



Workers' Compensation Board Pharmacy Benefit Plan

1.0 Introduction

Options for pharmaceutical care have greatly expanded over the past several years. New pharmaceuticals and pharmaceutical treatment modalities are introduced to the medical community on an almost daily basis. Prescribers continue to be deluged by the pharmaceutical industry, patient requests, print and other media, all trying to impact prescribing patterns.

The current New York Workers' Compensation Board (WCB) pharmacy benefit provides little structure, guidance or oversight as to what prescribers may prescribe for claimants. Although reimbursement levels for brand, generic and compounded products are established, there are few parameters as to what medications can be utilized.

The Board is considering the implementation of a drug formulary which will provide stronger oversight of medications to ensure high-quality cost-effective medications are selected and that they are used for an approved indication and/or via an approved route of administration.

2.0 Current Benefit Structure

- A. Subchapter M of the Codes, Rules and Regulations of New York, Pharmacy and Durable Medical Goods Fee Schedules and Appendices, describes the structure of the pharmacy benefit plan for claimants in New York's Workers' Compensation system. Part 440 describes the Pharmacy Fee Schedule, applicability, etc.
- B. The current pharmacy benefit plan, which has been in effect since July 11, 2007, defines the payment methodology for medications prescribed by Workers' Compensation Board approved practitioners. The reimbursement schedule is as follows¹:

Status	Drug Item	Price	Dispensing Fee	Reimbursement
Uncontroverted	Brand	AWP ² – 12%	\$4.00	Price + Dispensing Fee = "X"
	Generic	AWP – 20%	\$5.00	Price + Dispensing Fee = "Y"
Controverted	Brand		\$6.00	"X" plus 25% plus \$6.00
	Generic		\$7.50	"Y" plus 25% plus \$7.50
	Compounded Product	Sum of ingredient costs	"single dispensing fee per compound"	

¹ This pricing structure shall not apply to prescription drugs or medicines provided as part of treatment governed by the medical and hospital fee schedule (§440.5(e)).

² "Average Wholesale Price" or "AWP" means the average wholesale price of a prescription drug as provided in the most current release of the Red Book published by Thomson Reuters or Medi-Span Master Drug Database by Wolters Kluwer Health or any successor publisher, on the day a prescription drug is dispensed or other nationally recognized drug pricing index adopted by the Chair or Chair's designee.

- C. Authorized prescribers may order any medication they choose. There is no drug formulary in place; no requirement for preapproval/prior authorization; no process to insure high-quality cost-effective medications are utilized.
- D. In accordance with Workers' Compensation Law, §440.6, when a brand name drug is prescribed to treat an injury for which a self-insured employer or insurance carrier is liable, a generic equivalent, if available, shall be provided unless the prescribing physician specifically provides otherwise on the prescription in accordance with New York Education Law §6810(6).
 - 1. Payment is made for Food and Drug Administration (FDA) approved medications regardless of whether the medication is prescribed for an approved indication and/or via an approved route of administration. For example, compounded topical products, composed of multiple commercially available products, are prescribed and reimbursed by carriers. However, the topical route of administration for many of these products is not approved by the FDA. There have been several reports in the literature of harm to patients and/or family members, including death, subsequent to receiving these preparations³.
- E. AWP which is utilized for reimbursement is subject to "manipulation."
 - 2. The AWP of a drug often varies based on package size (i.e. a bulk package of 10,000 units typically has a lower AWP per unit than a package size of 100 units).
 - 3. Products can be acquired by a pharmaceutical distributor in large quantity packages, repackaged into smaller containers, assigned a new National Drug Code (NDC) by the distributor/re-packager, and sold at significantly higher AWP on a per unit basis. This results in a relatively inexpensive product becoming very expensive. These higher prices (of repackaged items) are utilized to calculate the reimbursement outlined in current regulations.

3.0 Recommendation

The Board needs to establish a comprehensive prescription drug benefit program that addresses the issues identified above and works to ensure that claimants receive high-quality cost-effective medications.

