

REGULATORY AND LEGISLATIVE UPDATES

2015 SESSION REVIEW



CONTENTS

5	Introduction
7	Drug Formularies
11	Opioid Analgesics
15	Compounded Medications
19	Medical Marijuana
23	Prescription Drug Monitoring Programs
27	Physician Dispensing
31	Continued Collaboration



2015 REGULATORY AND LEGISLATIVE UPDATES

As the last vestiges of summer fade and renewed rivalries are played out on gridirons across the country, it's time to look back over the political struggles in state houses and regulatory offices this past legislative season. Most state legislatures have adjourned sine die for the year, but a handful of legislative bodies still have some unfinished business and session time ahead.

Pennsylvania has a newly elected Democratic governor tangling with a Republican legislature over fiscal issues. The budget passed by the legislature, but was vetoed by Governor Wolf earlier in the year, and they are now nearly three months late finalizing a budget for the current year. A stop gap budget passed by the legislature in late September was also vetoed. Insiders note that, as of this writing, they are not even close to hammering out a deal. If no agreement can be reached, watch for an end run by Republicans who will peel off some conservative Democrats to get to a veto-proof majority on the budget vote. New Jersey continues to meet, but no workers' compensation or other major issues are on the horizon. The Michigan legislature is also rumbling along and has several medical marijuana-related bills in the possession of various committees, though at this point it doesn't look like any of them will move this year.

Overall, 2015 has been a very active year on both the legislative and regulatory fronts with many workers' compensation proposals debated. Moreover, the deliberations were once again replete with competing ideas, raw emotion, and political intrigue. The following provides an update on the workers' compensation regulatory and legislative changes that occurred this year.

DRUG FORMULARIES

2015 Regulatory and Legislative Updates

The broadly acclaimed and stellar results of the drug formularies in Texas, Washington, and Ohio have spawned formulary initiatives in state houses and administrative offices across the country. With many states still significantly challenged by high rates of prescription medication misuse, abuse, and deaths, news of a potentially successful solution is enthusiastically received and explored. Our government affairs team engaged with policy makers and stakeholders in California, Louisiana, Arkansas, Tennessee, and North Carolina.

Other states indicating interest in a drug formulary are Georgia, South Carolina, Maine, Michigan, and Montana. We have had contact with policy makers in each of these states and continue to share our expertise, working with stakeholders to help build consensus around policies that not only leverage Pharmacy Benefit Manager (PBM) tools and expertise, such as clinical utilization controls on approved medications, including compounded medications, but also ensure injured workers receive safe and effective medication therapy.

2015 REGULATORY AND LEGISLATIVE UPDATES

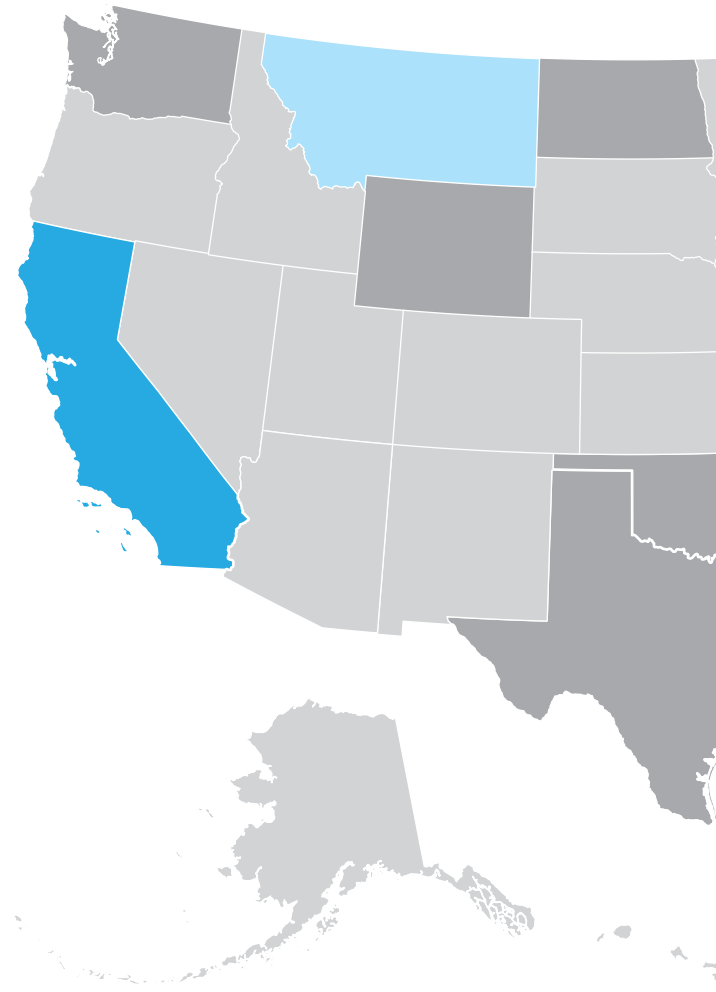
- States with existing legislation/regulations
- States with legislative/regulatory activity in 2015
- States contemplating legislative/regulatory action

