Mitchell
6220 Greenwich Drive
San Diego, CA 92122
858.368.7000
mitchell.com

August 22, 2018

Industrial Commission of Arizona
800 West Washington Street
Phoenix, AZ 85007

Delivered via email to mro@azica.gov

Re: Prescription Dispensing in Closed-Door Pharmacy Settings

Dear Commissioners :

Earlier this year the Arizona Legislature passed SB1111. The legislation contained a provision directing the Industrial Commission to consider issues related to the dispensing of prescription medications in settings that are not accessible to the general public (closed-door pharmacy settings). Such settings include physician dispensing, non-network mail order pharmacies and non-retail compounding pharmacies. Thank you for the opportunity to offer our perspectives on the dispensing of prescription medications in these closed-door pharmacy settings and their impact on the Arizona workers' compensation system. Mitchell is a leading provider of pharmacy benefit management services, managed medical care, bill review, utilization review, independent medical reviews and EDI claims reporting in workers' compensation systems across the country. We have been a leading voice on policy issues related to providing the best, most cost-effective pharmacy care to injured workers. Our government affairs team is actively involved in legislative and regulatory discussions across the country related to the most effective delivery of pharmacy care to injured workers. Our experience in those policy developments helps shape the perspective shared in these comments.

States across the country are grappling with challenges associated with the dispensing of medications to injured workers from closed-door pharmacy settings. Employers and insurance carriers report increased claim costs associated with longer claim duration, higher medical costs and higher pharmaceutical costs when injured workers obtain their prescriptions in closed-door pharmacy settings.

In 2009, the Industrial Commission of Arizona adopted a fee schedule regulation aimed at curbing pricing abuses associated with repackaged medications being dispensed by physicians. Prior to the adoption of the regulation, bulk medications were repackaged and given a new National Drug Code (NDC) and "assigned" a new average wholesale price (AWP). The assigned AWP would often be 300-500% greater than the AWP of the same drug dispensed in a traditional retail setting. The regulation adopted in 2009 required reimbursement for repackaged drugs to be based on the NDC and AWP of the bulk product used in the repackaging. The regulation worked for a time until some creative repackagers approached select drug manufacturers and had them manufacture "boutique" drugs in unique strengths not available in a retail setting. The "boutique" drugs are assigned a new NDC and a new AWP which is often more than 100% higher than the same medication found in a different strength in a retail setting. The Workers' Compensation Research Institute (WCRI) released a study highlighting this practice in July

of 2017. One example of a "boutique" drug is cyclobenzaprine in a 7.5mg strength. The same medication is dispensed in retail pharmacies typically at 5mg or 10mg strengths. The WCRI report found: *"the price paid for the new strength was between $3.09 and $4.24 per pill, while the average price paid for the existing strengths ranged from $0.38 to $1.85 per pill…"*

Several states have taken action to minimize the problem with repackaged drugs by limiting when a physician can dispense medications to an injured worker. For example, Pennsylvania passed legislation in 2014, limiting physician dispensing to an initial, one-time, 7-day supply for Schedule II and III opioids and 30 days for all other drugs. California, as part of their drug formulary, requires physicians to obtain prior authorization from the claims administrator prior to dispensing a prescription except in an identified "initial fill" situation that occurs within the first 7 days following an injury. Most of those initial fills are limited to 4 days. Five states prohibit physician dispensing altogether. We are not aware of any clinical study that demonstrates better adherence or better outcomes when an injured worker obtains pharmacy care from their physician. In fact, our experience would indicate the opposite is true. Dispensing doctors frequently argue that allowing injured workers to access to medications in the doctor's office is more convenient for the patient. That may be true on an initial visit, but most injured workers will drive past several pharmacies when traveling to their doctor's office for a refill.

Another area of abuse we see in the closed-door pharmacy arena is compounded medications. There is a legitimate need for compounded medications for a small percentage of the population who can't use medications as they were designed to be used. Typically, a patient has tried and failed on a traditional medication before a compounded medication, tailored to their specific situation, is prescribed. Over the last several years, the workers' compensation industry has wrestled with high-cost compounds that are pre-packaged, mass-produced and distributed from the doctor's office or a mail-order facility to the patient. These compound creams and medications are frequently billed at well over $1,000 for a 30-day supply. The vast majority of the compounds have not undergone clinical trials to measure efficacy and are not FDA approved. We frequently see these high-cost compounds prescribed as first-line therapy without any indication that other therapies have been tried and failed.

