed formulary require preauthorization, a prescribing doctor may prescribe any other FDA-approved drug without preauthorization. Additionally, drugs included in the closed formulary, but dispensed for use during the first seven days post-injury, do not require preauthorization and are not subject to retrospective review of medical necessity.

General: A commenter recommends that only brand name drugs be excluded from the closed formulary, and that the Division should establish a pharmaceutical and therapeutics committee, comprised of pharmacists and doctors, to review the use of brand name drugs on a claim-by-claim basis when a prescribing doctor wishes to prescribe a brand name drug for an injured employee.

Agency Response: The Division declines to make the changes. Drugs excluded from the closed formulary are excluded based on the chemical composition of the pharmaceutical and not upon a drug's generic or brand name status. For example, the risks and benefits of the brand name drug Soma and the generic drugs Carisoprodol are, with few exceptions, essentially the same. Further, there is no need to establish a separate pharmaceutical and therapeutics committee since the Division has developed an appeals process as required by the Labor Code to review on a claim-by-claim basis the use of drugs excluded from the closed formulary. The appeals process will assess the medical necessity of the prescription for a drug excluded from the closed formulary, including the necessity of a brand name drug versus a generic drug, if requested by the prescribing doctor.

General: Commenters provide various recommendations and reasons for delaying the implementation dates of the proposed rules, offering the following suggestions: One commenter recommends delaying implementation to July 1, 2011 without impacting the proposed January 1, 2013 date for legacy claims. Another commenter recommends

delaying implementation of all of the proposed rules to sometime between September 1, 2011 and January 1, 2012, and two corresponding years for legacy claims. Other comment recommendations include moving the implementation date to September 1, 2012 with legacy claim implementation date delayed to January 1, 2014. Another commenter recommends the implementation of new rule change from 2013 to 2015 to allow adequate time to adjust patient care where needed. A different commenter further supports delaying application of the closed formulary to legacy claims, further segmenting application of the closed formulary to legacy claims based on date of injury, or not specifying an effective date at this time. The reasons provided for delayed implementation include: the need to change policies; develop, test, and implement programming requirements; the need to appropriately train and educate prescribing doctors, pharmacists, insurance carriers, and other affected entities; and for insurance carriers to implement and refine their utilization and review processes.

Agency Response: The Division carefully reviewed and considered these recommendations and has amended the rules to provide additional time for system participants to prepare for the implementation of the rules. All dates that were proposed to be January 1, 2011, are changed to September 1, 2011. All legacy claim date references are similarly changed by the corresponding eight months. The insurance carrier's identification activity for legacy claims is changed from proposal in subsection (b)(2) to reflect a date of "Beginning no later than March 1, 2013," rather than the

proposal date of July 1, 2012. Also, the effective date for claims with dates of injury proposed to be on or after January 1, 2013 is changed to September 1, 2013.

General: Commenters express support for the phased-in applicability and implementation date approach as proposed for the closed formulary over time to allow for continuity of care. Providing for no transition period would disrupt the continuity of care of injured employees in many cases by requiring sudden changes in drug regimens in use for many years.

Agency Response: The Division agrees with and appreciates the supportive comments and notes that the specific applicability dates for the rules have been adjusted as noted in the previous comment and response.

General: A commenter advises that there are a number of other systemic problems without the closed formulary that adversely affect pharmacy stakeholders, including chronic short pays due to vague and ambiguous reimbursement guidelines and standards, as well as inadequacy of the dispute resolution process to curb bad faith patterns of deliberate reimbursement gamesmanship.

Agency Response: The Division recognizes the commenter's concerns, but notes that these comments are outside the scope of the proposed rules.

General: Commenters recommend that the Department adopt rules allowing bundling of egregious claims and issue swift and serious enforcement action on any carriers that abuse the system.

Agency Response: The Division recognizes the commenters' concerns regarding claim disputes and potential complaints, but notes that these comments are outside the scope of the proposed rules.

General: Commenters recommend that the Division amend each proposed rule to clarify the applicability of the rules in order to specifically exclude claims subject to Labor Code §504.053.

Agency Response: The Division disagrees. Labor Code §504.053 is explicit in its details concerning political subdivisions that self-insure individually and collectively, their ability to contract directly with health care providers and the consequences of the election and applicable statutory provisions related to the election. Inserting amendments to the adopted rules would be duplicative of the statutory provisions of Labor Code §504.053 and is unnecessary.

§134.500(3): Commenters are concerned with adopting the ODG formulary and whether there will be sufficient "Y" drugs in all categories. A commenter states it is critical that sufficient options are available for each category to provide medication alternatives when some medications prove ineffective or when the injured employee has

an adverse reaction to a drug prescribed. The commenter is further concerned that the Division has not adequately addressed this issue in the proposal and believes the closed formulary must serve the goal of limiting access to inappropriate medications while still ensuring that a broad range of medication remains available to treat the injured employees of Texas. Another commenter offers numerous shortcomings of the rule proposals and ODG Appendix A, such as: some of the drugs listed should not be covered by workers' compensation as they have no injury-related use; all appropriate generic versions of drugs in some therapeutic categories are not included; some high cost, brand name drugs that have generic alternatives are inappropriately included in the closed formulary; and some therapeutic categories of drugs commonly employed in workers' compensation are omitted completely. One commenter states there are certain drugs in the drug classes considered that do not appear to have been considered at all. If a closed formulary is implemented, the commenter recommends that all drugs in that particular class should be considered.

Agency Response: The Division clarifies that the closed formulary is not just the "Y" drugs listed in ODG Appendix A that are available to treat an injured employee. The closed formulary is defined as, "all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes: (A) drugs identified with a status of 'N' in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; (B) any compound that contains a

drug identified with a status of 'N' in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates, and (C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care **as defined by Labor Code §413.014(a)."**

The Division further clarifies that the closed formulary identifies drugs that require preauthorization and injured employees have access to all other FDA-approved drugs that are reasonable and necessary to their health care. Pharmaceutical services included in the closed formulary and prescribed for injured employees have to conform to the treatment guidelines and are subject to retrospective review. For purposes of understanding the closed formulary and those medications that require preauthorization approval (the appeals process), the ODG "N" drug designation and investigational and experimental drugs are the key and critical elements to the closed formulary. Drugs identified in ODG Appendix A with a status of "Y" are only a small subset of all FDA-approved drugs, which are included in the closed formulary. The "N" designation means that a drug is not recommended for use and will require preauthorization. Investigational or experimental drugs are not yet broadly accepted as the prevailing standard of care in the health care community and will require preauthorization as well.

The ODG meets the provisions outlined in Labor Code §413.011(e). Appendix A is a reflection of the recommendations detailed in the Division's adopted treatment guidelines.

§134.500(3): A commenter suggests the Division has not adopted a traditional, more commonly acceptable closed formulary, noting that generally, a closed formulary includes drugs that are covered, while an open formulary specifies drugs that are not covered. While it does not appear that the instant proposed formulary possesses the hallmarks of a formal closed formulary system, it does take steps in that direction.

Agency Response: The Division understands the commenter's concerns; however, the Division adopts a closed formulary that fulfills the statutory definition of closed formulary under Labor Code §408.028(b) and the related legislative objectives of HB 7.

§134.500(3): A commenter opines that if a physician is forced to use the closed formulary, he or she will be using drugs which are actually more expensive than those now being used.

Agency Response: The Division clarifies that the guiding principle for adopting a closed formulary is primarily to focus on the appropriateness and medical necessity of the particular medication. It is not clear from the commenter's noted concern whether the cost referenced is the actual unit cost, or the interest in curbing unnecessary utilization and controlling costs. In any event, the Division believes the added scrutiny

through the preauthorization process will control the overall system cost use of medications for work-related injuries. Under the closed formulary, a prescribing doctor still has access to all FDA-approved drugs and the "N" drugs, which are excluded from the closed formulary and are still available through the preauthorization process.

§134.500(3): A commenter states there appears to be a level of ambiguity between the ODG guidelines and the closed formulary. For instance, the commenter appears to note from review of the ODG treatment guidelines that opioids can only be given for two-week time periods. The decision to prescribe opioids for less than 30 days is best left to the judgment of the physician based on the specific circumstances for a given patient.

Agency Response: The Division clarifies that the Division selected the most current edition of the ODG because it meets the provisions outlined in Labor Code §413.011(e). Additionally, the guidelines are updated by integrating the findings of new studies as they are conducted and released. Further, the ODG guidelines are designed to reduce excessive or inappropriate medical care while safeguarding necessary medical care by providing clear data on optimum frequency and duration of treatments. However, the health care provider must consider care above or below the guidelines consistent with the unique factors associated with the injury. The Division notes that treatment may not be denied solely on the basis that the treatment for the compensable injury in question is not specifically addressed by the treatment guidelines. The Division anticipates that

prescribing doctors will support their decisions to treat outside the guidelines through the statement of medical necessity or when required, a request for preauthorization. The guidelines in ODG Appendix D provide suggestions for documenting instances regarding the medical necessity of treatments and services that are not recommended, not included in, or exceed the recommendations of the treatment guidelines.

§134.500(3): A commenter states that opioids are not warranted once maximum medical improvement (MMI) has been attained. The commenter seeks clarification as to how that translates to the need for pain medication disappearing. If opioids are stopped, the commenter states, appropriate weaning guidelines should be followed.

Agency Response: The Division clarifies that the proposed rules did not address the continued use of opioids after MMI. The closed formulary rules, as adopted, provide communication tools regarding appropriate weaning efforts. Likewise, the pain chapter of ODG addresses weaning.

§134.500(3): Regarding the first sentence in Appendix A, "…formulary only applies to the classes listed…," a commenter seeks clarification if this means the entire class of drugs is now an "N," or just the specific ones listed, for example, Chlonidine and Fentanyl. In addition, the commenter seeks clarification about the various forms drugs come in, for example, tablets or transdermal patches. The commenter seeks clarification as to what the proper approach is when an ODG "N" drug is not

recommended as a first line drug, but is recommended as a third line treatment, and whether preauthorization is required if the physician is prescribing the drug as a third line drug.

Agency Response: The Division clarifies that for purposes of the closed formulary, a drug requires preauthorization approval if it has a drug status "N" and is on the "N" list regardless of whether the drug was prescribed as first, second, or third line, and regardless of the form in which it comes.

§134.500(3): A commenter believes that the Legislature intended that there be a use of all generic drugs, and for those drugs that are not generic, to have a closed formulary for the trade name type drugs that should be used. Further, all generic drugs that are FDA-approved should be used, and then the closed formulary should address those drugs that are not generic.

Agency Response: The Division clarifies that there is already a statutory provision in and rule that require the use of generic drugs in the Texas workers' compensation system. Labor Code §408.028(b) and §134.502 of this title (relating to Pharmaceutical Services) require prescribing doctors to prescribe generics and over-the-counter alternatives to treat injured employees when appropriate. Additionally, all FDA-approved drugs are included in the closed formulary, except drugs with ODG status "N," compounds that include drugs with ODG status "N," and investigational or experimental drugs **as defined by** Labor Code §413.014(a). Therefore, the closed formulary

includes all generic drugs or compounded generic drugs that are not excluded as a result of their "N" status.

The Division disagrees that the closed formulary should consist only of trade name type drugs. Such a model is not required under the Texas Workers' Compensation Act (Act).

§134.500(3)(A): Commenters seek clarification as to how the system is to handle a drug which initially was not indicated as an "N" and which was prescribed for prolonged therapy (180-day prescription calls for multiple refills) and prior to a subsequent refill, ODG switched the drug indication from "Y" to "N." The commenters seek additional clarification regarding whether the injured employee will be required to switch to a different medication therapy mid-prescription; whether the pharmacy and pharmacy processor would be denied payment if the refill is dispensed/processed; whether this prevents a refill from being dispensed until the proper preauthorization is secured; when should preauthorization requirements for indicated "N" drugs apply: date of prescription, dispense, or date the bill is presented to the end payer; and whether drugs not on the list as "Y" or "N" will inherently be treated exactly like a "Y" drug by PBM/payers. One commenter recommends the Division determine if the application of "N" status would apply to claims by date of prescription, date of dispensing, or date of billing.

Agency Response: The Division clarifies that it is the date the prescription is written that controls its status, which is then considered good and binding for the duration of the

prescription. Consequently, if a drug's status changes at some point after the prescription date, the change will not have an effect on that particular prescription, and preauthorization will not be required since the applicable drug's status is based on the date of the prescription. There are additional pharmacy rules and laws, including but not limited to, the Texas Pharmacy Act and the Texas State Board of Pharmacy rules that will also control where applicable. Regarding the commenter's concern whether drugs not on the list as "Y" or "N" will inherently be treated exactly like a "Y" drug, the Division clarifies that not all FDA-approved drugs are listed in Appendix A of ODG. Only drugs specifically identified with a status of "N," compounds which include a drug with a status of "N" and experimental or investigational drugs are excluded from the closed formulary and require preauthorization. Drugs included in the closed formulary may be prescribed without preauthorization, but are subject to retrospective review of medical necessity.

§134.500(3)(A) and (B): Some commenters seek clarification concerning the use of the term "current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary." Commenters are concerned that the Division failed to indicate an official "implementation" time frame or lead time according to which the pharmacy marketplace should integrate any changes to the ODG drug appendix, since Appendix A is not static and is subject to change with addition and removal of drugs as well as changes in drug indication of "Y" or "N." Commenters seek

clarification whether updated ODG drug appendix data should be applied on a monthly, quarterly, or annual basis when released/published by ODG. Other commenters recommend that whenever an ODG formulary modification is made, that there be a minimum of a 30-day notice before having system-wide effect as this will provide payers and pharmacies, and/or their agents, time to adequately invest the necessary resources to program updates in the system. Some commenters believe without clarification regarding the timing of ODG updates, confusion as to the proper edition on which to base preauthorization approval requests may occur.

Agency Response: The Division disagrees and declines to make the suggested change. Information regarding Appendix A in ODG, and any updates or changes, will be kept on the Division's website, just as changes with other treatments and services within the ODG treatment guidelines are currently maintained.

§134.500(3)(B) and §134.500(4): Some commenters suggest all compound drugs should be excluded from the closed formulary, or require preauthorization. A commenter encourages the Division to adopt a rule to restrict compounding to instances where it is medically necessary, and require the prescribing physician to provide a scientifically valid reason as to why non-compounded existing medications are not sufficient to treat the injured employee.

Agency Response: The Division disagrees. The purpose of these rules is to adopt a closed formulary which excludes drugs with status "N," compounds that include drugs

with status "N," and investigational or experimental drugs **as defined by** Labor Code §413.014(a). The Division initially considered requiring preauthorization for all compound drugs. However, with stakeholder feedback and, in the interest of curbing the expense of numerous preauthorization requests, the Division reconsidered and adopts a more measured approach as specified in the proposal, which is requiring preauthorization only for those compounds that contain an "N" drug. The Division notes that an insurance carrier has the ability to conduct retrospective utilization review for all compounds not containing an "N" drug so that insurance carriers have the ability to only pay for medically necessary care.