CALIFORNIA

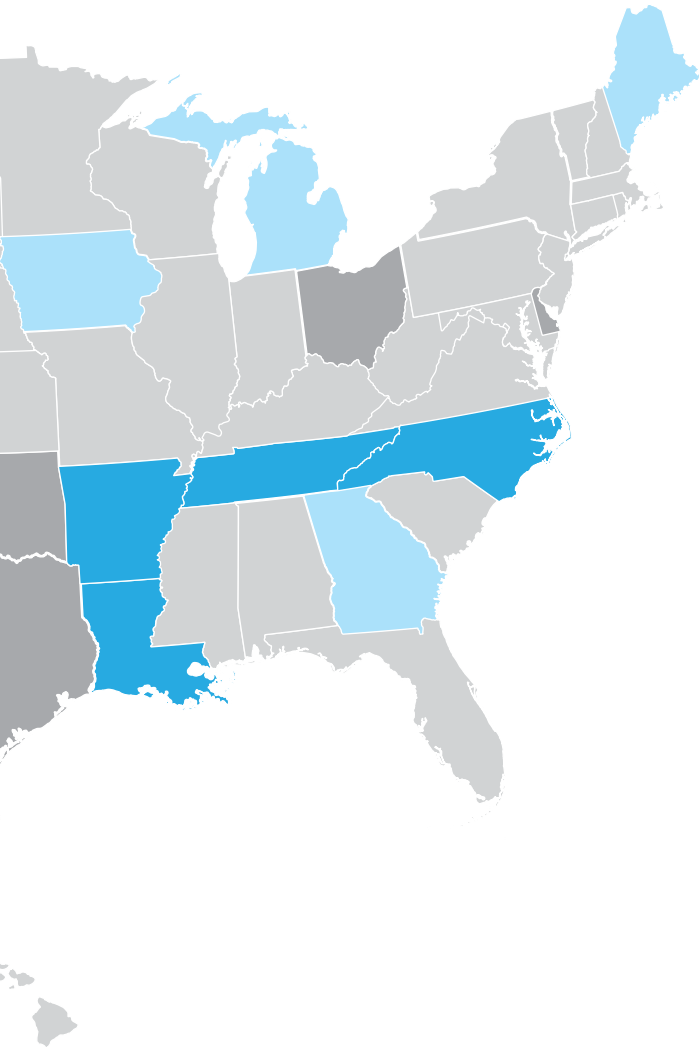
The California legislature spent a good part of the year deliberating on AB1124, sponsored by Assembly Member Henry Perea. The bill passed out of the Assembly early in the year, but then stalled in a Senate Committee. Assembly Member Perea cobbled together a small working group to hammer out a consensus bill over the summer break. We were invited to participate in that working group and help build that consensus. While the group was working over the break, the California Labor Secretary announced at a workers' compensation conference that the Division of Workers' Compensation (DWC) already has the rulemaking authority to create a drug formulary and would immediately begin working on a solution no matter what happened with AB1124 in the legislature. The first public forum was hosted by the DWC on September 8, and we were there to offer comment about our experience with drug formularies in other states. AB1124 passed the legislature in the early morning hours of September 12 and included some critical provisions to help guide the DWC's effort and to ensure that once the formulary is adopted it can be updated in a timely manner. The DWC is currently seeking input from interested stakeholders as they begin shaping their formulary policy.

LOUISIANA

The Louisiana legislature attempted to pass a bill to create a drug formulary, but it ran into stiff opposition from some medical provider and applicant attorney groups. Not to be deterred, the newly appointed director of the Office of Workers' Compensation, Patrick Robinson, decided to implement a formulary by rule. An informal draft was released in late July and the rule was discussed at the Advisory Group meeting in August. Our government affairs team provided input and participated in the hearing. The hearing was reflective of the same interests that clashed during the legislative process. As proposed, the formulary in Louisiana would be based on the Texas model using the Official Disability Guidelines (ODG) as a basis, but allowing their medical advisory committee to make adjustments to the ODG Appendix A to better meet the needs of the injured worker population in Louisiana. A revised draft of the rule is anticipated in October.



DRUG FORMULARIES



ARKANSAS

Arkansas completed work on a rule formulary in late 2014. The formulary closely followed the Texas model except that compounded medications would be subject to a pre-authorization process and drugs included in the formulary could still be screened to make certain they were related to and appropriate for the injury being treated. Following the election of a new governor last November, any administrative rule that was in process was stalled while the incoming staff reviewed all of the pending rules. The formulary rule appears to be mired in this review process and there is no word on when it might be released, if at all.

NORTH CAROLINA

The North Carolina legislature inserted language into HB97, a budget bill, directing the North Carolina Industrial Commission to study the potential impacts of a drug formulary for injured state employees. It is interesting to note that officials from the North Carolina Industrial Commission recently attended the Texas Division of Workers' Compensation (DWC) Conference, perhaps indicating that they are looking at the Texas model.

TENNESSEE

Tennessee released a draft formulary rule this summer and held a public hearing in late August. The original draft did not have a provision for retrospective review of medications and this created considerable concern for employers and payers alike. The rule proposed uses the ODG Appendix A as the basis for the formulary and would require pre-authorization for compounded medications. The rule also allowed for the pre-screening of "Y" drug medications to make certain they were appropriate for and related to the injury. Our government affairs team has met with Administrator Hudgens and with Dr. Snyder, the Tennessee medical director, and we participated in the public hearing. The Bureau of Workers' Compensation noted that it had received extensive comments on the draft rule and they are currently working to address concerns that were raised by the various stakeholders. It is anticipated that a re-drafted rule incorporating the constructive suggestions will be sent to the Attorney General's office for review before heading to the legislative review committee later this fall.

OPIOID ANALGESICS

2015 Regulatory and Legislative Updates

In spite of recent efforts to control opioid analgesics, such as the rescheduling of hydrocodone combination products (HCPs), the prescribing of opioid analgesics remains at epidemic levels. In September, the Centers for Disease Control (CDC) announced a new program, Prescription Drug Overdose: Prevention for States. The program will provide grants to states to help combat prescription drug overdoses. So far 16 states have been selected to receive grants. There are some early signs that prescribing levels may be tapering off slightly for injured workers. Our 2015 Workers' Compensation Drug Trends Report indicated a reduction in the prescribing of opioid analgesics by just over 9% across our book of business. This is encouraging news and demonstrates that strong clinical and educational programs can have a positive impact on reducing the utilization of opioid analgesics. To that end, a number of states have proposed treatment guidelines or other controls on opioid analgesic medications.

2015 REGULATORY AND LEGISLATIVE UPDATES

- States with existing legislation/regulations
- States with legislative/regulatory activity in 2015
- States contemplating legislative/regulatory action

CALIFORNIA

California is currently modifying their non-acute chronic pain guidelines. The public comment period closed on September 14 and the Division of Workers' Compensation (DWC) is in the process of evaluating the feedback and making changes on the proposed rules based on the same. The goals of the new guidelines are to provide physicians with information on proven alternatives to opioid analgesics for managing pain, as well as suggesting tools to help the physician better monitor their use. The DWC will likely also consider how these guidelines will work in conjunction with a drug formulary.

