**SUBCHAPTER F. PHARMACEUTICAL BENEFITS.**
**28 TAC §§134.500, 134.501, 134.502, 134.503, 134.504,**
**134.520, 134.530, 134.540, AND 134.550.**
**REPEAL OF 28 TAC §§134.506 AND 134.510.**

**INTRODUCTION.** The Texas Department of Insurance, Division of Workers' Compensation (DWC) adopts the following changes to 28 TAC Chapter 134, Subchapter F, concerning pharmaceutical benefits: repeal 28 TAC §§134.506 and 134.510, and amend 28 TAC §§134.500, 134.501, 134.502, 134.503, 134.504, 134.520, 134.530, 134.540, and 134.550. Subchapter F implements Texas Labor Code §§408.028 and 413.011, and Texas Insurance Code Chapter 1305. The DWC medical advisor recommended the amendments to the commissioner of workers' compensation under Labor Code §413.0511(b).

The amendments to §§134.500, 134.501, 134.502, 134.503, and 134.520 are adopted without changes to the proposed text published in the August 23, 2024, issue of the *Texas Register* (49 TexReg 6397). Sections 134.500, 134.501, 134.502, 134.503, and 134.520 will not be republished.

The amendments to §§134.504, 134.530, 134.540, and 134.550 are adopted with changes to the proposed text published in the August 23, 2024, issue of the *Texas Register* (49 TexReg 6397). DWC reverted to existing text in parts of §§134.504, 134.530, 134.540, and 134.550 in response to comments to avoid unintended consequences. Sections 134.504, 134.530, 134.540, and 134.550 will be republished.

**REASONED JUSTIFICATION.** The changes update and reorganize Subchapter F. Repealing §§134.506 and 134.510, and amending §§134.500, 134.501, 134.502, 134.503, 134.504, 134.520, 134.530, 134.540, and 134.550 is necessary to remove obsolete provisions and to update references and language to be consistent with other rules. Labor

Code §408.028 requires the commissioner by rule to adopt a closed formulary under §413.011, as well as a fee schedule, and provides requirements for prescribing prescription drugs, generic pharmaceutical medications, and over-the-counter alternatives. Insurance Code Chapter 1305 authorizes the establishment of workers' compensation health care networks for providing workers' compensation medical benefits and provides standards for the certification, administration, evaluation, and enforcement of their delivery of health care services to injured employees. The changes also include nonsubstantive editorial and formatting changes that make updates for plain language and agency style to improve the rule's clarity.

**Section 134.500.** The changes delete the definition of "open formulary." The Texas workers' compensation system now uses a closed formulary, so the reference to an open formulary is unnecessary. The changes correct a reference to the injured employee's Social Security number to specify only the last four digits of the number. The changes also renumber the paragraphs where needed and make editorial and formatting updates for plain language and agency style. Amending §134.500 is necessary to enhance the rule's clarity and accuracy.

**Section 134.501.** The changes correct obsolete references and make editorial and formatting updates for plain language and agency style. Amending §134.501 is necessary to enhance the rule's clarity and accuracy.

**Section 134.502.** The changes make editorial and formatting updates for plain language and agency style. Amending §134.502 is necessary to enhance the rule's clarity.

**Section 134.503.** The changes make editorial and formatting updates for plain language and agency style. Amending §134.503 is necessary to enhance the rule's clarity.

**Section 134.504.** The changes correct obsolete references and make editorial and formatting updates for plain language and agency style. In response to a comment, DWC

removed a proposed change that would have required only the last four digits of the claimant's Social Security number, and retained the existing requirement for the full number. Amending §134.504 is necessary to enhance the rule's clarity and accuracy.

**Section 134.506.** Section 134.506 is repealed because it is an obsolete transitional provision. Repealing §134.506 is necessary to ensure that the published rules are current.

**Section 134.510.** Section 134.510 is repealed because it is an obsolete transitional provision. Repealing §134.510 is necessary to ensure that the published rules are current.

**Section 134.520.** The changes update the section title to remove an unnecessary reference to the 2011 transition to a closed formulary, add the sentence, "The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use," to be consistent with §§134.530 and 134.540, and make editorial and formatting updates for plain language and agency style. Amending §134.520 is necessary to enhance the rule's clarity and accuracy.

**Section 134.530.** The changes remove unnecessary references, correct obsolete references, and make editorial and formatting updates for plain language and agency style. Amending §134.530 is necessary to enhance the rule's clarity and accuracy. In response to a comment, DWC removed a proposed change that would have specified the prescribing doctor or pharmacy as the requester for a medical interlocutory order.

**Section 134.540.** The changes remove unnecessary references, correct obsolete references, and make editorial and formatting updates for plain language and agency style. Amending §134.540 is necessary to enhance the rule's clarity and accuracy. In response to a comment, DWC removed a proposed change that would have specified the prescribing doctor or pharmacy as the requester for a medical interlocutory order.