Options for a NYS Workers' Compensation Prescription Drug Program include, but are not limited to:

- A. Recommend carriers contract with a Pharmacy Benefit Manager (PBM) for the administration of a pharmacy benefit outlined by the Board, including implementation of the established NYS Workers' Compensation Prescription Drug Formulary.
- B. Establish a Workers' Compensation Prescription Drug Formulary that would include:
 - 1. Tiered level coverage,
 - 2. Preferred Drug List, and
 - 3. Determine disposition of drug rebates.
 - 4. Require preapproval for non-formulary, non-preferred items.
- C. Provide payment only for drugs that are administered via an FDA-approved route of administration.
- D. Impose limitations on the prescribing of compounded medications.
 - 1. Billable monthly only.
 - 2. Require that route of administration for the compounded drug is FDA-approved.
 - 3. Establish a fair dispensing fee for compounded medications.
- E. Require compliance with MTGs on drug recommendations for all prescriptions, both inside and outside of NYS.

³ Pomerleau A, Gooden C, Fantz C, Morgan B, Dermal Exposure to a Compounded Pain Cream Resulting in Severely Elevated Clonidine Concentration, *J. Med. Toxicology* (2014) 10:61064

Pollack A, Pharmacies Turn Drugs into Profits, Pitting Insurers vs. Compounders, *The New York Times*, August 13, 2014.

- F. Adjust reimbursement methodology
 - 4. AWP of largest available container
 - 5. Modify discount off AWP for both brand and generic products.

3.1 Pharmacy Benefit Manager (PBM)

- A. Require all carriers/self-insured employers provide PBM services. The PBM would be responsible for administering the drug benefit program on behalf of the carrier (or self-insured employer).
- B. The carrier /self-insured, via the PBM, would be responsible for ensuring compliance with established guidelines and protocols, processing and paying prescription drug claims, contracting with pharmacies, making recommendations regarding the creation of a NYS Workers' Compensation Formulary and ongoing updates to the formulary.
- C. This would work to drive high-quality care while controlling total prescription spend, consistent with WC regulations/requirements, and negotiating discounts and rebates with drug manufacturers.
- D. Consistent with current regulations, employers would be required to post information about the pharmacy network and/or incorporate this notification into their new employee orientation process, as well as directly notify each employee when an injury is reported to the employer (in the claimant information package).
- E. The Board, working with stakeholders, would be responsible for establishing the PBM program criteria, formulary and performance monitoring standards.

3.2 Pharmacy Reimbursement Strategy

- A. The PBM would be responsible for working with the payer to implement the Board-defined reimbursement strategy for brand and generic products (i.e. AWP minus a fixed percentage plus a dispensing fee).
- B. Other strategies should be implemented by the PBM, including the requirement that reimbursement must be based on the AWP of the package size actually being used for dispensing and reimbursing NDCs for repackaged drugs based on the original manufacturer's AWP.
- C. The Board, in conjunction with stakeholders and their PBMs, would also establish a Maximum Allow Cost (MAC) List. The MAC list generally refers to a list of products that includes the upper limit or maximum amount that a plan will pay for generic drugs and brand name drugs that have generic versions available (multi-source brands).
 - 1. Some of the factors that would be considered when setting prices and choosing products for inclusion on the MAC list are: availability of the product in the marketplace; whether the product is available from more than one manufacturer; how the product is rated by the FDA in relation to the brand drug, and price differences between the brand and generic products.
- D. The concept of reimbursement at the lesser of contractual allowance, or "usual and customary", should be introduced as well.

3.3 Establish a Workers' Compensation Prescription Drug Formulary

- A. A prescription drug formulary is a listing of medications that are approved to be prescribed/dispensed under a particular insurance plan.
 - 1. Formulary development and maintenance is a dynamic process.
 - 2. Selection of products for inclusion in the formulary is based, first on clinical efficacy and safety, and then on cost-effectiveness of the drug.
 - 3. Drugs may be assigned to tiers or levels so that preferred drugs can be prescribed without additional approval and other drugs would require pre-approval.
 - 4. The preferred drugs would correlate with the Board's MTG's recommendations.

