TITLE 28. INSURANCE

PART 2. TEXAS DEPARTMENT OF INSURANCE, DIVISION OF WORKERS' COMPENSATION

CHAPTER 134: BENEFITS--GUIDELINES FOR MEDICAL SERVICES, CHARGES, AND PAYMENTS

SUBCHAPTER F: PHARMACEUTICAL BENEFITS

Title 28 Texas Administrative Code (TAC) §134.500, §134.530 and §134.540

INTRODUCTION. The Texas Department of Insurance, Division of Workers' Compensation (division) proposes to amend 28 Texas Administrative Code (TAC) §134.500, *Definitions*; and proposes conforming amendments to 28 TAC §134.530, *Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks;* and 28 TAC §134.540, *Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks*. The proposed changes amend the definition of the closed formulary to exclude any prescription drug created through compounding, and to require preauthorization for all prescription drugs created through compounding.

An informal working draft of the rule text was published on the division's website on June 16, 2017, and the division received 22 comments. If adopted, these amendments become effective July 1, 2018.

BACKGROUND AND PURPOSE. House Bill 7 (HB 7), enacted by the 79th Texas Legislature, Regular Session, amended Labor Code §408.028, *Pharmaceutical Services*, to require that the commissioner of workers' compensation adopt a closed formulary. After extensive collaboration with system participants, including medical providers and insurance carriers, the commissioner adopted a

series of rules to implement the closed formulary and transition injured employees' claims to the closed formulary.

Implementation of the closed formulary has had a significant effect on the use of pharmaceuticals in the Texas workers' compensation system. Cost for pharmaceuticals has decreased significantly since the initial applicability of the closed formulary. Likewise, the use of opioids and other potentially addictive drugs has decreased dramatically. These changes have been monitored through a series of reports issued by the Texas Department of Insurance Workers' Compensation Research and Evaluation Group (REG).

From 2010 to 2015, total payments for all prescriptions decreased by 38%. In contrast, total payments for compounded drugs increased by 98% over the same time period.

Pharmacy services for new claims (by injury year):

- Between Fiscal Injury Year (FIY) 2011 (pre-formulary) and FIY 2012 (post-formulary), the number of injured employees receiving N-drugs (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) decreased by 67%.
- N-drug costs decreased by 78%, and N-drug costs as a percentage of all drug costs decreased by 74% (from 20% of total to 5% of total).
- The average number of N-drug prescriptions per claim decreased by 32%.
- The number of N-drug prescriptions decreased by more than 70% across all drug groups.

Pharmacy services for all claims (new and legacy claims by service year):

- Between Fiscal Service Year (FSY) 2011 (pre-formulary) and FSY 2014 (post-formulary for legacy claims), the number of injured employees receiving N-drugs decreased by 83%.
- The number of N-drug prescriptions decreased by 85%.
- N-drug costs decreased by 80%. The number of N-drug prescriptions decreased by more than 80% in all drug groups. Costs decreased by more than 70% in all drug groups.

As a result of concerns expressed by system participants and the division's obligation to monitor the closed formulary, generally, analysis of compounded drug activity was undertaken based on pharmacy data collected by the division. The following observations, presented by the division to the Texas House of Representatives Business and Industry Committee, are noteworthy.

- Compounded drug payments increased from $5.87 million (4% of total prescription reimbursement) in calendar year (CY) 2010 to $11.6 million (12% of total prescription reimbursement) in CY 2015.
- Pharmacy medical billing data indicates a 14% increase in the number of compounded drugs paid from CY 2010 to CY 2014.
- Reimbursement per compounded drug increased 141% from CY 2010 to CY 2015 ($316 to $760).
- From FY 2010 to FY 2014, ingredient costs for a selected group of ten commonly compounded drugs increased between 82% and 1,474%.

Per the division's analysis, as the use of compounded drugs for work-related injuries has increased over the last five years, the cost of compounded drugs as a percentage of total pharmacy costs has more than doubled.

In response to these findings, the division initiated a plan-based audit of several physicians prescribing compounded drugs in the system. The audit was conducted by the division's Office of the Medical Advisor.

