

Compound Drugs and Convenience Packs: A Rising Crisis and its Impact on your Business

I. Introduction & Background

The concept of drug compounding has been around since the inception of pharmacy. While neighborhood pharmacies that compounded their own drugs were once common, industrialization and the introduction of patent law led to a dramatic decrease in drug compounding starting in the 1920's. In the 1930's and 1940's an estimated 60% of all medications were compounded, compared to only 1% of drugs in the 1980's and 1990's (History of Custom Made Medications). Lately however, compound drug prescriptions seem to be on the rise once again, especially in the Workers' Compensation arena. Although compounds are medically necessary in some instances, their efficacy, safety, and rapidly rising costs have become increasingly scrutinized throughout the medical community. The purpose of this whitepaper is to explore the issues and latest trends around compounds, their effect on the Workers' Compensation industry, and to identify potential solutions to a growing problem.

Pharmacy compounding is defined as combining drug ingredients to create a medication that is otherwise unavailable in manufactured form. Compound drugs can be made for patients that are allergic to non-active ingredients or need medication in alternative modes of administration or dosages. According to the California Workers' Compensation Institute (CWCI), "In Workers' Compensation, compounded drugs are often associated with a means of delivering pain relief through a topical cream" (Ireland and Swedlow 2). Medical foods on the other hand are products the Orphan Drug Act defines as: "a food which is formulated to be

consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation” (Federal Drug Administration Website). Medical foods which provide nutritional vitamins and minerals can also be combined with generic drugs to produce a capsule known as a co-pack. The commonalities between compound drugs, medical foods, and co-packs are unmistakable: since 2006 they have become an enormous and growing area of concern for the federal government, state pharmacy boards, and health care payers.

II. Why Should I Care About Compound Drugs, Co-Packs, & Medical Foods?

While the United States Food and Drug Administration (FDA) does oversee the combination of certain drugs that are mass produced and commercially available, it does not regulate pharmacy produced compounds (that meet certain low quantity and safety standards) and gives states full jurisdiction over governing laws and regulations. The lines between when the FDA should require an approval and registration and when it shouldn't are extremely blurry: pharmacies should only compound drugs after receipt of a prescription, but are also allowed to stock and supply physicians with compounds who in turn can prescribe up to a 72 hour prescription to patients directly from their offices (Wynn 7). Without FDA regulations and labeling, the size or volume of a 72 hour supply is left to the physician's discretion. Furthermore, states do not require pharmacies to report any testing information, which leads to a lack of data surrounding safety concerns for drug compounds. The Official Disability Guidelines (ODG), a source for evidence-based medical treatment and disability duration guidelines for Workers' Compensation injuries, also questions the efficacy and safety of compound drugs stating that topical analgesics are “largely experimental in use with few randomized controlled trials to

determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended” (Work Loss Institute). California has its own set of guidelines called the Medical Treatment Utilization Schedule (MTUS) which is based on the ODG and views compound drugs in the same light.

Like compound drugs, the FDA does not require drug companies to submit individual medical food products or co-packs for approval (the generic drugs in co-packs are FDA approved, but their packaged combination with a medical food many times is not). In fact, the FDA as recently as August 2010 sent letters to one of the largest producers of co-packs in the country warning them to seek FDA approval or quit marketing their products (Wynn 12). Clearly the FDA has some major concerns regarding the safety and effectiveness of medical foods and co-packs, and like compound drugs very few clinical studies exist to prove their concerns are unjustified.