LOUISIANA

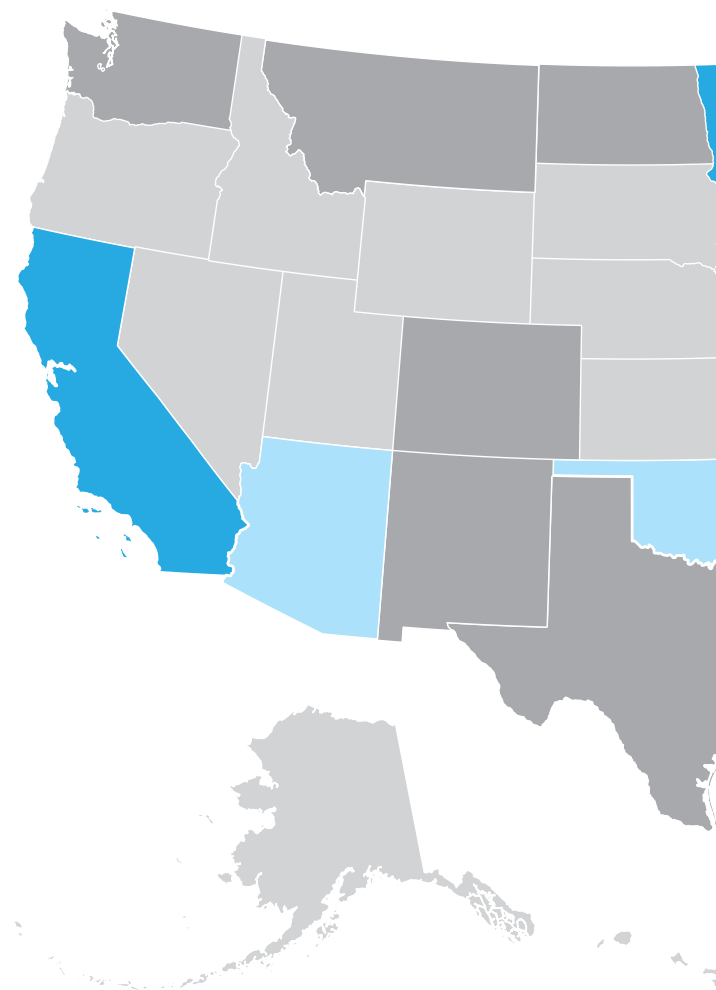
Louisiana is moving forward with the adoption of their pain treatment guidelines, even though there is a pending legal challenge to the Workers' Compensation Administration's authority to regulate or determine appropriate medical treatment. The proposed guidelines are based on those used by Colorado and contain significant changes to the current protocols used in the Louisiana workers' compensation system. These guidelines will also play an important role as Louisiana develops their drug formulary.

MINNESOTA

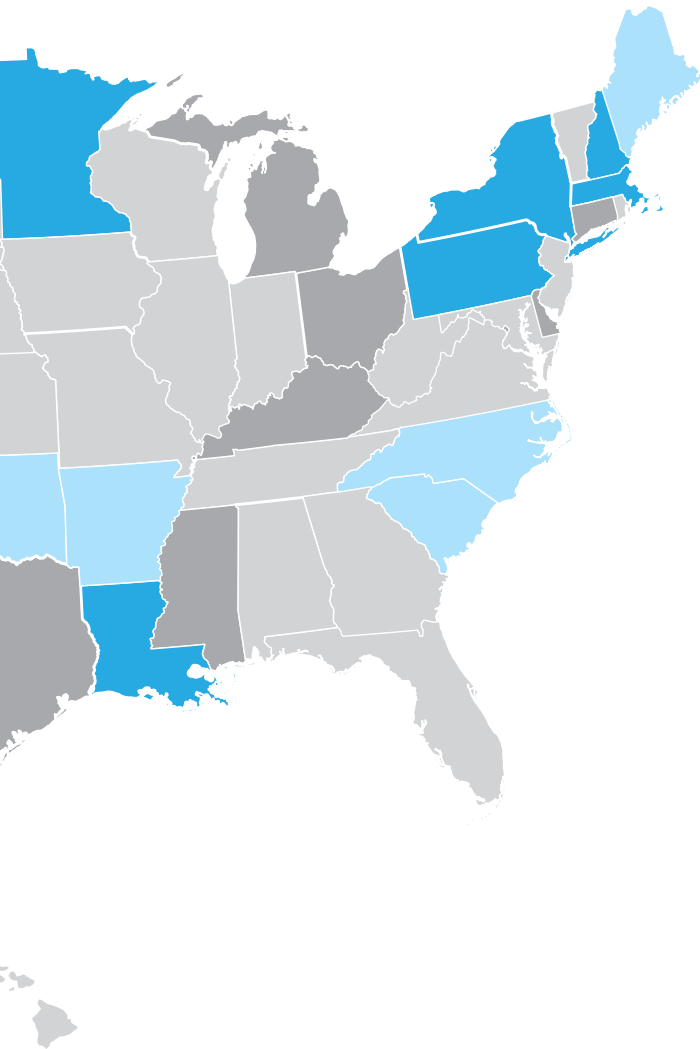
Minnesota made some minor changes to their opioid guidelines; most notably, they added a requirement that a patient receiving an opioid analgesic must disclose the use of any medical cannabis. The rule also strengthened their drug testing requirements.

PENNSYLVANIA

A recent Commonwealth court ruling in Pennsylvania may jeopardize their current treatment guidelines including those related to opioid analgesics. The court ruled that the updates to the American Medical Association (AMA) guidelines that were automatically adopted without intentional legislative involvement placed "unchecked discretion completely in the hands of a private entity." The court ruled that the treatment guidelines were unconstitutional. That ruling is being appealed.



OPIOID ANALGESICS



MASSACHUSETTS

The Massachusetts legislature is considering S.1032, sponsored by Senator Robert Hedlund. The legislation would prohibit all pharmacies from dispensing medications containing opioids. On its face the proposal seems quite dramatic, but it certainly highlights the concern and frustration that many lawmakers have regarding controlling the misuse and abuse of opioid analgesics in their states. The bill is currently in committee awaiting a hearing.

NEW HAMPSHIRE

New Hampshire attempted several bills to provide opioid education and controls, but ultimately settled on a bill, HB271, to allow for an unlicensed individual to administer an opioid antagonist in the event of an apparent overdose. Otherwise, much of the workers' compensation focus during the session was on the adoption of a medical fee schedule, so opioid analgesics didn't receive the attention warranted to earn passage of any other legislation. This result is disappointing since New Hampshire has acknowledged an opioid problem in their state workers' compensation system. Moreover, the governor's reform commission, of which we were a part, strongly recommended education and controls to help contain rising medical and indemnity costs associated with the use of opioid analgesics.

NEW YORK

New York launched some major changes to their pain treatment guidelines, adding strong requirements for screening patients for potential addiction issues and conducting regular drug testing. Under the new rule, an employer or insurance carrier is not allowed to see the test results. What to do with test results indicating problematic behavior is, therefore, left to the discretion of the prescribing physician. Our government affairs team is working with the Workers' Compensation Board staff and other stakeholders to create a rule environment that would allow the prescribing physician to collaborate with clinical pharmacists and other professionals to determine the most clinically appropriate treatment plan when an injured worker demonstrates potentially unsafe, abusive, or addictive behavior patterns.

