THE SENTINEL

KEEPING WATCH OVER WORK COMP LEGAL TRENDS

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Quarterly Newsletter

TENNESSEE RULE UPDATE: DRUG FORMULARY

On November 30, 3015, the Tennessee Department of Labor and Workforce Development began the process of finalizing rules that adopt the Work Loss Disability Institute's Official Disability Guidelines (ODG) and the Tennessee Department of Health's Chronic Pain Guidelines. The rules also create a closed drug formulary primarily based on the ODG formulary. The formulary rules, scheduled to go into effect on February 28, 2016 (though not all provisions will be applicable on that date), will require providers to receive authorization from the workers' compensation payor before the payor may be required to reimburse for medications dispensed to the injured worker if those medications are excluded by the drug formulary.

Conceptually, the Tennessee formulary rules are similar to formulary rules found in the Texas and Oklahoma workers' compensation systems; however the Tennessee rules build upon Tennessee's existing utilization review (UR) rules and add several new restrictions that do not exist in Texas or Oklahoma.

EXCLUDED CATEGORIES

The Tennessee formulary excludes three types of medications:

1. Drugs identified with a status of "N" in the current edition of the ODG;
2. Any compound or topical medication;
3. Any investigational or experimental drug that has not yet been identified as a "Y" or "N" drug in the ODG and which is not yet accepted as the prevailing standard of care.

This Newsletter includes regulatory updates in Tennessee, Arizona, and North Carolina and an update on medical marijuana payment rules

The workers' compensation cost containment space is constantly evolving. Managing compliance changes across multiple jurisdictions can be a challenging and almost impossible task.

PRIUM has developed a compliance and regulatory consulting group to assist payers and stakeholders in tracking and managing their ongoing compliance efforts.

While both the Texas and Oklahoma workers' compensation formularies exclude ODG "N" drugs and investigational or experimental drugs, and the Oklahoma formulary excludes all compound medications, Tennessee is the first non-monopolistic state (so far) to adopt a workers' compensation formulary that excludes non-compounded topical medications. What's more, the term "topical" is defined in the rules, and the definition is surprisingly broad. The definition *explicitly* includes "inhalers." It also includes any prescription substance that is:

- not injected or ingested, and
- is used on the skin or other membrane or applied to exterior or exposed surfaces.

This suggests that the category of "topicals" would include not only all topical creams, but also patches, and even sublingual and buccal medications. Notably, the formulary rules exclude "any" topical -- not just those topical medications with an ODG "N" drug ingredient.

Prior Authorization and Review

The new rules tie the evaluation of prior authorization requests to Tennessee's existing UR and UR appeal processes. The formulary rules state that certain classes of excluded medications (specifically, ODG "N" drugs and compound or topical medications) should not be approved unless their use in a particular case is supported by documentation of evidence-based medicine.

There are, however, some new requirements pertaining to the UR process as applied under the formulary rules. In evaluating requests for authorization of medications, UR will have to apply the ODG and the Tennessee Department of Health's Chronic Pain Guidelines. As with any other UR determination, UR denials of excluded medications may be subject to the existing UR appeal process, which is conducted by the Medical Director of the Bureau of Workers' Compensation; however the rules also present a new option referred to as an "expedited determination." Unlike typical UR appeals, expedited determinations may only be requested by a provider. (In its response to comments on the proposed rules, the Bureau explicitly declined to permit claimants to request an expedited determination.) An expedited determination may be requested within 15 business days of the prior approval denial or within five business days of a reconsideration denial (if the payer has reconsidered and upheld the initial UR denial).

Application Date

While the Texas and Oklahoma closed formularies adopted a straightforward system for determining whether and when the formulary would apply to a claim (essentially by looking solely at a claim's date of injury), the Tennessee approach is more complicated. Rather than determining when formulary may apply to a *claim*, the adjuster must determine when the formulary will apply to *individual medications* in a claim. In essence, the two groups are as follows:

- If a medication was prescribed for the first time in a claim on or after January 1, 2016, the formulary may be applied to subsequent fills of that medication in that claim six months after the effective date of the rules.

- If a medication was prescribed for the first time in a claim prior to January 1, 2016, the formulary may be applied to subsequent fills of that medication in that claim twelve months after the effective date of the rules.

The current listed effective date for the formulary rules is February 28, 2016, so the anticipated formulary application dates for the above groups are August 28, 2016 and February 28, 2017, respectively.

Medical Marijuana Payment Restriction Update

Medical marijuana laws have been passed in 40 jurisdictions, but only 24 jurisdictions broadly permit its use. The other 16 jurisdictions have legalized some limited forms of medical marijuana for very specific uses, typically cannabis oil for seizure treatment. In the April 2015 edition of the Sentinel, we included an article discussing payment restrictions for medical marijuana for workers' compensation payers. Since that article was published, there have been a few meaningful changes.

The following table reflects those changes, in italics, and categorizes the 24 broad medical marijuana jurisdictions based on payment restrictions contained in their respective medical marijuana laws.