§134.500(3)(B) and §134.500(4): A commenter states the inclusion of all compounds violates statutory standards that the Division must use in adopting a closed formulary since the commenter asserts the closed formulary is a treatment guideline. The commenter further opines that allowing compounds is contrary to evidence-based, scientifically valid, and the outcome-focused regulation of the Labor Code, including the requirement to reduce excessive or inappropriate medical care. Nevertheless, the commenter concedes that compound drugs may be medically necessary at times.

Agency Response: The Division disagrees in part. The Division disagrees that including compounds in the closed formulary violates statutory standards. The Division is required to adopt a closed formulary wherein an injured employee who sustains a compensable injury is afforded all health care reasonably required by the nature of the

injury as and when needed in accordance with Labor Code §408.021. Compounds containing an "N" drug will require preauthorization. The commenter's premise that the closed formulary is a treatment guideline is incorrect since Appendix A is a reflection of the evidence-based recommendations detailed in the Division's adopted treatment guidelines, and Appendix A does not provide specific recommendations regarding an appropriate course of care for specific types of injuries, whereas the ODG treatment summaries do provide specific direction concerning appropriate care. The Division agrees with the commenter's concession that compound drugs may at times be medically necessary.

§134.500(3)(B) and §134.500(4): Commenters recommend rule wording regarding compounding that reiterates the requirements of Labor Code §408.021 by stating: "The compounding of a drug must be reasonably required by the nature of the injury and must cure or relieve the effects naturally resulting from the compensable injury, promote recovery, or enhance the ability of the employee to return to or retain employment."

Agency Response: The Division disagrees. The recommended wording is applicable by statute and it is not necessary to re-state statutory language in adopted rules.

§134.500(3)(B) and §134.500(4): Commenters recommend the rules state compounding shall not be used to provide nutritional supplements, medical foods or

other non-pharmaceutical substances unless a clear and compelling medical need exists based on the patient's original industrial injury and current clinical status.

Agency Response: The Division disagrees. The Division has defined "Nonprescription drug or over-the-counter medication" and "Prescription drug" under §134.500(8) and §134.500(12) of this title. Additionally, injured employees are entitled to medically necessary treatments and services including non-prescription drugs and over-the-counter medications. Therefore, no additional clarification regarding compounding is necessary.

§134.500(3)(B) and §134.500(4): A commenter clarifies that the need for compounding is based on a physician's decision for a specific patient's need, and not a pharmacist's profit goals.

Agency Response: The Division agrees and further clarifies that the health care must be reasonably required pursuant to Labor Code §408.021 and in accordance with Labor Code §401.011(18-a) and §401.011(22-a).

§134.500(3)(B) and §134.500(4): A commenter states the pharmacy fee guideline rule should stress the statutory requirements set forth in Labor Code §408.021. The fee guideline should place a cap on the amount pharmacies are paid if a drug is compounded. Such a provision should preclude the likelihood that future abusive

behavior involving compounding will occur and will not financially incentivize compounding.

Agency Response: The Division recognizes the commenter's concerns regarding the pharmacy reimbursement structure, but notes that these comments are outside the scope of the proposed rules.

§134.500(6): Commenters state the definition for generically equivalent is incorrect, and the commenters therefore have concerns about "switching" or assuming that another drug in the same therapeutic category would have the same effect as the original one the physician prescribed.

Agency Response: The Division disagrees. Occupations Code Title 3 Subtitle J (Texas Pharmacy Act) governs health professions in Texas and is applicable to pharmacy and pharmacists. The Legislature enacted the definitions of "Generically equivalent," "Pharmaceutically equivalent" and "Therapeutically equivalent" under Occupations Code §562.001(1), (2) and (3), respectively, which the Division has incorporated in its adopted rule.

§134.500(6)(B): A commenter indicates the word "intensity" in the proposed definition of "generically equivalent" is not a pharmaceutical or medical term, and implied in the rule proposal, probably refers to either efficacy, potency or another medical term. The

commenter requests clarification and proper medical wording to define what the rule is attempting to state.

Agency Response: The Division clarifies that the word "intensity" is a component of the Occupations Code §562.001(3) definition of "therapeutically equivalent," which "means pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity." Since the word "intensity" is part of the statutory definition, the Division does not have the authority to replace what has been enacted, or substitute the word with a medical term that the legislature might not have intended. What is meant by "intensity" may be interpreted by applicable medical experts on a case-by-case basis if the issue of "generically equivalent" arises during a medical dispute.

§134.500(6) and (14): A commenter states the proposed rules contain multiple terms relating to equivalency of medications which are at once duplicative, but also seem to open an avenue for utilization of therapeutic substitution, which is neither acceptable nor has been decisively approved by the Texas Legislature as public health policy. The proposed definition of generically equivalent is common and accepted public health policy in formularies; however, it also contains a definition for "substitution" in §134.500(14), which is too vague and appears to provide an avenue for substituting an entirely different drug than prescribed.

Agency Response: The Division disagrees. The adopted definition of "substitution" in §134.500(14) is taken directly from the Texas Pharmacy Act, which states that substitution "means the dispensing of a drug or a brand of drug other than the drug or brand of drug ordered or prescribed." (Occupations Code §551.003(41)). The Texas Pharmacy Act also defines "generically equivalent" and "therapeutically equivalent" under Occupations Code §562.001(1) and §562.001(3). Occupations Code §551.002 declares the legislative public health, safety, and welfare purpose of the Texas Pharmacy Act.

§134.500(7): A commenter opines the proposed definition of "medical emergency" is too restrictive and that not every medical emergency will include severe pain. If it can reasonably be expected that a patient's health or bodily function is placed in serious jeopardy or that serious dysfunction of a body organ or part will result, but there is no severe pain, it would seem that immediate medical attention would still be required. Another commenter states that a medical emergency means a patient's health would be in "serious jeopardy" or an organ would be in "serious dysfunction," and this requirement puts the patient at unnecessary risk and is not in line with either the standard of care, or rules in other government sponsored health programs.

Agency Response: The Division clarifies that the definition of "medical emergency" does not limit the circumstances to severe pain; rather severe pain is included as one of the many components. Furthermore, the definition of "medical emergency" is a long-

standing definition in the Texas workers' compensation system as adopted in §133.2 of this title (relating to Definitions). Also, the definition is consistent with Insurance Code §1305.004(a)(13) and §4201.002(2). The Division notes that the term "unreasonable risk" is used throughout the rules as a modifier to clarify an action may be taken prior to a medical emergency or to prevent a medical emergency.

§134.500(10): A commenter recommends new language for the term "prescribing doctor," which is "a physician or dentist who prescribes prescription drugs or over the counter medications in accordance with the physician's or dentist's license and state and federal laws and rules." The commenter states the inclusion of an advanced practice nurse or physician assistant as included in the proposed definition conflicts with how the term "doctor" is defined by the Labor Code §401.011(10), and requests that all references to these terms be deleted, and placed in a new definition for "Other prescribing health care practitioners." The suggested definition for the new term is, "an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders, under Occupations Code Chapter 157, and who prescribes prescription drugs or over the counter medication under the physician's supervision and in accordance with the health care practitioner's license and state and federal laws and rules."

Agency Response: The Division disagrees and declines to make the recommended change, and believes the definition provides clear delineation that an advanced practice

nurse or physician's assistant are delegated this authority by doctors, specifically physicians, and is not an assumed authority. Occupations Code Chapter 157 governs the authority of physicians to delegate certain medical acts including the delegation to advanced practice nurses and physician assistants. Occupations Code §157.001 grants general authority to a physician to delegate to a qualified and properly trained person acting under the physician's supervision any medical act that a reasonable and prudent physician would find within the scope of sound medical judgment, which includes the "carrying out or signing a prescription drug order" as defined by Occupations Code §155.051(2). The advanced practice nurse and physician assistant are appropriate delegatees under Occupations Code Chapter 157 and they are defined in Occupations Code §157.051(1) and §157.051(3).

§134.500(13): Commenters recommend that the language be modified to provide, "A statement of medical necessity shall include…" to clarify the mandatory nature of all elements. Failure to submit a complete statement should constitute both an act of non-compliance with the rule by the prescribing doctor or health care practitioner, and failure to submit a complete statement.

Agency Response: The Division agrees that the recommended language does provide clarity to the mandatory nature of each of the elements, and adopted §134.500(13) has been changed to state, "A statement of medical necessity shall include: …"

§134.500(13): A commenter states the phrase, "and supporting evidence-based documentation" is unnecessary and unduly burdensome. The commenter contends that the information required in (13)(F) is more than sufficient to show medical necessity and that requiring "supporting evidence-based documentation" would make it significantly more difficult for an injured employee to obtain necessary medication. The commenter would further emphasize that any medications dealt with in (13) would have received FDA approval based upon valid scientific study of their safety and efficacy. While the prescribing doctor might not have these studies in his or her possession, they certainly exist for the drug to have been approved by the FDA. The evidence-based medicine of the safety and efficacy of medications approved by the FDA are the studies that led to the drug receiving FDA approval. A prescription should be filled, if the injured employee or prescribing doctor establishes that the medication satisfies the requirements of §134.500(13)(F). Another commenter opines that supporting evidence-based documentation should not include documentation from the manufacturer of the drug.

Agency Response: The Division notes the commenter's concern regarding the burdensome nature of providing this information, especially by an injured employee, and agrees with the first commenter's recommendation. Moreover, the Division also agrees that §134.500(13)(F) satisfies the Division's expectation that the statement of medical necessity should thoroughly provide the documentation that supports the drug exclusion. Consequently, the Division has deleted from the adopted rule the requirement to provide supporting evidence-based documentation in the definition of

statement of medical necessity. Because of this deletion in the adopted rules, the issue raised by the second commenter is moot.

§134.500(13): A commenter believes that required preauthorization of drugs excluded from the closed formulary is going to result in basically a 100 percent denial rate because a statement of medical necessity submitted as part of the preauthorization process will require proof of a medical emergency, and proof that the requested drug has previously been prescribed and dispensed. For example, the commenter states that because it is not a medical emergency, an injured employee will not have access to compounds that include drugs on the "N" list, such as Ketamine or Ketoprofen. This is too time-consuming and the result is not beneficial to the injured employee.

Agency Response: The Division disagrees. Preauthorization is the appeals process in the closed formulary that is required by Labor Code §408.028. Preauthorization enables the injured employee to have access to "N" drugs, compounds that include "N" drugs and investigational or experimental drugs **as defined by** Labor Code §413.014(a), if these drugs are determined to be medically necessary. A medical emergency need not exist for the preauthorization of a drug excluded from the closed formulary. An unreasonable risk of medical emergency is required when a prescribing doctor or pharmacist is pursuing an MIO in accordance with §134.550. The unreasonable risk of medical emergency is evaluated by the prescribing doctor and is not limited to certain circumstances, severe pain or set components for which the

prescribing doctor has the final decision based on the health care reasonably required by the injured employee. The statement of medical necessity is a communication tool designed to establish the medical necessity of the treatment for the injured employee's condition and to facilitate payment.

§134.506: Some commenters state it is unclear whether the Commissioner has the statutory authority to adopt an open formulary and request clarification of the purpose of amending the section. One commenter suggests deleting references to "open formulary" from both the title and from subsections (a), (d), and (f) of this section. Additionally, a commenter seeks clarification of what, if any, utilization review requirement would apply to legacy claims if the open formulary is not adopted. The commenter states it is also unclear when the open formulary applies to legacy claims as the proposal does not provide a specific effective date as in other proposed rules.

Agency Response: The Division clarifies the intent of the proposed §134.506 is to implement amendments to Labor Code §408.028 and update and continue the existing rule until such time that all claims become subject to the pharmacy closed formulary. The Division notes there would be no guidance or direction, including utilization review requirements, provided to system participants for those claims with the latter phase-in date (legacy claims) without such an extension of the open formulary, thus creating confusion as to medically appropriate prescription medications, treatment guidelines, preauthorization requirements, and retrospective review considerations. Additionally, to

address commenters' concerns and to provide further clarification, the Division has re-worded the adopted subsection as follows: "For claims with dates of injury prior to September 1, 2011 (for purposes of this section, referred to as 'legacy claims'), the open formulary as described in §134.500(9) of this title (relating to Definitions) remains in effect until those claims become subject to the closed formulary in accordance with §134.510 of this title (relating to Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011)."

§134.506: A commenter recommends that rule 134.506 should provide that in the interim period of January 1, 2011 and December 31, 2012, physicians and other prescribing health care practitioners can prescribe all FDA-approved prescription and over-the-counter drugs. Additionally, the commenter recommends the rule provide that physicians and other prescribing health care practitioners are required to prescribe generic pharmaceutical medications and clinically appropriate over-the-counter alternatives to prescription medications unless otherwise specified by the prescribing doctor, in accordance with applicable state law.

Agency Response: The Division declines to make the change because the definition of an open formulary in adopted §134.500(9) covers much of this recommended language. Further, the adopted changes to §134.506 clarifies that the open formulary as described in §134.500(9) remains in effect until those claims become subject to the closed formulary in accordance with §134.510 of this title (relating to Transition to the

Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011). There also remain in effect other rules in Chapter 134, Subchapter F relating to Pharmaceutical Benefits. These rules are §134.502 of this title (relating to Pharmaceutical Services) and §134.504 of this title (relating to Pharmaceutical Expenses Incurred by the Injured Employee).

§134.506(b): A commenter supports the provisions of this subsection, as it should reduce the prescribing of medically unnecessary and inappropriate drugs to injured employees.

Agency Response: The Division agrees and appreciates the supportive comment.

§134.506(c): A commenter supports this provision of the rule proposal.

Agency Response: The Division appreciates the supportive comment.

§134.506(d): A commenter recommends the deletion of subsection (d) of this section based on the commenter's previous assertion that the Commissioner does not have the statutory authority to amend §134.506 or adopt a new rule. The commenter offers the following recommended language should the Division not delete subsection (d) as suggested: "Drugs prescribed and dispensed for claims not subject to a certified network with dates of injury before January 1, 2011 do not require preauthorization, except as required by Labor Code §413.014."

Agency Response: The Division disagrees and declines to make the change. The section as proposed, and with further adopted modifications as indicated, provides a sufficient definition and applicability of legacy claims.

§134.506(e): A commenter offers the following recommended language should the Division not delete subsection (e) as suggested: "Drugs prescribed and dispensed for claims subject to a certified network with dates of injury before January 1, 2011 shall be preauthorized in accordance with Insurance Code Chapter 1305 and Chapter 10 of this title (relating to Workers' Compensation Health Care Networks)."

Agency Response: The Division disagrees and declines to make the change. The section as proposed and with further adopted modifications as indicated provides a sufficient definition and applicability of legacy claims.

§134.506(f): A commenter is concerned that the broad language could circumvent network and non-network preauthorization requirements for investigational or experimental drugs. If preauthorization is required and is not requested, the insurance carrier should be able to deny payment for failure to obtain preauthorization. The language in proposed subsection (f) suggests that if it is prescribed and dispensed without preauthorization (even if required), it would be subject to retrospective review for medical necessity.

