LOOKING INTO THE
POLITICAL HORIZON

What to Watch for in the 2016 Regulatory
and Legislative Season
Looking into the Political Horizon

A new political year is rolling in on the heels of a tumultuous and hectic 2015. The workers’ compensation industry is being tugged from opposite ends. On one side are employers who express concern that they are losing control over care costs, and are promoting opt-out options. On the other side are employee groups claiming that an erosion of benefits for injured workers violates the long-standing workers’ compensation compact, and are resorting to lawsuits challenging the adequacy or constitutionality of the current system. These efforts have garnered the attention of a handful of Democrats in Congress who are calling for more oversight of state workers’ compensation systems by the U.S. Department of Labor. The industry itself is caught between two polarizing interests that are stressing the ability to provide the best possible care at reasonable costs, and creating a challenge to crafting a balance that will help allay the concerns of both sides. Amidst this upheaval, politicians and policymakers at the state level are looking for creative ways to maintain a healthy workers’ compensation system, while trying to satisfy various constituent groups. All of this against the backdrop of a potentially caustic election cycle at both the national and state levels. The year 2016 will be interesting for workers’ compensation politics and policy.

On top of this, there are additional issues impacting our industry. Each year our government affairs team provides an outlook of pharmacy and ancillary care issues that we see looming over the political horizon. Here is our summary of what we believe to be the monumental issues in 2016.

Opioid Analgesics

In mid-December, the Centers for Disease Control and Prevention (CDC) issued a press release indicating that in 2014, deaths from all opioids (both legal and illegal) hit record levels, increasing 14% over 2013. Deaths from commonly prescribed opioid analgesics increased by 9%. These alarming statistics have already prompted the CDC to produce and release for public comment, draft opioid prescribing guidelines. The topic of addiction to prescription drugs has also made it into the dialogue of the presidential campaign, as candidates share their personal experiences with family members addicted to prescription drugs. Given this national attention, we anticipate that states will ramp up their efforts to help reduce opioid use within their workers’ compensation systems by looking at a number of tools.

CDC Guidelines for Prescribing Opioids for Chronic Pain

While the development of these guidelines earned some criticism from key members of Congress because of a perceived lack of transparency, the guidelines themselves are a good starting point. They recommend, among other things, using alternatives to opioids, such as NSAIDS, acetaminophen, and physical therapy, as first-line treatment of chronic pain; using drug testing to monitor compliance if opioids are prescribed; and patient questionnaires to assess potential addiction risk. The guidelines also include information from various studies detailing the risks and benefits of opioid use related to treating chronic pain. The CDC is accepting comments, and the guidelines will be further refined based on stakeholder feedback.

Treatment Guidelines/Prescribing Limitations

Increasingly states are looking at treatment guidelines to help ensure that injured workers are being treated using best practices. Treatment guidelines are also being used to steer physicians away from prescribing opioids for chronic pain and other injuries. Additionally, states are imposing time and quantity limits on the prescribing of opioids.

The Tennessee Bureau of Workers’ Compensation published a rule that includes a combination of the Work Loss Data Institute Official Disability Guidelines (ODG) and the Tennessee Department of Health Chronic Pain Guidelines, and also includes limitations on prescribing opioids. The proposed rule will be heard by a legislative committee in January 2016 and is expected to go into effect on February 28.

New Hampshire Governor Hassan commissioned a study of their workers’ compensation costs at the end of 2014, and the commission recommended treatment guidelines and other controls for opioids. We anticipate the New Hampshire legislature will see a proposal this year.

Louisiana has a number of proposals being bantered about, which include adopting specific guidelines for the prescribing and use of opioids. Other states looking at treatment guidelines and prescribing restrictions include Arizona, California, Georgia, Massachusetts, New Jersey, Pennsylvania, New York, Vermont, and Wisconsin. We expect that the CDC proposed guidelines for treating chronic pain will spawn some additional interest at the state level to either adopt guidelines or to harmonize existing guidelines with the federal proposal.
Formularies
As Texas continues to trumpet their success in controlling the use of certain opioid analgesics with their closed drug formulary, other states are exploring this option. Tennessee has published a drug formulary rule patterned after Texas. That rule is expected to win legislative approval sometime in January and will be effective February 28, 2016. California will spend a good part of 2016 talking with stakeholders and establishing a working group to develop a formulary for their workers’ compensation system. North Carolina will be conducting a study on how a Texas-like formulary would impact the cost and care of injured state workers. Georgia has been making informal inquiries and talking to a handful of stakeholders about a formulary in their state. Montana has also discussed the option of a drug formulary, as has Maine and Michigan. The Louisiana Medical Advisory Committee has a draft rule in their possession and several business lobby groups are pushing for either agency or legislative action on moving a formulary concept forward. Groups in New York and New Hampshire have also been talking about the viability of a formulary for their injured workers. As Texas, Oklahoma, and other states enjoy success in controlling opioid analgesics through a drug formulary, we anticipate more states will jump on the formulary bandwagon.

