

## 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

**1. INTRODUCTION.** The Commissioner of Workers' Compensation (commissioner), Texas Department of Insurance, Division of Workers' Compensation (division) adopts amendments to 28 Texas Administrative Code (TAC) §134.500, *Definitions*; and adopts 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 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.

The amendments are adopted without changes to the proposed text published in the January 19, 2018, issue of the *Texas Register* (43 TexReg 319). In accordance with Government Code §2001.033, the division's reasoned justification for these amended sections is set out in this order, which includes the preamble and the rules. The preamble contains a summary of the factual basis for the rules, a summary of comments received from interested parties, names of the entities that commented and whether they were in support of, or in opposition to, the adoption of the rules, and the

reasons why the division agrees or disagrees with the comments and recommendations.

The public comment period ended on February 20, 2018. The commissioner conducted a public hearing on February 15, 2018.

**2. REASONED JUSTIFICATION.** House Bill 7 (HB 7), enacted by the 79<sup>th</sup> 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 health care 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. As adopted, the closed formulary applies to network and non-network claims, regardless of the injured employee's date of injury.

Implementation of the closed formulary has had a significant effect on the use of pharmaceuticals in the Texas workers' compensation system. The use of opioids and other potentially addictive drugs by injured employees has decreased dramatically. Likewise, the cost for pharmaceuticals has decreased significantly since the initial applicability of the closed formulary. 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 doctors 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 health care 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 adopted 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 will be dispensed to injured employees. Of considerable importance, these rule amendments clarify for stakeholders the division's requirements regarding compounded drugs in the closed formulary.

Until now, §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*, required 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 did not require preauthorization for compounded drugs that did not contain an “N” drug. The adopted rule amendments 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 require preauthorization prior to dispensing.

Therefore, the division adopts amendments to §134.500 to exclude from the closed formulary “any prescription drug created through compounding.” The division uses 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 could 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 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 are transitioned into 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*.

### **3. SUMMARY OF COMMENTS AND AGENCY RESPONSE.**

General: Commenters expressed support for the proposal. Commenters stated that preauthorization of compounded drugs will protect injured employees by ensuring that such medications are medically necessary, reasonably required and appropriate prior to being dispensed. Commenters stated that the adopted amendments are consistent with the Labor Code's requirement that the closed formulary be evidence-based. A commenter stated that the adopted amendments ensure that a prescription for compounded drugs comports with the division's adopted treatment guidelines or network guidelines and other treatment standards outlined in the Insurance Code and Texas Administrative Code. Commenters stated that the cost and use of compounded drugs has increased over the past several years but that these adopted amendments should reduce compounded drug system costs and compounded drug utilization. Commenters stated that the adopted amendments will clarify for stakeholders the division's requirements regarding compounded drugs and reduce litigation costs created under the division's current rule.

Agency Response: The division appreciates the support and agrees that the adopted rules comport with the division's adopted evidence-based treatment guidelines and that injured employees continue to have access to medically-necessary and efficacious compounded drugs after approval through the preauthorization process. The division agrees that compounded drugs costs have increased and preauthorization should lead to some downward pressure to reduce costs. Further, clarity in administrative processes may reduce the instances of disputes and their related costs.



General: Commenters stated that preauthorization of compounded drugs is not required for initial pharmaceutical coverage, in emergency medical care situations, and for inpatient medical care.

Agency Response: The division agrees that preauthorization is not required for initial pharmaceutical coverage as outlined in 28 TAC §134.501, *Initial Pharmaceutical Coverage*, nor is preauthorization required for emergency medical care situations. Compounded drugs filled under these circumstances are, however, subject to retrospective review for medical necessity. The division notes that the closed formulary does not apply to inpatient medical care.

General: Commenters stated that other state and federal workers' compensation jurisdictions require that compounded drugs be preauthorized.

Agency Response: The division recognizes that other state and federal workers' compensation jurisdictions may require that compounded drugs be preauthorized. The division notes that each jurisdiction may have unique rationale for those decisions. The division has determined that preauthorization of compounded drugs assures that Texas' injured employees have access to medically necessary and efficacious compounded drugs.

General: A commenter stated that the adopted amendments ensure that injured employees receive the health care guaranteed by Labor Code §408.021.

Agency Response: The division agrees that injured employees are entitled to medical benefits as outlined in §408.021. While entitlement to health care does extend to, and include, compounded drugs when proven medically necessary, compounded drugs are not recommended as a first-line therapy by the current edition of the ODG,

the division's adopted treatment guidelines, nor is the medical necessity and efficacy of compounded drugs well-established per evidence-based medicine standards.

