ADVISORY NO. 502

TOPIC: SOAH SAYS COMPOUND DRUG REQUIRES PREAUTHORIZATION

A judge at the State Office of Administrative Hearings has agreed with an insurance carrier that by compounding multiple ingredients into a single cream, a pharmacy created a new drug that the Food and Drug Administration has not recognized or approved. The judge concluded that the resulting cream is investigational or experimental, requiring preauthorization under Rule 134.530(b)(1)(C).

The June 2, 2016 decision in *Travelers Indemnity Co. of Connecticut v. American Specialty Pharmacy* (SOAH Docket No. 454-16-1884.M4-NP) came after the carrier appealed a Division decision awarding the pharmacy more than $1,600 for a prescription that had compounded several drugs into a topical cream prescribed to treat carpal tunnel syndrome.

The compound did not contain an "N" drug, that would have required preauthorization under Rule 134.530(b)(1)(B). So, the carrier made the case for preauthorization under subsection (b)(1)(C) that requires preauthorization of an investigational or experimental drug.

The carrier's expert, a Board-Certified Anesthesiologist with a PhD in pharmacology, testified that the compound constituted a new drug, is non-approved, and is not broadly accepted as the prevailing standard of care. Under Labor Code Sec. 413.014, an investigational or experimental drug is one for which there is early, developing scientific or clinical evidence demonstrating the potential efficacy of the treatment, but that is not yet broadly accepted as the prevailing standard of care, thus requiring preauthorization. The Carrier argued the compounded cream was a new drug, was investigational or experimental, and required the preauthorization the pharmacy had failed to obtain.

The carrier's expert also testified to the medical necessity question. The topical medication compounded from Fluriprofen POW, Cyclobenzaprine POW HCL, Baclofen POW, Ethoxy Liq Diglycol, Propylene Liq Glycol, and Versapro cream was not medically necessary and not within the accepted standard of care. The mix of drugs had apparently been "grabbed out of air."

The SOAH judge agreed and found that by compounding the multiple ingredients into a single cream, the pharmacy created a new drug that the FDA had neither recognized nor approved. The judge concluded that the topical cream was an investigational or experimental drug not broadly accepted as the prevailing standard of care. Thus, preauthorization was required. Absent that preauthorization, the pharmacy was not entitled to payment.

The carrier was aided by the pharmacy's failure to appear at the hearing and challenge the carrier's position. The carrier was also helped by the quality of its expert testimony. The carrier's witness is the editor of the Pain chapter of the Official Disability Guidelines.

The pharmacy still may appeal the decision to Travis County District Court under the substantial evidence rule. Absent evidence in the record controverting the carrier's expert, the obstacles to any successful appeal are indeed substantial.

This case is an important step in the struggle to deal with the compound drug issue, one increasing in frequency and cost. According to a recent study conducted by CompPharma, compounding prescriptions in the study data set increased almost five-fold from 2007 to 2012, increasing from 6,416 to 30,669. The study showed that compounding in Texas was on the rise, with six states – CA, TX, NY, FL, GA and PA – representing 80.10% of all compound prescriptions during the study period.

If carriers and self-insureds pursue the premise that a compound drug requires preauthorization, they should obtain medical support as demonstrated in the current SOAH case. And it may be prudent to also retrospectively review a compound for medical necessity. A good start is the following from the Official Disability Guideline: "The use of compound agents requires knowledge of the specific effect of each agent, and how it will be useful for the specific therapeutic goal required." The doctor and pharmacy must be able to scientifically justify the medical necessity of the drugs, singularly and in combination.

The Division of Workers' Compensation has not commented publicly on the decision. We are advised that implications of the decision are still under review by agency legal staff. Accordingly, at the current time, the Division has not indicated whether it agrees with the holding from the SOAH decision. Prior to the SOAH decision, the Division's position was that they did not view a compound as being an investigational or experimental drug and thus, unless that compound contained a drug identified with a status of "N", preauthorization was not required. The SOAH decision is not the last word on the issue.

Please contact Steve Tipton (smt@fol.com), Bobby Stokes (rds@fol.com) or James Sheffield (jrs@fol.com) if you should have any questions regarding this Advisory.