As the United States continues to emerge from years of an economic recession, renewed attention is turning to economic development and job creation in most states. Employers considering relocation or looking to expand carefully consider the cost of doing business in a particular location. Workers’ compensation premiums are one of the costs scrutinized as employers evaluate alternatives. Consequently, states are looking for ways to reduce workers’ compensation premium costs.

One strategy that has proven impactful is controlling medication utilization. This is particularly the case with medications that have shown a propensity to create dependency or addiction, are dispensed at exorbitant costs despite the availability of lower cost alternatives, are unrelated to the workers’ compensation illness or injury, or where the use a medication would be considered an “off-label” usage or formularies, which are approved medication lists often based on clinical review of evidence-based medicine and both nationally and regionally approved medical treatment guidelines.

In addition to controlling workers’ compensation costs, policymakers are interested in formularies to improve safety. Years of intense marketing by drug manufacturers, coupled with the designation of pain as the fifth vital sign in the mid-1990’s, have created a pain-related prescribing culture that is firmly entrenched in American medicine. The result, as declared by the Centers for Disease Control (CDC) is a national epidemic. In 2013, more than 43,900 people in the United States died of drug overdoses. These adverse events have disproportionately impacted workers’ compensation care. This is because the vast majority of workplace illness and injuries involve pain, and subsequently, its treatment.

Recent research indicates that the long-term use of certain medications to treat pain is actually creating additional costs on the claim by inhibiting return-to-work due to negative side effects like addiction, psychological and emotional issues and new physical ailments attributable to long-term use of the prescribed medication. One such study indicated that 50 percent of patients taking opioid analgesics experienced adverse effect, such as constipation, nausea and vomiting, chronic itching, cognitive impairment, respiratory depression, tolerance and physical dependence, aberrant drug-related behavior, dry mouth and urinary retention, as well as others.²

**Formularies and the pharmacy benefit manager**

Workers’ compensation pharmacy benefit managers (PBM) not only make pharmacy benefit management more efficient and effective, they also help to manage costs through medication utilization management. One of the ways to help to monitor appropriate medication utilization is to apply formularies. PBM in the group health arena have used formularies for decades, and in workers’ compensation, for almost as long. Over the years, as evidenced-based medicine evolved, formularies moved from

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a more general application to an injury-specific one. With PBMss now commonplace in the workers’ compensation marketplace, all use unique strategies to manage their formularies in an effort to control escalating costs and to reduce the instances of medication misuse and abuse.

At Optum®, proprietary formularies are at the foundation of our electronic adjudication process. When an injured worker presents a prescription to a pharmacist for dispensing, all retail transactions flowing through our network follow one of three paths:

- The prescription is identified as meeting the program criteria and is ‘approved’ with all program parameters applied.
- The prescription is identified as part of the program; however, something about the transaction prevents adjudication without additional input. Both the pharmacist and claims professional are electronically alerted of the need for review. If approved by the claims professional, all program parameters are applied and the injured worker receives their prescription. If disapproved, the prescription is rejected.
- The prescription is identified as part of the program, however falling outside of the program criteria. As a result, it is rejected.

Program parameters include proprietary formularies as well as multi-faceted drug utilization review (DUR) criteria, and any applicable program-specific or state-specific business rules. This process is the first line of defense against claims leakage and medication misuse and abuse. The purpose of this process is not to prevent an injured worker from receiving medication therapy, but rather to ensure that the injured worker receives the right medication at the right time, in the right dose and for the right duration. Their purpose is to help optimize the therapy regimen and assure the injured worker receives the safest, most efficacious care. Moreover, our experience has found this approach to be highly effective, yielding better clinical and financial outcomes for our clients and the injured workers we serve.

**The Texas closed formulary**

The use of a state-specific closed formulary first occurred in Texas. As a small part of a very large workers’ compensation reform package in 2005, the Texas Legislature directed the newly created Division of Workers’ Compensation (DWC) to develop a “closed formulary” for prescription medications used to treat injured workers. After foundational rules were implemented, such as medical data reporting and treatment guidelines, the DWC adopted their closed formulary rule in 2010. The rule had an effective date of September 1, 2011 for new claims and September 1, 2013 for “legacy claims,” claims with a date of injury prior to September 1, 2011. Since the division had adopted the Official Disability Guidelines’ (ODG) treatment guidelines, it was a logical and natural fit to use the ODG drug formulary, Appendix A, as the basis for the Texas closed formulary. The rule development created an “inclusive” formulary that included all FDA-approved medications. Medications excluded from the formulary are drugs with an “N” status in the ODG Appendix A, experimental and investigational drugs and any non-FDA-approved drugs. Excluded medications can be prescribed, but require approval through a regulator-defined prospective utilization review (UR) process that verifies the demonstration of medical necessity by the prescribing physician. “N” does not mean no, but it does mean that other, first-line medication alternatives exist and should be explored before an “N” drug is prescribed. At this time in Texas, drugs included in the formulary, which are “Y” drugs and all other FDA-approved medications, are dispensed without restriction and can only be subjected to retrospective utilization review.
Following the 2005 reforms in Texas, one of the first changes the newly created DWC implemented was the adoption of billing standards and state reporting of claims data. The newly formed division was anxious to get a broad picture of the paid medical claims activity in the Texas workers’ compensation system and wanted to use that information to guide future reforms (a side benefit in the closed formulary adoption was that Texas had developed a solid baseline from which to measure the formulary’s impact).