COMPOUNDED MEDICATIONS

2015 Regulatory and Legislative Updates

High cost compounded medications continue to plague the workers' compensation marketplace. Historically compounded medications have been used as an alternative form of therapy when traditional oral medications did not work or could not be tolerated by the patient. Today, the industry is seeing compounded medications that generally come in the form of a topical cream and are frequently prescribed as a first-line treatment, often without documented medical necessity or medical evidence supporting the medication's efficacy for the condition. With the financial impact of compounds growing at a rate of nearly 40% over last year, regulators and policy makers are taking notice. Several states are taking action.

California, Tennessee, and Louisiana are considering drug formulary designs that would require some form of pre-authorization for compounded medications. The pre-authorization requirement would create an appropriate gate-keeping tool that allows for compounded medications to be utilized when there is a demonstrated medical need and would also help weed out the unnecessary use of high-cost compounded medications when there is no medical justification for their use.

2015 REGULATORY AND LEGISLATIVE UPDATES

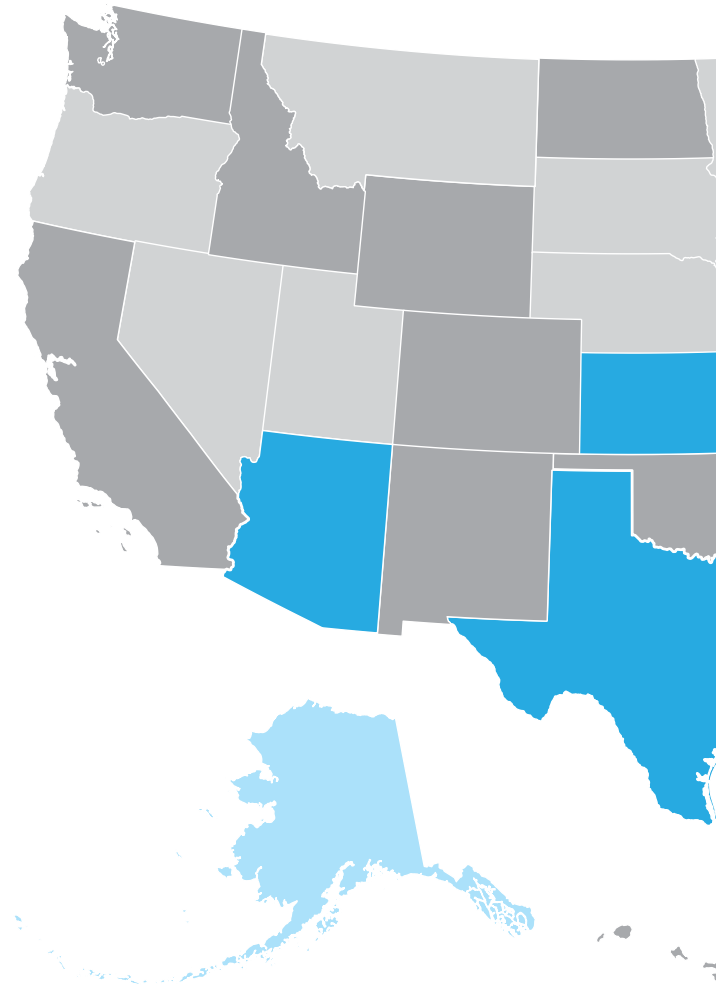
- States with existing legislation/regulations
- States with legislative/regulatory activity in 2015
- States contemplating legislative/regulatory action

ARIZONA

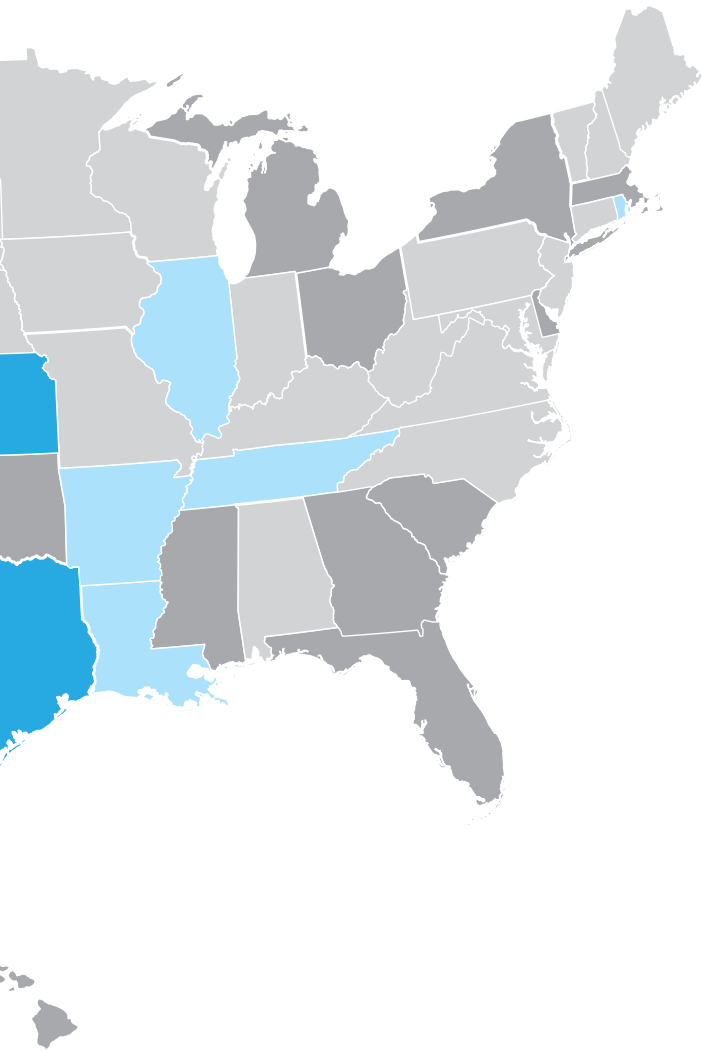
In 2014, Arizona adopted the ODG chronic pain treatment guidelines. However, during the rulemaking process adopting the ODG guidelines, the Industrial Commission decided that it would need to initiate another rulemaking process to develop the rules for pre-authorizing treatment that fell outside of these guidelines, such as compounded medications. A working group recommended a utilization review process last December that created the framework for the rulemaking, and since that time the group has been working with the Commission on the rule language and details on how to implement the rule. However, in late September of this year, two commissioners and the executive director of the Industrial Commission resigned over questionable per diem payments made to the commissioners. The distraction created by the resignations and subsequent investigations will likely further delay work on the rule until next year. In the meantime, employers have created a pilot program using a voluntary review process. Our government affairs team will continue to provide comments and work with the Industrial Commission as the rulemaking advances.