Agency Response: The Division agrees the language is confusing and has changed the wording in adopted subsection (f) to clarify that drugs included in the open formulary that do not require preauthorization and are prescribed and dispensed for legacy claims are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier.

§134.510(a) and (b): Commenters support bifurcated implementation of the closed formulary for drugs that are prescribed and dispensed for outpatient use as the phase-in approach for non-catastrophic legacy claims with over-use of prescription medications would devastate the system if all preauthorization were to be required at once.

Agency Response: The Division agrees and appreciates the supportive comments.

§134.510(a) and (b): A commenter opposes the staggered implementation of the closed formulary for legacy claims and recommends deletion of this section as it is inappropriate and unworkable, and is merely a method to eliminate all the benefits of the closed formulary for such claims. While understanding that in some rare, particular situations, treatment with a drug excluded from the closed formulary may be appropriate, the commenter opines it is the medical provider that should be able to file a statement of medical necessity. After review, if medical necessity to depart from the closed formulary is demonstrated, the claimant could be treated with drugs excluded from the closed formulary.

Agency Response: The Division disagrees and declines to make the suggested deletion. Cognizant of the complex clinical questions related to the ongoing use of drugs excluded from the pharmacy closed formulary and the significant change to require prospective review for drugs excluded from the pharmacy closed formulary, the Division is utilizing a measured approach to implement the pharmacy closed formulary. This phased-in application will facilitate an orderly transition from the existing open formulary to the pharmacy closed formulary. This is important due to the number of injured employees that are currently utilizing drugs that will be excluded from the pharmacy closed formulary and the potential number of preauthorization requests if the dates are not staggered. Through the transition process, which includes ongoing system-wide education and training of the pharmacy closed formulary, a reduction of requests to use drugs not included in the pharmacy closed formulary would reduce the potential impact on the system. This reduction of requests should occur with the appropriate and measured utilization of the pharmacological management of legacy claims.

§134.510(a) and (b): Commenters understand the reason for separate implementation dates for new and legacy injured employees. However, these two timelines working in tandem may create an opportunity for some insurance carriers to abuse the system and deny legitimate payment to pharmacies.

Agency Response: The Division disagrees. All system participants are required to comply with all Division rules concerning the closed formulary, including billing and reimbursement requirements, and as such are subject to the monitoring and compliance activities of the Division.

§134.510(a) and (b): Commenters recommend the Division, insurance carriers, and treating physicians begin transitioning legacy patients over the next couple of years from "N" drugs to approved formulary drugs.

Agency Response: The Division agrees, and further clarifies this as one of the goals through adoption of this section.

§134.510(a) and (b): Commenters suggest the Division should work with the Texas Medical Board and the Texas Medical Association to educate physicians through continuing education units and seminars on the transition provisions. The benefits would be a smoother transition to the new closed formulary guidelines, fewer burdens on pharmacy stakeholders, and more reliable care for injured employees.

Agency Response: The Division agrees that education is an important component and is developing initiatives to educate system participants on the appropriate application of the pharmacy closed formulary rules and other pertinent Department and Division rules. The Division is currently coordinating educational content and opportunities with system participants, including professional organizations.

§134.510(a) and (b): Regarding the three-year period for legacy claims, a commenter seeks clarification regarding who, in the process, is to ensure that a statement of medical necessity accompanies the prescription for "N" drugs; and, what an insurance carrier's recourse would be if that is not provided. The commenter requests clarification regarding whether the insurance carrier can stop payment for a drug based in that situation.

Agency Response: The Division clarifies that the adopted rules concerning the pharmacy closed formulary designate a two-year period for preparing to transition legacy claims to the requirements of the closed formulary. This two-year period is changed from proposal and is September 1, 2011 to September 1, 2013. Until that time, there should not be a denial of payment on a legacy claim by an insurance carrier based on the applicability of the closed formulary, since the effective date of the closed formulary for legacy claims will not occur until September 1, 2013. However, during this transition period the Division's and certified networks' adopted treatment guidelines continue to apply and should be utilized as the standard for retrospective review of pharmaceutical services. Additionally during that two-year transition time, all system participants are encouraged to help educate one another to ensure that the need for the medications excluded from the closed formulary are conveyed with a statement of medical necessity by the prescribing doctor, which will facilitate discussions of alternatives and injured employee needs with the insurance carrier. This discussion of

ongoing pharmacological management will help alleviate a forced preauthorization request when the closed formulary becomes applicable.

The Division clarifies the intent is to facilitate a transition of legacy claims through a mutual agreement between the parties. However, it is not the Division's intent to create another administrative requirement and potential administrative violation by mandating the statement of medical necessity. An insurance carrier may request a statement of medical necessity, but this request alone does not authorize the insurance carrier to approve or deny the request. Further, the Division notes the requirements for responding to a request for a statement of medical necessity are included in §134.502 of this title.

§134.510(b): A commenter recommends that a process needs to be set in an additional rule that provides for pharmacological case management (e.g., where the insurer believes the injured employee may be addicted to the prescription drugs) for both legacy and new claims in which prescription drugs that have been excluded from, exceed, or are not addressed by the ODG treatment guidelines can be discussed by the prescribing doctor, treating doctor (if appropriate), and insurance carrier's medical advisor to determine an appropriate course of action with future prescriptions and refills for the drug(s) in question. The commenter states it is probable that the majority of physicians will not be willing to timely respond to requests by insurers to discuss pharmacological management of legacy claims since there is no requirement to do so,

and as borne by the attempt in a previous pilot study on treatment planning. The commenter will be working with other associations and interested stakeholders to develop a rule concept for pharmacological case management to be shared with the Division at a future date.

Agency Response: The Division disagrees that a new rule for pharmacological case management is necessary at this time to prepare for the transition of legacy claims to the pharmacy closed formulary. However, the Division acknowledges the concerns of the commenter, and clarifies that the adopted rule at subsection (b)(1)(C) and (b)(2)(B)(i) and (ii) are modified from proposal to allow and require equal exchange of information between the prescribing doctor and the insurance carrier. New subsection (b)(1)(C) clarifies, "When a prescribing doctor or insurance carrier is contacted by the other party regarding ongoing pharmacological management, the parties must provide each other a name and phone number and date and time to discuss ongoing pharmacological management." Additionally, new subsection (b)(2) states, "Beginning no later than March 1, 2013, the insurance carrier shall: (A) identify all legacy claims that have been prescribed a drug excluded from the closed formulary after September 1, 2012; and (B) 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 closed formulary for legacy claims; and (ii) the information required in paragraph (1)(C) of this subsection." The Division plans to closely monitor the implementation of the initial closed formulary for new claims in anticipation of the

transition for legacy claims, including the review and consideration of any future rule concepts submitted by interested system participants.

§134.510(b): A commenter opines that injured employees who are in great pain, not likely to ever return-to-work, and when taking appropriate medications over a period of time, have no need to have their prescribing doctors justify to insurance carriers why the best care they can get is being delivered. The commenter asserts that group health plans once in a while request a doctor to justify major changes; but once is all it takes and there is no continued back and forth communications as is common in the workers' compensation system.

Agency Response: Labor Code §408.028(b) requires the Commissioner by rule to adopt a closed formulary, which includes the identification of an appeals process for claims in which a treating doctor determines and documents that a drug not included in the formulary is necessary to treat an injured employee's compensable injury. Prior to implementation of rules addressing this closed formulary objective, prescription medications for injured employees have not consistently been subject to prospective scrutiny for medical necessity, and subsequently have become a significant driver of long-term medical costs to the Texas workers' compensation system. Implementation of Labor Code §408.028(b), through this rule adoption, attempts to address potential overutilization of prescription medications, as these noted drug exclusions from the closed formulary are treatment and services that are now folded into other treatments

and services that also require preauthorization. The Division further clarifies that the prescribing doctor has the opportunity, through preauthorization, to explain any circumstances that might be unique to the injured employee's situation, as noted by the commenter.

§134.510(b)(1): A commenter recommends the Division Medical Advisor and Medical Quality Review Panel actively identify prescribing doctors who prescribe "N" drugs to injured employees or who prescribe an inordinate amount of drugs within the closed formulary and initiate appropriate remedial action or impose sanctions as a proactive measure if the administrative burden is too high to apply the closed formulary to all open claims effective January 1, 2011.

Agency Response: The Division notes that recommendations regarding the duties of the Office of the Medical Advisor and the Medical Quality Review Panel are outside the scope of these proposed rules. However, regardless of the applicability of the closed formulary, prescriptions are subject to retrospective review and the applicability of the Division's or certified network's treatment guidelines. In prescribing pharmaceutical services, prescribing doctors must comply with Division rules as well as the rules of the Texas Medical Board. Further, the Division clarifies that system participants may file complaints to the Medical Advisor through the Division's complaint resolution process when appropriate to facilitate necessary care of the injured employee.

§134.510(b)(1)(A): Commenters recommend changing the word "should" to "shall" to ensure that whenever a physician prescribes an "N" drug, that they be required to include a statement of medical necessity to facilitate an efficient utilization review process for 72-hour preauthorization determinations. One commenter additionally recommends the words "or that exceed or are not recommended by" be added so that subsection (b)(1)(A) would read, "The prescribing doctor shall include a statement of medical necessity as defined in §134.500(13) of this title (relating to Definitions) with the prescription for drugs excluded from, or that exceed or are not recommended by the closed formulary."

Agency Response: The Division declines to make the changes. The Division clarifies the intent is to facilitate a transition of legacy claims through a mutual agreement between the parties. However, it is not the Division's intent to create another administrative requirement and potential administrative violation by mandating the statement of medical necessity. Since the services are subject to retrospective review, the additional recommended language for subsection (b)(1)(A) is unnecessary.

§134.510(b)(1), (c), and (d): A commenter recommends a revision of subsection (b)(1) with additional subparagraphs be added as follows: "(D) When contacted by the insurance carrier, the prescribing doctor must participate in discussions of ongoing pharmacological management. The failure to participate constitutes a violation of a commission rule. (E) If no agreement is made about future pharmacological benefits,

the prescribing doctor shall submit a treatment plan for preauthorization. The insurance carrier shall process the request for preauthorization of the pharmacological treatment plan in accordance with §134.600 of this title (relating to Preauthorization, Concurrent Review, and Voluntary Certification of Health Care). (F) If an agreement about future pharmacological benefits is reached, the insurance carrier and a prescribing doctor will be deemed to have entered into a voluntary certification agreement in accordance with §134.600 of this title regarding the application of the pharmacy closed formulary for individual legacy claims on claim-by-claim basis. (G) A voluntary certification agreement shall document the agreement and the terms of the agreement. A copy of the agreement shall be sent by U.S. mail or via transmission of a facsimile to the prescribing doctor, treating doctor and injured employee. (H) Health care provided as a result of the agreement is not subject to retrospective review of medical necessity. (I) If no agreement is reached and documented by January 1, 2013 for a legacy claim, the requirements of §§134.530, 134.540, and 134.550 of this title shall apply." The commenter recommends deletion of proposed subsections (c) and (d) based on these recommended rule revisions by the commenter, which incorporate the concepts of proposed (c) and (d).

Agency Response: The Division declines to make the changes and declines to delete subsections (c) and (d) as proposed; but clarifies that some modifications have been made to this section to allow and require equal exchange of information between the parties, which are the prescribing doctor and the insurance carrier. These rules, with

additional modifications, and other Division rules address the commenter's concerns regarding agreements, but without imposing further administrative requirements.

§134.510(b)(2): A commenter suggests duties imposed on the insurance carriers for legacy claims be restricted to only those claims where active treatment (received prescriptions in the preceding 180 days) is being rendered. Identifying all legacy claims is too administratively burdensome to the insurance carriers. Another commenter requests clarification as to whether these notices are to be sent to all legacy claimants, or only those legacy claimants with ongoing active prescriptions.

Agency Response: The Division agrees that the proposed language is potentially confusing and adopted §134.510(b) is modified to clarify the expectations concerning notifications for legacy claims and that notifications should be provided for all legacy claims that have been prescribed a drug excluded from the closed formulary after September 1, 2012.

§134.510(b)(2): A commenter recommends prescribing doctors who continue to prescribe "N" medication on legacy claims after January 1, 2011 should be required to timely respond to the notices required by subsection (b)(2) with a plan for ongoing pharmacological management consistent with Division adopted treatment guidelines and closed formulary as a proactive measure if the administrative burden is too high to apply the closed formulary to all open claims effective January 1, 2011.

Agency Response: The Division agrees and changes have been made in the adopted subsection (b)(1) and (2) that address the parties providing each other a name, phone number, and date and time to discuss ongoing pharmacological management when one of the parties initiates the discussion. Although a plan is not required by the rule, the discussion between the parties is intended to result in an agreement for ongoing pharmacological management consistent with Division adopted treatment guidelines and closed formulary.

§134.510(b)(2): A commenter affirms that it should be peer-to-peer review and discussions of such activity, and not an adjuster, and additionally opines that the rule fails to acknowledge the treating doctor as gatekeeper for the provision of all health care. The commenter recommends the rule be amended to incorporate the treating doctor's role as the gatekeeper for the delivery of all health care benefits to include pharmaceutical benefits.

Agency Response: The Division agrees with the commenter's statement that peers are to review and discuss such ongoing pharmacological management. The Division notes that discussions regarding ongoing pharmacological management are considered a component of utilization review and therefore adjusters are prohibited from participating in those discussions. However, the Division disagrees that the roles of a treating doctor as outlined in the Texas Workers' Compensation Act and Division rules need further clarification or restatement because the purpose of this subsection is to

facilitate transition of legacy claims through active communication between the treating doctor and the insurance carrier to assure the continuity of care for injured employees during the transition to the closed formulary. Although the treating doctor and prescribing doctor should be in communication concerning the injured employee's care, the prescribing doctor is likely the most appropriate individual to substantiate the need for the prescribed medication and any attendant requirements of the closed formulary.

§134.510(c): A commenter recommends the rules be changed to have the voluntary certification go through the preauthorization process since it is unlikely insurance carriers will seriously consider voluntary certification requests and without preauthorization, there would be no process for appealing a denial to an insurance carrier.

Agency Response: The Division declines to make the specific change recommended by the commenter; however, the Division notes changes to this subsection have been made based on public comment to clarify that agreements may be made for both certified network and non-network claims. The preauthorization process will become effective upon implementation of the legacy claims to the closed formulary, or September 1, 2013. The agreements referenced in §134.510 are a voluntary process, and are documented by a signed and binding agreement reached by two or more parties, which eliminates the need for any denial appeals. Since these agreements are

voluntary, there is no need to impose the time constraints required in the preauthorization process.

§134.510(c): A commenter requests clarification regarding 28 TAC §134.600 and its adoption under Labor Code §413.014, and how networks are meant to follow the requirements of §134.600 as it relates to voluntary certification of pharmaceuticals. The commenter suggests the requirements regarding voluntary certification needs to be specified for networks. The commenter provides pertinent language references from proposed §134.510(c), Insurance Code §1305.351(c), and Labor Code §413.014(f).