Therefore, all compounded drugs are available to an injured employee after medical necessity is determined using the preauthorization process.

General: A commenter stated that the division's proposal addresses the difficulty of verifying the "N" drug status for powder-form ingredients by requiring all compounded drugs to be preauthorized.

Agency Response: The division notes that requiring preauthorization for all compounded drugs will provide clarity for system participants.

General: A commenter stated that if preauthorization is denied, the injured employee, treating doctor or pharmacy can request an independent review of the disputed prescription under division rule 133.308.

Agency Response: The division agrees that a requestor has access to the medical dispute resolution process under 28 TAC §133.308, *MDR of Medical Necessity Disputes*. The division clarifies that a requestor may pursue an independent review only after reconsideration of an adverse determination made during the preauthorization process.

General: Several commenters stated that since most compounded medications dispensed in the worker's compensation system are non FDA-approved for patient safety and efficacy, compounded medications are investigational and experimental drugs in most cases.

Agency Response: As stated in Labor Code §408.021, an injured employee is entitled to all health care reasonably required by the nature of the injury as and when

needed. The threshold question in this concept is the medical necessity of the treatment or service as opposed to the classification of experimental or investigational nature of the proposed health care. In the case of these adopted amendments concerning compounded drugs, preauthorization directly addresses the medical necessity issues, rendering experimental or investigational determinations moot.

General: A commenter stated that compound medications are expensive and that injured workers do not benefit from them. The commenter also stated that when a compound medication prescription is retrospectively reviewed, the medication is never found to be reasonable or necessary per the ODG.

Agency Response: The division acknowledges the comment, but clarifies that the adoption of the amended rules will ensure that the medical necessity of compounded drugs received by injured employees will be reviewed prior to dispensing. This prospective review should protect injured employees and ensure their health and safety. Although compounded drugs are not recommended as a first line option in the division's adopted treatment guidelines, the utilization review process will consider and evaluate evidence and rationale submitted with the preauthorization request. Requirements for submission of a preauthorization request are included in §134.600 of this title, regarding Preauthorization, Concurrent Utilization Review, and Voluntary Certification of Health Care. Detailed information related to overcoming the division's adopted treatment guidelines is included in Appendix D of the ODG. Appendix D provides a process to assist doctors in justifying their request to provide services not recommended by the ODG treatment guidelines.

General: A commenter opposes the division's proposal, as published, because it "is in essence a ban on compounded medications for injured workers due to payers' concern for their bottom lines."

Agency Response: The division disagrees. Under the Texas Workers' Compensation Act, 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 health care does extend to, and include, compounded drugs when proven medically necessary, compounded drugs are not recommended as a first-line therapy by the current edition of the ODG, the division's adopted treatment guidelines, nor is the medical necessity and efficacy of compounded drugs well-established per evidence-based medicine standards. Therefore, all compounded drugs are available to an injured employee after medical necessity is determined using the preauthorization process.

Although the division has a responsibility to contain costs in the Texas workers' compensation system, the purpose of these adopted rule amendments is to focus on the medical necessity and efficacy of drugs created through compounding. Costs are a factor, but the purpose of preauthorization in the workers' compensation system is to determine the medical necessity and efficacy of proposed health care treatments and services before they are delivered to injured employees. At the conclusion of a

preauthorization process, approval eliminates medical necessity as a rationale for a reimbursement denial.

General: A commenter recommended that the division create a “limited formulary of compounded medication products” whereby the division would “(i)dentify and make exceptions for compounded prescription therapy that provides an alternative to the abusive and addictive side effects of oral controlled substances.” The commenter also recommended that the division “(d)evelop a list of active pharmaceutical ingredients (APIs) in compounds based on data that reflects improved outcomes and cost-effective alternatives to commercially available products;” “(i)dentify these APIs in a closed formulary; and provide incentives for identified patients with a history or potential for abuse and addiction to seek effective compounded medication treatment.” The commenter stated that these recommendations “(offer) immediate access to effective alternative therapies that reduce drug costs in the system” which “benefit(s) carriers and injured workers.”

Agency Response: The division declines to implement the commenter’s recommendations. The division’s adopted treatment guidelines are a compilation of the evidence basis for services provided within the Texas workers’ compensation system. Currently, the ODG does not recommend the use of compounded drugs as a first line option for injured employees. If there is evidence related to the medical efficacy of a particular or specific compounded drug, that information should be submitted to ODG for evaluation and consideration in the context of treatment guidelines. This process for evaluating evidence is documented on the ODG website at the link titled “Suggest ODG Updates.”

