SUBCHAPTER D – DISPUTE OF MEDICAL BILLS
28 TAC §133.306

1. <u>INTRODUCTION</u>. The Commissioner of Workers' Compensation (Commissioner), Texas Department of Insurance, Division of Workers' Compensation (Division) adopts amendments to §133.306, concerning Interlocutory Orders for Medical Benefits. These amendments are adopted with changes to the proposed text published in the July 16, 2010, issue of the *Texas Register* (35 TexReg 6236).

In accordance with Government Code §2001.033, the Division's reasoned justification for these amendments is set out in this order, which includes the preamble, which in turn includes the rule. The preamble contains a summary of the factual basis of the rule, 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 rule, and the reasons why the Division agrees or disagrees with the comments and recommendation.

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

2. <u>REASONED JUSTIFICATION</u>. These amendments are necessary to coordinate with, and supplement, rules pertaining to the implementation of statutory provisions of House Bill (HB) 7, enacted by the 79th Legislature, Regular Session, effective September 1, 2005 which require the adoption of a pharmacy closed formulary.

HB 7 added requirements to the Labor Code concerning pharmaceutical services which provided under amended Labor Code §408.028(b) that:

> The commissioner by rule shall adopt a closed formulary under Labor Code §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, the Division also adopts amendments to §134.500 and §134.506 and adopts new §§134.510, 134.520, 134.530, 134.540, and 134.550 of this title (relating to Pharmaceutical Benefits), which are adopted elsewhere in this edition of the *Texas Register*.

Additionally, HB 2515, enacted by the 76th Legislature, Regular Session, effective September 1, 1999 adopted Labor Code §413.055, which allows the Commissioner of Workers' Compensation to enter an interlocutory order for the payment of all or part of medical benefits. The order may address accrued benefits, future benefits, or both accrued benefits and future benefits. An insurance carrier is entitled to request reimbursement from the Subsequent Injury Fund for any overpayments of benefits made under an order entered if the order is reversed or modified by final arbitration, order, or decision of the Commissioner, or a court.

Labor Code §402.042 requires the Commissioner to develop and implement policies that clearly define the respective responsibilities of the Commissioner and the staff of the Division. Section 133.306 of this title was originally adopted to achieve this goal. Subsection (a) provided for the delegation of the Commissioner's authority to

enter interlocutory orders to Division staff and subsections (b) and (c) set forth standards for Division staff to enter such orders.

In order to supplement the legislative requirement to adopt a pharmacy closed formulary, the Division, in consultation with the Division's Medical Advisor, adopts amendments to this section for consistency of issuing interlocutory orders for medical benefits.

There are two non-substantive changes from proposal. In subsection (b), paragraph (3) replaces the term "a utilization review agent" with "an insurance carrier" when describing the circumstances in which the Division may enter an interlocutory order, including when an insurance carrier makes an adverse determination for drugs excluded from the Division's closed formulary. This change from proposal allows for consistently applied terms in both this section and the adopted sections relating to a pharmacy closed formulary published elsewhere in this issue. Subsection (b) paragraph (3) also includes a second non-substantive change for clarification to indicate that the Division may enter an interlocutory order for drugs "prescribed on or after September 1, 2011" after an insurance carrier makes an adverse determination when a drug is excluded from the Division's closed formulary. This change harmonizes this subsection with applicable provisions of the Division's closed formulary. These changes do not materially alter issues raised in the proposal, introduce new subject matter or affect persons other than those previously on notice.

3. <u>HOW THE SECTION WILL FUNCTION</u>. The adopted rule amendments provides the process in which the Division may enter interlocutory orders in certain situations relating to the delivery of pharmaceutical benefits, and apply to both certified network claims and those claims not subject to certified networks. The adopted rule amendments further update the existing interlocutory order process after an adverse determination by an insurance carrier for drugs prescribed on or after September 1, 2011 and excluded from the Division's pharmacy closed formulary. The amendments to §133.306 accommodate the Medical Interlocutory Order (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 drugs excluded from the closed formulary and that were previously prescribed and dispensed to them. The distinction between the interlocutory orders is that injured employees continue to have access to interlocutory orders for medical care through §133.306 without the need to meet the medical emergency component or other specific requirements outlined in §134.550. 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 also pursue an interlocutory order for medical benefits as set forth in §133.306, 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. Additionally, §133.306 does not limit interlocutory orders to prescription services as does §134.550.