**Section 134.550.** The changes correct obsolete references, update DWC's website address, clarify text, and make editorial and formatting updates for plain language and

agency style. Amending §134.550 is necessary to enhance the rule's clarity and accuracy. DWC removed a proposed change that would have specified the prescribing doctor or pharmacy as the requester for a medical interlocutory order. In response to a comment, DWC also removed proposed changes to §134.550(h) to avoid unintentional conflicts in the timeframes for reconsideration of a preauthorization denial, and reverted to the existing text of that subsection with minor nonsubstantive edits.

**SUMMARY OF COMMENTS AND AGENCY RESPONSE.**

**Commenters:** DWC received two written comments and no oral comments. The Office of Injured Employee Counsel commented in support of the proposal. Texas Mutual Insurance Company (Texas Mutual) commented in support of the proposal with changes. There were no commenters against the proposal.

**Comment on Subchapter F.** The Office of Injured Employee Counsel stated that they supported DWC's proposed changes to remove obsolete provisions and to update references and language to be consistent with other rules.

**Agency Response to Comment on Subchapter F.** DWC appreciates the comment.

**Comment on §134.501.** Texas Mutual suggested that DWC consider revising §134.501(a)(4) to recognize that reimbursement may be made based on DWC pharmacy fee guidelines or at a contract rate authorized by Labor Code §408.0281.

**Agency Response to Comment on §134.501.** DWC appreciates the comment but declines to make the change. The lack of medical fee disputes involving that fee guideline indicates that the existing language in §134.501(a)(4) is sufficient, and DWC did not propose substantive changes to it. In addition, §134.503(f) already allows the insurance

carrier to reimburse prescription medications or services at a contract rate that is inconsistent with the fee guideline as long as the contract complies with the provisions of Labor Code §408.0281 and applicable DWC rules.

**Comment on §134.504.** Texas Mutual recommended that DWC not adopt the proposed change to §134.504(a)(1)(A) that reduced the Social Security number reporting requirement to only the last four digits because the change would create difficulties for insurance carriers in complying with their medical EDI data reporting requirements under 28 TAC Chapter 134, Subchapter I, which requires the full Social Security number.

**Agency Response to Comment on §134.504.** DWC appreciates the comment and has removed the proposed change. The existing requirement for the full Social Security number remains.

**Comment on §134.510.** Texas Mutual stated that they supported the repeal of §134.510 but suggested that DWC consider whether repealing the provisions allowing agreements under subsections (c) and (d) could be problematic if any claims remain with an evergreen pharmacy agreement in place.

**Agency Response to Comment on §134.510.** DWC appreciates the comment but has proceeded with the repeal. The repeal is not retroactive, so existing agreements for long-ago claims should not be affected. Removing the obsolete provisions is necessary to ensure that the rules are current and accurate.

**Comment on §§134.530 and 134.540.** Texas Mutual recommended that DWC keep the existing language in §§134.530(e)(4) and 134.540(e)(4) intact to ensure that there are no

unintended consequences limiting the request of medical interlocutory orders under §§133.306 or 134.550.

**Agency Response to Comment on §§134.530 and 134.540.** DWC appreciates the comment and has removed the proposed change. The existing requirements, which do not mention the prescribing doctor or pharmacy, remain.

**Comment on §134.550.** Texas Mutual recommended that DWC keep the language in current §134.550(h) intact to avoid unintentional conflicts in the timeframes for reconsideration of a preauthorization denial in §§134.600(o) and 19.2011(a)(1) and (9). Texas Mutual also recommended that DWC continue to use the acronym "MIO" to distinguish pharmacy medical interlocutory orders to address potential emergency situations from other types of medical interlocutory orders.

**Agency Response to Comment on §134.550.** DWC appreciates the comment and has removed the proposed change to §134.550(h), reverting to the existing text in that subsection. DWC declines to revert to the "MIO" acronym in the rule text, as "MIO" stands for "medical interlocutory order," and is clearer to read. There should be no confusion and no substantive change in simply spelling out an acronym to make the rule more accessible to readers. Differentiating types of medical interlocutory orders should be simple, as the requests and orders include their type. For example, a request for a medical interlocutory order under §134.550 states that it is being made under that section.

## SUBCHAPTER F. PHARMACEUTICAL BENEFITS.

## REPEAL OF 28 TAC §§134.506 AND 134.510.

**STATUTORY AUTHORITY.** The commissioner of workers' compensation adopts the repeal of §§134.506 and 134.510 under Labor Code §§408.028, 413.0511, 402.00111, 402.00116, and 402.061, and Insurance Code Chapter 1305.