If there are reasons that a drug created through compounding should be considered an appropriate alternative to another drug or treatment protocol for a specific injured employee, that rationale should be documented and submitted with the preauthorization request. ODG's Appendix D – Documenting Exceptions to the Guidelines provides guidance on documenting exceptions to the guidelines.

General: A commenter advised the division to “recognize and account for reducing duplicate opioid therapy or other controlled substances from current practices.”

Agency Response: The division clarifies that at the direction of the Legislature, the division has adopted evidence-based treatment guidelines and a pharmacy closed formulary. Further, the closed formulary rules apply to certified networks and the evidence-based guidelines applicable to the certified network. These actions have led to a significant decrease in the use of opioids and other dangerous drugs in the Texas workers' compensation system. The medical necessity justification of a drug created through compounding as an alternative to the use of another prescription drug, or another treatment, may be made through the preauthorization process.

General: A commenter recommended that the division should “(c)onsider ‘maximum allowable costs’ to appropriate therapy that meets the goals” of ensuring “effective and appropriate use of less risky alternatives” and “(a)ligns with the Texas Legislature’s goal to reduce opioid use and addiction among Texans.”

Agency Response: The division disagrees as this comment is outside the scope of the amended rules, which do not address reimbursement of pharmaceuticals. The changes to the closed formulary are primarily concerned with the medical efficacy and the medical necessity of drugs created through compounding. The division agrees that

appropriate use of health care is important and believes that requiring preauthorization for drugs created through compounding assures the medical necessity of the prescribed compounded drug. The division implemented a closed formulary at the direction of the Legislature and as a result, use of drugs excluded from the closed formulary, including opioids, has declined significantly and has been identified as a model for other states' workers' compensation programs.

General: A commenter stated that "health plans often use prior authorization as a means of delaying, and likely denying care, ultimately interfering with appropriate clinical care." The commenter stated that "(p)hysicians who believe compounding medications are the most appropriate approach, will likely discontinue this course of treatment due to increased administrative challenges." Another commenter stated that "requiring preauthorization for all compounds is not in the best interest of the health and safety of our state's injured workers" because "it will only lead to more administrative costs for insurance carriers, pharmacists and health care providers, while also threatening the health and recovery of the state's injured workers."

Agency Response: The division disagrees that preauthorization interferes with appropriate clinical care. Since compounded drugs are not recommended as a first line therapy option in the division's adopted treatment guidelines, the utilization review process considers and evaluates evidence and clinical rationale submitted with the preauthorization request. Consequently, the adopted rule amendments will ensure that compounded drugs received by injured employees are medically necessary and reviewed prior to dispensing. This process of obtaining preauthorization for compounded drugs is the same as for any drug excluded from the closed formulary or

other treatment or service that requires preauthorization. In short, preauthorization is not about delaying or denying care, nor is it intended to create administrative challenges. Rather, preauthorization is an opportunity to justify recommended health care for an injured employee while assuring their health and safety.

General: A commenter stated that compounded drugs benefit injured employees and “significantly improves pain and return-to-work timeframes.”

Agency Response: Although the division has not been presented with any data that specifically supports this categorical statement, the statute requires that only medically necessary services be provided to injured employees. In general, medically necessary and appropriate health care leads to better treatment outcomes and return-to-work time frames. After medical necessity is determined using the preauthorization process, the preauthorized compounded drug is available to the injured employee.

General: A commenter wrote that “(d)ecisions on patient health should be determined through the triad relationship of patient, physician, and pharmacist.”

Another commenter wrote that a pharmacist is best situated to obtain preauthorization because of his/her “in-depth knowledge of a prescribed compound and the duty to dispense medicine.” The commenter continued that requiring a doctor to obtain preauthorization is outside “a doctor’s scope of practice.”

Agency Response: The division notes that the physician-patient relationship is the cornerstone of medical care. It is the responsibility of the prescribing physician to order compounded drugs and document their medical necessity. A pharmacist is not a physician; a pharmacist dispenses medication at the direction of a physician. The physician’s duty is to the patient; the physician does not abdicate that responsibility to



the pharmacist. However, the cooperation between health care providers and injured employee is important in developing the appropriate course of treatment to facilitate early and appropriate return-to-work. In the Texas workers' compensation system, the treating doctor is responsible for coordinating services necessary for the injured employee's recovery and is best positioned to understand the factors related to the injury and is best positioned to make the case for the medical necessity of a particular treatment or service. Pharmacists, like other ancillary health care providers, are available to assist and advise the treating doctor or prescribing doctor when appropriate.