KANSAS

In the new fee schedule implemented by Kansas for 2015, a provision was added requiring prior authorization from the employer or insurance carrier before dispensing a compounded or physician-dispensed medication.



COMPOUNDED MEDICATIONS



TEXAS

Following his inauguration in January, Governor Abbott appointed Commissioner Ryan Brannan to lead the Texas DWC. Commissioner Brannan immediately opened his door to stakeholders and we were among the first to meet with him, providing data extolling the success of the Texas closed formulary, but also pointing out a couple of areas of concern, including compounded medications and unrelated or non-indicated medications. We also suggested areas where improvements could be made to contain costs. Recognizing that the DWC has been fielding complaints from the payer community about the compounded medication problem for more than a year, the commissioner commenced a rule making to modify the required data elements to help more clearly identify compounded medications and their associated costs in their state-reporting system. That effort appears to be paying off as the DWC announced at their conference in mid-September that preliminary data is confirming what they have been hearing from industry about the high costs of compounded medications. Our government affairs team will continue to work with the Texas regulators to evaluate new data as it becomes available and advocate for changes that enable greater control over compounded medications, both clinically and financially.

MEDICAL MARIJUANA

2015 Regulatory and Legislative Updates

The use of marijuana, or cannabis, in its various forms is gaining popularity throughout the country for treating a multitude of medical maladies. During the 2015 legislative season, at least 18 states considered legislation to approve or modify the use of medical marijuana in their jurisdictions. In New Mexico, the Appellate Court weighed in on two workers' compensation cases, and in both ruled that the payer must reimburse for medical marijuana if it is deemed medically necessary. The rulings create a legal conundrum for payers since marijuana is still an illegal substance at the federal level and reimbursing injured workers for the drugs could expose them to potential criminal penalties for money laundering, racketeering, or other federal crimes. Congress added a rider in Section 538 of the Consolidated and Further Continuing Appropriations Act of 2015 prohibiting the Department of Justice (DOJ) from expending any funds to prosecute caregivers or users of medical marijuana in states where it has been deemed legal. Nonetheless, payers are justified in being concerned about potential civil and criminal prosecution.

In a February 2015 memo distributed to all federal prosecutors, the DOJ Appellate Section Chief noted that "the Department's position is that Section 538 does not bar the use of funds to enforce the CSA's criminal prohibitions or to take civil enforcement and forfeiture actions against private individuals or entities consistent with the Department's guidance regarding marijuana enforcement." Clearly, such a statement demonstrates that payers could be at risk. Regardless of the federal position, states continue to legalize the use of medical marijuana.

Late last year the Drug Enforcement Administration (DEA) formally asked the Food and Drug Administration (FDA) to consider rescheduling marijuana from a Schedule I drug to a medically-approved level. Rescheduling is an intensive and time-consuming process. When the drug being considered is classified Schedule I, the process is further complicated, requiring an additional volume of special permits and review by the DEA just to conduct clinical trials, which in and of themselves can be very time consuming, often taking months or years to complete. Comparatively, the legislative process to reschedule a drug simply requires Congress to change the Schedule level in a bill. That process can be much quicker, but is also fraught with the potential for political fallout.

Our government affairs team remains engaged at both the state and federal level to monitor developments on this critical issue. As states consider medical marijuana laws it is important to ensure those laws make it clear that, until marijuana is considered a legal substance, insurers and employers are not required to provide reimbursement for its use. Without that exemption from payment, payers will find themselves in a legal tug-of-war between state and federal laws.

2015 REGULATORY AND LEGISLATIVE UPDATES

- States with existing legislation/regulations
- States with legislative/regulatory activity in 2015
- States contemplating legislative/regulatory action

ARIZONA

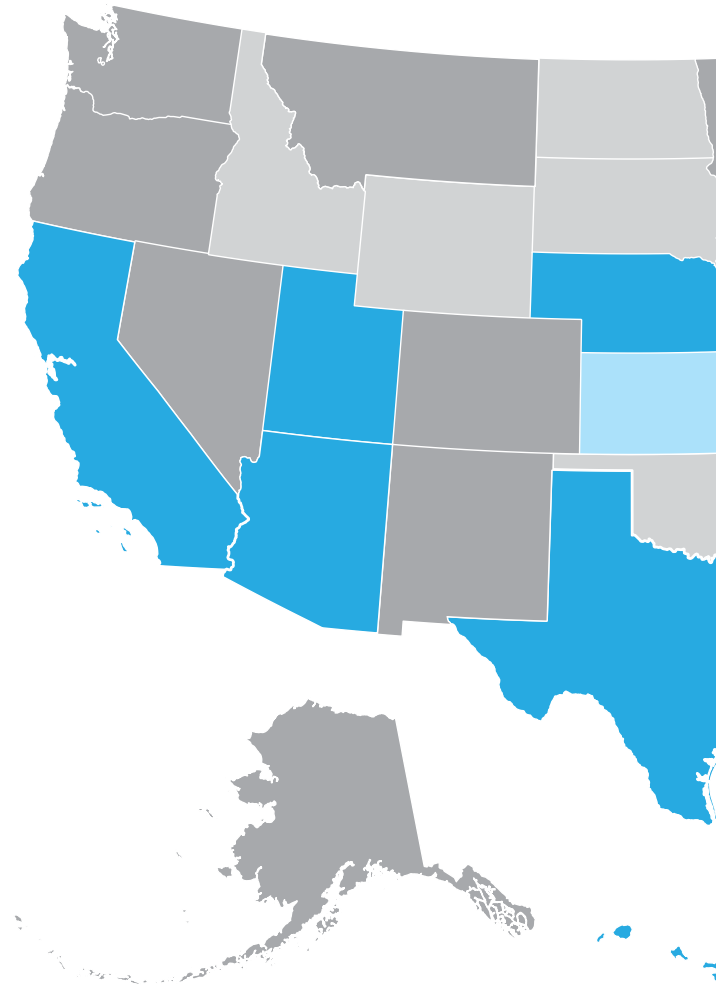
Arizona prudently passed legislation to protect employers and insurance carriers from finding themselves at odds with federal law. HB2346, sponsored by Representative Karen Fann, specifically stated that insurance carriers and self-insured employers can't be compelled to pay for medical marijuana for injured workers.