Labor Code §408.028 governs pharmaceutical services. It requires the commissioner by rule to adopt a closed formulary under §413.011, and provides requirements for prescribing prescription drugs, generic pharmaceutical medications, and over-the-counter alternatives. It requires the commissioner by rule to allow an employee to buy over-the-counter alternatives to prescribed or ordered medications, and to get reimbursement from the insurance carrier for those medications. It also requires the commissioner by rule to allow an employee to buy a brand-name drug instead of a generic pharmaceutical medication or over-the-counter alternative to a prescription medication if a health care provider prescribes a generic pharmaceutical medication or an over-the-counter alternative to a prescription medication. Section 408.028(f) requires the commissioner by rule to adopt a fee schedule for pharmacy and pharmaceutical services that will: (1) provide reimbursement rates that are fair and reasonable; (2) assure adequate access to medications and services for injured workers; (3) minimize costs to employees and insurance carriers; and (4) take into consideration the increased security of payment that Labor Code Title 5, Subtitle A, affords.

Labor Code §413.0511 requires DWC to employ or contract with a medical advisor. The medical advisor must be a doctor, as defined in §401.011. The medical advisor's duties include making recommendations about the adoption of rules and policies to: develop, maintain, and review guidelines as provided by §413.011, including rules about impairment ratings; reviewing compliance with those guidelines; regulating or performing other acts related to medical benefits as required by the commissioner; and determining

minimal modifications to the reimbursement methodology and model used by the Medicare system as needed to meet occupational injury requirements.

Labor Code §402.00111 provides that the commissioner of workers' compensation shall exercise all executive authority, including rulemaking authority under Title 5 of the Labor Code.

Labor Code §402.00116 provides that the commissioner of workers' compensation shall administer and enforce this title, other workers' compensation laws of this state, and other laws granting jurisdiction to or applicable to DWC or the commissioner.

Labor Code §402.061 provides that the commissioner of workers' compensation shall adopt rules as necessary to implement and enforce the Texas Workers' Compensation Act.

Insurance Code Chapter 1305 authorizes the establishment of workers' compensation health care networks for providing workers' compensation medical benefits and provides standards for the certification, administration, evaluation, and enforcement of their delivery of health care services to injured employees.

**TEXT.**

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

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

**SUBCHAPTER F. PHARMACEUTICAL BENEFITS.**

**28 TAC §§134.500, 134.501, 134.502, 134.503, 134.504,**

**134.520, 134.530, 134.540, AND 134.550.**

**STATUTORY AUTHORITY.** The commissioner of workers' compensation adopts amendments to §§134.500, 134.501, 134.502, 134.503, 134.504, 134.520, 134.530, 134.540, and 134.550 under Labor Code §§408.028, 408.0281, 413.011, 413.0141, 413.0511, 402.00111, 402.00116, and 402.061, and Insurance Code Chapter 1305, including §§1305.003, 1305.101, and 1305.153.

Labor Code §408.028 governs pharmaceutical services. It requires the commissioner by rule to adopt a closed formulary under §413.011, and provides requirements for prescribing prescription drugs, generic pharmaceutical medications, and over-the-counter alternatives. It requires the commissioner by rule to allow an employee to buy over-the-counter alternatives to prescribed or ordered medications, and to get reimbursement from the insurance carrier for those medications. It also requires the commissioner by rule to allow an employee to buy a brand-name drug instead of a generic pharmaceutical medication or over-the-counter alternative to a prescription medication if a health care provider prescribes a generic pharmaceutical medication or an over-the-counter alternative to a prescription medication. Section 408.028(f) requires the commissioner by rule to adopt a fee schedule for pharmacy and pharmaceutical services that will: (1) provide reimbursement rates that are fair and reasonable; (2) assure adequate access to medications and services for injured workers; (3) minimize costs to employees and insurance carriers; and (4) take into consideration the increased security of payment that Labor Code Title 5, Subtitle A, affords.

Labor Code §408.0281 provides requirements for the reimbursement of pharmaceutical services.

Labor Code §413.011 requires the commissioner to adopt health care reimbursement policies and guidelines that reflect the standardized reimbursement structures found in other health care delivery systems with minimal modifications to those reimbursement methodologies as necessary to meet occupational injury requirements. To achieve standardization, it requires the commissioner to adopt the most current reimbursement methodologies, models, and values or weights used by the federal Centers for Medicare and Medicaid Services, including applicable payment policies relating to coding, billing, and reporting. It also requires the commissioner to develop one or more conversion factors or other payment adjustment factors, taking into account economic indicators and the requirements of §413.011(d), which requires that fee guidelines be fair and reasonable, and designed to ensure the quality of medical care and to achieve effective medical cost control. It requires the commissioner to consider the increased security of payment that Labor Code, Title 5, Subtitle A, provides in establishing the fee guidelines.