General: Commenters stated that compounds are needed by injured employees unable to swallow oral medications, or are allergic to other medications, and those with burn injuries. A commenter stated that compounds are also a safe alternative to addictive drugs. Another commenter stated that "the Food and Drug Administration recognizes that compounding drugs can serve important patient needs."

Agency Response: The division agrees and restates that compounded drugs are not being excluded as a treatment option for injured employees. For example, in situations where an injured employee is unable to swallow oral medications or is allergic to other medications, compounded drugs may be appropriate for specific injured employees. This is consistent with the information concerning compounding contained in the ODG. The preauthorization process is the avenue for prescribing doctors to establish the medical necessity and appropriateness of the compounded drug.

General: A commenter opined that compounds used for pain relief improve return-to-work outcomes because they only affect the site of pain and are not systemic and

therefore reduce the overall costs to the workers' compensation system. Another commenter stated that compounds that are made for transdermal pain relief can be delivered directly to the site of the injury without subsequent side effects and can lead to a faster recovery for the patient. Another commenter wrote that "(w)hen a compound is used for pain relief, it only affects the site of the pain and is not systemic."

Agency Response: The division disagrees. The division has received no data or documentation that identifies compounded drugs as a more effective treatment option than other services or treatments to improve return-to-work outcomes, and therefore, does not establish overall cost reduction to the system. Further, the division's medical advisor disagrees and notes that there is no published data that supports the notion that compounded drugs do not have a systemic effect.

General: A commenter wrote that preauthorization for all compounds delays the recovery of injured employees and their return-to-work because of the administrative costs and time involved in obtaining preauthorization which may be revoked later through retrospective review.

Agency Response: The division disagrees that preauthorization of compounded drugs will delay recovery and return-to-work of injured employees. The time frames for the approval of preauthorization of compounded drugs is consistent with the time frames for any prescription or service that requires preauthorization. Generally, this process is required to be completed within three working days. If preauthorization is obtained, medical necessity of the compounded drug is not subject to retrospective review. This activity assures that pharmacy bills are not denied by an insurance carrier for medical necessity purposes after the prescription has been dispensed to the injured

employee. Billing for the claim must meet the requirements of the rules related to billing and reimbursement. However, the claim is subject to the other administrative questions of compensability, extent, and liability.

General: A commenter wrote that rather than requiring preauthorization for all compounds, “Texas (should) set a reasonable cap on compound medications and require preauthorization for any compound that exceeds the cap.” The commenter stated that “(r)equiring preauthorization on the most expensive drugs will help ensure that the costs to the workers’ compensation system are reduced, while not endangering an injured worker’s access to needed medication.”

Agency Response: The division disagrees that requiring preauthorization endangers an injured employee’s access to compounded drugs. Injured employees have access to compounded drugs when medical necessity is determined. Compounded drugs will be treated like any other drug requiring preauthorization. Although the division has a responsibility to control costs in the Texas workers’ compensation system, the primary reason for preauthorization is to assure that medically necessary and efficacious compounded drugs are available to injured employees. Medical necessity remains a constant while the cost of a compounded drug may be impacted by the volume or frequency of use of the compounded drug.

General: The commenter “believes the proposed changes have the potential to harm injured workers” and “will delay or deny access to health care for our state’s injured workers.”

Agency Response: The division disagrees. Preauthorization will assure that only medically necessary compounded drugs are dispensed to injured employees. The time

frames for the approval of preauthorization of compounded drugs is consistent with the time frames for any prescription or service that requires preauthorization. Generally, this process is required to be completed within three working days. Details of these processes and time frames are contained in Texas Department of Insurance and division rules, specifically as outlined in Chapters 10, 19, 134, and 137 of this title (relating to *Workers' Compensation Health Care Networks, Licensing and Regulation of Insurance Professionals, Benefits-Guidelines for Medical Services, Charges and Payments, and Disability Management*, respectively). These time frames are not currently a barrier to the timely provision of health care, including prescriptions.

General: A commenter stated that it “believes that the division’s decision to exclude prescriptions and refills that are written prior to July 1, 2018, will avoid disruptions in injured employees’ medical treatment.”

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

General: A commenter stated that the division has elected to rely on medical interlocutory orders under 28 TAC §134.550 to address the needs of injured employees with allergies or disabilities instead of providing exceptions in the body of the rule. The commenter noted that the process for seeking a medical interlocutory order is not simple since health care providers seeking medical interlocutory orders to obtain compounded drugs for injured employees must request preauthorization, submit a detailed request for a medical interlocutory order and submit a request to a utilization review agent. The commenter stated that none of these submissions are currently required for obtaining a compounded drug that does not contain an “N” status drug.