Since the prescription and use of compound drugs, co-packs, and medical foods has risen so quickly over the last few years, very few official studies have examined the national trends. The RAND Center for Health and Safety in the Workforce study conducted in January 2011

states “[Besides California] Florida and Texas were commonly identified as other states with high usage rates [of compound drugs and co-packs] but several interviewees noted it is a growing but generally unrecognized problem elsewhere” (Wynn 26). One can get a good idea as to what is occurring by examining the plethora of data that has come out of California in recent months. Why has California been so quick to catch on to these recent trends? One theory is that they were already closely monitoring the financial implications of repackaged physician dispensed drugs (PDD) which were being marked up several hundred percent before being prescribed to patients. In 2006 PDDs accounted for over half of all Workers’ Compensation prescription costs in California and almost 60% of Workers’ Compensation prescription costs nationwide (Ireland and Swedlow 1). At the end of the first quarter in 2007 California legislators revised their pharmacy fee schedule to limit such pricing, and by 2008 PDD and the costs associated with them had dropped over 90% (Ireland and Swedlow 1). With their profits being cut so dramatically, data suggests that drug companies, pharmacies, and doctors quickly came up with a new solution to replace the revenue lost due to 2007 legislation: compound drugs, medical foods, and co-packs. Figures 1 and 2 below from the California Workers’ Compensation Institute clearly illustrate the suspect timing of a gigantic increase in both the amount and costs associated with compound drugs, co-packs, and medical foods. From 2006 to 2009, the most recent data available at the time of the CWCI study, the amount of bulk drugs (the primary ingredient in compound drugs) and associated drugs with the same service date as the bulk drug (the secondary ingredients in compound drugs) increased 1,086% and 674% respectively. Over the same period the amount of NDC codes associated with co-packs increased by 78,868%. The percentage of paid prescription dollars for these products in Figure 2 tells the same story: dollars paid for bulk and associate drugs increased a combined 1,222% from 2006-2009 while dollars

paid for co-packs increased an eye popping 104,815%. Currently, \$1 out of every \$8 spent on Workers' Compensation prescriptions in California is for a co-pack or compound drugs, both of which are mostly unregulated, have never proven effective in clinical trials, and have cheaper and rigorously tested and FDA approved drug alternatives.

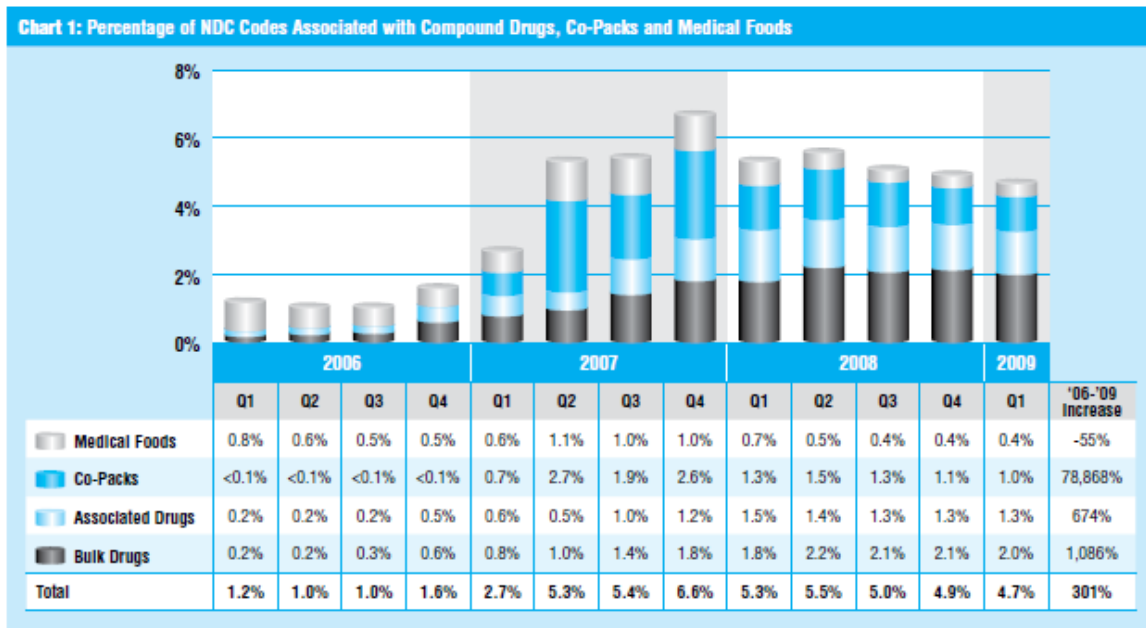


Figure 1- Percentage of Compound Drugs, Co-Packs, and Medical Foods Prescribed (Ireland and Swedlow 4)

