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SARA A. AUSTIN

DATE: February 15, 2017

TO: The House Labor and Industry Committee

FROM: The Pennsylvania Bar Association

SUBJECT: H.B. 18, P.N 463

The concept behind this proposed legislation seeks to fundamentally transform the delivery of medical treatment to Pennsylvania's injured workers by imposing evidence-based drug formularies in an effort to control the wide-spread opioid crisis in Pennsylvania.

Defendants, employers, and carriers should pause before making this radical change to the long-standing workers' compensation law. Consider what happens if the evidence-based drug formularies selected are more favorable to either the employees, their unions, or their lawyers. In Wisconsin, an employer was prevented from cross-examining a physician appointed by the state's equivalent of the Department of Labor and Industry. That prohibition was affirmed by the Wisconsin Supreme Court[1]. The defendants in any workers' compensation matter should be vigilant about wanting a focused, individualized approach to employees presenting with an alleged work injury that requires treatment with prescriptions drugs. Bear in mind that selection of any evidence-based drug formulary will be influenced by the party in power in the administration, which is always subject to future change. This means that whatever the selected drug formularies are, they will be equally as immune from challenge by employers or carriers as they are from claimants.

Evidence-based drug formularies may actually increase cost, where the "evidence" identifies newer, patent protected and expensive biologic or genetic therapies which workers may then insist upon at increased cost. These additional regulations can also lead to increase compliance costs, particularly if the formulary is regularly updated as scientific studies indicate to the medical/legal panel that a particular drug is appropriate for diagnosis. This can lead to an unintended consequence of shifting the cost of work injuries to private or government agency health plan coverage as a work around to avoid the limits of a guideline or formulary.

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[1] *Aurora Consolidated Health Care v. Labor and Industry Review Commission*, 340 Wis. 2d 367, 814 N.W. 2d 824 (2012).

As for employees, the imposition of "one size fits all" drug formularies on injured workers places them at risk of losing individualized treatment for their specific injury. Instead of leaving treatment decisions to doctors and their patients, drug formularies will effectively delegate medical decisions to a panel far removed from the circumstances and nuances of each particular case. The proposed approached runs entirely against the current trend in medicine which is geared towards tailoring treatment to the individual based on multiple factors as opposed to simple cookbook medicine. We know of no epidemiological studies demonstrating the validity of these drug formularies, just studies that say we have an opioid epidemic in our state.

The mission statement of the Pennsylvania's workers' compensation program states that the program was "established to reduce injuries and provide lost wages and medical benefits to Pennsylvania employees who become ill or injured through the course of their employment so they can heal and return to the workforce."[2] The proposed drug formularies foster unfair treatment of both employers and injured workers by mandating treatment to comply with generic guidelines without regard to individual circumstances and potentially delaying healing and returning to work. Thus, the proposed drug formularies that risk individualized treatment by prescription drugs runs counter to the Pennsylvania's workers' compensation program mission statement.

Not only will these "cookie cutter" drug formularies effect Pennsylvania injured workers and employers it will affect Pennsylvania doctors. Additional treatment regulations will interfere with medical decisions exposing doctors to malpractice concerns should approved therapies run counter to a doctor's independent medical judgment. This could create the unwanted consequence of reducing the number of medical providers willing to treat work injuries. Furthermore, many questions will arise on how any new regulations will interface with regulations on topics as diverse as physician dispensing, opioid data base requirements, and medical cannabis.

Experience teaches that formularies, as adopted in other states such as Washington[3] and Wyoming,[4] rely heavily on the use of generic medications in place of brand names or new drugs under patent protection. This represents an unwarranted interference in medical decision making, which is best resolved by a doctor and a patient on a case by case basis since generic medications are not the same medication as a name brand. When a new drug is submitted to the Food and Drug Administration (FDA) the manufacturer must show the bioavailability of the drug and its active metabolites. In contrast, when a manufacturer submits a generic prescription drug to the

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[2] http://www.dli.pa.gov/Individuals/Workers-Compensation/publications/Documents/2015%20WC%20Annual%20Report.pdf

[3] Washington Department of Labor and Industries (February, 2016). Outpatient Formulary. Available at: http://www.lni. wa.gov/ClaimsIns/Files/Providers/DrugFormulary.pdf.

[4] Wyoming Division of Workers Compensation, Chapter 10, Sections 19 & 25. Available at: http://soswy.state.wy.us/Rules/ RULES/8195.pdf

FDA, they are not required to show data for active metabolites[5]. Also generic prescription drugs that are seeking FDA approval have to show between 80% and 125% of the bio availability[6] of the name brand equivalent. This is a significant amount of variability and suggests prescribing should be left to the doctor, not a regulatory process.

The Workers' Compensation Section of the PBA is divided roughly even between lawyers for employees or claimants and lawyers for employers or carriers with the addition of some workers' compensation judges and WCAB members. As advocates for those on both sides of workers' compensation claims, we believe that adopting drug formulary regulations will almost certainly produce unintended consequences for both employers/insurers and patients and is directly contrary to the express requirement of the Workers' Compensation Law that reasonable medical services must be provided to injured workers.

Sincerely,

Sara A. Austin

Sara A. Austin, President
Pennsylvania Bar Association

[5] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm389370.pdf
[6] Bio availability is measured as the time to achieve the peak concentration of the drug in the bloodstream and the total amount of drug absorbed into the body.