Agency Response: The Division disagrees that specific direction is necessary to apply §134.510(c) to claims subject to a certified network. The Division, however, notes that the language in subsections (c) and (d) is amended from proposal to clarify that an agreement can be made between an insurance carrier and a prescribing doctor to ensure continuity of care during this transition of legacy claims. The specific reference to §134.600 of this title is not necessary, and is therefore removed. The adopted language now reads, "(c) Agreement. To ensure continuity of care, notwithstanding subsection (a), an insurance carrier may enter into an agreement regarding the application of the pharmacy closed formulary for individual legacy claims on a claim-by-claim basis." Adopted subsection (d)(3) now reads, "(3) Denial of a request for an agreement is not subject to dispute resolution."

§134.530(a) and §134.540(a): Commenters offer differing recommendations about the use of the terms "prescribed and dispensed." One commenter recommends rule language be based on the date of prescription, and not the date dispensed. Another commenter recommends the deletion of the words "prescribed and," stating it would be better to base the rules only on the date of the dispensing of the drug since the industry tracks pharmaceuticals based on dispensing date. Records are not kept regarding the date of prescription and using the date of prescription creates the potential for possible abuse if application of the rules depends on the date of writing the prescription.

Agency Response: The Division disagrees. The purpose for using the terms is to clarify that the closed formulary applies to the prescribing doctor at the beginning of the prescription process, as well as to the pharmacy at the actual dispensing of the medication. It is the prescription date that controls the determination of whether the drug requires preauthorization. This concept is important during the initial implementation of the closed formulary, when both conditions might not be met. Consequently, inclusion of both prescribing and dispensing emphasizes these requirements.

§134.530(b): Commenters seek clarification and guidance on how the application of the closed formulary impacts or influences prescription refills. Commenters request clarification whether each and every refill of a standing prescription require

preauthorization and whether preauthorization requirements apply to each new prescription (standing long-term therapies), or only changes in treatment therapies.

Agency Response: The Division clarifies that refills of previously preauthorized prescriptions should not require additional preauthorization, as it is covered in the initial approval. New prescriptions for previously prescribed and dispensed drugs require preauthorization.

§134.530(b): Clarification is requested by commenters whether insurance carriers/employers may contract with their PBM to provide blanket preauthorization for specific drugs, drug classes, treatment therapies or prescribing doctors in lieu of sending each indicated "N" drug through the required preauthorization process. Commenters reference costs of preauthorization compared to the price of some "N" drugs, where the preauthorization cost would far exceed actual reimbursement.

Agency Response: The Division clarifies that insurance carriers/employers cannot contract with their PBM to provide blanket preauthorization for specific drugs, drug classes, treatment therapies or prescribing doctors in lieu of sending each indicated "N" drug through the required preauthorization process. This type of contracting would essentially permit insurance carriers/employers and their PBMs to nullify the closed formulary through contract, because drugs are excluded from the formulary to ensure their proper use on a case by case basis. Moreover, a "blanket" determination of medical necessity would not meet the statutory goals of providing cost-effective and

necessary medical care to injured employees, because a "blanket" determination would, by definition, not actually determine whether the health care at issue was medically necessary for any particular claim. The Division also clarifies that unless PBMs are certified utilization agents, PBMs, in accordance with Department rules, are not permitted to conduct any utilization review activities.

§134.530(b): Commenters state the rules create a gap between prescribing of a drug by the treating doctor, dispensing by retail pharmacy, processing by PBM/third party biller, billing/reimbursement for the medication and pharmacy related pharmacy services, and further summarizing that the Division Form-066 lacks proper designated space on the physical bill form for capture and transmittal of either a preauthorization number and/or a statement of medical necessity, while the NCPDP 5.1 file format lacks the elements necessary to capture and transmit information related to attachment data such as statement of medical necessities. Commenters note this will raise costs for all pharmacy providers, insurance carriers and slow delivery of care to injured employees waiting for their "N" drugs at the retail pharmacy, and recommend as a long-term solution that the Division examine possible alterations to the Form-66 billing form or delay implementation until adoption of the NCPDP D.0 file format in 2012. Another commenter recommends the Division revise the DWC-066 form to include diagnosis codes on the billing form. The prescribing doctor would be responsible for providing the diagnosis codes to the dispensing pharmacy to support usage of a specific medication,

whether it is for standard treatment or off-label use. This information addition to the billing form will put it in line with other billing forms used in the workers' compensation industry. The form could be structured similarly to the CMS-1500 in which each line item is cross referenced to the corresponding diagnosis code. It could be potentially used in combination with a letter of medical necessity if further medical evidence is needed, or alone if the diagnosis is descriptive enough to explain why the medication was prescribed.

Agency Response: The Division notes that modification to the billing forms is outside the scope of the proposed rules. The commenters' suggestions have been forwarded to Division staff responsible for billing and reporting requirements.

§134.530(b)(1) and §134.540(b)(1): A commenter states the preauthorization process for network and non-network claims must follow an identical action plan. As currently stated, the preauthorization process should be revised such that any request be reviewed based upon medical necessity and relatedness to the compensable injury at all levels of preauthorization.

Agency Response: The Division clarifies that the preauthorization processes of medical necessity in both network and non-network settings qualify as utilization review, pursuant to Chapters 10, 19, 134, and 137 of this title (relating to Workers' Compensation Health Care Networks, Utilization Review, Benefits--Guidelines for Medical Services, Charges and Payments, and Disability Management, respectively).

Certified utilization review agents and insurance carriers are given certain administrative flexibility to effectively apply the requirements set forth in Chapters 10, 19, 134, and 137.

§134.530(b)(1) and §134.540(b)(1): A commenter notes, by not providing direction on the diagnoses of: infection, prophylaxis for infection – including prophylaxis for HIV infection, eye injury, and allergic reaction, the commenter will be required to obtain preauthorization before the medications can be dispensed to the patient by the pharmacy. The preauthorization requirement will cause delays in patients receiving proper care and will create significant bottlenecks in pharmacies ability to provide timely service.

Agency Response: The Division clarifies use of a particular drug is dependent on medical necessity, generally established by evidence-based medicine of the treatment guidelines. However, a diagnosis is not specifically required to be listed or noted in the treatment guidelines for the closed formulary to apply. For example and regardless of diagnosis, drugs excluded from the closed formulary (e.g., "N" drugs) require preauthorization, and all other drugs (e.g., drugs included in the closed formulary) do not require preauthorization and are subject to retrospective review.

§134.530(b)(1) and §134.540(b)(1): A commenter is concerned that the cost and complexity of the preauthorization and appeals process will interfere with a physician's

prescribing authority and prevent patients from receiving the treatment best suited to treat their conditions.

Agency Response: The Division disagrees that the prescribing physician's ability to provide appropriate and medically necessary care to injured employees is compromised by the applicability of the closed formulary. Prescribing doctors have access to essentially the entire pharmacopeia of FDA-approved drugs with a relatively small number requiring preauthorization. The Labor Code requires that the Division's treatment guidelines and protocols be evidence-based, scientifically valid, and outcome focused, and designed to reduce excessive or inappropriate medical care while safeguarding appropriate medical care. The preauthorization process for those drugs excluded from the closed formulary will validate the medical necessity of those drugs using the concepts of evidence-based medicine outlined in the treatment guidelines.

§134.530(b)(1), (d)(1), and §134.540(b)(1), (d)(1): Commenters state when a treating physician writes a prescription which includes an "N" drug, the physician should be required to provide a statement of medical necessity which should accompany the prescription. The treating doctor is the only one who can provide this documentation.

Agency Response: The Division disagrees that additional language is necessary. The Division recognizes, however, that certain pharmacies might wish to coordinate this activity with the prescribing doctor when the prescribing doctor has not requested preauthorization for a drug excluded from the closed formulary. Additionally, a

pharmacy, as a business practice, might also wish to communicate with the prescribing doctor if additional documentation is likely to be needed for the use of the drug included in the closed formulary. A pharmacy may request a statement of medical necessity when necessary to substantiate the medical necessity of a prescription, and the prescribing doctor shall provide the statement of medical necessity within 14 days in accordance with §134.502 of this title.

§134.530(b)(4) and (5) and §134.540(b)(2) and (3): A commenter requests clarification whether a trial for an intrathecal drug delivery system (not typically a surgical procedure) requires preauthorization. The commenter also requests clarification on the following scenario: if two doctors treating a patient, a surgeon who implants, and a pain management doctor who handles the drug prescription and refills, whether one or both preauthorizations should be submitted. The commenter requests clarification whether both preauthorizations are required, and whether they are required at the same time. For example, some surgeons will fill the pump with saline at implantation and have the pain management doctor fill the initial pain pump drug.

Agency Response: The Division clarifies that a trial may not require preauthorization if certain criteria for the trial is recommended by the Division's adopted treatment guidelines or the applicable network's treatment guideline. For injured employees not subject to a certified network in this example, surgeries in a facility setting require preauthorization in accordance with §134.600 of this title. If a separate provider is

prescribing medications that are excluded from the closed formulary beyond the trial, this provider, too, must seek preauthorization. The Division notes, however, that the provisions regarding preauthorization for intrathecal drug delivery system refills is provided under adopted new subsection (c) of §134.530 and §134.540.

§134.530(b)(4) and (5) and §134.540(b)(2) and (3): A commenter agrees with the proposed annual preauthorization requirements, stating it is very good and appreciated. However, regarding annual preauthorization for drug refills, commenter hopes the Division will be available for assistance and facilitation when working out these arrangements between insurance carriers and health care providers to ensure continual patient coverage and access to care.

Agency Response: The Division appreciates the supportive comment, and believes that the rules provide clear direction concerning refills of previously preauthorized intrathecal drug delivery systems. Additionally, the MIO process provides a mechanism to continue the use of a previously preauthorized drug in the event of an unreasonable risk of a medical emergency. Further, the Division clarifies the Office of the Medical Advisor is available when appropriate to facilitate necessary care of the injured employee.

§134.530(b)(4) and (5) and §134.540(b)(2) and (3): A commenter objects to the rule provisions and states there should be no assumptions made that refills warrant a one

year preauthorization approval. As a minimum, refills should require re-evaluation by the prescribing physician and be subject to preauthorization at least every six months if the drugs are either excluded from, exceed the treatment parameters, or is not recommended by the closed formulary. This proposal is contrary to the Division's statutory duty to promote the delivery of high quality, medically necessary health care treatment.

Agency Response: The Division disagrees. Cognizant of utilization review costs in Texas, which the Workers' Compensation Research Institute reports is high compared to other states, an annual review of a previously preauthorized medication is a measured, cost effective approach. This is particularly important since prior to the adoption of these rules, the review of intrathecal drug delivery system refills was not previously required at any time after implantation of the pump.

§134.530(b)(5) and §134.540(b)(3): A commenter recommends added language to include "exceed the treatment parameters, or is not recommended by..." so that the recommended additions to §134.530(b)(5) and §134.540(b)(3) read, "Refills of an intrathecal drug delivery system with drugs excluded from, exceed the treatment parameters, or is not recommended by the closed formulary, ..."

Agency Response: The Division declines to make the change. The implementation of the closed formulary is the primary focus of these rules. However, throughout the rule development process, system participants consistently noted there was confusion as to

the application of the treatment guidelines concerning "drugs excluded from, exceeding the treatment parameters, or not recommended by the treatment guidelines" when often these concepts were conditional and difficult for pharmacists to evaluate. A stakeholder consensus was formed early in the rule development process that a clear demarcation of drugs requiring preauthorization be implemented. Drugs excluded from the closed formulary require preauthorization. All other drugs are subject to retrospective review. In either case, the prescribing and dispensing of drugs must be consistent with the Division's or network's treatment guidelines.

§134.530(b)(6) and §134.540(b)(4): A commenter recommends a new paragraph to both rule subsections as follows: "A statement of medical necessity shall be submitted with the request for preauthorization that discusses and justifies the continuing need for drug delivery by an intrathecal drug delivery system and must be accompanied by evidence-based medical evidence."

Agency Response: The Division declines to make the change. The preauthorization process includes all the required information of a statement of medical necessity. Hence, requiring an additional statement of medical necessity is a redundant and unnecessary administrative function. If a utilization review agent believes that the submitted information will lead to a denial, the utilization review agent may pursue any necessary information through a peer-to-peer discussion with the requestor as required by Insurance Code Chapter 4201 and Chapter 19 rules.

§134.530(c): A commenter states clarification is needed on "Y" drugs that are used outside of the ODG guideline as this situation places the pharmacy in a position of risk, and regulations should be provided to help minimize or eliminate much risk as possible to the pharmacy. The commenter recommends a maximum time period of 20 days for retrospective review should be established.

Agency Response: The Division clarifies that drugs included in the closed formulary are subject to retrospective review. Most services provided in the Texas workers' compensation system are provided on this basis, regardless of the provider type. Additionally, only about ten percent of the total number of prescriptions written in calendar year 2008 was denied retrospectively. Although this is not an insignificant number, the alternative is to require preauthorization of all prescriptions, regardless of the closed formulary. This approach was universally rejected by system participants during the rule development process. Regarding the commenter's recommendation of a maximum time period for retrospective reviews, the Division clarifies that these time frames for processing claims are addressed in Labor Code §408.027.

§134.530(c) and §134.540(c): A commenter states the proposed rules are at odds with how workers' compensation drugs are commonly dispensed under current practice. The commenter further states that ignoring the current practices creates a danger of unintended consequences and runs the risk of increasing retrospective reviews, and thus, inadvertently increasing the administrative costs of handling pharmacy

reimbursements. The proposal poses the risk that pharmacies may be reluctant to provide prescription fills in the absence of an immediate electronic guarantee of payment.

Agency Response: The Division disagrees. Labor Code §408.028 requires the adoption of a closed formulary. Current Division rules require pharmaceutical services to be provided in accordance with the Division's treatment guidelines, which became effective May 1, 2007. All current prescribing practices, therefore, should be conforming to these treatment guidelines. There may be some additional costs for preauthorization when compared to retrospective review; however, these costs may be offset by a potential decreased utilization of drugs excluded from the closed formulary. This is especially relevant in light of the Workers' Compensation Research Institute's March 2010 report titled, *Prescription Benchmarks for Texas,* which indicated that Texas was higher on the utilization of prescription drugs compared to most other states studied. The average number of pills per claim with prescriptions in Texas was 41 percent higher than the 16-state median and the average number of prescriptions per claim was 34 percent higher. The Division clarifies that insurance carriers may guarantee payment to health care providers through an agreement for any drugs that do not require preauthorization. The same rationale applies to claims that are subject to a network as indicated in §134.540 of this title.

§134.530(c)(2): A commenter supports this provision and hopes there will be few instances where the retrospective review provision will result in non-payment to a pharmacy, ensuring timely access to medication is a laudable goal advanced by not requiring preauthorization for drugs included in the closed formulary.

Agency Response: The Division appreciates the supportive comment.

§134.530(c)(2): A commenter recommends deletion of this paragraph because if adopted, it would undermine the effectiveness of the treatment guidelines, at least as applied to pharmaceuticals. The Legislature's recent comprehensive reform legislation will not achieve its goals of providing quality medical care while at the same time providing such medical care in the most cost-efficient manner if adopted treatment guidelines are not rigorously enforced. Allowing prescriptions that exceed or not addressed in the medical treatment guidelines to be dispensed without any preauthorization defeats the purpose of treatment guidelines, and signals a worrisome trend that the guidelines will not be enforced in the future.