CALIFORNIA

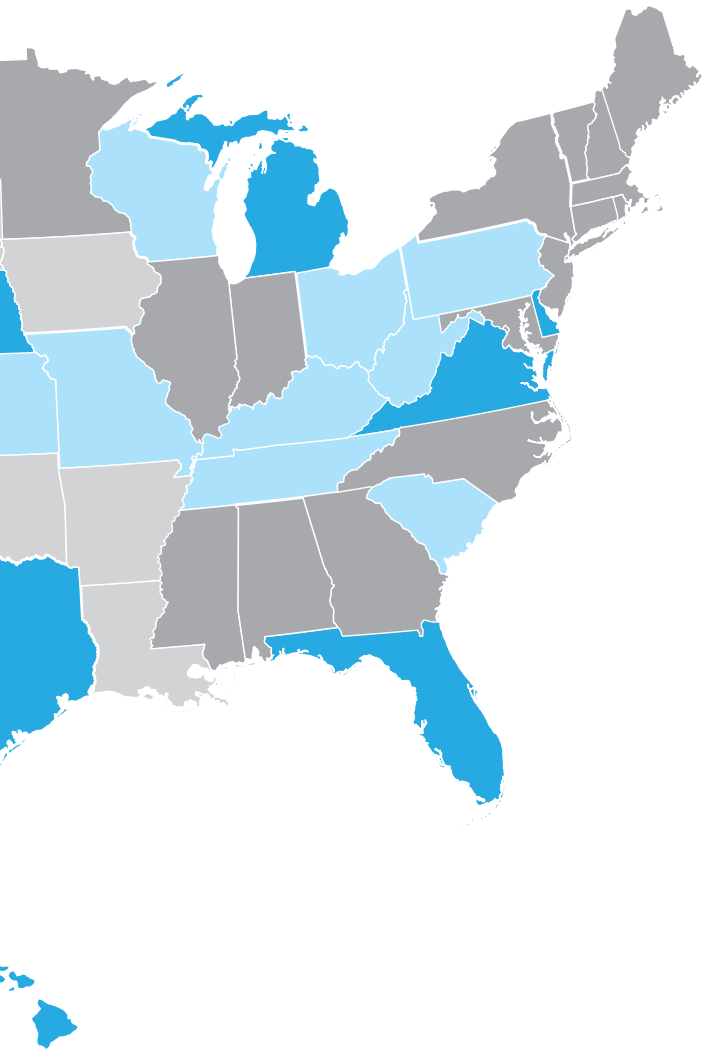
On October 9, California Governor Jerry Brown signed into law three bills known collectively as the Medical Marijuana Regulation and Safety Act. The bills are designed to build a strong regulatory framework around the cultivation and distribution of medical marijuana in the state. Citing concerns about safety to both individuals and the environment from the unregulated cultivation of marijuana, the Governor lauded the three bills as a major step forward demonstrating California's commitment to a well-controlled medical marijuana system. Regulators are already at work drafting rules for the new standards, which will be fully implemented by January 1, 2018. While the Medical Marijuana Regulation and Safety Act is not specific to workers' compensation, it is foreseeable that the controlled environment established will influence any future rules or regulations for our industry. Our team will certainly be watching how this unfolds in the months and years ahead.

UTAH

After passing legislation two years ago authorizing the use of cannabis oil to treat seizures in children, Utah took a run at passing legislation to expand to a full medical marijuana offering. The bill failed on a 14-15 vote in the Senate, with the Senate President casting the deciding vote.



MEDICAL MARIJUANA



DELAWARE

Delaware passed legislation approving limited use of cannabis oil to treat seizures and other conditions.

FLORIDA

Florida passed legislation approving limited use of cannabis oil to treat seizures and other conditions.

HAWAII

Hawaii passed a full medical marijuana bill.

MICHIGAN

Michigan, in a move contrary to protecting carriers, attempted a law that would have required auto insurers to pay for medical marijuana. The bill did not get far, but is likely to return in a future session.

NEBRASKA

Nebraska passed legislation approving limited use of cannabis oil to treat seizures and other conditions.

TEXAS

Texas passed legislation approving limited use of cannabis oil to treat seizures and other conditions.

VIRGINIA

Virginia passed legislation approving limited use of cannabis oil to treat seizures and other conditions.

PRESCRIPTION DRUG MONITORING PROGRAMS

2015 Regulatory and Legislative Updates

Prescription Drug Monitoring Programs, or PDMPs, were initially implemented as an enforcement tool to identify potential pill mills or over-prescribers and to identify drug seeking behavior by patients. Over the last several years, as states have been plagued with persistently high deaths as a result of overdoses from prescription drugs, the state legislatures have sought ways to adapt their PDMPs to help with prevention of prescription drug misuse and abuse. A number of states worked on PDMP issues this past year.

Other states are working on sharing agreements so that databases can be accessed across state borders to help disrupt drug seeking that crosses state lines. There has also been some talk about creating a centralized federal database to consolidate all of the information into a single source. For any database to be successful, it has to be easy to use and accessible to all health care professionals involved in the prescribing, dispensing, and managing of prescription drugs.

2015 REGULATORY AND LEGISLATIVE UPDATES

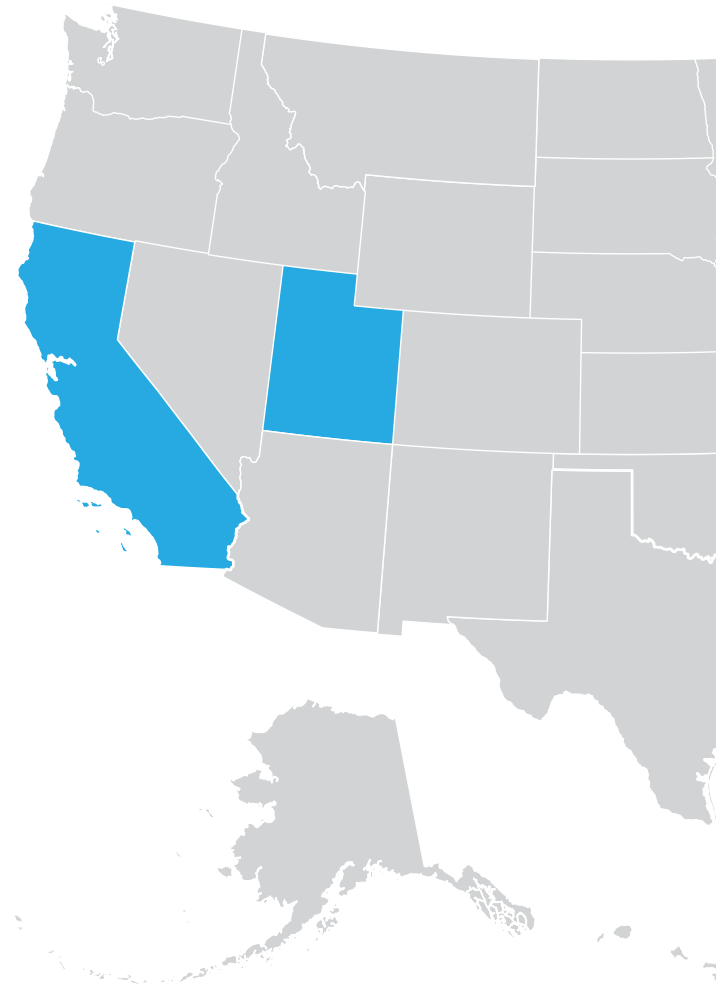
- States with existing legislation/regulations
- States with legislative/regulatory activity in 2015
- States contemplating legislative/regulatory action

