CompPharma

CompPharma Platform on Pharmacy Compounding

Issue:
Workers' compensation payers are concerned about the proliferation of compounded medications prescribed to injured workers despite the lack of the Food and Drug Administration (FDA) approval and clinical evidence to support efficacy and safety.

The overwhelming majority of compounds prescribed to injured workers are topical pain formulations (e.g., cream, ointments, and gels). These compounded topical formulations are being directly marketed to prescribers with primary emphasis on the profitability of these compounds coupled with claims of efficacy for pain.

The costs of these compounds are unjustifiably expensive. Payers are experiencing substantial increases in pharmacy benefits cost without subsequent improvement in therapeutic outcomes for injured workers (e.g., improvements in reported pain and function, return to work, and reduction in medication use, including opioids).

Background:
Pharmacy compounding is a practice of formulating, mixing, or altering active pharmaceutical ingredients (APIs), by or under the supervision of a licensed pharmacist, to create a unique medication intended for patient consumption. The practice of pharmacy began as compounding before drug manufacturing emerged as a business in the 1950s and '60s.

The practice of pharmacy compounding was gradually supplanted by drug manufacturing companies operating under the regulatory guidance and restrictions of the FDA. Under FDA regulations, drug manufacturers are legally permitted to market medications and make claims of efficacy only for the specific disease that has been thoroughly studied in randomized clinical trials. These trials result in specific dosing, frequency, duration of therapy, safety and efficacy monitoring parameters, etc.

Pharmacy compounding is not regulated by the FDA, which is responsible for "…protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs…," Instead, the practice of pharmacy compounding is under the purview of state boards of pharmacy.

Compounding can appropriately be utilized for the following general situations:

- **Drug shortages**- when manufacturers are unable to provide FDA-approved medications for various reasons, compounding pharmacies can prepare such medications until the shortage is

resolved. This represents a rare situation in which a compounding pharmacy is allowed to replicate an FDA approved medication.

- **Special dosage forms for patient populations with special needs**- this typically includes geriatric and pediatric patients. Patients who have lost ability to swallow (e.g., geriatric patients; patients with feeding tubes) and require a medication that is only available as a solid dosage form can have such medication altered into a liquid form. Pediatric patients may require an adult dose to be diluted, dosage forms changed, or even flavored.
- **Patients who have allergies** - some patients may be allergic to drug fillers such as lactose or color dyes. Compounding can be used to prepare drugs without such allergic substances. However, prescribers should look for an alternative non-compound drugs. A compound should be considered when it is the only option left.

Compounding should be reserved as a treatment option only when patient needs are not met by manufactured products. However, workers' compensation has seen a steady increase in prescriptions for topical compounded preparations and prescriptions for sterile compounded drugs. In fact, the use of compounded drugs in workers' compensation has increased nearly five-fold in the past five years. Along with increased use, the prices charged for compounds have risen dramatically.

A concerted effort has been launched by payers along with their pharmacy benefit managers (PBMs) to investigate, assess, and address this troubling trend. CompPharma researched the trend, and published its findings in 2013. Its compound drug research showed:

- Compounds have not been clinically proven to be more effective than commercially available, manufactured drugs. In fact, there is no efficacy data at all for the types of compounds seen in workers' compensation claims.
- Compounds pose a risk to patient health as they have not been proven safe by FDA standards
- Compounds are often not medically necessary
- The regulation and enforcement of compounding pharmacies varies from state to state, which makes it difficult to ensure safety and efficacy.

Recommendations:

CompPharma proposes the following recommendations in response to the initial findings of the investigation and assessment of the growing trend of compound use in workers' compensation:

1) **Jurisdictions should allow payers to implement prior authorization procedures for all compounded medications.**

   To assure the patient safety and medical necessity for compounded medications, a time-limiting prior authorization procedure would allow the payer the privilege to:

   - Seek documentation from the prescriber regarding the clinical rationale that supports the medical necessity of the compound (letter of medical necessity)

- Allow the payer and PBM partners to assess the documentation provided by the prescriber to ensure that all FDA approved options have been exhausted
- Seek specific descriptions and details from the pharmacy regarding the formulation and the methods used to make the compound
- Seek consent from the patient to verify the patient's understanding and acceptance that the compound is not an FDA approved medication and may pose unknown risk to patient health (informed consent)
- Ensure the pharmacy is properly licensed, registered, or accredited to provide compounding services
- Ensure no regulatory sanctions have been levied against the pharmacy

2) Jurisdictions should enhance billing and reimbursement requirements

To ensure that reimbursement for compounds are equitably administered for all payers:

- State fee schedules should support ingredient-level reimbursement equal to the sum of the allowable fee for each ingredient under the state's existing fee schedule for brand and generic drugs plus a single dispensing fee per compound
- Billing formats should be consistent with National Council for Prescription Drug Programs (NCPDP) D.0 standards that requires the pharmacy to submit line item details of all ingredients used in the compound

3) Jurisdictions should also consider expanding state-level "Sunshine" type laws to include required reporting by pharmacies

The determination of medical necessity for compounds requires collaborative efforts by the prescriber, payer, and payer consultants, such as medical directors, nurse case managers, utilization review services, and PBMs. The presence of financial incentives to prescribers undermines these efforts and may conflict with the medical necessity of such compounds.