Several states have capped reimbursement for compounded medications at a set rate. Colorado, for example, has a four-tiered reimbursement schedule for compounded topicals ranging from $80.00 for a 30-day supply to $370 for a 30-day supply. Texas, Arkansas, Tennessee, and California require prior authorization before a compounded medication can be prescribed.

One final area that should be addressed are mail-order pharmacies that are not affiliated or contracted with the employer or insurance carrier. These mail order pharmacies offer their services through legal counsel or physicians used by the injured worker. Costs for medications dispensed in these closed-door options frequently are 30-50% more expensive than the same medications dispensed in a retail pharmacy setting with no commensurate benefit for the additional cost. A number of states have addressed this issue by requiring injured workers to obtain pharmacy care from a pharmacy network designated by the employer. New York is one state that requires injured workers to use network pharmacies, with some exceptions for rural settings. If a non-network pharmacy dispenses a medication, they will be reimbursed at fee schedule until they are notified by the employer or insurance carrier that the injured worker is subject to a pharmacy network and future fills from the non-network pharmacy will not be honored.

Most employers and insurance carriers use a pharmacy benefit manager (PBM) to receive and process their prescription drug claims. PBMs help to ensure that the injured worker is receiving a medication that is appropriate for his/her injury, adheres to established, evidence-based treatment guidelines, and avoids

any potentially harmful interactions with other medications prescribed. The PBM can also identify situations where a patient is not refilling prescriptions in a timely manner, or is filling them too soon, both situations indicating the injured worker is not adhering to their pharmacy regimen appropriately. The PBM is also positioned to uncover drug use trends that could indicate an injured worker is becoming dependent or addicted to a particular medication. The more information a PBM has, the better able they are to ensure that an injured worker is receiving the most appropriate medication and is properly utilizing that medication. When a medication is filled in a closed-door pharmacy setting, the PBM is rarely aware of the fill until long after it happens, if at all, and too late to take advantage of any clinical controls that might be in place. The lack of clinical controls can lead to unnecessary prescribing of medications or the prescribing of less-effective medications for the worker's injury or illness, leading to increased pharmacy and medical costs and longer claim durations. The closed-door pharmacy settings mentioned above all circumvent the clinical controls that are in place to help ensure the injured workers is receiving the most appropriate care for their injury.

To help curb the problems we see associated with closed-door pharmacy settings, we recommend the following options:

- If the Commission has the statutory authority necessary, we recommend that the Commission adopt a rule allowing employers to establish a pharmacy network and require injured workers to use that network for obtaining pharmacy care. This option would allow for employers and insurers to curb current abuses and prevent future abuses by contracting with the various entities for reasonable reimbursement rates, and more importantly, connecting them into the technology that helps provide the clinical controls that are designed to deliver the best possible pharmacy care to the injured worker. Closed-door pharmacies would have the option of joining the network provided they agreed to adhere to the clinical controls and agree to reimbursement on par with the reimbursement for prescription medications in the retain setting. It is important to note that the networks of the major workers' compensation PBMs include over 80% of the retail pharmacies across the country. Some of those PBMs contract with a limited number of closed-door pharmacy providers.
- If the first option is not possible at this time, we recommend that prescriptions dispensed in a closed-door pharmacy setting be limited to an initial fill of 7-14 days, provided the medication is dispensed in the first seven days following the date of injury. The 7-14 day time frame allows for the claim to be established (or denied) and provides sufficient time for an injured worker to transition to a retail pharmacy setting.
- Reimbursement for medications in a closed-door setting should be comparable to reimbursement for medications dispensed in a traditional retail setting. If the pharmacy network option is adopted, the reimbursement for closed-door prescriptions will be managed by contract. If the limited fill option or no limits are imposed, reimbursement should be as follows:
    - Repackaged medications should be reimbursed as stated in the 2017 pharmaceutical fee schedule adopted by the Commission. We recommend adding language stating that "boutique" strength drugs not generally dispensed in the retail pharmacy setting shall not be prescribed or dispensed without prior authorization from the employer or insurance carrier. An employer or insurance carrier may deny payment for these medications if they are dispensed without prior authorization.
    - Compounded medications (in any setting) shall not be prescribed or dispensed without prior authorization from the employer or insurance carrier. An employer or insurance carrier may deny payment for these medications if they are dispensed without prior authorization.

We applaud the Arizona legislature and the Industrial Commission for recognizing the troubling practices experienced with closed-door pharmacies. We appreciate the opportunity to offer comment and recommendations. Should you have any questions about our comments, or require additional information, please contact Brian Allen, vice president of government affairs, at Brian.Allen@mitchell.com or at 801-903-5754.

Sincerely,

Brian Allen