SUBCHAPTER F. PHARMACEUTICAL BENEFITS.
28 TAC §§134.500, 134.501, 134.502, 134.503, 134.504,
[~~134.506, 134.510,~~] 134.520, 134.530, 134.540, AND 134.550.

INTRODUCTION. The Texas Department of Insurance, Division of Workers' Compensation (DWC) proposes 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 recommends the amendments to the commissioner of workers' compensation under Labor Code §413.0511(b).

EXPLANATION. 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 proposed 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 proposed 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 proposed changes correct a reference to the injured employee's Social Security number to specify only the last four digits of the number. The proposed 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 proposed 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 proposed 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 proposed 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 proposed changes correct a reference to the claimant's Social Security number to specify only the last four digits of the number. The proposed changes also correct obsolete references and make editorial and formatting updates for plain language and agency style. 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 proposed 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 proposed 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.

Section 134.540. The proposed 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.

Section 134.550. The proposed 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.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Deputy Commissioner for Health and Safety Mary Landrum has determined that during each year of the first five years the proposed changes are in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the sections, other than that imposed by the statute. This determination was made because the proposed changes do not add to or decrease state revenues or expenditures, and because local and state government entities are only involved in enforcing or complying with the proposed changes when acting in the capacity of a workers' compensation

insurance carrier. Those entities will be impacted in the same way as an insurance carrier and will realize the same benefits from the proposed changes.

Deputy Commissioner Landrum does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. For each year of the first five years the proposed changes are in effect, Deputy Commissioner Landrum expects that enforcing and administering the proposed changes will have the public benefits of ensuring that DWC's rules are clear, organized, current, and accurate, as well as ensuring that they conform to Labor Code §§408.028 and 413.011, and Insurance Code Chapter 1305, which promotes transparent and efficient regulation.

Deputy Commissioner Landrum expects that the proposed changes will not increase the cost to comply with Labor Code §§408.028 and 413.011, or with Insurance Code Chapter 1305, because they do not impose requirements beyond those in the statutes or create obligations beyond those in the current 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. As a result, any cost associated with implementing the changes does not result from the enforcement or administration of the proposed changes.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. DWC has determined that the proposed changes will not have an adverse economic effect or a disproportionate economic impact on small or micro businesses, or on rural communities because the proposed changes remove obsolete provisions; update references; and revise the text for consistency, plain language, and agency style only. They do not change the people the rule affects or impose additional costs. As a result, and in accordance with Government Code §2006.002(c), DWC is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. DWC has determined that this proposal does not impose a possible cost on regulated persons. As a result, no additional rule amendments are required under Government Code §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT. DWC has determined that for each year of the first five years that the proposed amendments are in effect, the proposed rule:

- will not create or eliminate a government program;

- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the agency;

- will not require an increase or decrease in fees paid to the agency;

- will not create a new regulation;

- will expand, limit, or repeal an existing regulation;

- will not increase or decrease the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

DWC made these determinations because the proposed rule enhances efficiency and clarity; conforms the language to current agency structure, practice, and related rules; repeals obsolete provisions; and makes editorial changes for plain language and agency style. The proposed changes do not change the people the rule affects or impose additional costs.

TAKINGS IMPACT ASSESSMENT. DWC has determined that no private real property interests are affected by this proposal, and this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action. As a result, this proposal does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

REQUEST FOR PUBLIC COMMENT. DWC will consider any written comments on the proposal that DWC receives no later than 5:00 p.m., Central time, on September 23, 2024. Send your comments to RuleComments@tdi.texas.gov; or to Texas Department of Insurance, Division of Workers' Compensation, Legal Services, MC-LS, P.O. Box 12050, Austin, TX 78711-2050.

To request a public hearing on the proposal, submit a request before the end of the comment period to RuleComments@tdi.texas.gov; or to Texas Department of Insurance, Division of Workers' Compensation, Legal Services, MC-LS, P.O. Box 12050, Austin, TX 78711-2050. The request for a public hearing must be separate from any comments. If DWC holds a public hearing, it will consider written and oral comments presented at the hearing.