Labor Code §413.0141 allows the commissioner by rule to require an insurance carrier to pay for specified pharmaceutical services sufficient for the first seven days following the date of injury if the health care provider requests and receives verification of insurance coverage and a verbal confirmation of an injury from the employer or from the insurance carrier as provided by §413.014. The rules must provide that an insurance carrier is eligible for reimbursement for pharmaceuticals paid under §413.0141 from the subsequent injury fund if the injury is determined not to be compensable.

Labor Code §413.0511 requires DWC to employ or contract with a medical advisor. The medical advisor must be a doctor, as defined in §401.011. The medical advisor's duties include making recommendations about the adoption of rules and policies to: develop, maintain, and review guidelines as provided by §413.011, including rules about

impairment ratings; reviewing compliance with those guidelines; regulating or performing other acts related to medical benefits as required by the commissioner; and determining minimal modifications to the reimbursement methodology and model used by the Medicare system as needed to meet occupational injury requirements.

Labor Code §402.00111 provides that the commissioner of workers' compensation shall exercise all executive authority, including rulemaking authority under Title 5 of the Labor Code.

Labor Code §402.00116 provides that the commissioner of workers' compensation shall administer and enforce this title, other workers' compensation laws of this state, and other laws granting jurisdiction to or applicable to DWC or the commissioner.

Labor Code §402.061 provides that the commissioner of workers' compensation shall adopt rules as necessary to implement and enforce the Texas Workers' Compensation Act.

Insurance Code Chapter 1305 authorizes the establishment of workers' compensation health care networks for providing workers' compensation medical benefits and provides standards for the certification, administration, evaluation, and enforcement of their delivery of health care services to injured employees.

Insurance Code §1305.003(b) provides that Chapter 1305 controls if there is a conflict between Title 5, Labor Code, and Chapter 1305 as to the provision of medical benefits for inured employees, the establishment and regulation of fees for medical treatments and services, the time frames for payment of medical bills, the operation and regulation of workers' compensation health care networks, the regulation of health care providers who contract with those networks, or the resolution of disputes regarding medical benefits provided through those networks.

Insurance Code §1305.101(c) requires in part that prescription medication and services be reimbursed as provided by Labor Code §408.0281, other provisions of Title 5, Labor Code, and applicable rules of the commissioner of workers' compensation.

Insurance Code §1305.153 governs provider reimbursement. Subsection (a) states that the amount of reimbursement for services provided by a network provider is determined by the contract between the network and the provider or group of providers. Subsection (c) requires that out-of-network providers who provide care as described by §1305.006 be reimbursed as provided by Title 5, Labor Code, and applicable rules of the commissioner of workers' compensation. Subsection (d) subjects billing by, and reimbursement to, contracted and out-of-network providers to Title 5, Labor Code, and applicable rules of the commissioner of workers' compensation, as consistent with Chapter 1305. But applying those rules may not negate reimbursement amounts negotiated by the network.

**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 under 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 prescription drug created through compounding prescribed before July 1, 2018, 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;

(C) any prescription drug created through compounding prescribed and dispensed on or after July 1, 2018; and

(D) any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of 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) 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.

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

(11) 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.

(12) 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 must include:

(A) the injured employee's full name;

(B) the date of injury;

(C) the last four digits of the injured employee's Social Security number;

(D) the diagnosis code or codes;

(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.

(13) 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.

**§134.501. Initial Pharmaceutical Coverage.**

(a) For injuries that occur on or after December 1, 2002, the insurance carrier must pay for specified pharmaceutical services sufficient for the first seven days following the date of injury, regardless of issues of liability for or compensability of the injury that the insurance carrier may have, if, before providing the pharmaceutical services, the health care provider obtains both a verification of insurance coverage and an oral or written confirmation that an injury has been reported.

(1) For purposes of this rule, specified pharmaceutical services are prescription drugs and over-the-counter medications prescribed by a doctor that cure or relieve the effects naturally resulting from the compensable injury, promote recovery, or enhance the ability of the injured employee to return to or retain employment.

(2) In determining the first seven days following the injury, the date of the injury is not counted. The first day after the date of injury is "day one." The last day of the seven-day period is "day seven."

(3) If the pharmaceutical services are provided after day one, the insurance carrier's reimbursement under this section is limited to the date the pharmaceutical services were actually provided through day seven. (Example: The pharmaceutical services were provided on day four. The insurance carrier's liability for payment under this section would be for pharmaceutical services in an amount prescribed that would be the quantity sufficient for days four, five, six, and seven.)

(4) Payment for the specified pharmaceutical services for the first seven days following the date of injury must comply with §134.503 of this title (Pharmacy Fee Guideline). The insurance carrier must not deny, prorate, or reduce the dispensing fee for the initial prescription even if the health care provider provided pharmaceutical services beyond the first seven days following the date of injury, and the insurance carrier disputes or denies the pharmaceutical services beyond the first seven days following the date of injury.