Agency Response: The Division disagrees. The applicability of treatment guidelines (as proposed in subsection (c)(2) of this section, but adopted as (d)(2)) remains in place and acts as the standard for determining medical necessity in the Texas workers' compensation system. The Division's discussions with system participants, through numerous informal drafts and stakeholder meetings, indicate that current practice does not support the concept that pharmaceuticals are currently being preauthorized in the

workers' compensation system even when they are outside or in excess of the treatment guidelines. Consequently, most prescriptions are reviewed retrospectively with an approximate ten percent denial rate in calendar year 2008. This rule conforms with the actual utilization review practice in the majority of the system today, and removes confusion concerning which drugs require preauthorization, and when they require preauthorization.

§134.530(d)(1): A commenter states since antibiotics are not considered in the closed formulary, one should assume that special authorization will be required to get such prescriptions filled.

Agency Response: The Division disagrees. FDA-approved antibiotics are included in the closed formulary. The Division notes, however, that the provisions regarding the appeals process is provided under adopted new subsection (e) of §134.530.

§134.530(d)(1): A commenter recommends that the section be modified to give the insurance carrier the power to issue certification periods of up to 90 days for excluded drugs that require preauthorization.

Agency Response: The Division disagrees that any modifications are required. Labor Code §413.014(f) supports insurance carriers and health care providers voluntarily discussing health care treatment and treatment plans, and pharmaceutical services. Therefore, if an insurance carrier, through its utilization review agent, believes that a

prescription should be written or approved for a time period other than what is submitted by the requestor, the insurance carrier may discuss that alternative with the requestor.

§134.530(d)(1): Commenters seek clarification on how non-formulary drugs will be preauthorized. A commenter opines that the introduction of a loosely standardized preauthorization process and unclear guidance on medical necessity could result in unintended costs, unfairly shift the burden further onto pharmacists, and potentially damage reliable and timely access to care by injured employees for certain drugs. Of particular concern is the process of preauthorizing drugs that are not included in the closed formulary. The commenter is concerned that 28 TAC §134.502(f) gives the prescribing doctor up to 14 working days to issue a statement of medical necessity when asked by a non-physician, creating a potentially serious delay in the timely delivery of care. The treating physician is best suited and appropriately licensed to determine what pharmacy care will best meet the needs and desired outcomes for an injured employee.

Agency Response: The Division clarifies that the preauthorization process for non-network claims is set out in §134.600 of this title, and the utilization review standards of preauthorization are detailed in Chapter 19 of this title (relating to Agents' Licensing). Further, the Division's adopted treatment guidelines provide direction for the delivery of services in the Texas workers' compensation system. For network services, individual network treatment guidelines apply as well as specific preauthorization processes that

are outlined and available for participating network providers. Although the prescribing doctor is allowed 14 days to respond to a request for a statement of medical necessity, the prescribing doctor may respond as soon as the request is made. Since the treating physician is best suited and appropriately licensed to determine what pharmacy care will best meet the needs and desired outcomes for an injured employee, the prescribing doctor should build those concepts into the timeframes for the response to the request for a statement of medical necessity.

§134.530(d)(1): A commenter requests clarification regarding ongoing coverage for "N" drugs, and if an insurance carrier is allowed to identify certain drugs for which there are no benefits, and perform utilization review for those drugs and/or allow or approve those drugs.

Agency Response: The Division clarifies that injured employees are entitled to all medical benefits in accordance with Labor Code §408.021. The adoption of the closed formulary does not contradict this portion of the Labor Code, but identifies drugs that are not included in the closed formulary and which require preauthorization to establish medical necessity.

§134.530(d)(1): A commenter states the appeal process should require approval within 24 hours and allow for dispensing of a 72-hour emergency supply of the prescribed medication. Neither the Department nor the Division has set guidelines as to how to

proceed with prior approval process; instead, the responsibility is on the physician to contact the insurance carrier for preauthorization and procedures may vary depending on the insurance carrier.

Agency Response: The Division clarifies that the preauthorization period for approval is governed by the Insurance Code Chapter 4202 and Chapter 19 of this title (relating to Agents' Licensing), and the dispensing of emergency supplies is governed by the Occupations Code and/or Texas State Board of Pharmacy rules.

§134.530(d)(1): A commenter recommends that the Division host on its website and include in the rule-making process, a requirement of insurance carriers to post and keep current their preauthorization approval processes in a public, clear, and transparent manner, accessible to both patient and provider.

Agency Response: The Division clarifies that preauthorization in the Texas workers' compensation system is utilization review and must be conducted by certified utilization review agents, or insurance carriers registered to perform utilization review. The Life, Health and Licensing Division of the Department is responsible for reviewing and approving applications for utilization review certification. Utilization review must be conducted in accordance with the Insurance Code requirements and Department rules, and consequently the utilization review processes do not vary by insurance carrier.

§134.530(d)(1), (f)(2) and §134.540(d)(1): A commenter observes the use of outside guidelines for formulary and treatment decisions takes the power of medical decision-making out the hands of the physician, and guidelines are not easily obtained and publicly available. To assure the transparency and validity of the process by which patients will be switched from a stabilized medicine to a price-based alternative, the guidelines establishing such a switch should be made available to the public at no cost. Evidence-based medicine is vaguely described and can result in the implementation of a system that is cost-based instead of outcomes focused. Another commenter opines the use of evidence-based medicine as vaguely described in the proposed rules could lead to a system where it is only used as an arbitrary cost-cutting tool, placing cost-savings over patient well-being.

Agency Response: The Division disagrees. The Labor Code §413.011(e) requires the Commissioner of Workers' Compensation to adopt treatment guidelines that are evidence-based for use in the non-network system. Similarly, Insurance Code Chapter 1305 and Chapter 10 of this title also require a certified network to have treatment guidelines that are evidence-based and that care provided within these guidelines is considered reasonably required. These guidelines are the standard to apply for the care of injured employees in whose claim is not subject to a certified network, or is subject to a certified network respectively. The health care provider must consider care above or below the guidelines consistent with the unique factors associated with an injury. These rules and the disability management concept anticipate certain care

outside or inconsistent with the treatment guidelines be managed by the treating doctor as coordinated by the utilization review processes. Care provided within the guidelines is presumed reasonable as specified in Labor Code §413.017 and also assumed to be health care reasonably required as specified in Labor Code §401.011(22-a). Labor Code §413.011(e) also states treatment may not be denied solely on the basis that the treatment for the injury in question is not specifically addressed by the treatment guidelines. Further, Labor Code §401.011(18-a) defines evidence-based medicine. The Division also clarifies that the decisions concerning the drugs excluded from the closed formulary are not priced-based, but are consistent with the recommendations outlined in the Division's treatment guidelines. Injured employees continue to have access to drugs excluded from the closed formulary through the preauthorization process based on medical necessity. The Division notes, however, that the provisions regarding the appeals process is provided under adopted new subsection (e) of §134.530 and §134.540.

§134.530(d)(2): A commenter suggests this portion of the rule proposal should be modified to state that the Division will request the statement of medical necessity from the prescribing doctor. The commenter agrees that a statement of medical necessity will facilitate the preauthorization process, but is concerned that these provisions will be of limited effectiveness if the Division is not the requestor. If the Division were the requestor, there would be a greater chance that the statement of medical necessity

would be provided and, accordingly, that information essential to making the correct preauthorization decision would be obtained and considered. The only apparent consequence of a prescribing doctor not providing the statement of medical necessity would be a referral for an administrative violation. However, that enforcement mechanism cannot feasibly be pursued by injured employees against their treating doctors due to the negative consequences such a referral would pose to the doctor-patient relationship. If the Division is going to be the requestor, the rule should be revised to clearly state that and to explain how an injured employee or a non-prescribing doctor requestor would ask the Division to request the statement of medical necessity. Alternatively, if the Division is not to be the requestor, the rule should delineate sufficient consequences of the prescribing doctor's failure to comply to ensure that the statement can be obtained.

Agency Response: The Division disagrees. Utilization review, including preauthorization, is a process of review of the medical necessity and appropriateness of health care services, generally on a peer-to-peer basis that is traditionally between the requesting health care provider and the insurance carrier. The commenter's suggestion that the Division begin processing statements of medical necessity for specific bills is contrary to the recommendations in the Sunset Advisory Committee Report issued July 20, 2010, which suggested that the Division has a limited role in making decisions on individual claims. Further, the Sunset Advisory Committee Report indicated that insurance carriers are well positioned to manage individual claims. System participants

are capable of communicating with each other and sharing required information without inserting the Division into a completely clerical process. However, the Division is available to resolve disputes if the system participants fail to complete the documentation requirements.

§134.530(d)(3): A commenter recommends that this be modified to permit a reconsideration process of preauthorization denials prior to requests for a full independent review organization (IRO) review because it would be more efficient if there was an opportunity for the insurance carrier to process a reconsideration of a denied medication prior to requesting an IRO review.

Agency Response: The Division declines to make the change, but notes that proposed subsection (d)(3) has been relettered to (e)(3) as a result of renumbering changes made throughout the section. Further, the Division clarifies that the reconsideration process is not required in the event of an MIO request in order to expedite the process and avoid a medical emergency for the injured employee. The insurance carrier may continue to attempt to resolve any potential dispute with the prescribing doctor as Labor Code §413.014(f) supports insurance carriers and health care providers voluntarily discussing health care treatment and treatment plans, and pharmaceutical services.

§134.530(e)(1): A commenter recommends deletion. The commenter states retrospective review of medical treatment and pharmaceuticals is essential to effective workers' compensation medical cost containment. Rules that would eliminate both preauthorization and retrospective review for initial pharmaceutical coverage for drugs within the closed formulary increases the risk that unnecessary pharmaceutical costs will continue to impair the Texas workers' compensation system. At the very least, drugs within the closed formulary should be within the treatment guidelines and should be subject to retrospective review. Drugs that are excluded from the closed formulary should be subject to preauthorization and the treatment guidelines as well as retrospective review. The commenter recommends adoption of the language proposed in the initial December 2008 informal working draft rules that struck the correct balance by retaining retrospective review of initial pharmaceutical coverage but prohibiting preauthorization: "Subject to retrospective review, drugs prescribed in accordance with §134.501 of this title (relating to Initial Pharmaceutical Coverage) may be dispensed without preauthorization in accordance with §134.600 of this title. However, such prescription and dispensing is subject to the process for review and audit of workers' compensation medical bills in accordance with §133.230 and §133.240 of this title." The commenter states there is no justification or policy rationale for prohibiting preauthorization and retrospective review for initial pharmaceutical coverage where such prescriptions are either not within the medical treatment guidelines or are not within the adopted closed formulary.

Agency Response: The Division declines to make the change, and notes, however, that the provisions regarding initial pharmaceutical coverage is provided under adopted new subsection (f) of §134.530. The provisions of Labor Code §413.0141 allow the Commissioner to require payment for specified pharmaceutical services for the first seven days following the date of injury when certain criteria are met. Additionally, the initial pharmaceutical requirements (initial fill) were considered in several stakeholder meetings. Although medical necessity is a key component of the delivery of any services in the Texas workers' compensation system, the unique delivery system for pharmaceutical services complicates the medical necessity decisions for initial fill pharmaceutical services in the first seven days after an injury. Allowing initial fills of prescriptions assures timely access to needed drugs for injured employees and begins their immediate journey to return-to-work. Further, this approach assures that pharmacists are not denied payment due to a retrospective review of medical necessity for the initial seven day period post-injury. Retrospective review and denial of payment for these initial pharmacy services in the first seven days post-injury threatens the ability of injured employees to receive these initial fill prescriptions when the claim itself may not yet be reported to the insurance carrier.

§134.530(e)(1): A commenter expresses support of proposed language and agrees that retrospective review of medication decisions made during that period would have the potential to significantly undermine the statute.

Agency Response: The Division appreciates and agrees with the supportive comments.

§134.530(e)(1): Commenters state that the injury speaks for itself, pain level is self-evident, allergies to medications and the timing of the event (weekends). Although the proposal calls for a seven-day period, the cost of providing a 30-day versus a seven-day prescription is not substantially different. Certainly there is a decrease in product cost, however splitting a prescription and then establishing a mechanism to track/monitor the remaining balance is costly and the recommendation is to change this to 30 days first fill in all circumstances.

Agency Response: The Division declines to make the change and clarifies the requirement of Labor Code §413.0141 only provides the Commissioner the authority to extend first fill payments to pharmaceutical services sufficient for the first seven days following the date of injury.

§134.530(e)(1): A commenter seeks clarification regarding proposed language and whether "no preauthorization" means PBMs/payers must allow that "Y" or "N" drug, or can allow it. As an example, the commenter seeks clarification if a PBM has to allow Embeda ("Y") and Enbrel ("N") for first fill.

Agency Response: The Division clarifies that adopted §134.530(e) allows drugs included in the closed formulary to be dispensed without preauthorization and are not

subject to retrospective review of medical necessity during the initial seven days after the date of injury. Drugs excluded from the closed formulary ("N" drugs), may also be dispensed without preauthorization during the initial seven days after the date of injury, but are subject to retrospective review, except investigational and experimental drugs which always require preauthorization. Regarding the commenter's notation of PBMs, the Division clarifies that unless PBMs are certified utilization review agents, PBMs, in accordance with Department rules, are not permitted to conduct any utilization review activities.

§134.530(e)(1) and (2): Commenters recommend deletion of language subjecting initial fill of "N" drugs to subsequent retrospective review to ensure that injured employees can receive immediate pharmacy treatment with medications that are indicated as "N" on the closed formulary, and note that proposal language may be somewhat confusing and possibly force a chilling effect, specifically on initial dispensing of "N" drugs meant to protect the injured employee where instant preauthorization is unattainable, and defeat the purposes of the Labor Code in addressing initial fills. One commenter asserts that because the initial fill is subject to retrospective review, many pharmacies may choose not to provide the initial fill on "N" drugs since there is significant risk of non-payment. Another commenter disagrees with proposal and states the existence of Labor Code §413.0141 demonstrates the legislative intent to provide broad access to medication during the first seven days following an injury. Retrospective review runs counter to that

objective and intent and the commenter recommends appropriate modification of this provision so that there is no retrospective review in the first seven days, not even those drugs not included in the closed formulary.

Agency Response: The Division declines to make the changes. In developing the rules, the Division was required to harmonize the requirement to adopt a closed formulary and the authority of the Commissioner to adopt rules regarding initial pharmaceutical services. Although some system participants requested retrospective review of all initial pharmaceutical services, others requested the opposite approach of no review of any initial fill regardless of status relative to the closed formulary. As a result, the Division has established an approach that maintains the intent of the adoption of a closed formulary and provides access to initial pharmaceutical services without requiring a potentially burdensome and costly preauthorization process. Further, the Division clarifies that the initial fill drugs dispensed in the first seven days after the injury are currently subject to retrospective review for medical necessity.