SUBCHAPTER F. PHARMACEUTICAL BENEFITS.

[~~28 TAC §§134.506 AND 134.510~~].

STATUTORY AUTHORITY. DWC proposes repealing §§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.

CROSS-REFERENCE TO STATUTE. Subchapter F implements Labor Code §§408.028 and 413.011. Section 408.028, formerly V.A.C.S. Art 8308-4.69, was recodified as §408.028 by House Bill 752, 73rd Legislature, Regular Session (1993), and last amended in 2011. Section 413.011 was enacted by House Bill 2600, 77th Legislature, Regular Session (2001), and last amended in 2007.

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. DWC proposes 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.

CROSS-REFERENCE TO STATUTE. Subchapter F implements Labor Code §§408.028 and 413.011. Section 408.028, formerly V.A.C.S. Art 8308-4.69, was recodified as §408.028 by House Bill 752, 73rd Legislature, Regular Session (1993), and last amended in 2011. Section 413.011 was enacted by House Bill 2600, 77th Legislature, Regular Session (2001), and last amended in 2007.

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 [~~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 [~~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 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) 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.~~]

(9) [~~(10)~~] Prescribing doctor--A physician or dentist who prescribes prescription drugs or over-the-counter [~~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 [~~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) [~~(11)~~] Prescription--An order for a prescription or nonprescription drug to be dispensed.

(11) [~~(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.

(12) [~~(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 [~~brand name~~] drug where applicable. A statement of medical necessity must [~~shall~~] 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 [~~social security~~] number;

(D) the diagnosis code or codes [~~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.

(13) [~~(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.

§134.501. Initial Pharmaceutical Coverage.

(a) For injuries that [~~which~~] occur on or after December 1, 2002, the insurance carrier must [~~(carrier) shall~~] 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 [~~prior to~~] providing the pharmaceutical services, the health care provider [~~(HCP)~~] 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) [~~(1)~~] 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 [~~shall be counted as~~] "day one." The last day of the seven-day period is [~~shall be known as~~] "day seven."

(3) [~~(2)~~] 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) [~~(3)~~] Payment for the specified pharmaceutical services for the first seven days following the date of injury must comply with [~~shall be in accordance with~~] §134.503 of this title (Pharmacy Fee Guideline [~~relating to Reimbursement Methodology~~]). The insurance carrier must not deny, prorate, or reduce the dispensing fee for the initial prescription [~~shall not be denied, prorated, or reduced~~] even if the health care provider [~~HCP~~] 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 [~~HCP~~] can verify insurance coverage and confirm the existence of a report of an injury by calling the employer or the insurance carrier. On [~~Upon~~] request, the employer or [~~and/or~~] the insurance carrier must [~~shall~~] verify coverage and confirm any report of an injury. For verifying insurance coverage, the health care provider [~~HCP~~] can also review the division's [~~commission's~~] internet-based coverage verification system.

(1) The health care provider must [~~HCP shall~~] 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 [~~HCP shall~~] affirm on the bill for the pharmaceutical services, in the form and manner prescribed by the division [~~commission~~], that the health care provider [~~HCP~~] 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 [~~HCP~~] may dispense prescription or nonprescription medications in the amount ordered by the prescribing doctor under [~~in accordance with~~] applicable state and federal law (not to exceed the limits imposed by §134.502 of this title ([~~relating to~~] Pharmaceutical Services)).

(e) The health care provider [~~HCP~~] 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 ([~~relating to~~] Preauthorization, Concurrent Utilization Review, and Voluntary Certification of Health Care).

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

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

(2) Injured employees [~~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 [~~and/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 [~~and/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 ([~~relating to~~] Investigation of an Injury and Notice of Denial or Dispute [~~Denial/Dispute~~]).

§134.502. Pharmaceutical Services.

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

(1) The doctor must indicate [~~It shall be indicated~~] on the prescription that the prescription is related to a workers' compensation claim.