(b) The insurance carrier may be eligible for reimbursement from the subsequent injury fund (SIF) for payments made under subsection (a) as provided in Chapter 116 of this title.

(c) The health care provider can verify insurance coverage and confirm the existence of a report of an injury by calling the employer or the insurance carrier. On request, the employer or the insurance carrier must verify coverage and confirm any report of an injury. For verifying insurance coverage, the health care provider can also review the division's internet-based coverage verification system.

(1) The health care provider must document verifications and confirmations not obtained in writing by indicating how the verification or confirmation was obtained (date obtained, from whom, etc.).

(2) The health care provider must affirm on the bill for the pharmaceutical services, in the form and manner prescribed by the division, that the health care provider verified that there is insurance coverage and confirmed that an injury has been reported.

(d) Notwithstanding any other provision of this section, the health care provider may dispense prescription or nonprescription medications in the amount ordered by the prescribing doctor under applicable state and federal law (not to exceed the limits imposed by §134.502 of this title (Pharmaceutical Services)).

(e) The health care provider and insurance carrier may voluntarily discuss approval of pharmaceutical services beyond the seven days following the date of injury as provided in Texas Labor Code §413.014(e) and §134.600 of this title (Preauthorization, Concurrent Utilization Review, and Voluntary Certification of Health Care).

(f) Communication is important to ensure prompt delivery of pharmaceutical services.

(1) Injured employees are encouraged to immediately report their injury to their employer.

(2) Injured employees are encouraged to ask for, and employers to provide, a written statement that confirms an injury was reported to the employer and identifies the date of injury (as reported by the injured employee) and the employer's insurance carrier. Verifying that there is insurance coverage or confirming that an injury was reported does not waive the employer's right to contest compensability under Texas Labor Code §409.011 should the insurance carrier accept liability for the payment of benefits.

(3) The insurance carrier's verification of coverage or confirmation of a reported injury does not waive the insurance carrier's right to further review the claim under Texas Labor Code §409.021 and §124.3 of this title (Investigation of an Injury and Notice of Denial or Dispute).

**§134.502. Pharmaceutical Services.**

(a) A doctor providing care to an injured employee must prescribe for the employee medically necessary prescription drugs and over-the-counter medication alternatives as clinically appropriate and applicable in accordance with applicable state law and as provided by this section.

(1) The doctor must indicate on the prescription that the prescription is related to a workers' compensation claim.

(2) When prescribing an over-the-counter medication alternative to a prescription drug, the doctor must indicate on the prescription the appropriate strength of the medication and the approximate quantity of the over-the-counter medication that is reasonably required by the nature of the compensable injury.

(3) The doctor must prescribe generic prescription drugs when available and clinically appropriate. If in the medical judgment of the prescribing doctor a brand-name drug is necessary, the doctor must specify on the prescription that brand-name drugs be dispensed in accordance with applicable state and federal law, and must maintain documentation justifying the use of the brand-name drug, in the patient's medical record.

(4) The doctor must prescribe over-the-counter medications instead of a prescription drug when clinically appropriate.

(b) When prescribing, the doctor must prescribe in accordance with §134.530 and §134.540 of this title (Closed Formulary for Claims Not Subject to Certified Networks and Closed Formulary for Claims Subject to Certified Networks, respectively).

(c) The pharmacist must dispense no more than a 90-day supply of a prescription drug.

(d) Pharmacies and pharmacy processing agents must submit bills for pharmacy services in accordance with Chapter 133 (General Medical Provisions) and Chapter 134 (Benefits--Guidelines for Medical Services, Charges, and Payments).

(1) Health care providers must bill using national drug codes (NDC) when billing for prescription drugs.

(2) Compound drugs must be billed by listing each drug included in the compound and calculating the charge for each drug separately.

(3) A pharmacy may contract with a separate person or entity to process bills and payments for a medical service. However, these entities are subject to the direction of the pharmacy, and the pharmacy is responsible for the acts and omissions of the person or entity.

(4) Except as allowed by Labor Code §413.042, the injured employee must not be billed for pharmacy services.

(e) The insurance carrier, injured employee, or pharmacist may request a statement of medical necessity from the prescribing doctor.

(1) If an insurance carrier requests a statement of medical necessity, the insurance carrier must provide the sender of the bill a copy of the request at the time the request is made.

(2) An insurance carrier must not request a statement of medical necessity unless in the absence of such a statement the insurance carrier could reasonably support

a denial based on extent of, or relatedness to, the compensable injury or based on an adverse determination.