CALIFORNIA

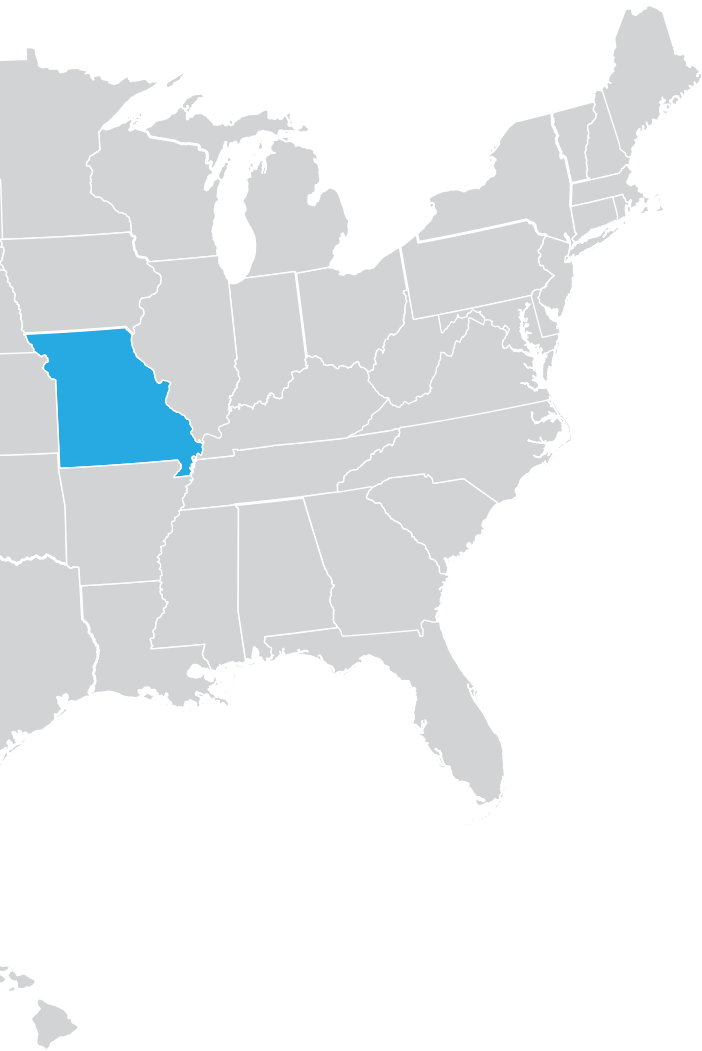
The California legislature passed a law in 2013 that created a sustainable funding source for their PDMP and also required that all prescribers and dispensers complete an application to access the database via the internet. The applications were originally due on January 1, 2016, but the current version of the PDMP does not support all available internet browsers so legislation was passed this year to delay the application due date to July 1, 2016, giving the agency time to fix the browser access issue. Senator Lara sponsored legislation during the 2015 session, SB 462, that would have required all prescribers and all dispensers to check the database before prescribing or dispensing a Schedule II, III, or IV drug. Due to the browser access issue the bill was held. Watch for it again next year.

UTAH

Utah passed legislation that would restrict law enforcement access to the database unless the agency obtained a search warrant. The DEA is considering legal action to prevent the law from taking effect, arguing that such a requirement circumvents federal authority and hampers their ability to enforce federal law.



PRESCRIPTION DRUG MONITORING PROGRAMS



MISSOURI

Missouri remains the lone state without a PDMP. The state legislature tried once again to pass a law to authorize the creation of a PDMP, and we were optimistic that 2015 would be the year the legislation passed. Alas, the measure failed again as legislators continue to be concerned about potential privacy issues.

PHYSICIAN DISPENSING

2015 Regulatory and Legislative Updates

The high cost of repackaged medications associated with physician dispensing continues to be a problem for workers' compensation payers. Over the last several years, many states have adopted policies requiring that reimbursement be based on the Average Wholesale Price (AWP) using the National Drug Code (NDC) of the original manufacturer's product used in the repackaging. Those policy changes had an initial positive impact, reining in the cost of repackaged medications. However, a January 2015 report, "Are Physician Dispensing Reforms Sustainable?" by the Workers' Compensation Research Institute (WCRI) revealed data that would indicate that the pricing reforms for repackaged medications could be eroded if manufacturers decide to manipulate pricing at their level, noting cyclobenzaprine HCL being dispensed in California as an example. The studied medication was typically dispensed in 5mg and 10mg strengths sold in pharmacies for \$.35 to \$.70 per pill. A manufacturer developed a new 7.5mg strength pill that was dispensed almost exclusively by physicians at a cost of \$2.90 to \$3.45 per pill. Policymakers took notice and are now working on strategies to maintain control over the cost of physician dispensed medications.

Our government affairs team has been at the forefront of this issue for several years. We are actively working with legislators and regulators across the country to share our expertise on this issue, helping form appropriate policy in this important area of concern.