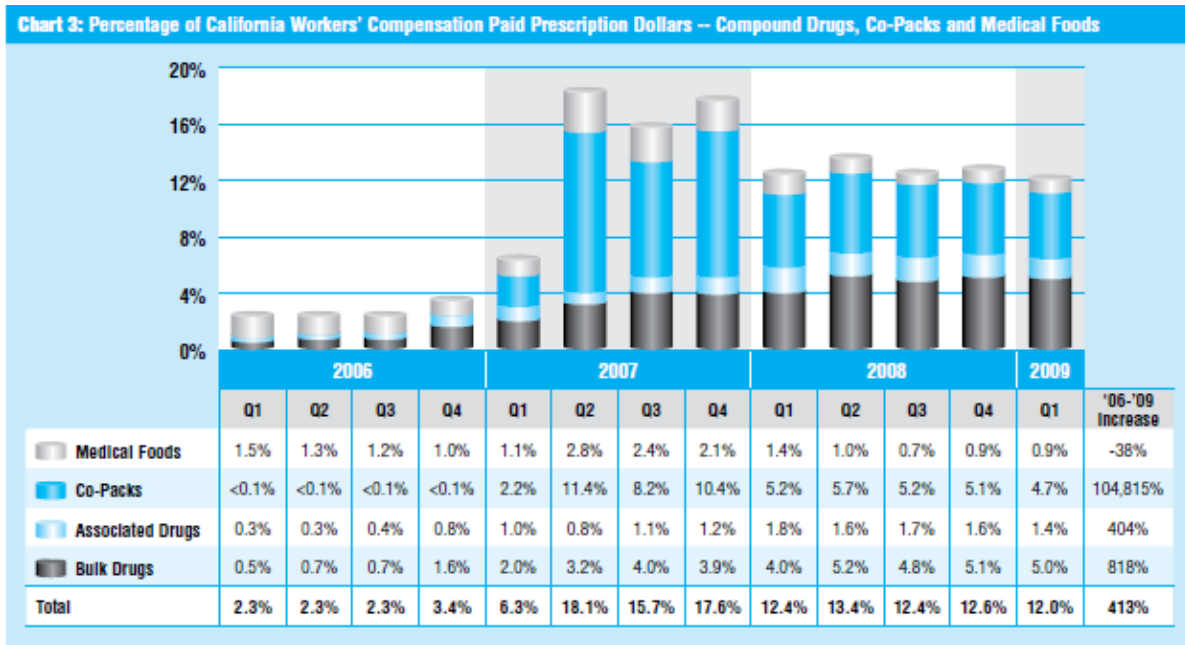


Figure 2- Percentage Compound Drugs, Co-Packs, and Medical Foods Prescriptions Paid (Ireland and Swedlow 6)

From Figure 2 above we can see that *not only are costs spiraling out of control, but the bills are getting paid.* The RAND Center for Health and Safety in the Workplace conducted a rigorous study on the impact of compound drugs, co-packs, and medical foods in January 2011. The RAND report explains that under the California's Official Medical Fee Schedule (OMFS) regulations are outlined for determining payment on compound drugs based on the Medi-Cal fee schedule and its database of drugs. When billing a compound drug an NDC code is required for each ingredient, but since OMFS is based on the Medi-Cal formulary, not all drugs prescribed to Workers' Compensation patients appear in the database. When a compound drug ingredient has a NDC code that is not in the database, then default pricing is used to determine the cost. Default pricing can use the underlying drug unit cost (although most compound drug ingredients do not have a defined underlying drug) or taking 83% of the lowest priced therapeutic equivalent as determined by the FDA's Orange Book (Wynn 15). The problem