Under adopted subsection (a), the Commissioner may delegate the authority to issue interlocutory orders for approved and/or future medical benefits to Division staff.

Adopted subsection (b) provides that the Division may enter an interlocutory order for accrued or future medical benefits. Adopted paragraph (1) states the first circumstance, which is when the Division determines that an insurance carrier has disputed medical benefits as the result of the liability dispute that an insurance carrier has raised in accordance with §124.2 concerning Carrier Reporting and Notification Requirements. Adopted paragraph (2) sets forth the second set of circumstances, which occur at the conclusion of the medical dispute process, namely (A) the Division determines that an insurance carrier has disputed medical benefits as the result of a liability, compensability, or extent of injury dispute that an insurance carrier has raised in accordance with §124.2, and the Division deems that the disputed medical benefits are or were medically necessary and constitute health care reasonably required; or (B) the Division determines that future medical benefits for which preauthorization is required are medically necessary and constitute health care reasonably required. Adopted paragraph (3) indicates the third circumstance, which is when an insurance carrier makes an adverse determination for drugs prescribed on or after September 1, 2011 and excluded from the Division's closed formulary as set forth in §§134.510, 134.530,

134.540, and 134.550 of this title concerning Requirements for the Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to September 1, 2011; Requirements for the Use of the Closed Formulary for Claims Not Subject to Certified Networks; Requirements for the Use of the Closed Formulary for Claims Subject to Certified Networks; and Medical Interlocutory Order, respectively, and the Division determines that those medical benefits are or were medically necessary and constitute health care reasonably required.

Under adopted subsection (c), absent the interlocutory order in subsections (a) and (b), the Division shall enter an interlocutory order only when the injured employee would not receive medical benefits that are medically necessary and constitute health care reasonably required.

Under adopted subsection (d), a party shall comply with an interlocutory order on the earlier of the seventh day after receipt of the order or the date the Division establishes in the body of the order.

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

Adopted subsection (f) provides that an insurance carrier that makes an overpayment pursuant to an interlocutory order may be eligible for reimbursement from the Subsequent Injury Fund (SIF). An insurance carrier must make a request for SIF reimbursement in accordance with applicable Division rules.

4. SUMMARY OF COMMENTS AND AGENCY'S RESPONSE.

§133.306: A commenter recommends the Division provide a process where injured employees may obtain medications through interlocutory orders. The commenter is concerned that the process in proposed §134.550 concerning Medical Interlocutory Order 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 in part that injured employees do need a process, and that process is identified in the interlocutory order of §133.306 of this title. The distinction between the types of interlocutory orders is that §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. Section 133.306 was originally adopted to provide an injured employee access to an interlocutory order for certain medical benefits and is amended to include any potential need for an interlocutory order that may arise due to adoption and implementation of the Division's closed formulary. Without these amendments, this section 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 allow the injured employee to seek an interlocutory order from the Division for needs that may arise due to the adoption and implementation of the Division's pharmacy closed formulary.

§133.306: Commenters provided statements concerning both this proposed amended section as well as proposed new §134.550, that may indicate confusion on the part of system participants as to why there are two sections dealing with apparently the same issue of interlocutory orders.

Agency Response: The Division clarifies the amendments to §133.306 are necessary to coordinate with, and supplement, rules pertaining to the implementation of statutory provisions of House Bill (HB) 7, enacted by the 79th Legislature, Regular Session, effective September 1, 2005 which require the adoption of a pharmacy closed formulary. The adopted amendments to §133.306 clarify and update the circumstances for existing interlocutory orders after an adverse determination by an insurance carrier for drugs prescribed on or after September 1, 2011 and excluded from the Division's pharmacy closed formulary as set forth in §§134.510, 134.530, 134.540, and 134.550 of this title (relating to Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to 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). Without this amendment, this section only allows an interlocutory order to be entered into in situations where there is 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.