Provisions Containing Workers' Compensation Payment Restrictions

Explicit	Implicit		No Restrictions
Arizona	Alaska	Massachusetts	Maryland
Illinois	California	Minnesota	*New Mexico*
Michigan	Colorado	Nevada	
Montana	Connecticut	New Hampshire	
Vermont	DC	New Jersey	
Washington	Delaware	New York	
	Hawaii	Oregon	
	Maine	Rhode Island	

Arizona and Illinois both adopted language that changed their classification from "Implicit" to "Explicit" and New Mexico has proposed language, which if adopted, will change their classification from "No Restrictions" or "Explicit".

Arizona

House Bill 2346 was signed by the Governor on April 4, 2015, amending ARS § 36-2814(a)(1). The new language is noted below:

> *"Nothing in this chapter requires: A government medical assistance program, a private health insurer or a workers' compensation carrier or self-insured employer providing workers' compensation benefits to reimburse a person for costs associated with the medical use of marijuana."*

Illinois

On January 1, 2016, Senate Bill 1571 went into effect amending § 410 ILCS 130/40(d) to include the following language:

> *"Nothing in this Act may be construed to require a government medical assistance program, employer, property and casualty insurer, or private health insurer to reimburse a person for costs associated with the medical use of cannabis." § 410 ILCS 130/40*

New Mexico

House Bill 195 was introduced on January 21, 2016, which amends Section 52-1-49 NMSA 1978 to include the following language:

> *"B. A workers' compensation carrier or an employer providing workers' compensation benefits is not liable for a claim for reimbursement associated with medical cannabis."*

If this bill is passed, New Mexico will become the 7th jurisdiction with an explicit exception for medical marijuana reimbursement on workers' compensation claims.

Arizona Rule Update: Guidelines & Preauthorization

In late 2015, Arizona finalized new rules that adopt medical treatment guidelines. The new rule *R20-5-1301* adopts the Official Disability Guidelines as the standard reference for use in treating injured workers' in the state. The rules specifically mention that the Guidelines are mandatory in the management of chronic pain and the use of opioids.

In addition to the adoption of medical treatment guidelines, the rules also create a new preauthorization process.

This process is completely voluntary and must be initiated by the Provider. In the event that the Payer receives a request for pre-authorization, they will have 10 business days to act. The Payer may act in one of three ways; reject the request as incomplete if it does not meet the requirements outlined in *R20-5-1303(B),* issue a determination (approval, modification, or denial), or request an independent medical examination.

Each of these actions requires a different type of notification and a different dispute resolution process.

One of the dispute resolution processes, Administrative Review, is a process which acts similar to the Texas IRO and California IMR processes. Under this new process, an injured worker or provider may request an appeal to the Commission if there previous requests were denied or unanswered. The Commission has indicated that they are going to contract with several peer review organizations to perform these Administrative Review level appeals.

These new rules create a variety of scenarios that a Payer may encounter which are unique to Arizona. Since Payers must be reactive to Provider requests for preauthorization and the Rules establish penalties for failure to comply with the response timeframes, establishing a plan of action for when a request for preauthorization is received will be an important task for Arizona claims administrators.

The new rules can be found at: http://apps.azsos.gov/public_services/register/2015/46/04_proposed.pdf

For additional details please contact PRIUM's Regulatory and Consulting Group.

North Carolina Preauthorization Process

On November 1, 2014, the North Carolina Industrial Commission introduced a new rule substantially changing the preauthorization process. Though the rule has now been in effect for more than a year, only a handful of entities seem to be participating, and several of them are neglecting explicit requirements of the rule. What's more, despite efforts by the North Carolina Industrial Commission, many stakeholders seem to be unaware that the rule exists. Some hold to preauthorization requirements that they had implemented prior to the adoption of the rule, unaware that those requirements may now be unenforceable. Others seem unaware that requiring authorization for certain treatments had ever been an option in this state. Fourteen months after the implementation of Rule 1001, it appears that there are still many payers, claims management entities, and utilization review (UR) vendors that are either unaware of the rule's existence or adamant that it will not be enforced.

The Old Process

For the past 20 years prior to the introduction of the rule, insurers had been permitted by statute[1] to require authorization for surgeries and inpatient admissions; however, during that time, there were no rules defining or limiting the preauthorization process, though the statute explicitly empowered the Commission to create rules to that effect.

[1] N.C. Gen. Stat. § 97-25.3

Under the statute, insurers faced minimal restrictions as to when they could require authorization. Additionally, the statute contained only a bare outline of the preauthorization process:

- Insurers could require authorization for "inpatient admission to a hospital, inpatient admission to a treatment center, and inpatient or outpatient surgery."
- Insurers could reduce reimbursement to a provider by up to fifty percent (50%) if the insurer had notified the provider in writing of its preauthorization requirement and the provider had failed to timely obtain preauthorization (though the Commission could later grant authorization if it determined that the treatment was reasonably required to effect a cure or give relief). The employee was not liable for the balance.
- Insurers could require no more than 10 days' advance notice for preauthorization.
- Insurers were required to respond to a request for preauthorization within two business days.
- If an insurer wished to require an examination to review a request for preauthorization, the examination was to be completed and the insurer's determination rendered within seven days of the request.
- The insurer's determination was to be in writing, with a copy provided to the employee, attending physician, and hospital or treatment center (if applicable).
- The insurer was required authorize services where an independent examination or second opinion concurred with the attending physician's recommendation for the requested services.