Under Labor Code §408.021, *Entitlement to Medical Benefits*, an injured employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed. More specifically, an injured employee is entitled to health care that cures or relieves the effects naturally resulting from the compensable injury; promotes recovery; or enhances the ability of the employee to return to or retain employment.

While entitlement to healthcare does extend to, and include, compounded drugs, compounded drugs are not recommended as a first-line therapy by the current edition of the division's adopted treatment guidelines, the *Official Disability Guidelines-Treatment in Workers' Comp* (ODG), and the medical necessity and efficacy of compounded drugs is not well-established per evidence-based medicine standards.

The purpose of the Compound Medications Plan-Based Audit was to promote the delivery of quality health care in a cost-effective manner, including protection of injured employee safety; to ensure that doctors adhere to the *ODG* / Appendix A, *ODG Workers' Compensation Drug Formulary* and medically-accepted standards of care for prescribing compounded drugs; and to determine the appropriateness of medical decision-making related to the prescription of compounded drugs by doctors or those acting under their supervision. The division found that prescribing doctors selected

for the audit generally did not demonstrate or document the efficacy or medical necessity of the prescribed compounded drugs dispensed to injured employees.

The proposed amendments are necessary to ensure that compounded drugs are prescribed to injured employees only when reasonably required and medically necessary to treat the injured employee's injury. Preauthorization of compounded drug prescriptions assures that the prescription comports with the commissioner's adopted treatment guidelines or the network's treatment guidelines and other treatment standards outlined in the Insurance Code and Texas Administrative Code. Preauthorization may also apply downward pressure on compounded drug system costs because only compounded drugs determined to be medically necessary would be dispensed to injured employees. Of considerable importance, these rule amendments will clarify for stakeholders the division's requirements regarding compounded drug in the closed formulary.

EXPLANATION OF THE PROPOSED AMENDMENTS. Currently, §134.530, *Requirements for Use of the Closed Formulary for Claims Not Subject to Certified Networks*, and §134.540, *Requirements for Use of the Closed Formulary for Claims Subject to Certified Networks*, require preauthorization for "any compound that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates." The division does not currently require preauthorization for compounded drugs that do not contain an "N" drug. The proposed rule amendments will require preauthorization for all compounded drugs prior to being dispensed, including compounded drugs that do not contain an "N" drug.

The most efficient means for requiring preauthorization is to amend the definition of closed formulary contained in §134.500, *Definitions*, to exclude not only compounded drugs that contain N-

status drugs, but all compounded drugs. By making conforming changes to §§134.530 and 134.540, all compounded drugs will require preauthorization prior to dispensing.

Therefore, the division proposes to amend §134.500 to exclude from the closed formulary "any prescription drug created through compounding." The division proposes using the phrase "any prescription drug created through compounding" rather than "compound drug" or "compound" because "compounding" is a defined term. In §134.500, "compounding" is defined as the preparation, mixing, assembling, packaging, or labeling of a drug or device under a number of specified circumstances. By contrast, "compound drug" and "compound" are not defined terms in the Texas Workers Compensation Act or division rules and using them would produce more confusion than clarity within the regulated community. The phrase "compounded drug" as used in this preamble is shorthand for "any prescription drug created through compounding" and is the term used in the REG's most recent study on the topic.

Section 134.530(b)(1) and §134.540(b) require preauthorization for drugs excluded from the closed formulary. Therefore, the effect of amending the definition of the closed formulary to exclude any prescription drug created through compounding is to require preauthorization of these drugs before they are dispensed. This proposed change does not prohibit the use of compounded drugs for injured employees when medically necessary; however, it does require that the medical necessity be determined prior to dispensing these drugs.

Prescriptions for compounded drugs not requiring preauthorization that are written before July 1, 2018, and refills for those prescriptions, will not be impacted by this rule change. However, any prescription drug created through compounding will require preauthorization when both prescribed and dispensed on or after July 1, 2018. The delayed applicability date should allow sufficient time for

the prescribing doctor, injured employee, and insurance carrier to revisit and review an injured employee's need for specific prescription compounded drugs. As compounded drugs transition to the preauthorization process, the likelihood of unreasonable risk of medical emergency resulting from an adverse determination is low. However, an unreasonable risk of medical emergency triggered by an adverse determination of a preauthorization request for a previously prescribed and dispensed compounded drug can be addressed promptly through the process outlined in §134.550, *Medical Interlocutory Order*.

