







Prevalence of Compound Medications in the Workers' Compensation Industry



What are compound medications?

A recent trend in medical treatment is the use of compound medications. Compounding refers to the process of creating a custom medication to treat a patient's medical condition. Compounds are used for individuals who:

- May need a specific drug combination due to allergies to certain ingredients
- Need a dosage that is not commercially available
- Want to improve delivery, such as making a smaller pill
- Need to alter ingredients from tablet form into a liquid

There are two types of pharmacy compounding: non-sterile and sterile. Non-sterile delivery mechanisms include topical creams and gels, oral liquids and pills. Sterile compounds refer to medications injected into the body directly, bypassing bodily filters, such as the liver and kidneys. Given that non-sterile compounds are generally lower-risk products, the standards for production of these drugs are less stringent than those for sterile compounds.

In devising a compound medication to treat an ailment, the physician determines the exact amount and combination of certain drugs that best suit the patient's needs and provide the most effective treatment.

The pharmacist then will make the individualized solution, creating a custom medication.

Recent Rise in Compound Use

The workers' compensation industry has been steadily impacted by the increase in prescribing customized compound medications. This rise is not only limited to workers' compensation but it is also prevalent in the health care industry as physicians look for alternatives to opioids. Compound prescriptions increased nearly fourfold over the last several years, while costs increased nearly 30 percent in 2013 compared with 2012.²

In the workers' compensation area, the use of compound medications rose 72 percent in 2013.³ Pain management physicians are among the most likely to prescribe compound medications for a



host of reasons, including limiting side effects of opioids, omitting ingredients that cause allergic or other side effects, providing a source of a drug in short supply and creating topical solutions to treat pain and avoid the internal system.

The number of ingredients in compounds has increased over the past few years with no documented medical efficacy, leading carriers to argue these medications are unpredictable and often too high in cost. Some compound bills have "been in the tens of thousands," according to Donald Lipsy, pharmacy benefits management communications and regulatory manager at Coventry Workers' Comp Services in Tucson, AZ.4



Regulatory Reactions by State

In response to the escalation in compound costs, certain states have started to implement their own forms of regulation. A common regulatory solution used by states is to require that compounds be billed at the ingredient level, meaning the cost will be based on the amount of each ingredient rather than overcharging based on the most expensive ingredient.



- Washington, Wyoming, Colorado, South Carolina and Idaho are examples of states that employ this method.⁵
- Mississippi requires pre-authorization for a compound cream and imposes a \$300-per-month and 120-gram cap per authorization.⁶
- Georgia limits reimbursement for compounds at three FDA-approved active ingredients per compound.
- Texas, pursuant to the closed formulary, requires prior authorization of "N" drugs in compounds.
- Similarly, Oklahoma requires prior authorization for all compounds pursuant to its new closed formulary.
- Ohio placed a \$600 reimbursement cap for compounds with a dispensing fee of \$12.50 for non-sterile drugs and \$25 for sterile drugs.⁸
- Louisiana requires compounded medications to be billed at the same reimbursement rate as generic medications.9
- California limits reimbursement of compounds to 100 percent of the Medi-Cal rate per ingredient and limits physician-dispensed compound reimbursement to the total cost for the compound at 300 percent, and not more than \$20, of the documented paid costs.¹⁰



The compounding phenomenon isn't a new concept but rather has been resurrected following decades of mass-produced medications.1 Widespread access to medical care, combined with treatment breakthroughs, has led physicians and pharmacists to reintroduce the concept of personalized medical treatment, thereby leading to a rise in compound prescriptions. This trend is likely a sample of state responses to control costs, and this trend is likely to continue as other states grapple with the increased use and high costs of compound medications.

So, do the benefits of compound medications outweigh the costs to the workers' compensation industry? Not surprisingly, information relating to the success of compounds is scant, given the personalized nature of these medications. By design, a compound may alleviate one person's ailment but not have the same effects in another, making quantifiable research hard to proffer.