§134.530(f) and §134.540(e): A commenter opposes the ability and authority of insurance carriers to retrospectively review the dispensing of prescriptions that do not require preauthorization, which the commenter states punishes the pharmacist, not the prescribing doctor.

Agency Response: In accordance with Labor Code §§408.021, 408.027, 413.014 and 413.031, and other relevant provisions under the Texas Workers' Compensation Act,

Insurance Code, department and division rules, the Division clarifies that insurance carriers are required to pay only for medically necessary treatments or services. The medical necessity of a treatment or service is established through the utilization review process, which includes prospective, concurrent, and retrospective review. If pharmacies believe that prescribing doctors are consistently prescribing drugs that are not medically necessary, the pharmacy may file a complaint with the Department. The Division clarifies that the initial fill drugs dispensed in the first seven days after the injury are currently subject to retrospective review for medical necessity. The Division notes, however, that the provisions regarding retrospective review is provided under adopted new subsection (g) of §134.530 and §134.540.

§134.530(f) and §134.540(e): In regards to ongoing coverage, the commenter seeks clarification about "Y" drugs that require no preauthorization, but are subject to retrospective review, and whether this means PBMs/payer must allow, or can allow.

Agency Response: The Division clarifies that preauthorization requirements for pharmaceutical services only apply to those drugs excluded from the closed formulary. Further, the Division clarifies that unless PBMs are certified utilization review agents, PBMs, in accordance with Department rules, are not permitted to conduct any utilization review activities.

§134.530(f)(3): A commenter recommends the language be modified to read: "A prescribing doctor who prescribes pharmaceuticals that exceed, are not recommended, or are not addressed by §137.100 of this title, is required to provide documentation of evidence-based medicine demonstrating that treatment within the guidelines of §137.100 of this title would not be effective and documentation upon request in accordance with §134.500(13) of this title and §134.502(e) and (f) of this title." To be effective, treatment guidelines must be consistently followed. While for particular individuals, variances from the guidelines may be necessary, it is critical that such variances be kept at a bare minimum. Otherwise, the guidelines will become "paper tigers" and easily breached. In addition to the statement of medical necessity, a prescribing doctor who is prescribing drugs that are either inconsistent with the guidelines or at levels in excess of the guidelines, should need to provide objective medical documentation demonstrating that treatment within the guidelines would be ineffective for the particular claimant.

Agency Response: The Division declines to make the change. The treatment guidelines continue to be in effect, and services not preauthorized continue to be subject to retrospective review. Currently, approximately ten percent of claims are denied retrospectively. If health care providers consistently practice outside the Division's treatment guidelines, the Division's Office of the Medical Advisor may pursue a review of those specific practices.

§134.540: A commenter questions the Commissioner's statutory authority to apply the open and closed formularies to workers' compensation networks because Insurance Code Chapter 1305 prohibits the delivery of prescription medication services through a network. Networks have contracts and relationships with their prescribing doctors and should have the ability to develop treatment guidelines and preauthorization requirements and processes that are tailored to the network's needs and relationships, which could be more restrictive or more liberal than preauthorization requirements and treatment guidelines adopted by the Commissioner for non-network claims.

Agency Response: The Division clarifies that Insurance Code §1305.101(c) states that: "Notwithstanding any other provision of this chapter, prescription medication or services, as defined by Section 401.011(19)(E), Labor Code, may not be delivered through a workers' compensation health care network." Insurance Code §1305.101(c) is also explicit that "Prescription medication and services shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the commissioner of workers' compensation."

An open formulary is applicable to both non-networks and certified networks because it is a continuation of pharmaceutical services initiated by the 77th Legislature, Regular Session through enactment of HB 2600 for the benefit of all injured employees in the workers' compensation system and implemented by the Division. The open formulary continues in effect for all prescription medication and services until such time as the closed formulary that is required by Labor Code §408.028(b) is fully

implemented. The continuation through a transition period is necessary in order for the claims with dates of injury prior to September 1, 2011 (legacy claims) to have a successful transition to the closed formulary. The transition provides an implementation "bridge" between the two systems because of the anticipated volume of legacy claims requiring preauthorization.

The Division's pharmacy closed formulary is also applicable to certified networks. Both Insurance Code Chapter 1305 which created certified networks and the Labor Code §408.028(b) provision requiring the Commissioner to adopt a closed formulary were enacted under HB 7 by the 79th Legislature, Regular Session. As clearly set forth by the Legislature, certified networks are only authorized to adopt treatment guidelines, return to work guidelines, and individual treatment protocols in accordance with Insurance Code §1305.304. Consequently, certified networks have the ability to develop treatment guidelines and preauthorization requirements and processes that are tailored to the network's needs and relationships, which could be more restrictive or more liberal than preauthorization requirements and treatment guidelines adopted by the Commissioner for non-network claims.

§134.540: A commenter recommends closed formulary rules be contained within one rule, not in separate rules, for network and non-network claims since the preauthorization process and treatment guidelines would never apply. Insurance Code §1305.351(c) provides that the Division's preauthorization requirements do not apply to

health care provided through a workers' compensation health care network, and the commenter asserts that under the Texas Workers' Compensation Act, prescription medication is never considered to be health care provided through a workers' compensation health care network, and therefore, Division preauthorization requirements should apply. The commenter further opines that Insurance Code §1305.101(c) also provides that prescription medication and services shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the Commissioner of Workers' Compensation; network treatment guidelines are adopted pursuant to Insurance Code §1305.304 and TDI rules; therefore, the Division's treatment guidelines apply to reimbursement for all prescription medication and not network treatment guidelines.

Agency Response: The Division disagrees and declines to make the change. The separation of sections 134.530 and 134.540 as adopted are necessary to clearly delineate the statements made by the commenter regarding differing treatment guidelines and preauthorization processes between claims subject to a certified network and claims not subject to a certified network. Regarding the commenter's statement concerning reimbursements for prescriptions, the Division notes it is outside the scope of the proposed rules.

§134.540: A commenter seeks clarification whether 28 TAC §134.501 of this title (relating to Initial Pharmaceutical Coverage) applies to certified networks as stated in Labor Code §413.0141 and by proposed §134.530(e)(1).

Agency Response: The Division clarifies that initial pharmaceutical requirements of Labor Code §413.0141 apply to both certified network and non-network claims since there is no conflict between Labor Code §413.0141 and Insurance Code Chapter 1305 and because reimbursement of pharmaceutical medication and services are governed by the Act and Division rules. Insurance Code §1305.101(c) states that: "(c) Notwithstanding any other provision of this chapter, prescription medication or services, as defined by Section 401.011(19)(E), Labor Code, may not be delivered through a workers' compensation health care network. Prescription medication and services shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the commissioner of workers' compensation." Consequently, the language in adopted §134.540 (f) is amended to indicate applicability to certified networks.

§134.540(b)(2) and (3): Commenters recommend that language for certified networks mirror provisions of non-network in §134.530(b)(4) and (5) as it pertains to preauthorizing and pain pumps. It would benefit patient care to have consistent processes in place for network and non-network settings since the closed formulary must be utilized in both scenarios, and would better facilitate the entire treatment

process. A commenter further states that any deviation from one guideline to another is difficult for health care providers to keep up with.

Agency Response: The Division agrees and the adopted rule language is changed to be consistent with the language included in §134.530. The change makes the certified network intrathecal drug delivery system refill appeal "process" consistent with the appeal "process" used by non-networks for intrathecal drug delivery system refills. The closed formulary applies to certified networks and non-networks and includes an appeal process. The adopted language addresses and explains the appeal process for refills when the drug is excluded from the closed formulary. The new subsection (c) addressing an intrathecal drug delivery system has necessitated the re-lettering of the remaining subsections of this section. This change simplifies the process for delivery of health care in both the certified network and non-network settings.

§134.550: A commenter recommends an injured employee be allowed to request an MIO, because they are the people most affected if medication is withheld.

Agency Response: The Division disagrees. Adopted elsewhere in this issue of the *Texas Register* are amendments to §133.306 of this title which allow injured employees to request an interlocutory order for drugs excluded from the closed formulary. The process of requesting an MIO under adopted §134.550 requires the involvement of the prescribing doctor to protect against potential abuse and also should help avoid an unreasonable risk of a medical emergency. The distinction in the interlocutory orders is

that under §134.550 a prescribing doctor or pharmacist may request an MIO for drugs excluded from the closed formulary when the drug was previously prescribed and dispensed and failure to fill the prescription may result in an unreasonable risk of a medical emergency for an injured employee. However, an injured employee may pursue an interlocutory order for continued access to health care, including pharmaceutical services excluded from the closed formulary, under §133.306 when the injured employee would not be able to receive medical benefits that are medically necessary and constitute health care reasonably required.

§134.550: A commenter indicates there is not opposition to the MIO concept, but believes as drafted, the MIO process could circumvent the preauthorization process. The commenter states there should be strict requirements for getting an MIO and some initial scrutiny as this should be a rare exception and not the rule. While the MIO will address the short-term problems with discontinuing an excluded drug, there is no requirement that the prescribing doctor submit a separate plan to transition the injured employees to a drug(s) that is included in the closed formulary.

Agency Response: The Division clarifies that the adopted requirements to request an MIO under adopted §134.550 requires the requestor to include documentation that a preauthorization request has been submitted and denied and that a request for an independent review has already been submitted. If an MIO is ordered, the disputed medical necessity of the prescription at issue will continue through the utilization review

and medical dispute resolution process until the issue is resolved and becomes final. At that time a party may seek to overturn the MIO and may also seek reimbursement from the Subsequent Injury Fund (SIF). This process does not compromise the initial preauthorization process. The MIO process will prevent medical emergencies that could be created by preauthorization denials and the prescribing doctor who has his or her MIO overturned would have to seek other treatment alternatives. The MIO will have initial scrutiny since there are many requirements that must be met before an MIO can be submitted as complete. Additionally, the Division will continue to monitor the MIO process during the time that the closed formulary takes effect for new injuries until the closed formulary applies to legacy claims in September of 2013, and will make changes if necessary.

§134.550: A commenter recommends deletion of this section as it creates a process by which a medical provider can bypass the closed formulary. The MIO process creates an easy method to short circuit the entire closed formulary and establishes a system ripe for abuse since it authorizes the medical provider to file for an MIO where there was a preauthorization denial. Drugs are excluded from the closed formulary for a reason, and it makes no sense to allow a doctor to bypass the safeguards of the closed formulary via an unsubstantiated claim of medical emergency. A commenter questions the creation of a closed formulary and a preauthorization process to combat

inappropriate and costly use of pharmaceuticals if the system is then going to authorize the same medical providers to bypass the system by filing an MIO.

Agency Response: The Division disagrees. The MIO process will prevent medical emergencies that could be created by preauthorization denials and a prescribing doctor whose MIO is overturned would have to seek other treatment alternatives. Section 134.550 contains documentation requirements providing initial scrutiny that must be met and completed and therefore would prevent abuse. Further, the medical threshold to meet is the unreasonable risk of a medical emergency. If an MIO is ordered the disputed medical necessity of the prescription at issue will continue through the utilization review process until the issue is resolved and becomes final. At that time a party may seek to overturn the MIO and may also seek reimbursement from the SIF. This process does not circumvent the preauthorization process.

§134.550: A commenter recommends the Division provide a process where injured employees may obtain medications through interlocutory orders. The commenter is concerned that the process may be too complex, and recommends streamlining such that once a prima facie showing has been made that the potential for a medical emergency exists if the medication is suddenly withdrawn, the MIO should be entered.

Agency Response: The Division agrees that injured employees need a way to have access to drugs if an unreasonable risk of a medical emergency arises. Section 134.550 is established to allow health care providers to provide necessary information

to validate the need for the continued use of a previously prescribed and dispensed drug that is now being denied through the statutorily required appeals process. The prescribing doctor and pharmacists are best qualified to provide the information required by §134.550 including the unreasonable risk of a medical emergency. These adopted provisions in §134.550 are a safety net for injured employees subject to a potential medical emergency when denied preauthorization of a previously prescribed drug which is not included in the Division's pharmacy closed formulary. Without the section amendments, §133.306 would only have allowed an interlocutory order to be entered into in situations where there is a compensability, liability, or extent of injury dispute and the Division determines that the prescribed drug was medically necessary or after the conclusion of the medical dispute process. The amendments to §133.306 accommodate the MIO as set forth in the new adopted §134.550 with the purpose of providing a system by which a prescribing doctor or pharmacy is able to obtain an MIO in cases where an injured employee faces an unreasonable risk of a medical emergency because they have been denied "N" drugs that have previously been prescribed and dispensed to them. Although the process outlined for an MIO in §134.550 is limited to pharmacists and prescribing doctors, injured employees may continue to use the processes outlined in amended §133.306 to pursue interlocutory orders concerning medical benefits.

§134.550(a): A commenter states it is clear from review of the legislative intent of HB 2512 that the Commissioner of Insurance or his designee must review a request for an interlocutory order and conclude that a disputed prescription constitutes essential medical benefits prior to the issuance of an MIO. The commenter recommends that the Medical Advisor, or Assistant Medical Advisors, as his designees, review the request and issue the MIOs. The commenter asserts the MIOs should not be reviewed and processed by non-medical staff and without determination by clinically qualified individuals that the disputed prescription is essential medical benefits.

Agency Response: The Division clarifies that under Labor Code §§402.0111, 402.00116, 402.00128 and 402.042, the Commissioner has the authority to designate who will review the request for an interlocutory order or MIO, and issue such orders.

§134.550(c)(9): A commenter states it is not clear how the required statement differs from a statement of medical necessity.

Agency Response: The Division clarifies that the information included in the statement of medical necessity document is required as part of the preauthorization process to establish medical necessity. The information required by §134.550(c)(7) to (c)(11) are affirmative statements that the requirements for an MIO have been met.

§134.550(d): A commenter expresses concern about the proposal to process incomplete requests and opines that an incomplete request for an MIO should not be

accepted by the Division. Inappropriate and unnecessary pharmaceutical benefits could be provided to an injured employee if the Division acts upon an incomplete request for an MIO. The commenter states the Division should identify the required elements of the request that are missing and contact the submitting physician, providing the physician with an opportunity to submit the missing elements of the request within a specific period of time set out in the rule. The MIO process should include a review of the proposed prescription refill to determine appropriateness, medical necessity, quality health care, and potential for medical emergency has been met if prescription drugs not provided to the injured employee.

Agency Response: The Division disagrees that additional restrictions are required for the Division to evaluate a request for an MIO. The purpose of the MIO is to prevent the potential medical emergency noted in the request. Since time is of the essence, the Division needs the flexibility to approve requests in the event that an administrative error or omission by the requestor would potentially jeopardize the health of an injured employee. Additionally, the Division will continue to monitor the MIO process during the time that the closed formulary takes effect for new injuries until the closed formulary applies to legacy claims in September of 2013, and will make changes if necessary.