Since new §134.550 addresses instances where preauthorization denials of a previously prescribed and dispensed drug excluded from the closed formulary poses an unreasonable risk of a medical emergency to an injured employee, the purpose of new §134.550 then, is to provide 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.

Consequently, §133.306 is amended to accommodate the MIO process as set forth in new §134.550.

§133.306(f): Commenter recommends substitute language, consistent with Labor Code §413.055 and HB 2512: "An insurance carrier that makes an overpayment pursuant to an interlocutory order shall be eligible for reimbursement from the Subsequent Injury Fund. An insurance carrier must make a request for reimbursement in accordance with §116.11 of this title (relating to Request for Reimbursement from the Subsequent Injury Fund)."

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 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 that have higher priority, namely (a)(1) and (a)(2), reimbursement is not guaranteed. The insurance carrier is eligible for reimbursement, but payment is not always assured.

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

For: None.

For, with changes: Insurance Council of Texas and Office of Injured Employee Counsel.

Against: None.

Neither for or Against: None.

6. STATUTORY AUTHORITY. These amendments are adopted under Labor Code §§413.055, 410.032, 410.168, 408.027, 408.0271, 409.009, 409.0091 410.209,

408.028, 401.011(22-a), 408.021, 413.002, 413.011, 413.013, 413.031, 413.051, 402.042, 402.00128, 402.00111, 402.061, and 402.00116, and Insurance Code Chapters 1305, 4201, and 4202.

Labor Code §413.055 allows the Commissioner to enter interlocutory orders regarding medical benefits and these orders may be disputed at a hearing but the order is binding during the appeal. Labor Code §413.055 also allows for reimbursement from the Subsequent Injury Fund for reversed or modified orders. Labor Code §410.032 requires a benefit review officer who presides at the benefit review conference to consider a request for an interlocutory order and to give the opposing party the opportunity to respond before issuing an interlocutory order. Labor Code §410.168 allows a hearing officer to enter an interlocutory order for the payment of all or part of medical benefits or income benefits. The order may address accrued benefits, future benefits, or both accrued benefits and future benefits. The order is binding during the pendency of an appeal to the appeals panel. Labor Code §408.027 requires a health care provider to submit a claim for payment to the insurance carrier not later than the 95th day after the date on which the health care services are provided to the injured employee 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 carrier of the provider's claim. Labor Code §408.0271 allows an insurance carrier to demand a refund from the health care provider for the portion of payment on the claim that was received by the health care provider but which the insurance carrier determines to be inappropriate. The health care provider may appeal the insurance

carrier's determination. 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. Labor Code §410.209 provides that the Subsequent Injury Fund shall reimburse an insurance carrier for any overpayment of benefits made under an interlocutory order or decision that is reversed or modified. Labor Code §408.028 requires the adoption of a pharmacy closed formulary in the workers' compensation system. Labor Code §408.028 also requires an appeals process for the pharmacy closed formulary. Labor Code §401.011(22-a) defines the term "health care reasonably required" when used in the Texas workers' compensation system. Labor Code §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. Labor Code §413.002 sets forth specified Division duties and responsibilities regarding medical review. Labor Code §413.011 requires the Commissioner to adopt health care reimbursement policies and guidelines to ensure the quality of medical care and to achieve effective medical cost control, in addition the Commissioner is required to adopt treatment guidelines, return-to-work guidelines, disability management rules, and establish medical policies and guidelines. Labor Code §413.013 requires the Division by rule to establish programs related to health care treatments and services for dispute