Prescription Drug Monitoring Programs (PDMP)
PDMPs are increasingly being discussed as another tool to be utilized in combating prescription drug abuse. Used properly, and broadly, PDMPs can shed light on drug seeking behavior, diversion, and over-prescribing. However, most states currently make the use of a PDMP voluntary, and there is generally a significant time lag between the time of prescribing or dispensing and the time the transaction actually gets entered into the database, if at all. The technology used is also a stand-alone platform that is not integrated into the practice management or e-prescribing software, creating an extra step in already hectic doctor’s offices and pharmacies.

A task force in Maryland has recommended to their legislature that use of the PDMP become mandatory. Physician groups are already lining up against this proposal citing challenges with the technology and the fact that only physicians are allowed access to the database. Missouri, the only state that currently does not have a PDMP, will likely consider once again legislation to authorize its creation. New York recently announced that it will be joining the National Association of Boards of Pharmacy PMP InterConnect hub. The hub allows states to share PDMP data across state lines to help prevent cross border drug seeking behavior or trafficking. As technology enhancements and connectivity issues are resolved, watch for more states to push for mandatory PDMP reporting.

Cost Controls
With the inflation in average wholesale price of certain brand and generic medications, the high cost of some specialty medications, and the escalating costs of compounded medications, states could be motivated to make some changes to address emerging cost drivers.

Fee Schedules
Fee schedules are under discussion in a couple of states. Virginia has had a taskforce meeting for several months and it appears that there is a draft proposal that will be submitted to the legislature for consideration. While a fee schedule for pharmacy and ancillary care was on the table during the discussions, the current proposal does not contain any language impacting pharmacy or ancillary care. Though, as the bill moves through the process, a fee schedule for prescription drugs could be revived.

The Louisiana Office of Workers’ Compensation Administration has submitted a fee schedule proposal to their Medical Advisory Committee. The idea of a fee schedule in Louisiana has been a political football for several years. With a new governor and likely a new workers’ compensation administrator coming on board, the proposal could stall in the committee while the transition dust settles. However, with a reasonable proposal in writing, the business community may take that to the legislature for a statutory resolution. For some states it has been a long time since they revisited their fee schedules and as costs rise, they may look to do so.

Compounded Medications
Since the beginning of modern pharmacy care, compounded medications have played a narrow, but vital role in treating individuals with unique physiological needs based on specific criteria of medical necessity. There is a growing trend, however, in workers’ compensation where injured workers are receiving very high cost compounded medications as first-line treatments and without any indication of a specific medical need or condition that would justify the use of a compounded medication. Most of these compounded medications are pre-packaged topical creams that are billed at several thousand dollars for a monthly supply.

Several states have taken action to combat the use of these high-cost compounded medications by requiring some type of pre-authorization before prescribing. Most workers’ compensation treatment guidelines also indicate that compounded medications are not recommend. States with a drug formulary typically do not include compounded medications on their recommended lists. Tennessee will address compounded medications by placing them on the “not recommended” list of their formulary.
California, North Carolina, and Louisiana are expected to follow suit as they adopt formularies. Texas is currently collecting data on the utilization and cost of compounded medications in their system. The Texas legislature is poised to hold a committee hearing on the issue as well. We anticipate that this critical analysis in Texas will provide a genesis for change in how compounded medications are treated in their drug formulary and how they are reimbursed.

**Physician Dispensing**

Over the last several years, a significant number of states have taken action to address physician dispensing by benchmarking reimbursement based on the average wholesale price (AWP) of the original product used in the repackaging. This had an initial cost-saving impact, but over time, the savings have eroded. Some repackers have gone directly to manufacturers and worked with them to create special strengths of medication for their distribution network. These newly-formulated strengths are assigned an AWP that is three to four times higher than the traditional strengths of the same medication distributed through retail pharmacies, allowing the repackers to circumvent the cost controls by inflating the price at the manufacturer level. In an effort to close this loophole, several groups are pushing for time limits or prohibitions on physician dispensing or using an average rate per gram of active ingredient to establish the average wholesale price of a medication. We are not aware of any specific or filed legislative efforts at this writing, but do expect that sometime in the next few months a legislative or regulatory effort to close this loophole will emerge.