FISCAL NOTE. Mr. Matthew Zurek, Executive Deputy Commissioner for Health Care Management, has determined that for each year of the first five years the proposed amendments will be in effect, there will be no fiscal impact to state or local governments as a result of enforcing or administering the proposal. There will be no measurable effect on local employment or the local economy as a result of the proposed new sections. Local government and state government as a covered regulated entity will be impacted in the same manner as persons required to comply with the proposed amendments, as described below.

PUBLIC BENEFIT AND COSTS. Mr. Zurek has determined that for each year of the first five years the proposed amendments are in effect, there will be a number of public benefits. The public benefits anticipated as a result of the proposed amendments include greater uniformity and cost certainty in the prescribing and dispensing of compounded drugs to injured employees. Additionally, the division anticipates the proposed amendments will facilitate the appropriate use of compounded drugs in the Texas workers' compensation system, resulting in improved quality of care, improved return-to-work outcomes, and fewer disputes.

These proposed amendments will help improve the quality of medical care provided to injured employees throughout the system. When compounded drugs that are not included in the pharmacy closed formulary are prescribed, injured employees can be assured that the medical necessity of the prescribed drug has been reviewed. By adding this medical review check point, the safe use of the compounded drug increases because the injured employee's use of the prescription is subject to an additional level of medical necessity review. Collaboration between the pharmacist, prescribing doctor, and the utilization review agent in such situations assures the best interests of the injured employee. Finally, preauthorization of compounded drugs should serve to encourage full consideration of alternative pharmaceutical options presumed reasonable under the division's and certified networks' treatment guidelines, as well as compliance with these treatment guidelines.

This proposal may affect the following system participants: 1) injured employees; 2) employers; 3) health care providers (including prescribing physicians and compounding pharmacies); 4) insurance carriers; 5) utilization review agents; and 6) independent review organizations (IROs).

Injured employees should benefit from a system that provides consistent preauthorization requirements for compounded drugs. An added benefit for the injured employee is the certainty of medical necessity provided through the preauthorization process. Additionally, the formulary continues to offer the injured employee access to the complete spectrum of reasonable and necessary pharmaceuticals. Physicians will not be prohibited from prescribing compounded drugs when the prescriber demonstrates that compounded drugs are a medically necessary treatment option for an injured employee. Injured employees benefit when they receive timely, appropriate care which facilitates return to work.

Employers also benefit when injured employees receive timely, appropriate care which facilitates return to work, and may realize indirect benefits through decreased premiums as a result of decreased medical benefit and indemnity costs through improved delivery of health care.

Prescribing doctors should benefit from adoption of the proposed amendments and the clarification of preauthorization requirements in the Texas workers' compensation system. This clarity allows prescribing doctors to better coordinate the needs of injured employees, with the dispensing of necessary drugs, and management of the prescribing doctor's role in the preauthorization process. Though there is a potential for new administrative costs related to the preauthorization process, the amount of this cost is dependent upon the specific business practices of the physician's office. Currently, any drug that does not require preauthorization is subject to retrospective utilization review. Thus, potential costs related to the preauthorization process should be offset to the extent that physicians were previously required to provide statements of medical necessity in the retrospective review process. In either instance, prescribing doctors would be providing information and rationale to the utilization review agent in the manner outlined in Chapter 10, Subchapter F and §§134.500, 134.520, 134.530, 134.540 and 134.600 of this title.

Pharmacists should benefit from the proposed amendment. Currently, pharmacists are uncertain as to preauthorization requirements for compounded drugs and the applicability of treatment guideline recommendations. The proposed amendment clarifies that compounded drugs are excluded from the pharmacy closed formulary so that preauthorization is required. This clarification provides administrative certainty as to which drugs require preauthorization, and when. Further, pharmacists will benefit by the avoidance of any future litigation costs relating to compounded drugs and their potential investigational or experimental status.