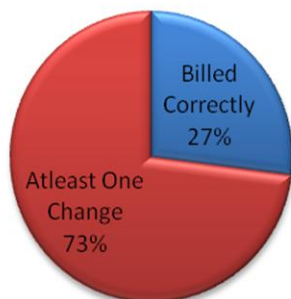
with the latter method is that bulk ingredients are not FDA-approved drugs and therefore do not have clear therapeutic equivalents. In many instances bills include only one NDC code but will give a breakdown of the other ingredients, increasing the chances that the bill will be processed using the single high-priced NDC code and thus be overpriced. Another common method of incorrect billing is when individual ingredients reflect the NDC listed amount of ingredients instead of the portion actually used to make the compound, again leading to overpriced bills. The growing concern with compound drugs and co-packs is not limited to medical necessity and patient safety, but also includes inherent problems with determining the correct payment in the limited number of cases where these drugs *are* appropriate (Wynn 15-17).

III. What Can Workers' Compensation Payers do about it?

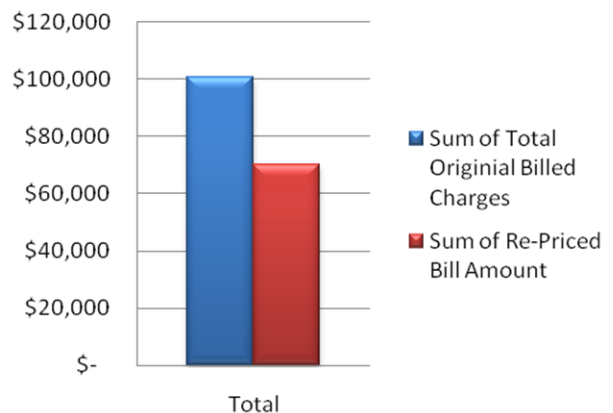
The RAND Center for Health and Safety in the Workplace lists several options for payers to guarantee payments are “appropriate and reasonable.” With regards to medical appropriateness, MTUS does not offer straightforward guidelines for the use of compound drugs, medical foods, or co-packs due to the lack of evidence from clinical trials. A payer may dispute the appropriateness of these drugs only after completing a formal utilization review process. Some payers also use pharmacy benefit management (PBM) companies to help manage their drug claims, but custom products like compound drugs and co-packs are rarely in PBM formularies which makes them particularly difficult and expensive to process. Furthermore, many of the physician dispensed drugs are submitted directly to the payer, even if they are using a PBM. Often the payer does not have the capacity or expertise to process these complicated bills in a timely manner. The best way to limit the growing impact of compound drugs and co-packs is to control the care provided to injured workers throughout the course of the claim, making sure it is both appropriate and cost effective (Wynn 22-26).

In 2010, **PRIUM**, an Atlanta based utilization review company, introduced a Compound Drug Management Program that helps address the two primary issues with compound drugs: overpriced bills and lack of medical necessity. The process is simple, turnkey, and offers a high ROI because it is a shared risk program where customers only pay 25% of their savings. While this program can be used in any jurisdiction, the primary focus is California due to the scope of the issue and the statutory support provided. **PRIUM** offers two different products in its Compound Drug Management Program: the Compound Drug Re-Pricing Review where the appropriate price is calculated to California Fee Schedule, and the Compound Drug Comprehensive Review which evaluates the medical necessity of the compound drug per California MTUS Guidelines and if approved then calculates the appropriate price per California Fee Schedule. In a recent 2011 project for a California client, **PRIUM** was able to deliver a 73% impact rate (at least one change made related to medical necessity or an incorrectly priced bill) and a \$3.81: \$1 return on investment after **PRIUM**'s fees (results depicted below). For more information on how **PRIUM** can help manage your growing compound drug, medical foods, or co-pack costs email sales@prium.net or call 1-888-588-4964.

Impact Rate on Compound Drugs



PRIUM's Financial Impact



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