**Network/Managed Care**

When it comes to managing the pharmacy costs of a claim, it is increasingly evident that managing utilization—making sure the injured worker receives the right medication at the right time in the right dose and for the right duration for his or her injury—is the best way to manage claim costs over the long term. Appropriate pharmacy care can aid in healing, speed the recovery and return-to-work process, as well as reduce pharmacy, other medical, and indemnity costs.

California recently strengthened its pharmacy network rules, and the Governor’s Commission in New Hampshire recommended using pharmacy benefit managers as one tool to help better manage costs. The New Hampshire proposal was discussed in 2015 and is anticipated to be on the table again in this year’s legislative session. New York has a very strong pharmacy network rule, but that rule has been under attack over the last several years through legislative efforts to promote pharmacy choice by the injured employee. So far the bill has not moved, but we do expect to see it again this legislative session.

Additionally, a number of states have passed legislation that allows pharmacies to challenge reimbursement for generic drugs based on a network’s maximum allowable cost (MAC) formula. MAC pricing calculates an average cost for a generic medication based on pricing from multiple wholesalers. Pharmacies are looking for a mechanism to challenge a MAC price if they purchased from a wholesaler who is above the MAC average. Most of the time workers’ compensation is exempt from these laws since pricing is regulated by a workers’ compensation fee schedule for prescription drugs. When workers’ compensation is not exempted, it creates a scenario where the MAC pricing law and the workers’ compensation fee schedule could conflict. Sources tell us that Utah is looking to modify its MAC pricing law to make it easier for pharmacies to contest reimbursement levels. Utah currently does not include workers’ compensation in the MAC pricing law, but we will be monitoring any potential legislation to ensure workers’ compensation remains excluded. There will be other states attempting to advance MAC pricing legislation. In every case, we will work to include an exemption for workers’ compensation to avoid potential statutory conflicts and unnecessary administrative costs.

**Medical Marijuana**

Proponents of medical marijuana continue their push in a number of states to legalize the use of marijuana for medical purposes. In Florida, groups are looking to the 2016 election for a vote on a revised proposal that is designed to close loopholes that prevented the 2014 measure from reaching the 60% support threshold. Last November, Ohio’s effort to legalize marijuana for both recreational and medical use fell short primarily over concerns that too few people would control the marijuana market and financially benefit under the proposed law. Supporters expect to see a revised proposal emerge to address those concerns.

Nevada will have an initiative to legalize marijuana for medical and recreational use. Two groups in Michigan are vying to place marijuana legalization on the ballot for 2016. Both proposals would legalize marijuana for recreational and medical use, but differ on their approaches to regulate the production and distribution of the drug. Utah approved the use of cannabis oil for treating seizures two years ago, and this year will consider a measure broadening the use of medical marijuana in other forms for a wider range of illnesses. Arkansas, South Dakota, Missouri, and Kentucky all have groups working on ballot measures to legalize the use of marijuana. Maine, Massachusetts, Rhode Island, and Vermont will consider legislation to legalize marijuana for recreational use. California will begin work on developing regulations around a trio of bills passed in late 2015 that are designed to create more structure and control over the growing, grading, and distribution of
medical marijuana, even as the state is poised to consider a 2016 ballot initiative to legalize marijuana for recreational use.

At the federal level, the CARERS Act was introduced in the U.S. Senate last February and is currently in the hands of a congressional committee. The bill is designed to relax federal restrictions on allowing individuals to cross state lines to access medical marijuana and would also ease controls for researchers looking to engage in studies on the medical uses of the drug. While the bill, at this point, has little chance of passage, it may have had some impact on the recent changes announced by the Drug Enforcement Agency (DEA). In late December the DEA relaxed regulations related to research on cannabidiol, an extract of the marijuana plant. The new rules would allow for easier access to greater quantities of cannabidiol for research purposes.