Clear preauthorization requirements will decrease the potential of reimbursement denials for drugs excluded from the pharmacy closed formulary. Data from the division's medical billing database shows that in 2016, approximately 25 percent of compounded drugs billed were denied by the insurance carrier retrospectively. Pharmacy charges for these denied prescriptions totaled approximately $6,000,000. During 2016, compounded drugs were reimbursed at approximately 83% of billed charges. Therefore, based on the 2016 reimbursement rate, pharmacies' loss of reimbursement for these prescriptions was estimated at $5,000,000. The categorical preauthorization requirement for compounded drugs should eliminate this economic loss because issues regarding the medical necessity of a compounded drug will be addressed before the compounded drug is dispensed. However, pharmacies may incur some administrative costs as a result of the proposed amendments. There is a potential for additional administrative costs related to the preauthorization process for pharmacies when they submit preauthorization requests for compounded drugs that did not previously require preauthorization. The amount of this cost is dependent upon the specific business practices of the pharmacy.

Additionally, health care providers (including prescribing doctors and pharmacists) currently pay in advance for IRO reviews regarding medical necessity disputes involving retrospective denials of health care; however, insurance carriers pay for IRO reviews related to preauthorization. This rule amendment, requiring preauthorization of compounded drugs, should eliminate the need for retrospective medical necessity dispute requests involving compounded drugs and, thus, the health care provider's responsibility for their current costs.

Health care providers, other than pharmacists or prescribing doctors, are unlikely to see any additional costs, and benefits would likely be indirect and realized as overall system improvements.

Insurance carriers should benefit from additional administrative clarity regarding preauthorization requirements for pharmaceuticals. Once a compounded drug requiring preauthorization is approved, no dispute exists regarding the medical necessity of the approved drug. In addition, carriers may realize cost savings if this change to the pharmacy closed formulary alters prescribing patterns so that over-utilized compounded drugs not preferred as a first-line treatment are passed over by prescribing physicians in favor of generally less expensive drugs included in the pharmacy closed formulary. Further, insurance carriers will benefit by the avoidance of any future litigation costs relating to compounded drugs and their potential investigational or experimental status.

Although the long term benefits of this change are difficult to quantify because they focus on cost avoidance and general system process improvements, preauthorization review of the use of compounded drugs should result in a decrease in the use of compounded drugs over time. However, insurance carriers may also experience increased administrative costs associated with implementation of the proposed rule amendment.

According to the REG's May 2017 *Baseline Evaluation of the Utilization and Cost Patterns of Compounded Drugs*, there were 20,751 compounded drug prescriptions in the workers' compensation system in 2016. Of these prescriptions, approximately 10% required preauthorization because they contained a status "N" drug. This means that approximately 18,600 compounded drug prescriptions did not require preauthorization. Under the proposed amendments, all 20,751 compounded drug prescriptions would have to be preauthorized before being dispensed.

Any compounded drug prescription that is included in the pharmacy closed formulary is currently subject to retrospective review. However, if the proposed rule is adopted, these reviews

would be conducted prospectively. If prescription patterns remain unchanged, approximately 20,000 preauthorization requests for compounded drugs may be processed in the first 12 months after the rule becomes effective. A worst case cost scenario for the preauthorization of compounded drugs excluded from the pharmacy closed formulary would be 20,000 preauthorization reviews multiplied by $120 per review (a standard industry estimated average cost for preauthorization reviews is $60 - $120 per review). Thus, the fiscal impact could be as much as $2.4 million but as little as $1.2 million for 20,000 preauthorization reviews. However, changes in prescription patterns by doctors may result in a reduction in the amount of requests to use compounded drugs, which would reduce the financial impact of the proposed rule on the system. There could be additional costs for insurance carriers if pharmacological management for injured employees is not utilized or is unproductive.

Ultimately, the net costs to insurance carriers for preauthorization of these claims will be the difference between the new preauthorization costs less the existing retrospective review costs. These costs are unique to the individual business practices of each insurance carrier as each utilizes unique retrospective review procedures.

