

# WORKING P A P E R

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## Use of Compound Drugs, Medical Foods, and Co- Packs in California's Workers' Compensation Program

### An Overview of the Issues

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CENTER FOR HEALTH AND SAFETY IN THE WORKPLACE

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## **SUMMARY**

There is considerable controversy over the growing use of compound drugs, medical foods, and co-packs for workers' compensation (WC) patients. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available. Unlike commercially available drugs, these products are not approved by the Food and Drug Administration (FDA) but rather are regulated by the state pharmacy board. Recently, some pharmacies have been making and marketing stock compound drugs for the WC patient population. Similarly, the use of medical foods (a food that is specially formulated and processed for seriously ill patients with a specific medical condition with distinctive nutritional requirements) and co-packages (co-packs) of a medical food and a generic drug is rapidly increasing among WC patients. A recent report issued by the California Workers' Compensation Institute (CWCI) found that payments for compound drugs, convenience packaging of drugs and medical foods (co-packs), and medical foods grew from 2.3 percent to 12.0 percent of medication expenses between the first quarter of January 2006 and the first quarter of 2009 (Ireland & Swedlow, August 2010).

Multiple parties are involved in delivering and paying for these products, each with financial interests at stake in how the products are used in California's WC program. Other health programs have adopted policies that provide more assurance that drugs are medically appropriate and payments are reasonable. As a result, they are not experiencing comparable issues related to use of these products.

The issues surrounding compound drugs, medical foods, and co-packs rest on uncertainties regarding whether the products are medically appropriate and whether payments are reasonable. Clarifying the rules and removing inappropriate financial incentives should help assure that workers receive the drugs and other pharmaceuticals that are needed to "cure or relieve" their illness or injury.

*Medical Necessity.* With respect to the medical necessity issues, the WC program needs general coverage requirements for compound drugs and medical foods and other nutritional products. The criteria could draw from FDA policy guidance on compounding drugs and the National Association of Boards of Pharmacy's Model Act. For example, the provision might require that the finished drug product:

- Include a least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved drug. This would eliminate OTC compound drugs.
- Include only active ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility. This would allow compounding only of bulk ingredients that are used in FDA-approved finished products and are manufactured in FDA-registered facilities.
- Is not a drug that was withdrawn or removed from the market for safety reasons.
- Is not a copy of a commercially available FDA-approved drug product.
- Include only active ingredients that have been supported as safe and effective for the prescribed indication by the FDA-approval process or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence but also clarify that a product is not covered unless there is evidence to support that it is medically appropriate.
- Prior authorization could be required when the active ingredient is not addressed in the Medical Treatment Utilization Schedule (MTUS) guidelines adopted by the Administrative Director.

The MTUS should be updated and expanded to address compound drugs as a product class. In addition to addressing the evidence-base

supporting the efficacy of ingredients frequently used in compounding, the guidelines should consider whether FDA-approved drugs should be tried prior to prescribing the compound drug and whether restrictions are appropriate on consecutive dispensing of 72-hour supplies of compound drugs (assuming the practice continues to be allowed). Similarly, the MTUS should address the medical appropriateness of medical foods. MTUS guidelines should not be necessary for co-packs as long as medical foods are addressed; instead, as discussed below, the Official Medical Fee Schedule (OMFS) allowances for these products should be clarified.

*OMFS allowances.* Review of sample bills and OMFS pricing policies indicates there is problem with how bulk ingredients are priced. The allowances in the MediCal database are based on average wholesale prices (AWP or self-reported "sticker" prices) for a single manufacturer. The OMFS is vulnerable to establishing excessive allowances as long as pricing relies on these AWP's and does not take advantage of multi-source pricing. Excessive allowances create incentives to market compound drugs to the WC population. This issue could be addressed by using an approach that is similar to the pricing formula used to establish the federal upper limit on multi-source drugs provided under Medicaid. Clarification is also needed to address ingredients that are not included in the MediCal database. For co-packs, consideration should be given to adopting the principle underlying the repackaged drug policy: base the allowance for the co-pack on the individual pricing for the medical food and the generic drug.

*Physician incentives.* Physician-dispensing creates financial incentives that affect the use of compound drugs and the other products results. California's pharmacy code (beginning at Business & Professions Code section 4000) includes within the definition of pharmacy compounding the preparation of drugs "for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated

by the prescriber.” Review of sample bills indicates there may be issues with both the quantity and the frequency of the drugs that are dispensed by some physicians. Recognizing patient convenience is a reason for dispensing the initial supply, a reasonable approach would be to cover an initial physician-dispensed supply but not refills.

The financial incentives for physician-dispensing of compounded drugs could also be reduced significantly by limiting the amount payable under the OMFS to the amount that the provider paid for the products plus a reasonable mark-up. Even if the policy were not applied to compound drugs, it should be considered for medical foods for which there are no quantity limitations on physician-dispensing and determining an appropriate price is problematic.

Financial incentives may also be involved in physician prescribing of pharmacy-dispensed compound drug products and medical foods. California Labor Code section 139.3 precludes a physician from referring patients for certain designated services (e.g. clinical laboratory and diagnostic imaging) if the physician or his immediate family has a financial interest with the entity that receives the referral. Adding pharmacy goods and services (including OTC drugs and nutritional products) to the list of designated services would provide more assurance that prescribed products are medically appropriate.

California’s WC experience with repackaged drugs suggests that “quick fixes” may address issues in the short-term but that the issues are likely to re-emerge in another fashion unless the underlying incentives are addressed. The use of repackaged drugs declined significantly when it was no longer profitable for physicians to prescribe them. However, fixing the payment policy on physician-dispensing of repackaged drugs fueled the increased use of compound drugs, medical foods, and co-packs. The benefits gained from making policy changes to ensure these products are medically appropriate and payments are reasonable are also likely to be temporary unless greater attention is given to improving the overall incentives through selective contracting with high-quality efficient providers and appropriately rewarding their performance.