Marijuana remains a Schedule I drug and the Department of Justice continues to prosecute marijuana growers, distributors, and funders. This creates concern for the workers’ compensation industry, especially in light of the recent appellate court decisions in New Mexico requiring employers and insurers to reimburse injured workers who qualify for the use of medical marijuana. Adding to the concern is a recent decision by the Minnesota health commissioner to include intractable pain as a condition treatable by medical marijuana. At least one injured worker in Minnesota has already filed a claim under this new ruling. Until action is taken at the federal level to reschedule marijuana, insurers and employers will remain in a cloud of uncertainty about their risk of prosecution under federal law if they are paying for what is still considered an illegal drug under federal law. The Schedule I status has also hindered research into the long-term medical benefits or side effects of the use of marijuana. Most of what we know is anecdotal. Substantive and comprehensive clinical studies and their definitive conclusions are years away.

**Other Initiatives**

A couple of years ago, New York embarked on a massive data portal project in an effort to convert literally millions of paper-filed forms into a digital format for easier and faster handling. The initial phases of that project were completed in 2015 and the Workers’ Compensation Board (WCB) is now looking to add medical claim and billing data to the portal to aid the WCB in tracking medical cost trends, and in enforcing billing and payment rules. This phase is in its early stages and the WCB is encouraging stakeholder involvement throughout the design and development process.

E-Billing continues to grow in popularity as states look to capture data about their workers’ compensation medical costs. Minnesota will be looking to enforce their existing e-billing laws more aggressively over the coming year, while Texas is evaluating their existing e-billing laws and levels of compliance to determine if any changes are needed in their system. As part of its overhaul, Virginia will be adding an e-billing requirement and we expect Tennessee to make progress on its legislative mandate to incorporate e-billing into their workers’ compensation system.

**Federal Medicare Set Asides**

As the dust settles from passage and implementation of the SMART Act and related regulatory requirements, congressional efforts on the Medicare Secondary Payer Act (MSP) should begin to taper off in 2016. Most of the action related to the MSP and its impact specifically on workers’ compensation settlements—workers’ compensation Medicare Set Asides (WCMSA)—will come from either a reigniting of existing rule-making efforts or engagement in new rule-making efforts by the Centers for Medicare and Medicaid Services (CMS).

Towards the end of 2015 CMS began to focus on several areas related to conditional payments, specifically towards recovering any payment amount made by CMS which is either the responsibility of the insurer or the injured party. We expect CMS to continue to extend the reach of the contractor charged with handling these processes, the Commercial Repayment Center (CRC), in 2016 and push further to collect recoverable dollars on liability, self-insured, no-fault, and, most importantly, workers’ compensation claims. Additionally, though at one time it seemed implausible, we anticipate that state Medicaid plans may consider similar actions and jump on the conditional recovery train, looking to recover state Medicaid dollars spent in connection with a workers’ compensation claim.

Coalition efforts are expected to continue on stalled rule-making on issues such as drug pricing, long-term drug utilization, application of state workers’ compensation guides and mandates, as well as lack of an appeals process and application to the WCMSA process. While there have been improvements, such as drug pricing being available on the CMS Portal, system stakeholders continue to struggle with a lack of a codified appeals process and look to make this a top priority in 2016. Recent changes in the CMS internal structure and staff will require further educational discussions and may stall rule-making efforts till mid or late 2016 on WCMSA issues.

On the legislative front, watch for continued development of concepts, such as the $25,000 safe harbor, creation of a “qualified MSA,” and implementation of a codified appeals process for WCMSAs, embodied in House Resolution 2649 and Senate Bill 1514. We are engaged with bill sponsors,
as well as House Ways and Means Committee and Senate Finance Committee staff to help ensure any final legislative product is fair and balanced, addresses the needs of system stakeholders, and benefits the system.

Our Government Affairs Team Remains Engaged

As 2016 shapes up to be another busy and exciting year for workers’ compensation policy, you can rest assured that our government affairs team will be actively working with state legislators and regulators to craft solutions that will bring results. Where possible we strive to join forces with the government affairs teams of our clients and industry trade groups to give greater weight to our collective voices. In every case we endeavor to keep our partners informed of any changes that might impact their business models or operations.

At the federal level, our team will continue to work with Senator Portman (R-OH), as well as Representatives Murphy (R-PA) and Ross (R-FL) on Medicare Set Asides and other critical issues during the coming congressional session.

Our goal is to work with our customers, partners, and allies to promote positive policy changes at the state and federal level that will help provide quality and effective pharmacy and ancillary care for injured workers, and to ease the administrative burdens to the workers’ compensation systems, while providing our care and services at the best possible value.

For questions or further details regarding this information, or to provide any tips or insights on coming legislative or regulatory initiatives in the states you serve, please contact Brian Allen, Vice President of Government Affairs at 801.230.8379 or Brian.Allen@HeliosComp.com.