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

(3) The doctor must [~~shall~~] 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 [~~shall~~] prescribe over-the-counter [~~OTC~~] medications instead [~~in lieu~~] of a prescription drug when clinically appropriate.

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

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

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

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

(2) Compound drugs must [~~shall~~] 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, [~~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 [~~shall~~] 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 [~~shall~~] provide the sender of the bill a copy of the request at the time the request is made.

(2) An insurance carrier must [~~shall~~] 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 [~~upon~~] extent of, or relatedness to, the compensable injury[~~,~~] or based on [~~upon~~] an adverse determination.

(f) The prescribing doctor must [~~shall~~] provide a statement of medical necessity to the requesting party no later than the 14th day after receiving the [~~receipt of~~] request. The prescribing doctor must [~~shall~~] not bill for, and [~~nor shall~~] the insurance carrier must not reimburse for, the statement of medical necessity.

(g) In addition to the requirements of §133.240 of this title ([~~relating to~~] 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 [~~shall~~] 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 ([~~relating to~~] 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 [~~shall apply the provisions of~~] Chapters 133 and 134 of this title ([~~relating to~~] General Medical Provisions and Benefits--Guidelines for Medical Services, Charges, and Payments, respectively).

(c) The insurance carrier must [~~shall~~] 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 [~~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 [~~shall~~] 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 ([~~relating to~~] 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 [~~shall~~] 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 [~~in accordance with~~] subsections (c)(1) or (d) of this section, reimbursement must [~~shall~~] 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 [~~shall~~]:

(1) develop one or more [~~a~~] reimbursement methodologies [~~methodology(ies)~~] for determining reimbursement under this subsection;

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

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

(4) on the division's request [~~upon request by the division~~], 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), [~~may be reimbursed~~] 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 [~~brand name~~] drug under [~~in accordance with~~] §134.502(a)(3) of this title ([~~relating to~~] Pharmaceutical Services), reimbursement must [~~shall~~] be as follows:

(1) the health care provider must [~~shall~~] dispense the generic drug as prescribed, and the insurance carrier must reimburse [~~shall be reimbursed~~] the fee established for the generic drug, under [~~in accordance with~~] subsection (c) or (f) of this section; or

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

(A) by the insurance carrier, the fee established for the prescribed generic drug under [~~in accordance with~~] 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 [~~brand name~~] drug under [~~in accordance with~~] subsection (c) or (f) of this section.

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

(i) On [~~Upon~~] request by the health care provider or the division, the insurance carrier must [~~shall~~] 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 [~~shall~~] remain in effect.

§134.504. Pharmaceutical Expenses Incurred by the Injured Employee.

(a) If [~~It may become necessary for~~] 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, [~~. In such instances~~] the injured employee may request reimbursement from the insurance carrier as follows:

(1) The injured employee must [~~shall~~] 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 last four digits of the claimant's Social Security [~~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 [~~provided~~] on an information sheet provided by the pharmacy, or the employee can ask the pharmacist for a printout [~~print out~~] of work-related [~~work-related~~] prescriptions for a particular time period. Cash register receipts alone are not acceptable.

(2) The insurance carrier must pay [~~shall make appropriate payment to~~] the injured employee under [~~in accordance with~~] §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 [~~receipt of~~] 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 [~~shall~~] include a full and complete explanation of the reasons [~~reason(s)~~] the insurance carrier reduced or denied the payment and must [~~shall~~] inform the injured employee of his or her right to request

medical dispute resolution under [~~in accordance with~~] §133.305 of this title (MDR--General [~~relating to Medical Dispute Resolution~~]).

(B) The statement must [~~shall~~] include sufficient claim-specific substantive information to enable the employee to understand the insurance carrier's position or [~~and/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 [~~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 [~~shall~~] pay the difference in cost between the generic drug [~~drugs~~] and the brand-name drug [~~brand name drugs~~]. 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 [~~brand name~~] drugs.