The details of the preauthorization process – such as how notice of preauthorization requirements was communicated to providers, how requests were to be reviewed, or who was eligible to review them – were left undefined. Insurers benefitted from a "gray area" that allowed them a great deal of discretion in deciding how preauthorization requirements were communicated and how requests were processed.

A Major Change, Relatively Unnoticed

04 NCAC 10A.1001, otherwise known as "Rule 1001," had initially been approved in 2012, with a proposed effective date of January 1, 2013;[2] however, the rule was apparently held in abeyance prior to publication. In 2014, the Commission announced on its website that several rules that had previously been held in abeyance were now scheduled to become effective on November 1, 2014. The rules were listed on a 144-page image PDF on the Commission's website. [3] Rule 1001, a mere three pages (p.92-94), was easily missed. Afterward, Rule 1001 received little discussion amidst the other changes taking place.

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[2] 27 N.C. Reg. 196, 1485
[3] http://www.ic.nc.gov/AllNewRules.pdf

Rule 1001 made substantial changes to North Carolina's preauthorization process and introduced several new requirements for insurers that wished to require authorization:

- Insurers were required to create a preauthorization policy that included a list of all services for which they would require authorization, and that policy was required to be posted on the insurer's website.
- Insurers that require preauthorization were required to file annually (by July 1) profiles for their peer review physicians and a copy of the guidelines used in their preauthorization reviews.
- Peer review physicians were required to be licensed in one of five specific states (essentially, North Carolina or a bordering state).
- Providers were required to use a new form – Form 25PR – to request authorization.
- Insurers were required to respond to all communications related to the request (not just the request itself) within two business days.
- The deadline for issuing a determination on a request was clarified to be seven business days from the request rather than two business days.
- Where circumstances warranted an extension of time to facilitate review, the insurer and requestor could agree to an extension of up to an additional seven business days; if no agreement was reached, an extension could only be granted by the Executive Secretary.
- Failure to respond to a request on time resulted in waiver of the insurer's right to contest the treatment.

The rule required substantial work on the part of the Commission. The Form 25PR had to be created so that providers could comply with the rule. Additionally, the Commission had to accommodate the required annual filings on its FTP site. The Commission's Executive Secretary was tasked with creating a process to accept and review requests for extension.

Through commendable effort by the Commission, the new process was implemented. A provisional Form 25PR was made available and the Commission's FTP site was opened to annual preauthorization filings. The Commission's Executive Secretary created a process for reviewing requests for extension. Additionally, prior to the opening of the FTP site to annual preauthorization filings, the Office of the Executive Secretary served as a valuable resource to entities that sought to comply with the new rule early on. The Commission issued several news bulletins on its website reminding providers and insurers that Rule 1001 was in effect and restating the requirements contained within the rule. But the question remained: would insurers continue to require preauthorization in light of the new requirements?

A Very Delayed Response

Meetings with carriers, self-insured employers, and managed care entities in the state revealed that many of those entities still utilized preauthorization practices that were invalid following Rule 1001. In most cases, the payers were simply not aware of the new rule, but there were a startling number of instances where the payer had been affirmatively advised by a vendor either that the rule had not yet taken effect or that such a rule did not exist. Surprisingly, we also encountered a handful of entities that had no preauthorization process at all in that state.

Following these discussions, we began investigating payers' participation in the Rule 1001 preauthorization process and their compliance with the rule's requirements. At the time of writing this article, only fourteen entities have filed medical practice guidelines.[4] Only eleven have filed peer reviewer profiles.[5] (It should, however, be noted that some of the entities are managed care companies who may represent multiple insurers or self-insured employers.) Of these, several entities filed after the July 1st deadline. Additionally, of those entities that have submitted annual filings, there are several for which we were not able to locate a preauthorization plan on their (or any associated) website.

While the scant participation and evident lack of compliance are disturbing, they show that *at least some* payers are making *at least some* effort to comply with Rule 1001, though it's not yet clear how strictly the Commission will enforce compliance with all aspects of the rule.

These observations have raised several questions that we will keep in mind in the coming months:

- *What will be the recourse for payers who require authorization for treatment without complying with Rule 1001?*
- *Will the Industrial Commission audit payers and preauthorization agents who submit untimely or noncompliant filings?*
- *To what extent will applicants' attorneys leverage a payer's noncompliance with Rule 1001 to overturn a denial of treatment?*
- *What will be the impact on payers that do not require preauthorization?*
  Will providers be required to comply with Rule 1001?

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[4] ftp://149.168.254.96/Rule%201001%20Medical%20Practice%20Guidelines/
[5] ftp://149.168.254.96/Rule%201001%20Peer%20Reviewer%20Profiles/

For more information about any of these topics, or for copies of any referenced documents, rules, publications, or laws, please contact PRIUM's compliance team at: compliance@prium.net or reach out to your account executive.

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