**Compelling results**

The first round of data released by Texas in October 2012 indicated a 60 percent reduction in the number of claims receiving “N” drug prescriptions and a corresponding reduction in cost for “N” drugs of 81 percent. Overall, the total number of prescriptions dropped 12 percent. Their next report was released in June of 2013 and illustrated similar results — a 59 percent reduction in claims with “N” drugs and a 80 percent reduction in “N” drug costs. In February 2015, the DWC released a more comprehensive study on the impact of the closed formulary. The cost to the system for non-formulary or “N” drugs had fallen by 83 percent. The total number of prescriptions for “N” drugs was reduced by 76 percent, and 65 percent fewer injured workers were receiving “N” drugs.

These accomplishments are the result of several factors. First, the Division invested a lot of time talking with and listening to stakeholders. Secondly, they instituted a strong data reporting system early on. Finally, the Division identified high prescribers and engaged them in an aggressive outreach program. This effort is one of the reasons for their success and is recognition of a basic but often ignored reality in the opioid debate — one of the best and most effective ways to encourage safe and appropriate utilization of opioid analgesics is through education.
Unintended consequences

Texas took a bold and innovative step when they adopted their closed formulary. As expected with any new idea, some unexpected and unforeseen consequences have created concern with stakeholders throughout the system.

• **The first concern to emerge was an increase in prescriptions not related to the workers’ compensation injury processing in the system.** In situations where an injured worker is receiving prescriptions for a general health condition (e.g., cholesterol or blood pressure medications) along with medications for a work-related injury, frequently the unrelated medications are processing as part of the workers’ compensation claim. These unrelated medications are “Y” drugs, or unaddressed by ODG, so they were not identified until after they were dispensed and reimbursed.

• **The second emerging concern was an increase in prescribed medications not indicated by the treatment guidelines as appropriate for a particular injury, even though the medications were not “N” drugs.** Within the ODG formulary there are “Y” drugs that are recommended for treating a particular injury, but are considered inappropriate for other injuries.

• **The third, latest and one of the more disturbing concerns to emerge is the prescribing of compounded medications containing all “Y” ingredients.** A recent example was a topical cream billed at $6,000 per month. The vast majority of these compounded medications lack medical evidence of their efficacy. Medical necessity is also typically unsubstantiated. However, absent a prospective review process, they are being dispensed and reimbursed before a retrospective review can occur.

Stakeholders throughout the system spend time, energy and money to dispense, bill and review workers’ compensation pharmacy benefits. The aforementioned concerns are seemingly exposing injured workers to unnecessary safety risks while also adding unnecessary financial burden to the system for everyone.

Interest in formularies extends beyond Texas, start to deliver results

Unintended consequences notwithstanding, the use of state-specific state formularies are proving beneficial in other states too.

• The Ohio Bureau of Workers’ Compensation announced their system has experienced a $20 million savings in drug costs since 2011, with $17.8 million of that savings attributed to controlling the dispensing of opioid analgesics. Ohio’s approach is a little different than the Texas closed formulary. Ohio created a narrower list of approved medications. Medications not on the list require prior authorization. Washington, another monopolistic state, took a similar approach.
The difference between state-specific and PBM formularies

As interest in the use of state-specific formularies continues to grow, the question is often asked, “What is the difference between a state-based formulary and a PBM formulary?” The fundamental difference is one of scope. State-specific formularies, like the one in Texas, typically contain a list of restricted medications that apply generally across all injuries in the workers’ compensation system. Other states, such as Washington, have a preferred drugs list (PDL) that outlines the “approved” medications that apply across all injuries in the workers’ compensation system. PBMs such as Optum, on the other hand, commonly employ injury-specific (and in some cases, patient-specific) formularies to help treating physicians, clinicians, pharmacists and payers tailor medication strategies for a particular injury to the unique needs of the injured worker.

While states have the ability to move to a more injury-specific strategy by adopting treatment guidelines, often the resources needed to ensure compliance with the established guidelines are inadequate or unavailable. In contrast, PBMs generally have utilization management systems and clinical expertise in place.

The best of both worlds

Combining state-specific formularies in tandem with PBM formularies creates an optimal medication management environment. A state-based formulary can lend strength to the medication management efforts of the PBM. For example, prior to the closed formulary in Texas, most of the PBM medication plans would have flagged many of the “N” drugs for some type of prospective review or screening. The challenge for adjusters and clinicians on the payer side was second-guessing the physician or saying no to treatment authorized by the physician. The availability of a list of “N” drugs, requiring prospective review and a statement of medical necessity, empowered physicians to say no to patients asking for specific medications, and helped guide prescribers to seek more efficacious alternatives. Incorporating a state-specific formulary can also give adjusters and clinicians tools to facilitate a conversation with the prescriber about medical necessity and the availability of medication alternatives and other therapeutic options. PBMs can support an “N” drug list or state-specific formulary by:

- Making available (and deploying) utilization management tools, clinical resources and domain expertise to screen for unrelated medications while helping to make certain any medications recommended by treatment guidelines are being appropriately prescribed.
- Watching for and managing any potentially harmful drug interactions or therapeutic duplication to improve patient safety.
• Encouraging adherence to treatment plans and guidelines by leveraging direct connectivity with the dispensing pharmacy.

• Providing a checks and balance system to confirm medical necessity of the prescribed medication therapy to promote safe and efficacious care, which can be particularly beneficial where compounded medications and opioid analgesics are involved.

Thus, state-specific and PBM formularies are not mutually exclusive. Rather, when permitted to work together, they can have a significant, positive influence on the cost and utilization of workers’ compensation pharmacy benefits, thus achieving better outcomes for everyone.