(1) The injured employee must [~~shall~~] notify the pharmacist of their choice to pay the cost difference between the generic and brand-name [~~brand name~~] drugs. An employee's payment of the cost difference is [~~constitutes~~] 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 [~~shall~~]:

(A) determine the costs of both the brand-name [~~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 [~~shall~~] review and process the bill from the pharmacist under Chapters [~~in accordance with Chapter~~] 133 and 134 ([~~pertaining to~~] General Medical Provisions and Benefits--Guidelines for Medical Services, Charges, and Payments [~~Payment~~], respectively).

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

The commissioner of workers' compensation [~~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~~]. The closed formulary applies to all drugs that are prescribed and dispensed for outpatient use.

§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 [~~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 [~~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

(C) [~~(D)~~] any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but that [~~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 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 [~~in accordance with~~] §134.600 of this title, and the preauthorization request must include the prescribing doctor's drug regimen [~~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 regimen [~~regime~~] proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regimen [~~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 must [~~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 under [~~in accordance with~~] subsection (g) of this section.

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

(1) When [~~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 requester [~~requestor~~], or injured employee must request approval of the drug by requesting preauthorization, including reconsideration, under [~~in accordance with~~] §134.600 of this title and applicable provisions of Chapter 19 of this title (Licensing and Regulation of Insurance Professionals [~~relating to Agents' Licensing~~]).

(2) If [~~preauthorization is being requested by~~] an injured employee or a requester [~~requestor~~] other than the prescribing doctor[~~,~~] requests preauthorization and [~~the injured employee or other requestor requests~~] a statement of medical necessity, the prescribing doctor must [~~shall~~] provide a statement of medical necessity to facilitate the preauthorization submission under [~~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 requester [~~requestor~~] may submit a request for medical dispute resolution under [~~in accordance with~~] §133.308 of this title ([~~relating to~~] MDR of Medical Necessity Disputes [~~by Independent Review Organizations~~]).

(4) In the event of an unreasonable risk of a medical emergency, the prescribing doctor or pharmacy can request an interlocutory order under [~~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 that [~~which~~] are prescribed for initial pharmaceutical coverage under[~~, 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 that [~~which~~] are prescribed for initial pharmaceutical coverage[~~,~~] under [~~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 paragraph [~~subsection~~] (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity under [~~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 under [~~in accordance with~~] §137.100 of this title is presumed reasonable as [~~specified in~~] 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 [~~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[~~,~~] 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 [~~is required to~~] provide documentation on [~~upon~~] request under [~~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 [~~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 [~~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;~~

~~(3) any prescription drug created through compounding prescribed and dispensed on or after July 1, 2018; and~~]

(3) [~~(4)~~] any investigational or experimental drug for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but that [~~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 under [~~in accordance with~~] the certified network's treatment guidelines and preauthorization requirements in [~~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 regimen [~~regime~~] proposed by the prescribing doctor differs from the medications, dosage or range of dosages, or drug regimen [~~regime~~] previously preauthorized by that prescribing doctor; or

(B) there is a change in prescribing doctor.

(d) Treatment guidelines. The prescribing of drugs must [~~shall~~] be under [~~in accordance with~~] the certified network's treatment guidelines and preauthorization requirements in [~~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 under [~~in accordance with~~] subsection (g) [~~(f)~~] of this section.

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

(1) When [~~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 requester [~~requestor~~], or injured employee must request approval of the drug in a specific instance by requesting preauthorization under [~~in accordance with~~] the certified network's preauthorization process established in [~~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 (Licensing and Regulation of Insurance Professionals [~~relating to Agents' Licensing~~]).

(2) If [~~preauthorization is pursued by~~] an injured employee or a requester [~~requestor~~] other than the prescribing doctor[~~,~~] requests preauthorization and [~~the injured employee or other requestor requests~~] a statement of medical necessity, the prescribing doctor must [~~shall~~] provide a statement of medical necessity to facilitate the preauthorization submission under [~~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 requester [~~requestor~~] may submit a request for medical dispute resolution

under [~~in accordance with~~] §133.308 of this title ([~~relating to~~] MDR of Medical Necessity Disputes [~~by Independent Review Organizations~~]).