(f) The prescribing doctor must provide a statement of medical necessity to the requesting party no later than the 14th day after receiving the request. The prescribing doctor must not bill for, and the insurance carrier must not reimburse for, the statement of medical necessity.

(g) In addition to the requirements of §133.240 of this title (Medical Payments and Denials) regarding explanation of benefits (EOB), at the time an insurance carrier denies payment for medications for any reason related to compensability of, liability for, extent of, or relatedness to the compensable injury, or for reasons related to an adverse determination, the insurance carrier must also send the EOB to the injured employee and the prescribing doctor.

**§134.503. Pharmacy Fee Guideline.**

(a) Applicability of this section is as follows:

(1) This section applies to the reimbursement of prescription drugs and nonprescription drugs or over-the-counter medications as those terms are defined in §134.500 of this title (Definitions) for outpatient use in the Texas workers' compensation system, which includes claims:

(A) subject to a certified workers' compensation health care network as defined in §134.500 of this title;

(B) not subject to a certified workers' compensation health care network; and

(C) subject to Labor Code §504.053(b)(2).

(2) This section does not apply to parenteral drugs.

(b) For coding, billing, reporting, and reimbursement of prescription drugs and nonprescription drugs or over-the-counter medications, Texas workers' compensation system participants must comply with Chapters 133 and 134 of this title (General Medical Provisions and Benefits--Guidelines for Medical Services, Charges, and Payments, respectively).

(c) The insurance carrier must reimburse the health care provider or pharmacy processing agent for prescription drugs the lesser of:

(1) the fee established by the following formulas based on the average wholesale price (AWP) as reported by a nationally recognized pharmaceutical price guide or other publication of pharmaceutical pricing data in effect on the day the prescription drug is dispensed:

(A) Generic drugs: ((AWP per unit) x (number of units) x 1.25) + $4.00 dispensing fee per prescription = reimbursement amount;

(B) Brand-name drugs: ((AWP per unit) x (number of units) x 1.09) + $4.00 dispensing fee per prescription = reimbursement amount;

(C) When compounding, a single compounding fee of $15 per prescription must be added to the calculated total for either paragraph (1)(A) or (B) of this subsection; or

(2) notwithstanding §133.20(e)(1) of this title (Medical Bill Submission by Health Care Provider), the amount billed to the insurance carrier by the:

(A) health care provider; or

(B) pharmacy processing agent only if the health care provider has not previously billed the insurance carrier for the prescription drug, and the pharmacy processing agent is billing on behalf of the health care provider.

(d) Reimbursement for nonprescription drugs or over-the-counter medications must be the retail price of the lowest package quantity reasonably available that will fill the prescription.

(e) Except as provided by subsection (f) of this section, if an amount cannot be determined under subsections (c)(1) or (d) of this section, reimbursement must be an amount that is consistent with the criteria listed in Labor Code §408.028(f), including providing for reimbursement rates that are fair and reasonable. The insurance carrier must:

(1) develop one or more reimbursement methodologies for determining reimbursement under this subsection;

(2) maintain in reproducible format documentation of the insurance carrier's methodologies for establishing an amount;

(3) apply the reimbursement methodologies consistently among health care providers in determining reimbursements under this subsection; and

(4) on the division's request, provide to the division copies of such documentation.

(f) Notwithstanding the provisions of this section, the insurance carrier may reimburse prescription medication or services, as defined by Labor Code §401.011(19)(E), at a contract rate that is inconsistent with the fee guideline as long as the contract complies with the provisions of Labor Code §408.0281 and applicable division rules.

(g) When the prescribing doctor has written a prescription for a generic drug or a prescription that does not require the use of a brand-name drug under §134.502(a)(3) of this title (Pharmaceutical Services), reimbursement must be as follows:

(1) the health care provider must dispense the generic drug as prescribed, and the insurance carrier must reimburse the fee established for the generic drug, under subsection (c) or (f) of this section; or

(2) when an injured employee chooses to receive a brand-name drug instead of the prescribed generic drug, the health care provider must dispense the brand-name drug as requested and must be reimbursed:

(A) by the insurance carrier, the fee established for the prescribed generic drug under subsection (c) or (f) of this section; and

(B) by the injured employee, the cost difference between the fee established for the generic drug in subsection (c) or (f) of this section and the fee established for the brand-name drug under subsection (c) or (f) of this section.

(h) When the prescribing doctor has written a prescription for a brand-name drug under §134.502(a)(3) of this title, reimbursement must be under subsection (c) or (f) of this section.

(i) On request by the health care provider or the division, the insurance carrier must disclose the source of the nationally recognized pricing reference used to calculate the reimbursement.

(j) Where any provision of this section is determined by a court of competent jurisdiction to be inconsistent with any statutes of this state, or to be unconstitutional, the remaining provisions of this section remain in effect.