§134.550(d) and (h): A commenter indicates there is an incentive to forego the requirement for reconsideration of denied drugs. The commenter asserts the Division reserves the discretion to find an MIO as complete retroactively, notwithstanding a lack

of rule requirements, compliance, increasing the danger of circumvention, and increased system cost seeking resolution of a vagueness.

Agency Response: The Division clarifies that the requirement for reconsideration prior to pursuing dispute resolution is waived when pursuing an MIO thereby facilitating the filling of a prescription in order to avert a potential medical emergency.

§134.550(k): A commenter requests clarification of the consequences of treating withdrawal as acceptance of the preauthorization denial of this subsection. Specifically, the commenter requests clarification of how the effects of acceptance of the denial differ from an adverse decision in a preauthorization medical necessity dispute resolution proceeding.

Agency Response: The Division is unable to comment on the effects of a withdrawal of an MIO request without a more detailed illustration of the question. The specific effects of a withdrawal are likely to be conditioned on the specifics of the case and the application of those factors to the case by the requestor.

§134.550(n): A commenter states the word "may" is cause for concern, and should be substituted with the word "shall." The commenter further recommends that rule language should clarify that payments made by insurance carriers pursuant to this section shall be eligible for reimbursement from the SIF in the event the MIO order is found to have been issued in error or a final decision of an IRO or contested case

hearing determines that the underlying prescription drugs were not medically necessary and/or appropriate and the MIO should not have been issued. Such recommended changes are consistent with the intent of HB 2512 and Labor Code §413.055.

Agency Response: The Division disagrees and declines to make the change. Labor Code §413.055 allows for reimbursement from the SIF for reversed or modified interlocutory orders. However, the reimbursement is contingent on meeting the requirements specified under §116.11 of this title (regarding Request for Reimbursement from the Subsequent Injury Fund) concerning when and how a reimbursement request is to be submitted. Further, reimbursement made pursuant to Labor Code §413.055 requires that the insurance carrier timely provide all documentation reasonably required to the SIF Administrator and to provide notice of any relevant pending dispute, litigation or other information that may affect the reimbursement request. Additionally, reimbursement is subject to §116.12 of this title (relating to Subsequent Injury Fund Payment/Reimbursement Schedule), which sets forth the reimbursement priority schedule, payment allocation and processing of reimbursement of claims. According to the priority schedule, claims by insurance carriers for reimbursement pursuant to Labor Code §413.055 are (a)(3) on the priority list. Since there are two categories of claims ahead, reimbursement is not guaranteed. The insurance carrier is eligible for reimbursement but payment is not always assured.

§134.550(p)(2): A commenter requests clarification on the need to provide for a second hearing process when an MIO has been entered. It is axiomatic that in any case where an MIO is being sought, the medical dispute process has already been invoked and the case is headed toward a hearing. Yet §134.550(p)(2) provides that if an MIO is entered, the insurance carrier may request a hearing. The commenter believes this would seem to be redundant unless it is envisioned that a separate hearing process where the MIO is granted has been held. If this is the case, the commenter questions what will happen if the results of the two separate hearings are inconsistent. In addition, it is unclear why the insurance carrier would need a hearing because this rule already provides for reimbursement from the SIF if the MIO is reversed.

Agency Response: The Division clarifies that Labor Code §413.055 establishes that a party that disputes an order under §413.055(a) is entitled to a hearing and that the order is binding during pendency of that appeal. Since the insurance carrier did not have a hearing when the MIO was requested, the hearing allowed by §413.055 is not redundant.

5. NAMES OF THOSE COMMENTING FOR AND AGAINST THE SECTIONS.

For: None.

For, with changes: Corporate Pharmacy Services, Inc.; CorVel Corporation; Covington Healthcare Associates, LLC; Insurance Council of Texas; Injured Workers' Pharmacy; Law Office of Pamela R. Beachley; myMatrixx; Office of Injured Employee

Counsel; Pfizer, Inc.; PMSI; Property Casualty Insurers Association of America; St. Mary's Managed Prescription Program; Texas Association of School Boards; Texas Lobby Solutions; Texas Mutual Insurance Company; Texas Pain Society; Texas Pharmacy Association; Texas Pharmacy Business Council; and Workers' Compensation Pharmacy Alliance.

Against: Memorial Compounding Pharmacy and PhRMA.

Neither for or Against: American Insurance Association; CompPharma; Coventry Workers' Comp Services; First Script Network Services; OccuMed; ReCept Pharmacy; State Office of Risk Management; and Stone River.

6. STATUTORY AUTHORITY. The amendments and new sections are adopted under the Labor Code §§408.028, 401.011, 413.0111, 413.055, 410.209, 413.0141, 402.042, 408.021, 408.027, 408.0271, 413.011, 413.013, 413.014, 413.015, 413.017, 413.020, 413.031, 409.009, 409.0091, 413.0511, 413.053, 402.00111, 402.00116, 402.00128, and 402.061; Insurance Code Chapters 1305, 4201, and 4202, Occupations Code §§551.003, 562.001 and 562.154 and Occupations Code Chapter 157 and Chapter 563. Labor Code §408.028 requires the adoption of a closed formulary in the workers' compensation system. Section 408.028 also requires an appeals process for the closed formulary as well as the use of generics and clinically-appropriate over-the counter alternatives to prescription medication. Section 401.011 contains definitions used in the Texas workers' compensation system (in particular, §401.011(18-a), the definition of

"evidence-based medicine," §401.011(19)(E), the definition of "health care," which includes a prescription drug, medicine or other remedy, and §401.011(42), the definition of "health care reasonably required."). Section 413.0111 requires that a rule on reimbursement of prescription medication or services must authorize pharmacies to use agents or assignees to process claims and act on behalf of pharmacies. Section 413.055 provides that the Commissioner may enter interlocutory orders regarding medical benefits, allows reimbursement under the Subsequent Injury Fund for reversed or modified orders and entitlement to a hearing to dispute the order which is binding during the pendency of the appeal. Section 410.209 requires the Subsequent Injury Fund to reimburse an insurance carrier any benefits overpayment made under an interlocutory order or decision that is reversed or modified. Section 413.0141 sets forth that the Commissioner may by rule provide that an insurance carrier shall provide for payment of specified pharmaceutical services for the first seven days following the date of injury if certain conditions are met. Section 402.042 requires the Commissioner to develop and implement policies clearly defining respective responsibilities of the Commissioner and Division staff. Section 408.021 states that an injured employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. Section 408.027 requires a health care provider to submit a claim for payment to the insurance carrier for health care services provided to the injured employee not later than the 95th date on which the health care services are provided and the insurance carrier must pay, reduce, deny or determine to

audit the health care provider's claim not later than the 45th day after the date of receipt by the insurance carrier of the health care provider's claim. Section 408.0271 allows for reimbursement by the health care provider if the insurance carrier determines that the health care services provided to the injured employee are inappropriate. Section 413.011 requires the Commissioner by rule to establish medical policies and guidelines relating to necessary treatment for injuries and designed to ensure the quality of medical care and to achieve effective medical cost control. Section 413.013 requires the Commissioner by rule to establish programs related to health care treatments and services for dispute resolution, monitoring and review. Section 413.014 requires preauthorization by the insurance carrier for specified health care treatments and services. This section also provides that a preauthorized treatment or service is not subject to retrospective review of its medical necessity. Section 413.015 requires insurance carriers to pay charges for medical services as provided in the statute and requires that the Commissioner by rule to ensure compliance with the medical policies and fee guidelines through audit and review. Section 413.017 provides a presumption of reasonableness for medical services fees that are consistent with Division medical policies and fee guidelines and medical services that are provided subject to prospective, concurrent or retrospective review as required by Division policies and authorized by the insurance carrier. Section 413.020 requires the Commissioner by rule to establish Division charges for evaluation of an insurance carrier or health care provider's services and fees. Section 413.031 provides for procedures for medical

dispute resolution. Labor Code §409.009 allows a person to file a written claim with the Division as a subclaimant if the person has provided compensation, directly or indirectly, to or for an employee, has sought, and has been refused compensation by the insurance carrier. Labor Code §409.0091 provides for reimbursement procedures for certain entities such as an insurance carrier and an authorized representative of an insurance carrier and includes reimbursement procedures for subclaims of health care insurers. Section 413.0511 requires that the Medical Advisor must make recommendations regarding the adoption of rules and policies concerning health care. Section 413.053 requires the Commissioner by rule to establish standards of reporting and billing governing both form and content. Section 402.00111 provides that the Commissioner shall exercise all executive authority, including rulemaking authority, under the Labor Code and other laws of this state. Section 402.00116 grants the powers and duties of chief executive and administrative officer to the Commissioner and the authority to enforce Labor Code Title 5, other workers' compensation laws of this state, and other laws granting jurisdiction to or applicable to the Division or Commissioner. Section 402.00128 vests general operational powers to the Commissioner to conduct daily operations of the Division and implement Division policy including the duty to delegate, assess and enforce penalties and enter appropriate orders as authorized by Labor Code Title 5. Section 402.061 provides the Commissioner the authority to adopt rules as necessary to implement and enforce the Texas Workers' Compensation Act. Insurance Code Chapter 1305 is the Workers'

Compensation Health Care Network Act and contains treatment guidelines and authorization requirements applicable to certified networks. Chapter 4201 concerns utilization review agents and applies to utilization review of health care service provided to a person eligible for workers' compensation medical benefits under Labor Code Title 5. Labor Code Title 5 prevails in the event of a conflict between Chapter 4201 and Labor Code Title 5. Chapter 4202 concerns independent review organizations, entities utilized in a dispute over the issue of medical necessity and reasonableness. Occupations Code §551.003 provides the definitions of "compounding" and "substitution". Section 562.001 provides the definition of "generically equivalent". Section 562.154 provides for distribution of compounded and prepackaged products to certain pharmacies. Occupations Code Chapter 157 allows a physician to delegate the authority to carry out or sign prescription drug orders to an advanced practice nurse or physician assistant. Chapter 563 concerns prescription requirements; delegation of administration and provision of dangerous drugs. The chapter also allows the dispensing of dangerous drugs in certain rural areas.

7. TEXT.

§134.500. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

(1) Brand name drug--A drug marketed under a proprietary, trademark-protected name.

(2) Certified workers' compensation health care network (certified network)--An organization that is certified in accordance with Insurance Code Chapter 1305 and department rules.

(3) Closed formulary--All available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but excludes:

(A) drugs identified with a status of "N" in the current edition of the Official Disability *Guidelines Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates;

(B) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; and

(C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in **Labor Code §413.014(a).**

(4) Compounding--As defined under Occupations Code §551.003(9), the preparation, mixing, assembling, packaging, or labeling of a drug or device:

(A) as the result of a practitioner's prescription drug order based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner-patient-pharmacist relationship in the course of professional practice;

(C) in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or

(D) for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing, except as allowed under Occupations Code §562.154 or Occupations Code Chapter 563.

(5) Generic--See generically equivalent in definition of paragraph (6) of this section.

(6) Generically equivalent--As defined under Occupations Code §562.001, a drug that, when compared to the prescribed drug, is:

(A) pharmaceutically equivalent--Drug products that have identical amounts of the same active chemical ingredients in the same dosage form and that meet the identical compendia or other applicable standards of strength, quality, and purity according to the United States Pharmacopoeia or another nationally recognized compendium; and

(B) therapeutically equivalent--Pharmaceutically equivalent drug products that, if administered in the same amounts, will provide the same therapeutic effect, identical in duration and intensity.

(7) Medical emergency--The sudden onset of a medical condition manifested by acute symptoms of sufficient severity, including severe pain that in the absence of immediate medical attention could reasonably be expected to result in:

(A) placing the patient's health or bodily functions in serious jeopardy; or

(B) serious dysfunction of any body organ or part.

(8) Nonprescription drug or over-the-counter medication--A non-narcotic drug that may be sold without a prescription and that is labeled and packaged in compliance with state or federal law.

(9) Open formulary--Includes all available Food and Drug Administration (FDA) approved prescription and nonprescription drugs prescribed and dispensed for outpatient use, but does not include drugs that lack FDA approval, or non-drug items.

(10) Prescribing doctor--A physician or dentist who prescribes prescription drugs or over the counter medications in accordance with the physician's or dentist's license and state and federal laws and rules. For purposes of this chapter, prescribing doctor includes an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders, under Occupations Code Chapter 157, who prescribes prescription drugs or over the

counter medication under the physician's supervision and in accordance with the health care practitioner's license and state and federal laws and rules.

(11) Prescription--An order for a prescription or nonprescription drug to be dispensed.

(12) Prescription drug--

(A) A substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;

(B) A drug that under federal law is required, before being dispensed or delivered, to be labeled with the statement: "Caution: federal law prohibits dispensing without prescription;" "Rx only;" or another legend that complies with federal law; or

(C) A drug that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a prescribing doctor only.

(13) Statement of medical necessity--A written statement from the prescribing doctor to establish the need for treatments or services, or prescriptions, including the need for a brand name drug where applicable. A statement of medical necessity shall include:

(A) the injured employee's full name;

(B) date of injury;

(C) social security number;

(D) diagnosis code(s);

(E) whether the drug has previously been prescribed and dispensed, if known, and whether the inability to obtain the drug poses an unreasonable risk of a medical emergency; and

(F) how the prescription treats the diagnosis, promotes recovery, or enhances the ability of the injured employee to return to or retain employment.

(14) Substitution--As defined under Occupations Code §551.003(41), the dispensing of a drug or a brand of drug other than the drug or brand of drug ordered or prescribed.

§134.506. Outpatient Open Formulary for Claims with Dates of Injury Prior to September 1, 2011.

(a) For claims with dates of injury prior to September 1, 2011 (for the purposes of this section, referred to as "legacy claims"), the open formulary as described in §134.500(9) of this title (relating to Definitions) remains in effect until those claims become subject to the closed formulary in accordance with §134.510 of this title (relating to Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011).

(b) Health care, including a prescription drug, for legacy claims not subject to a certified network shall be in accordance with the division's adopted treatment guidelines under §137.100 of this title (relating to Treatment Guidelines) except as provided by subsection (d) and (f) of this section.

(c) Health care, including a prescription drug, for legacy claims subject to a certified network shall be in accordance with the certified network's treatment guidelines

pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title (relating to Workers' Compensation Health Care Networks).

(d) Drugs included in the open formulary prescribed and dispensed for legacy claims not subject to a certified network do not require preauthorization, except as required by Labor Code §413.014.

(e) Drugs included in the open formulary prescribed and dispensed for legacy claims subject to a certified network shall be preauthorized in accordance with Insurance Code Chapter 1305 and Chapter 10 of this title.

(f) Drugs included in the open formulary that do not require preauthorization under subsections (d) and (e) of this section and are prescribed and dispensed for legacy claims are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier.

§134.510. Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011.

(a) Applicability. This section applies to claims with dates of injury prior to September 1, 2011 (for the purposes of this section, referred to as "legacy claims"), which are subject to §134.530 of this title (relating to Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks), §134.540 of this title (relating to Requirements for Use of the Closed Formulary for Claims Subject to

Certified Networks), and §134.550 of this title (relating to Medical Interlocutory Order) on and after September 1, 2013.

(b) Transition of legacy claims.