2015 REGULATORY AND LEGISLATIVE UPDATES

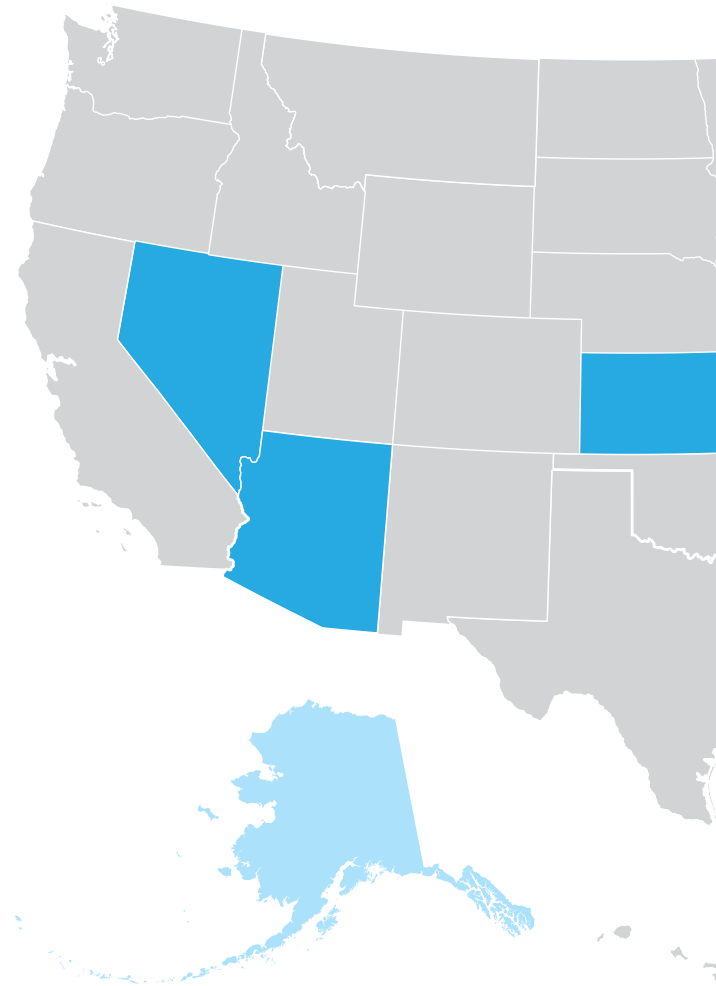
- States with existing legislation/regulations
- States with legislative/regulatory activity in 2015
- States contemplating legislative/regulatory action

ARIZONA

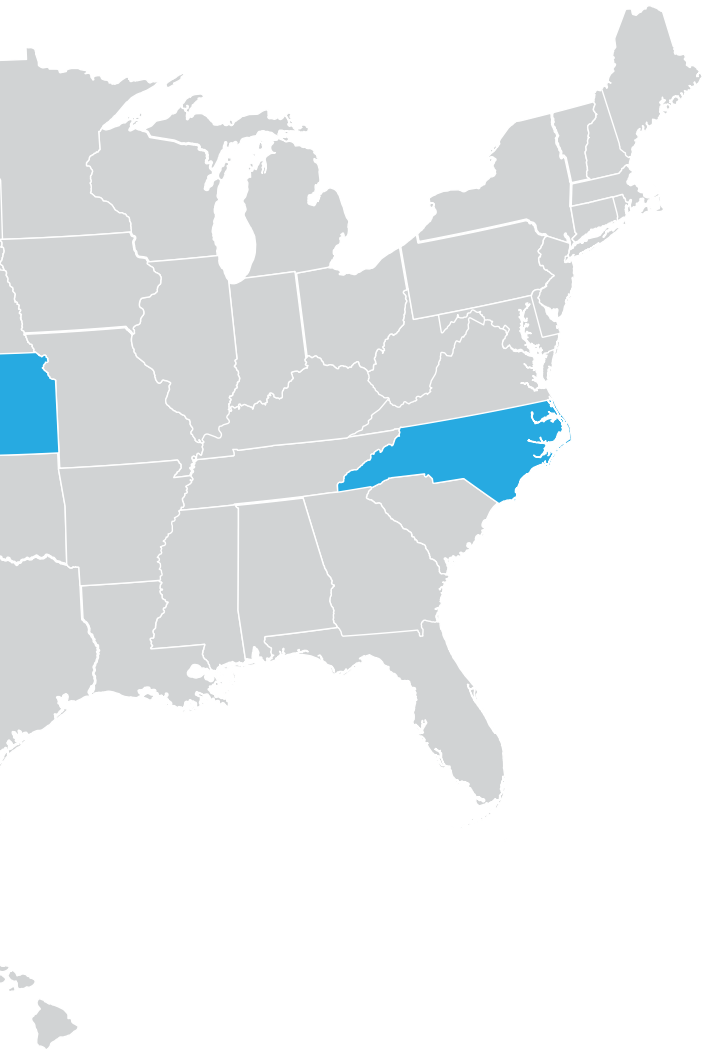
Arizona adopted their new fee schedule in August and included a provision that requires dispensing physicians to include the NDC of the original manufacturer's product used in the repackaging and to limit reimbursement based on the AWP of that original product.

NEVADA

On May 27, 2015, Governor Brian Sandoval signed Senate bill 231 into law. The bill limits physician dispensing of Schedule II and Schedule III drugs to 15 days and also requires that claims submitted for repackaged medications include the NDC for the original manufacturer's product used in the repackaging. Reimbursement will be determined using the NDC of the original product. An additional provision was added that prohibits outpatient physicians from seeking reimbursement for non-prescription drugs dispensed to injured workers. The bill takes effect on January 1, 2016 and should help reduce costs related to physician dispensed medications.



PHYSICIAN DISPENSING



NORTH CAROLINA

North Carolina expanded the 5-day dispensing time limitation from Schedule II to all scheduled medications.

KANSAS

Changes in the 2015 Fee Schedule for Kansas now require a physician to obtain prior approval from an insurance carrier or self-insured employer prior to dispensing a medication to an injured worker.



CONTINUED COLLABORATION

It has been a busy year for the workers' compensation regulatory and legislative arenas. As consideration towards additional regulatory and legislative changes to address these and other industry influences continues, we encourage policymakers and stakeholders throughout the system to be mindful of the valuable role a pharmacy benefit manager plays in managing pharmacy cost and utilization.

Just as the various regulatory and legislative changes discussed herein are intended ensure the system is safe, efficient, and cost-effective, Helios has long-advocated for solutions that balance the interests of payers and injured workers alike. We will continue to do so and encourage policymakers and stakeholders throughout the system to remain engaged with an open mind and a collaborative spirit as we work together to achieve better outcomes.

  Follow us @HeliosComp | 877.275.7674 | HeliosComp.com

Helios brings the focus of workers' compensation and auto no-fault Pharmacy Benefit Management, Ancillary, and Settlement Solutions back to where it belongs—the injured person. This comes with a passion and intensity on delivering value beyond just the transactional savings for which we excel. To learn how our creative and innovative tools, expertise, and industry leadership can help your business shine, visit HeliosComp.com. ©2015 Helios™ All Rights Reserved. CRS14-15216

HELIOS™