**§134.504. Pharmaceutical Expenses Incurred by the Injured Employee.**

(a) If an injured employee needs to purchase prescription drugs or over-the-counter alternatives to prescription drugs prescribed or ordered by the treating doctor or

referral health care provider, the injured employee may request reimbursement from the insurance carrier as follows:

(1) The injured employee must submit to the insurance carrier a letter requesting reimbursement along with a receipt indicating the amount paid and documentation concerning the prescription.

(A) The letter should include information to clearly identify the claimant such as the claimant's name, address, date of injury, and Social Security number.

(B) Documentation for prescription drugs submitted with the letter from the employee must include the prescribing health care provider's name, the date the prescription was filled, the name of the drug, employee's name, and dollar amount paid by the employee. As examples, this information may be on an information sheet provided by the pharmacy, or the employee can ask the pharmacist for a printout of work-related prescriptions for a particular time period. Cash register receipts alone are not acceptable.

(2) The insurance carrier must pay the injured employee under §134.503 of this title (Pharmacy Fee Guideline), or notify the injured employee of a reduction or denial of the payment within 45 days of receiving the request for reimbursement from the injured employee.

(A) If the insurance carrier does not reimburse the full amount requested or denies payment, the insurance carrier must include a full and complete explanation of the reasons the insurance carrier reduced or denied the payment and must inform the injured employee of his or her right to request medical dispute resolution under §133.305 of this title (MDR--General).

(B) The statement must include sufficient claim-specific substantive information to enable the employee to understand the insurance carrier's position or action on the claim. A general statement that simply states the insurance carrier's position

with a phrase such as, "not entitled to reimbursement" or a similar phrase with no further description of the factual basis does not satisfy the requirements of this section.

(b) An injured employee may choose to receive a brand-name drug rather than a generic drug or over-the-counter alternative to a prescription medication that is prescribed by a health care provider. In such instances, the injured employee must pay the difference in cost between the generic drug and the brand-name drug. The transaction between the employee and the pharmacist is considered final and is not subject to medical dispute resolution by the division. In addition, the employee is not entitled to reimbursement from the insurance carrier for the difference in cost between generic and brand-name drugs.

(1) The injured employee must notify the pharmacist of their choice to pay the cost difference between the generic and brand-name drugs. An employee's payment of the cost difference is an acceptance of the responsibility for the cost difference and an agreement not to seek reimbursement from the insurance carrier for the cost difference.

(2) The pharmacist must:

(A) determine the costs of both the brand-name and generic drugs under §134.503 of this title, and notify the injured employee of the cost difference amount;

(B) collect the cost difference amount from the injured employee in a form and manner that is acceptable to both parties;

(C) submit a bill to the insurance carrier for the generic drug that was prescribed by the doctor; and

(D) not bill the injured employee for the cost of the generic drug if the insurance carrier reduces or denies the bill.

(3) The insurance carrier must review and process the bill from the pharmacist under Chapters 133 and 134 (General Medical Provisions and Benefits--Guidelines for Medical Services, Charges, and Payments, respectively).

**§134.520. Outpatient Closed Formulary.**

The commissioner of workers' compensation adopts a closed formulary as defined in §134.500(3) of this title (Definitions). The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use.

**§134.530. 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.

(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 prescription drug created through compounding; 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 that 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 (Preauthorization, Concurrent Utilization 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 under §134.600 of this title, and the preauthorization request must include the prescribing doctor's drug regimen 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 regimen proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regimen 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 must be in accordance with §137.100 of this title (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 under subsection (g) of this section.

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

(1) When 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 requester, or injured employee must request approval of the drug by requesting preauthorization, including reconsideration, under §134.600 of this title and applicable provisions of Chapter 19 of this title (Licensing and Regulation of Insurance Professionals).

(2) If an injured employee or a requester other than the prescribing doctor requests preauthorization and a statement of medical necessity, the prescribing doctor must provide a statement of medical necessity to facilitate the preauthorization submission under §134.502 of this title (Pharmaceutical Services).

(3) If preauthorization for a drug excluded from the closed formulary is denied, the requester may submit a request for medical dispute resolution under §133.308 of this title (MDR of Medical Necessity Disputes).

(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 (Interlocutory Orders for Medical Benefits) or §134.550 of this title (Medical Interlocutory Order).

(f) Initial pharmaceutical coverage.

(1) Drugs included in the closed formulary that are prescribed for initial pharmaceutical coverage under 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 that are prescribed for initial pharmaceutical coverage under 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 under §133.230 of this title (Insurance Carrier Audit of a Medical Bill) and §133.240 of this title (Medical Payments and Denials), and applicable provisions of Chapter 19 of this title.

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

(2) 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 in §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 must provide documentation on request under §134.500(13) of this title (Definitions) and §134.502(e) and (f) of this title.