(1) At any time after September 1, 2011 and prior to September 1, 2013:

(A) The prescribing doctor should include a statement of medical necessity as defined in §134.500(13) of this title (relating to Definitions) with the prescription for drugs excluded from the closed formulary.

(B) The prescribing doctor or the insurance carrier may contact each other for a discussion of ongoing pharmacological management of the injured employee's claim.

(C) When a prescribing doctor or insurance carrier is contacted by the other party regarding ongoing pharmacological management, the parties must provide each other a name, phone number, and date and time to discuss ongoing pharmacological management of the injured employee's claim.

(2) Beginning no later than March 1, 2013, the insurance carrier shall:

(A) identify all legacy claims that have been prescribed a drug excluded from the closed formulary after September 1, 2012; and

(B) 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 closed formulary for legacy claims; and

(ii) the information required in paragraph (1)(C) of this subsection.

(c) Agreement. To ensure continuity of care, notwithstanding subsection (a) of this section, an insurance carrier and a prescribing doctor may enter into an agreement regarding the application of the pharmacy closed formulary for individual legacy claims on claim-by-claim basis.

(d) Agreement requirements.

(1) The insurance carrier shall document any agreement and the terms, and share a copy of the agreement with the prescribing doctor and injured employee.

(2) Health care provided as a result of the agreement is not subject to retrospective review of medical necessity.

(3) Denial of a request for an agreement is not subject to dispute resolution.

(4) If no agreement is reached and documented by September 1, 2013 for a legacy claim, the requirements of §§134.530, 134.540, and 134.550 of this title shall apply.

§134.520. Outpatient Closed Formulary for Dates of Injury On or After September 1, 2011.

The Commissioner of Workers' Compensation hereby adopts a closed formulary as defined in §134.500(3) of this title (relating to Definitions) for claims with dates of injury on or after September 1, 2011.

§134.530. Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks.

(a) Applicability. The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use for claims not subject to a certified network on or after September 1, 2011 when the date of injury occurred on or after September 1, 2011.

(b) Preauthorization for claims subject to the Division's closed formulary.

(1) Preauthorization is only required for:

(A) drugs identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates;

(B) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; and

(C) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined in **Labor Code §413.014(a).**

(2) When §134.600(p)(12) of this title (relating to Preauthorization, Concurrent Review, and Voluntary Certification of Health Care) conflicts with this section, this section prevails.

(c) Preauthorization of intrathecal drug delivery systems.

(1) An intrathecal drug delivery system requires preauthorization in accordance with §134.600 of this title and the preauthorization request must include the prescribing doctor's drug regime plan of care, and the anticipated dosage or range of dosages for the administration of pain medication.

(2) Refills of an intrathecal drug delivery system with drugs excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever:

(A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or

(B) there is a change in prescribing doctor.

(d) Treatment guidelines. Except as provided by this subsection, the prescribing of drugs shall be in accordance with §137.100 of this title (relating to Treatment Guidelines), the division's adopted treatment guidelines.

(1) Prescription and nonprescription drugs included in the division's closed formulary and recommended by the division's adopted treatment guidelines may be prescribed and dispensed without preauthorization.

(2) Prescription and nonprescription drugs included in the division's closed formulary that exceed or are not addressed by the division's adopted treatment guidelines may be prescribed and dispensed without preauthorization.

(3) Drugs included in the closed formulary that are prescribed and dispensed without preauthorization are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier in accordance with subsection (g) of this section.

(e) Appeals process for drugs excluded from the closed formulary.

(1) For situations in which the prescribing doctor determines and documents that a drug excluded from the closed formulary is necessary to treat an injured employee's compensable injury and has prescribed the drug, the prescribing doctor, other requestor, or injured employee must request approval of the drug by requesting preauthorization, including reconsideration, in accordance with §134.600 of this title and applicable provisions of Chapter 19 of this title (relating to Agents' Licensing).

(2) If preauthorization is being requested by an injured employee or a requestor other than the prescribing doctor, and the injured employee or other requestor

requests a statement of medical necessity, the prescribing doctor shall provide a statement of medical necessity to facilitate the preauthorization submission as set forth in §134.502 of this title (relating to Pharmaceutical Services).

(3) If preauthorization for a drug excluded from the closed formulary is denied, the requestor may submit a request for medical dispute resolution in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).

(4) In the event of an unreasonable risk of a medical emergency, an interlocutory order may be obtained in accordance with §133.306 of this title (relating to Interlocutory Orders for Medical Benefits) or §134.550 of this title (relating to Medical Interlocutory Order).

(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.

(g) Retrospective review. Except as provided in subsection (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 of this title (relating to Insurance Carrier Audit of a Medical Bill) and §133.240 of this title (relating to Medical Payments and Denials), and applicable provisions of Chapter 19 of this title.

(1) Health care, including a prescription for a drug, provided in accordance with §137.100 of this title is presumed reasonable as specified in Labor Code §413.017, and is also presumed to be health care reasonably required as defined by Labor Code §401.011(22-a).

(2) In order for an insurance carrier to deny payment subject to a retrospective review for pharmaceutical services that are recommended by the division's adopted treatment guidelines, §137.100 of this title, the denial must be supported by documentation of evidence-based medicine that outweighs the presumption of reasonableness established under Labor Code §413.017.

(3) A prescribing doctor who prescribes pharmaceutical services that exceed, are not recommended, or are not addressed by §137.100 of this title, is required to provide documentation upon request in accordance with §134.500(13) of this title (relating to Definitions) and §134.502(e) and (f) of this title.

§134.540. Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks.

(a) Applicability. The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use for claims subject to a certified network on or after September 1, 2011 when the date of injury occurred on or after September 1, 2011.

(b) Preauthorization for claims subject to the Division's closed formulary. Preauthorization is only required for:

(1) drugs identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates;

(2) any compound that contains a drug identified with a status of "N" in the current edition of the *ODG Treatment in Workers' Comp* (ODG) / Appendix A, *ODG Workers' Compensation Drug Formulary*, and any updates; and

(3) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but which is not yet broadly accepted as the prevailing standard of care as defined **in Labor Code §413.014(a).**

(c) Preauthorization of intrathecal drug delivery systems.

(1) An intrathecal drug delivery system requires preauthorization in accordance with the certified network's treatment guidelines and preauthorization requirements pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title (relating to Workers' Compensation Health Care Networks).

(2) Refills of an intrathecal drug delivery system with drugs excluded from the closed formulary, which are billed using Healthcare Common Procedure Coding System (HCPCS) Level II J codes, and submitted on a CMS-1500 or UB-04 billing form, require preauthorization on an annual basis. Preauthorization for these refills is also required whenever:

(A) the medications, dosage or range of dosages, or the drug regime proposed by the prescribing doctor differs from the medications dosage or range of dosages, or drug regime previously preauthorized by that prescribing doctor; or

(B) there is a change prescribing doctor.

(d) Treatment guidelines. The prescribing of drugs shall be in accordance with the certified network's treatment guidelines and preauthorization requirements pursuant to Insurance Code Chapter 1305 and Chapter 10 of this title. Drugs included in the closed formulary that are prescribed and dispensed without preauthorization are subject to retrospective review of medical necessity and reasonableness of health care by the insurance carrier in accordance with subsection (f) of this section.

(e) Appeals process for drugs excluded from the closed formulary.

(1) For situations in which the prescribing doctor determines and documents that a drug excluded from the closed formulary is necessary to treat an injured employee's compensable injury and has prescribed the drug, the prescribing doctor, other requestor, or injured employee must request approval of the drug in a specific instance by requesting preauthorization in accordance with the certified

network's preauthorization process established pursuant to Chapter 10, Subchapter F of this title (relating to Utilization Review and Retrospective Review) and applicable provisions of Chapter 19 of this title (relating to Agents' Licensing).

(2) If preauthorization is pursued by an injured employee or requestor other than the prescribing doctor, and the injured employee or other requestor requests a statement of medical necessity, the prescribing doctor shall provide a statement of medical necessity to facilitate the preauthorization submission as set forth in §134.502 of this title (relating to Pharmaceutical Services).

(3) If preauthorization for a drug excluded from the closed formulary is denied, the requestor may submit a request for medical dispute resolution in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations).

(4) In the event of an unreasonable risk of a medical emergency, an interlocutory order may be obtained in accordance with §133.306 of this title (relating to Interlocutory Orders for Medical Benefits) or §134.550 of this title (relating to Medical Interlocutory Order).

(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 and are subject to retrospective review of medical necessity.

(g) Retrospective review. Except as provided in subsection (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity in accordance with §133.230 of this title (relating to Insurance Carrier Audit of a Medical Bill), §133.240 of this title (relating to Medical Payments and Denials), the Insurance Code, Chapter 1305, applicable provisions of Chapters 10 and 19 of this title.

(1) In order for an insurance carrier to deny payment subject to a retrospective review for pharmaceutical services that fall within the treatment parameters of the certified network's treatment guidelines, the denial must be supported by documentation of evidence-based medicine that outweighs the evidence-basis of the certified network's treatment guidelines.

(2) A prescribing doctor who prescribes pharmaceutical services that exceed, are not recommended, or are not addressed by the certified network's treatment guidelines, is required to provide documentation upon request in accordance with §134.500(13) of this title (relating to Definitions) and §134.502(e) and (f) of this title.

§134.550. Medical Interlocutory Order.

(a) The purpose of this section is to provide a prescribing doctor or pharmacy an ability to obtain an medical interlocutory order (MIO) in instances where preauthorization denials of a previously prescribed and dispensed drug(s) excluded from the closed formulary poses an unreasonable risk of a medical emergency as defined in §134.500(7) of this title (relating to Definitions) and Insurance Code §1305.004(a)(13).

(b) A request for an interlocutory order that does not meet the criteria described by this section may still be requested pursuant to §133.306 of this title (relating to Interlocutory Order for Medical Benefits).

(c) An MIO will be issued if the request for an MIO contains the following information:

(1) injured employee name;

(2) date of birth of injured employee;

(3) prescribing doctor's name;

(4) name of drug and dosage;

(5) MIO requestor's name (pharmacy or prescribing doctor);

(6) MIO requestor's contact information;

(7) a statement that a preauthorization request for a previously prescribed and dispensed drug(s), which is excluded from the closed formulary, has been denied by the insurance carrier;

(8) a statement that an independent review request has already been submitted to the insurance carrier or the insurance carrier's utilization review agent in accordance with §133.308 of this title (relating to MDR by Independent Review Organizations);

(9) a statement that the preauthorization denial poses an unreasonable risk of a medical emergency as defined in §134.500(7) of this title;

(10) a statement that the potential medical emergency has been documented in the preauthorization process;

(11) a statement that the insurance carrier has been notified that a request for an MIO is being submitted to the division; and

(12) a signature and the following certification by the MIO requestor for paragraphs (7) - (12) of this subsection, "I hereby certify under penalty of law that the previously listed conditions have been met."

(d) A complete request for an MIO under this section shall be processed and approved by the division in accordance with this section. At the discretion of the division, an incomplete request for an MIO under this section may be considered in accordance with this section.

(e) The request for an MIO may be submitted on the designated division form available on the Texas Department of Insurance's website, http://www.tdi.state.tx.us/wc/indexwc.html. In the event the division form is not available, the written request must contain the provisions of subsection (c) of this section.

(f) The MIO requestor shall provide a copy of the MIO request to the insurance carrier, prescribing doctor, injured employee, and dispensing pharmacy, if known, on the date the request for MIO is submitted to the division.

(g) An approved MIO shall be effective retroactively to the date the complete request for an MIO is received by the division.

(h) Notwithstanding §133.308 of this title:

(1) A request for reconsideration of a preauthorization denial is not required prior to a request for independent review when pursuing an MIO under this section. If a request for reconsideration or an MIO request is not initiated within 15 days from the initial preauthorization denial, then the opportunity to request an MIO under this section does not apply.

(2) If pursuing an MIO after denial of a reconsideration request, a complete MIO request shall be submitted within five working days of the reconsideration denial.

(i) An appeal of the independent review organization (IRO) decision relating to the medical necessity and reasonableness of the drugs contained in the MIO shall be submitted in accordance with §133.308(t) of this title.

(j) The MIO shall continue in effect until the later of:

(1) final adjudication of a medical dispute regarding the medical necessity and reasonableness of the drug contained in the MIO;

(2) expiration of the period for a timely appeal; or

(3) agreement of the parties.

(k) Withdrawal by the requestor of a request for medical necessity dispute resolution constitutes acceptance of the preauthorization denial.

(l) A party shall comply with an MIO entered in accordance with this section and the insurance carrier shall reimburse the pharmacy for prescriptions dispensed in accordance with an MIO.

(m) The insurance carrier shall notify the prescribing doctor, injured employee, and the dispensing pharmacy once reimbursement is no longer required in accordance with subsection (j) of this section.

(n) Payments made by insurance carriers pursuant to this section may be eligible for reimbursement from the Subsequent Injury Fund in accordance with Labor Code §410.209 and §413.055, and applicable rules.

(o) A decision issued by an IRO is not an agency or commissioner decision.

(p) A party may seek to reverse or modify an MIO issued under this section if:

(1) a final determination of medical necessity has been rendered; and

(2) the party requests a benefit contested case hearing (CCH) from the division's chief clerk no later than 20 days after the date the IRO decision is sent to the party. A benefit review conference is not a prerequisite to a division CCH under this subsection. Except as provided by this subsection, a division CCH shall be conducted in accordance with Chapters 140 and 142 of this title (relating to Dispute Resolution--General Provisions and Dispute Resolution--Benefit Contested Case Hearing).

(q) The insurance carrier may dispute an interlocutory order entered under this title by filing a written request for a hearing in accordance with Labor Code §413.055 and §148.3 of this title (relating to Requesting a Hearing).

8. CERTIFICATION. This agency hereby certifies that the adopted amendments and sections have been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on _____, 2010.

_____
Dirk Johnson
General Counsel
Division of Workers' Compensation
Texas Department of Insurance

IT IS THEREFORE THE ORDER of the Commissioner of Workers' Compensation that §§134.500, 134.506, 134.510, 134.520, 134.530, 134.540 and 134.550 specified herein, concerning pharmaceutical benefits are adopted.

AND IT IS SO ORDERED.

_____
ROD BORDELON
COMMISSIONER OF WORKERS' COMPENSATION

ATTEST:

_____
Dirk Johnson
General Counsel

COMMISSIONER ORDER NO.

***28 TAC §§134.500, 134.506, 134.510, 134.520, 134.530, 134.540, and 134.550 regarding the Pharmacy Closed Formulary will become effective January 17th, 2011; notice of correction:**
http://info.sos.state.tx.us/pls/pub/regviewer$ext.RegPage?sl=R&app=9&p_dir=&p_rloc=233218&p_tloc=&p_ploc=&pg=1&p_reg=233218&ti=&pt=&ch=&rl=&issue=01/14/2011&z_chk=2035455&z_contains=134^^^.

For additional information about the effective date correction please see http://www.tdi.state.tx.us/wc/rules/adopted/documents/rxfcorr0111.pdf.