Agency Response: The division disagrees. The adopted rule requires prescribing doctors to submit a preauthorization request that outlines the medical necessity of a compounded drug. The division restates that compounded drugs are not being excluded as a treatment option for injured employees. For example, in situations where an injured employee is unable to swallow oral medications or is allergic to other medications, compounded drugs may be appropriate for specific injured employees. This is consistent with the information concerning compounding contained in the ODG.

The division clarifies that the preauthorization process is the avenue for prescribing doctors to establish the medical necessity and appropriateness of the compounded drug. Further, the division notes that a request for a medical interlocutory order for a compounded drug is only appropriate after a compounded drug has been previously prescribed and dispensed to an injured employee; an adverse determination has been made for a new prescription of the compounded drug; and the doctor states that there is the potential for an unreasonable risk of medical emergency for the injured employee.

General: A commenter suggested “that the Division develop a robust public education effort to insure that all injured employees, pharmacists and other medical providers are aware of the medical interlocutory order process and all the steps required to obtain an interlocutory order.”

Agency Response: The division agrees that education of system participants is an important part of the rule implementation process. Toward that end, the division engaged in significant efforts to assure the successful implementation of the closed formulary and will continue to incorporate information regarding this and any other rule

changes into its ongoing outreach activities to injured employees, health care providers and insurance carriers.

General: A commenter stated that “(c)ompounded drugs, including transdermal pain creams, contribute to the recovery of injured workers when they experience back pain.” The commenter also stated that “(t)ransdermal compounds also provide an injured worker a safe alternative to some of our country’s addictive drugs.”

Agency Response: The division restates that injured employees continue to have access to medically necessary compounded drugs by pursuing preauthorization under the adopted rule. If a compounded drug is an appropriate medically necessary alternative to an addictive drug, the prescribing doctor should include that information and rationale for the use of the compounded drug in the preauthorization request.

General: Several commenters expressed opposition to the rule and provided information that endorsed use of compounds in their particular case and expressed concern that they would not be able to receive a compounded medication as a result of this rule. Another commenter urged the commissioner to continue making compounded drugs accessible without a requirement of preauthorization.

Agency Response: The division disagrees that injured employees will not be able to receive medically necessary compounded medications as a result of this rule. An injured employee who sustains a compensable injury is entitled by statute to receive “all health care reasonably required by the nature of the injury as and when needed.” More specifically, an injured employee is entitled by statute 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 health care does extend to, and includes, compounded drugs, compounded drugs are generally not recommended as a first-line therapy by the current edition of the division's adopted treatment guidelines, the ODG, and the medical necessity and efficacy of compounded drugs is not well-established per evidence-based medicine standards. Preauthorization of drugs created through compounding will assure that only medically necessary compounded drugs are dispensed to injured employees.

#### **4. NAMES OF THOSE COMMENTING FOR AND AGAINST THE PROPOSAL.**

For: American Airlines Group; CompPharma; Healthesystems; Insurance Council of Texas; Mitchell; myMatrixx; National Association of Mutual Insurance Companies; Optum Workers' Compensation and Auto No-Fault Division; Office of Injured Employee Counsel; Property Casualty Insurers Association of America; State Office of Risk Management.

Against: Alliance of Independent Pharmacists of Texas; Memorial Compounding Pharmacy; Texas AFL-CIO; several individuals on behalf of themselves.

Neither for or against: AIG.

#### **5. STATUTORY AUTHORITY.**

The amendments are adopted 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 medications 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."

## **6. 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 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 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 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 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 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;

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

(4) 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.

## **7. CERTIFICATION.**

This agency certifies that legal counsel has reviewed the adoption and found it to be

a valid exercise of the agency's legal authority.

Issued at Austin, Texas, on \_\_\_\_\_, 2018.

\_\_\_\_\_  
Nicholas Canaday III  
General Counsel  
Texas Department of Insurance,  
Division of Workers' Compensation

The commissioner adopts amendments to §§134.500, 134.530, and 134.540.

\_\_\_\_\_  
W. Ryan Brannan  
Commissioner of Workers' Compensation

COMMISSIONER'S ORDER NO. \_\_\_\_\_

ATTEST:

\_\_\_\_\_  
Nicholas Canaday III  
General Counsel  
Texas Department of Insurance,  
Division of Workers' Compensation