(4) In the event of an unreasonable risk of a medical emergency, the prescribing doctor or pharmacy can request an interlocutory order under [~~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 that [~~which~~] are prescribed for initial pharmaceutical coverage[~~,~~] under [~~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 that [~~which~~] are prescribed for initial pharmaceutical coverage[~~,~~] under [~~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 paragraph [~~subsection~~] (f)(1) of this section, drugs that do not require preauthorization are subject to retrospective review for medical necessity under [~~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, and applicable provisions of Chapters 10 and 19 of this title.

(1) For [~~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 on [~~upon~~] request under [~~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 a [~~an~~] medical interlocutory order [~~(MIO)~~] when [~~in instances where~~] preauthorization denials of [~~a~~] previously prescribed and dispensed drugs [~~drug(s)~~] excluded from the closed formulary pose [~~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 prescribing doctor or pharmacy may still submit a request for an interlocutory order that does not meet the criteria described by this section under [~~may still be requested pursuant to~~] §133.306 of this title ([~~relating to~~] Interlocutory Orders [~~Order~~] for Medical Benefits).

(c) A [~~An MIO will be issued if the~~] request for a medical interlocutory order must contain [~~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) requester's [~~MIO requestor's~~] name (pharmacy or prescribing doctor);

(6) requester's [~~MIO requestor's~~] contact information;

(7) a statement that a preauthorization request for a previously prescribed and dispensed drug [~~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 under [~~in accordance with~~] §133.308 of this title ([~~relating to~~] MDR of Medical Necessity Disputes [~~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 a medical interlocutory order [~~an MIO~~] is being submitted to the division; and

(12) a signature and the following certification by the medical interlocutory order requester [~~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) The division will process and approve a [~~A~~] complete request for a medical interlocutory order [~~an MIO~~] under [~~this section shall be processed and approved by the division in accordance with~~] this section. At its discretion, [~~the discretion of~~] the division[,] may consider an incomplete request for a medical interlocutory order [~~an MIO under this section may be considered in accordance with this section~~].

(e) The request for a medical interlocutory order [~~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 be in writing and must contain the information in [~~provisions~~

~~of~~] 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 [~~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 requester submits the request [~~for MIO is submitted~~] to the division.

(g) An approved medical interlocutory order is [~~MIO shall be~~] effective retroactively to the date the division received the complete request for the medical interlocutory order [~~an MIO is received by the division~~].

(h) Notwithstanding §133.308 of this title:

(1) The requester has 15 days from the date the preauthorization was denied to request either reconsideration or a medical interlocutory order. [~~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) The requester does not have to request reconsideration before requesting a medical interlocutory order. [~~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.~~]

(3) If the requester submitted a request for reconsideration and it was denied, the requester has five working days after that denial to request a medical interlocutory order.

(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 [~~MIO shall~~] be submitted under [~~in accordance with~~] §133.308(t) of this title.

(j) The medical interlocutory order continues [~~MIO shall continue~~] in effect until the later of:

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

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

(3) agreement of the parties.

(k) If a requester withdraws [~~Withdrawal by the requestor of~~] a request for medical necessity dispute resolution, the requester accepts [~~constitutes acceptance of~~] the preauthorization denial.

(l) A party must [~~shall~~] comply with a medical interlocutory order [~~an MIO~~] entered under [~~in accordance with~~] this section, and the insurance carrier must [~~shall~~] reimburse the pharmacy for prescriptions dispensed under a medical interlocutory order [~~in accordance with an MIO~~].

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

(n) Payments made by insurance carriers under [~~pursuant to~~] this section may be eligible for reimbursement from the subsequent injury fund [~~Subsequent Injury Fund~~] under [~~in accordance with~~] Labor Code §§410.209 and 413.055 [~~§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 [~~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 must [~~shall~~] be conducted under [~~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 under [~~in accordance with~~] Labor Code §413.055 and §148.3 of this title ([~~relating to~~] Requesting a Hearing).

CERTIFICATION. The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Issued in Austin, Texas, on August 7, 2024.

Kara Mace
General Counsel
TDI, Division of Workers' Compensation