**§134.540. 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.

(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 prescription drug created through compounding; 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 that 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 under the certified network's treatment guidelines and preauthorization requirements in Insurance Code Chapter 1305 and Chapter 10 of this title (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 regimen proposed by the prescribing doctor differs from the medications, dosage or

range of dosages, or drug regimen previously preauthorized by that prescribing doctor; or

(B) there is a change in prescribing doctor.

(d) Treatment guidelines. The prescribing of drugs must be under the certified network's treatment guidelines and preauthorization requirements in 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 under subsection (g) of this section.

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

(1) When 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 requester, or injured employee must request approval of the drug in a specific instance by requesting preauthorization under the certified network's preauthorization process established in Chapter 10, Subchapter F of this title (Utilization Review and Retrospective Review) and applicable provisions of Chapter 19 of this title (Licensing and Regulation of Insurance Professionals).

(2) If an injured employee or a requester other than the prescribing doctor requests preauthorization and a statement of medical necessity, the prescribing doctor must provide a statement of medical necessity to facilitate the preauthorization submission under §134.502 of this title (Pharmaceutical Services).

(3) If preauthorization for a drug excluded from the closed formulary is denied, the requester may submit a request for medical dispute resolution under §133.308 of this title (MDR of Medical Necessity Disputes).

(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 (Interlocutory Orders for Medical Benefits) or §134.550 of this title (Medical Interlocutory Order).

(f) Initial pharmaceutical coverage.

(1) Drugs included in the closed formulary that are prescribed for initial pharmaceutical coverage under 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 that are prescribed for initial pharmaceutical coverage under 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 under §133.230 of this title (Insurance Carrier Audit of a Medical Bill), §133.240 of this title (Medical Payments and Denials), Insurance Code Chapter 1305, and applicable provisions of Chapters 10 and 19 of this title.

(1) 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 on request under §134.500(13) of this title (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 a medical interlocutory order when preauthorization denials of previously prescribed and dispensed drugs excluded from the closed formulary pose an unreasonable risk of a medical emergency as defined in §134.500(7) of this title (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 submitted under §133.306 of this title (Interlocutory Orders for Medical Benefits).

(c) A request for a medical interlocutory order must contain 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) requester's name (pharmacy or prescribing doctor);

(6) requester's contact information;

(7) a statement that a preauthorization request for a previously prescribed and dispensed drug, 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 under §133.308 of this title (MDR of Medical Necessity Disputes);

(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 a medical interlocutory order is being submitted to the division; and

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

(d) The division will process and approve a complete request for a medical interlocutory order under this section. At its discretion, the division may consider an incomplete request for a medical interlocutory order.

(e) The request for a medical interlocutory order must be in writing and must contain the information in subsection (c) of this section. A convenient form that contains the required information is on the division's website at https://www.tdi.texas.gov/forms/form20numeric.html.

(f) The requester must provide a copy of the request to the insurance carrier, prescribing doctor, injured employee, and dispensing pharmacy, if known, on the date the requester submits the request to the division.

(g) An approved medical interlocutory order is effective retroactively to the date the division received the complete request for the medical interlocutory order.

(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 a medical interlocutory order under this section. If a request for reconsideration or a medical interlocutory order request

is not initiated within 15 days from the initial preauthorization denial, then the opportunity to request a medical interlocutory order under this section does not apply.

(2) If pursuing a medical interlocutory order after denial of a reconsideration request, a complete medical interlocutory order must 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 medical interlocutory order must be submitted under §133.308(t) of this title.

(j) The medical interlocutory order continues in effect until the later of:

(1) final adjudication of a medical dispute about the medical necessity and reasonableness of the drug contained in the medical interlocutory order;

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

(3) agreement of the parties.

(k) If a requester withdraws a request for medical necessity dispute resolution, the requester accepts the preauthorization denial.

(l) A party must comply with a medical interlocutory order entered under this section, and the insurance carrier must reimburse the pharmacy for prescriptions dispensed under a medical interlocutory order.

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

(n) Payments made by insurance carriers under this section may be eligible for reimbursement from the subsequent injury fund under 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 a medical interlocutory order 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 must be conducted under Chapters 140 and 142 of this title (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 under Labor Code §413.055 and §148.3 of this title (Requesting a Hearing).

**CERTIFICATION.** The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on November 8, 2024.

Kara Mace
General Counsel
TDI, Division of Workers' Compensation

The commissioner adopts amended 28 TAC §§134.500, 134.501, 134.502, 134.503, 134.504, 134.520, 134.530, 134.540, and 134.550; and the repeal of 28 TAC §§134.506 and 134.510.

Jeff Nelson
Commissioner
TDI, Division of Workers' Compensation

Commissioner's Order No. 2024-8948