resolution, monitoring and review. Labor Code §413.031 provides procedures for medical dispute resolution. Labor Code §413.0511 states that the Medical Advisor shall make recommendations regarding the adoption of rules and policies. Labor Code §402.042 requires the Commissioner to develop and implement policies that clearly define the respective responsibilities of the Commissioner and the staff of the Division. Labor Code §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. Labor Code §402.00111 provides that the Commissioner of Workers' Compensation shall exercise all executive authority, including rule making authority, under Labor Code Title 5. Labor Code §402.061 provides the Commissioner of Workers' Compensation the authority to adopt rules as necessary for the implementation and enforcement of the Texas Workers' Compensation Act. Labor Code §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. Insurance Code Chapter 1305 contains all the provisions of the Workers' Compensation Health Care Network Act and applies to certified networks. Insurance Code §1305.101 provides that prescription medications and services shall be reimbursed as provided by the Texas Workers' Compensation Act and applicable rules of the Commissioner of Workers' Compensation. Insurance Code Chapter 4201 concerns utilization review agents and applies to utilization review of

health care services provided to a person eligible for workers' compensation medical benefits under Labor Code Title 5 or Insurance Code Chapter 1305. Insurance Code §4201.054 provides that Labor Code Title 5 prevails in the event of a conflict between Insurance Code Chapter 4201 and Labor Code Title 5. Insurance Code Chapter 4202 concerns independent review organizations, entities utilized in a dispute over the issue of medical necessity and reasonableness.

7. TEXT.

§133.306. Interlocutory Orders for Medical Benefits.

(a) The Commissioner of Workers' Compensation may delegate the authority to issue interlocutory orders for accrued and/or future medical benefits to division staff.

(b) The division may enter an interlocutory order for accrued or future medical benefits when:

(1) the division determines that an insurance carrier has disputed medical benefits as the result of a liability, compensability, or extent of injury dispute that an insurance carrier has raised in accordance with §124.2 of this title (relating to Carrier Reporting and Notification Requirements), and the division determines that those medical benefits are or were medically necessary and constitute health care reasonably required and are not subject to the medical dispute resolution process set forth in Chapter 133, subchapter D of this title (relating to Dispute of Medical Bills);

(2) at the conclusion of the medical dispute resolution process:

(A) the division determines that an insurance carrier has disputed medical benefits as the result of a liability, compensability, or extent of injury dispute that an insurance carrier has raised in accordance with §124.2 of this title, and the division deems that the disputed medical benefits are or were medically necessary and constitute health care reasonably required; or

(B) the division determines that future medical benefits for which preauthorization is required are medically necessary and constitute health care reasonably required; or

(3) an insurance carrier makes an adverse determination for drugs prescribed on or after September 1, 2011 and excluded from the division's closed formulary as set forth in §§134.510, 134.530, 134.540, and 134.550 of this title (relating to Requirements for the Transition to the Use of the Closed Formulary for Claims with Dates of Injury Prior to 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) and the division determines that those medical benefits are or were medically necessary and constitute health care reasonably required.

(c) Absent the interlocutory order as set forth in subsections (a) and (b) of this section, the division shall enter an interlocutory order only when the injured employee would not receive medical benefits that are medically necessary and constitute health care reasonably required.

(d) A party shall comply with an interlocutory order entered in accordance with this section on the earlier of the seventh day after receipt of the order or the date the division establishes in the body of the order.

(e) 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).

(f) An insurance carrier that makes an overpayment pursuant to an interlocutory order may be eligible for reimbursement from the Subsequent Injury Fund. An insurance carrier must make a request for reimbursement in accordance with §116.11 of this title (relating to Request for Reimbursement from the Subsequent Injury Fund).

8. CERTIFICATION. This agency hereby certifies that the adopted amendments 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.

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

IT IS THEREFORE THE ORDER of the Commissioner of Workers' Compensation that the amendments to §133.306 specified herein, concerning **the** Interlocutory Orders for Medical Benefits, are adopted.

AND IT IS SO ORDERED

ROD BORDELON
COMMISSIONER OF WORKERS' COMPENSATION

ATTEST:

Dirk Johnson
General Counsel

COMMISSIONER'S ORDER NO.