A 2006 survey by the FDA produced promising results. In this survey, the FDA collected samples of both active pharmaceutical ingredient (API) and finished compounded drug products from compounding drug pharmacies. All API samples passed analysis, leading to the conclusion that failures of the finished products were likely related to the compounding processes at the pharmacies.¹¹

A successful study performed by the Professional Compounding Centers of America (PCCA) found a marked increase in benefits from the use of transdermal solutions with patients who can't tolerate pill- or injection-based medications. "Because they allow medications to successfully



penetrate the skin, these transdermal creams show the potential to sidestep many common side effects of drugs, such as upset stomach, and minimize the effects on other organs. This reduction of side effects is particularly significant in pain treatment, meaning higher concentrations at the site of application and lower concentrations of the drug throughout the body."¹² The option to treat patients with alternative medical solutions should be welcome in light of the current pandemic surrounding opioid dependency and addiction in workers' compensation.

A white paper produced by CompPharma concludes that compounding medications is – and should remain – an option to treat patients with unique needs. ¹³ Federal and state guidance and oversight are fundamental to ensuring safe and judicial dispensing of compound medications.

Proposed legislation will likely continue to offer solutions aimed at regulating both costs and safe delivery of compound medications.

Additionally, as the industry is more consistently regulated, costs will likely become more predictable, thereby alleviating concerns expressed by payers.

In the interim, compounding will remain a hot topic. At the time of this writing, three pharmacies filed a lawsuit against Express Scripts following its announcement that it will stop paying for 1,000 of the most commonly prescribed compound ingredients. While this suit doesn't directly influence non-group health plans, like workers' compensation, it clearly brings to light the discord between payers and prescribers and threatens the continuity of patient care.

Ultimately the direction of medicine and treatment is geared toward specific needs of the patient, and therefore compound medication solutions will continue to be warranted. Availability of additional research and evidence from trials will also better enable the workers' compensation industry to determine when a compound drug is the ideal treatment module to cure the patient and decrease time off work, which should be the ultimate goal of all stakeholders.



¹ "What is Compounding? – PCCA – Professional Compounding Centers of America." What Is Compounding? – PCCA – Professional Compounding Centers of America. N.p., n.d. Web 17 Nov. 2014.

² Harrison, Sheena. "Rising Use and Cost of Compounded Medications in Workers Comp Sparks Concern." *Insurance News*. N.p., 06 July 2014. Web 17 Nov. 2014.

 $^{\rm 3}$ "Injured Worker Communication Drives Safer Treatment." The Express Scripts Lab. Express Scripts Lab, n.d. Web 01 Dec. 2014.

⁴ Harrison, Sheena. "Rising Use and Cost of Compounded Medications in Workers Comp Sparks Concern." *Insurance News.* N.p., 06 July 2014. Web 17 Nov. 2014.

⁵ Walls, A. Phillip, Seth Johnson, Michael Nguyen, Kate O'Lenic, Tim Pokorney and Sarah Randolph. Compounding is Confounding Workers' Compensation. Rep. CompPharma, 2014. Web. 17 Nov. 2014.

⁶ The Price of Compound Medications: Protecting the Injured through Clinical Management and Advocacy for Reform. Publication. Helios, 15 Oct. 2014. Web. 18 Nov. 2014.

7 Ibid.

⁸ Walls, A. Phillip, Seth Johnson, Michael Nguyen, Kate O'Lenic, Tim Pokorney and Sarah Randolph. Compounding is Confounding Workers' Compensation. Rep. CompPharma, 2014. Web. 17 Nov. 2014.

⁹ Ibid.

10 Ibid.

¹¹ "Drugs." 2006 Limited FDA Survey of Compounded Drug Products. FDA, 22 Mar. 2010. Web 01 Dec. 2014.

"Lipoderm® Transdermal Is Only Proven Base to Deliver Up to Four Medications At Once." PCCA- Professional Compounding Centers of America." 08 Mar. 2012. Web. 01 Dec. 2014.

¹³ Walls, A. Phillip, Seth Johnson, Michael Nguyen, Kate O'Lenic, Tim Pokorney and Sarah Randolph. Compounding is Confounding Workers' Compensation. Rep. CompPharma, 2014. Web. 17 Nov. 2014.