In addition, Government Code §2001.0045 requires a state agency to offset any costs associated with a proposed rule by: (1) repealing a rule imposing a total cost that is equal to or greater than that of the proposed rule; or (2) amending a rule to decrease the total cost imposed by an amount that is equal to or greater than the cost of the proposed rule. As described above, the division has determined that the proposed amendments will have a cost to insurance carriers, prescribing doctors, and pharmacies. However, Government Code §2001.0045(c)(6) states that the section does not apply to a rule that "is necessary to protect the health, safety, and welfare of the residents of this state." The division has determined that the proposed amendments are necessary

to ensure compounded drugs prescribed to injured employees are medically necessary and appropriate, which will protect injured employees' health, safety, and welfare. As a result, Government Code §2001.0045 does not apply to the proposed amendments and the division is not required to offset costs.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS.

In accordance with Government Code §2006.002(c), the division has determined that adoption of the proposed amendments may have a direct, adverse economic impact on insurance carriers, prescribing doctors, and pharmacies who qualify as small or micro-businesses, as well as rural communities who may be self-insured insurance carriers. The division's cost analysis and resulting estimated costs in the Public Benefit and Cost Note, above, is equally applicable to small and micro-businesses, and also rural communities. Because the division has determined that the proposed amendments may have an adverse economic impact on small and micro-businesses and rural communities, this proposal contains the required economic impact statement and regulatory flexibility analysis.

Based on a report run on September 22, 2017 on Texas-licensed insurance carrier's December 31, 2016 annual statements to the Texas Department of Insurance, department records show there are 10 insurance carriers writing workers' compensation and excess workers' compensation business in Texas with total national premiums (workers' compensation and other lines of business) of less than $6 million. As of September 20, 2017, Texas Comptroller of Public Accounts data found at https://fmx.cpa.state.tx.us/fmx/legis/ecoeffect/2007_oct/naicscodes.php shows that the State of Texas had 15,530 physician's offices, of which 14,724 qualify as small businesses, and 3,083 health and personal care stores (including pharmacies and drug stores), of

which 2,924 qualify as small businesses. According to the United States Census Bureau, Texas has scores of municipalities with a population of less than 25,000. According to division records, there are no certified self-insured employers that would be considered small or micro businesses.

There will be no difference in the cost of compliance between a large, small, or micro-business as a result of the proposed amendments. To alleviate the adverse economic cost that the proposed amendments may have on small or micro-businesses or rural communities, the division considered: (i) not adopting the proposed amendments; (ii) implementing different requirements or standards for the affected small and micro-businesses and rural communities; and (iii) exempting small and micro-businesses and rural communities from the requirements of the proposed amendments. Under Government Code §2006.002(c-1), an agency is required to consider alternative regulatory methods only if the alternative methods are consistent with the health, safety, and environmental and economic welfare of the state. The division has determined that the proposed amendments substantially contribute to the health, safety, and welfare of the state by ensuring that injured employees are receiving care that is medically necessary and appropriate.

Under Labor Code §408.021(a), an injured employee is entitled "to all health care reasonably required by the nature of the injury as and when needed" and "to health care that cures or relieves the effects naturally resulting from the compensable injury; promotes recovery; or enhances the ability of the employee to return to or retain employment." The purpose of the proposed amendments is to ensure that compounded drugs prescribed to injured employees are medically necessary and efficacious, and any variance in the requirements would defeat that purpose. Therefore, because this rulemaking is necessary to protect the health, safety, and welfare of the residents of this state, the

division has determined that there are no regulatory alternatives to its proposal which will sufficiently protect the health, safety, and environmental and economic welfare of the state.

GOVERNMENT GROWTH IMPACT STATEMENT. Government Code §2001.0221 requires that a state agency prepare a government growth impact statement describing the effects that a proposed rule may have during the first five years that the rule would be in effect. The proposed amendments will not create or eliminate a government program and will not require the creation or elimination of existing employee positions. The proposed amendments will not require an increase or decrease in future legislative appropriations to the division and will not result in an increase or decrease in fees paid to the division.

The proposed amendments do not create a new regulation because the existing closed formulary rules include preauthorization requirements for drugs excluded from the closed formulary. The new amendments build on existing regulation and require that all drugs created through compounding be preauthorized before they are dispensed. Currently, only compounded drugs that contain an N-drug require preauthorization. Therefore, the proposed amendments expand an existing regulation.

The proposed amendments increase the number of individuals subject to the rule's applicability. The division anticipates that the proposed amendments will positively affect the state's economy by ensuring that only medically necessary compounded drugs are prescribed and dispensed to injured employees. This increased certainty that a prescribed compounded drug will serve its intended purpose should result in increased resolution of work-related injuries and, therefore, improved return-to-work outcomes.

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

REQUEST FOR PUBLIC COMMENT. If you would like to submit written comments on this proposal, please submit your comments by 5:00 p.m. CST on February 20, 2018. Send written comments by email to rulecomments@tdi.texas.gov or by mail to Maria Jimenez, Texas Department of Insurance, Division of Workers' Compensation, Office of the General Counsel, MS-4D, 7551 Metro Center Drive, Suite 100, Austin, Texas 78744-1645

The division will conduct a public hearing on this rulemaking on Thursday, February 15, 2018 in the Tippy Foster Room of the Texas Department of Insurance, Division of Workers' Compensation, 7551 Metro Center Drive, Suite 100, Austin, Texas 78744. The public hearing will begin at 10:00 a.m. The division will consider written comments and public testimony presented at the hearing. The division provides reasonable accommodations for persons attending meetings, hearings, or educational events, as required by the Americans with Disabilities Act. If you require accommodations in order to attend the hearing please contact Maria Jimenez at (512) 804-4703 at least two business days prior to the hearing date. The hearing will also be audio streamed; to listen to the audio stream, access the DWC Calendar at www.tdi.texas.gov/wc/events/index.html.

STATUTORY AUTHORITY. Amended §§134.500, 134.530, and 134.540 are proposed under the authority of Labor Code §402.00111, *Relationship Between Commissioner of Insurance and Commissioner of Workers' Compensation; Separation of Authority; Rulemaking*; Labor Code

§402.00116, *Chief Executive*; Labor Code §402.00128, *General Powers and Duties of Commissioner*; Labor Code §402.061, *Adoption of Rules*; Labor Code §408.021, *Entitlement to Medical Benefits*; Labor Code §408.028, *Pharmaceutical Services*; Labor Code §413.011, *Reimbursement Policies and Guidelines; Treatment Guidelines and Protocols*; Labor Code §413.013, *Programs;* Labor Code §413.014, *Preauthorization Requirements; Concurrent Review and Certification of Health Care*; Labor Code §413.053, *Standards of Reporting and Billing*; Insurance Code, Chapter 1305, *Workers' Compensation Health Care Networks*; Insurance Code §4201.054, *Workers' Compensation Benefits*; and Occupations Code §551.003, *Definitions*.

Labor Code §402.00111 states that the commissioner of workers' compensation shall exercise all executive authority, including rulemaking authority, under the Texas Workers' Compensation Act.

Labor Code §402.00116 states that the commissioner of workers' compensation is the division's chief executive and administrative officer and shall administer and enforce the Texas Workers' Compensation Act, other workers' compensation laws of this state, and other laws granting jurisdiction to or applicable to the division or the commissioner of workers' compensation.

Labor Code §402.00128 states that the commissioner of workers' compensation shall conduct the daily operations of the division and otherwise implement division policy and, among other functions, may delegate; assess and enforce penalties; and enter appropriate orders.

Labor Code §402.061 states that the commissioner shall adopt rules as necessary for the implementation and enforcement of the Texas Workers' Compensation Act.

Labor Code §408.021 states that an employee who sustains a compensable injury is entitled to all health care reasonably required by the nature of the injury as and when needed.

Labor Code §408.028 states that the commissioner of workers' compensation by rule shall adopt a closed formulary under §413.011 and that rules adopted by the commissioner of workers' compensation shall allow an appeals process for claims in which a treating doctor determines and documents that a drug not included in the formulary is necessary to treat an injured employee's compensable injury. In addition, this section states that the commissioner of workers' compensation shall by rule require the use of generic pharmaceutical mediations and clinically appropriate over-the-counter alternatives to prescription medications unless otherwise specified by the prescribing doctor, in accordance with applicable state law.

Labor Code §413.011 requires the commissioner of workers' compensation to adopt by rule treatment guidelines and return-to-work guidelines and medical policies designed to ensure the quality of medical care and to achieve effective medical cost control.

Labor Code §413.013 requires the commissioner to establish by rule a program for prospective, concurrent, and retrospective review and resolution of a dispute regarding health care treatments and services, and its monitoring.

Labor Code §413.014 states that the commissioner of workers' compensation by rule shall specify which health care treatments and services require express preauthorization or concurrent review by the insurance carrier. If a specified health care treatment or service is preauthorized as provided by this section, that treatment or services is not subject to retrospective review of the medical necessity of the treatment or service.

Labor Code §413.053 states that the commissioner by rule shall establish standards of reporting and billing governing both form and content.

Insurance Code, Chapter 1305 is the Workers' Compensation Health Care Network Act and contains treatment guidelines and authorization requirements applicable to certified networks.

Insurance Code §4201.054 states that the commissioner of workers' compensation shall regulate as provided by Chapter 4201 a person who performs utilization review of a medical benefit provided under Title 5, Labor Code, and that the commissioner of workers' compensation may adopt rules as necessary to implement section 4201.054.

Occupations Code §551.003 provides the definitions for "compounding" and "substitution."

TEXT.

§134.500 Definitions

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

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

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

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

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

(B) any <u>prescription drug created through compounding prescribed before July 1, 2018</u> [~~compound~~] that contains a drug identified with a status of "N" in the current edition of the

ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates; [~~and~~]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(10) Prescribing doctor--A physician or dentist who prescribes prescription drugs or over the counter medications in accordance with the physician's or dentist's license and state and

federal laws and rules. For purposes of this chapter, prescribing doctor includes an advanced practice nurse or physician assistant to whom a physician has delegated the authority to carry out or sign prescription drug orders, under Occupations Code Chapter 157, who prescribes prescription drugs or over the counter medication under the physician's supervision and in accordance with the health care practitioner's license and state and federal laws and rules.

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

(12) Prescription drug--

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

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

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

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

(A) the injured employee's full name;

(B) date of injury;

(C) social security number;

(D) diagnosis code(s);

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

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

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

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

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

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

(1) Preauthorization is only required for:

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

(B) any prescription drug created through compounding prescribed before July 1, 2018 [~~compound~~] that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates; [~~and~~]

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

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

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

(c) Preauthorization of intrathecal drug delivery systems.

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

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

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

(B) there is a change in prescribing doctor.

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

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

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

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

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

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

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

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

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

(f) Initial pharmaceutical coverage.

(1) Drugs included in the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are not subject to retrospective review of medical necessity.

(2) Drugs excluded from the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization, except as referenced in subsection (b)(1)(C) of this section, and are subject to retrospective review of medical necessity.

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

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

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

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

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

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

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

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

(2) any <u>prescription drug created through compounding prescribed before July 1, 2018</u> [~~compound~~] that contains a drug identified with a status of "N" in the current edition of the ODG Treatment in Workers' Comp (ODG) / Appendix A, ODG Workers' Compensation Drug Formulary, and any updates; [~~and~~]

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

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

(c) Preauthorization of intrathecal drug delivery systems.

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

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

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

(B) there is a change prescribing doctor.

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

reasonableness of health care by the insurance carrier in accordance with subsection (f) of this section.

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

(1) For situations in which the prescribing doctor determines and documents that a drug excluded from the closed formulary is necessary to treat an injured employee's compensable injury and has prescribed the drug, the prescribing doctor, other requestor, or injured employee must request approval of the drug in a specific instance by requesting preauthorization in accordance with the certified network's preauthorization process established pursuant to Chapter 10, Subchapter F of this title (relating to Utilization Review and Retrospective Review) and applicable provisions of Chapter 19 of this title (relating to Agents' Licensing).

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

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

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

(f) Initial pharmaceutical coverage.

(1) Drugs included in the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are not subject to retrospective review of medical necessity.

(2) Drugs excluded from the closed formulary which are prescribed for initial pharmaceutical coverage, in accordance with Labor Code §413.0141, may be dispensed without preauthorization and are subject to retrospective review of medical necessity.

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

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

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

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 at Austin, Texas, on January 8, 2018.

X

Nicholas Canaday III
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Texas Department of Insurance,
Division of Workers' Compensation