- B. The PBMs would also be responsible for administering a prescription drug rebate program (i.e. to work with drug manufacturers to negotiate rebates for formulary items).
 - 1. The rebate program would be utilized to offset the total overall cost of the medications.
- C. Administration of a pre-approval program for non-preferred and non-formulary medications would also be the responsibility of the PBM.
- D. The formulary would establish criteria related to the prescribing of medications.
 - 1. One such requirement should be that medications that are covered under the program must be delivered via a FDA-approved administration route for the prescribed product. This would serve to eliminate the prescribing of treatment modalities of questionable efficacy (i.e., administering medications approved for oral administration via the transdermal route).
- E. Additionally, the formulary would establish and implement standards for prescribing medication. Such standards should include:
 - 1. Maximum days' supply.
 - 2. Quantity limits.
 - 3. Mandatory generic prescribing.
 - 4. Maximum requested refills per month (i.e. when compounded topical preparations are pre-approved, ensure that the prescription quantity is sufficient to provide a month's supply to the patient, or other quantity as approved via the pre-approval process).

3.4 Pre-Approval Program

- A. A pre-approval program should be implemented as part of the PBM's scope of services.
- B. Pre-approval is an approach used by payers to decide if they are going to pay for a particular medication for a particular patient in a particular instance before the drug is dispensed.
- C. It is incumbent on the prescribing physician to obtain pre-approval based upon the WCB established formulary.
- D. Examples of when pre-approval might be required include:
 - 1. Prescribing of a brand name product when a generic equivalent or generic therapeutic equivalent exists.
 - 2. Costly medications; potentially including all medications over "X" dollars, all compounded products (including topical treatments), etc.
 - 3. Drugs not on the formulary and identified as medically necessary by the prescriber. Often more than one drug can be used to treat a particular medical condition. If a prescriber requests a particular medication, the prescriber must justify why the requested drug is required and why the formulary drug(s) is/are not acceptable for the patient.
 - 4. The WCB will establish an appeals process that can be utilized by providers who are dissatisfied by the decision(s) of the PBM.
 - 5. Drugs usually covered by the insurance company but are being used at a dose higher than "normal."
 - 6. Prescribing outside of the Board's MTGs would be incorporated into the pre-approval program.

3.5 Drug Utilization Review (DUR)

- A. The PBM should implement a DUR on behalf of the payer.
- B. DUR programs help to ensure that prescriptions for outpatient drugs are appropriate, medically necessary, and not likely to result in adverse medical consequences and/or drug-drug interactions.

- C. DUR programs utilize professional medical protocols, computer technology and data processing to assist in the management of data regarding the prescribing of medications and the dispensing of prescriptions over periods of time.
- D. Responsibilities of DUR programs typically include:
 - 1. Establishing and implementing medical standards and criteria for retrospective and concurrent DUR programs;
 - 2. Developing, selecting, applying and assessing education interventions for physicians, pharmacists and claimants that improve overall claimant population care;
 - 3. Reviewing therapeutic classes subject to the preferred drug program; and
 - 4. Insuring compliance with Non-Acute Pain Opioid Monitoring recommendations and other MTGs accepted by the Board.
- E. The development and use of the Board's MTGs should correlate with DUR activities.

3.6 Physician Dispensing

- A. Physician dispensing currently aligns with New York State Education rules, allowing a physician to dispense a 72-hour supply of a medication.
- B. The Board might consider limiting this to dispensing commercially available oral medications only and not allowing payment to physicians for dispensing compounded topical preparations.
- C. Reimbursement for physician dispensing should be comparable to that which would be made at a commercial pharmacy.

4.0 Summary

The need to provide high-quality, cost-effective pharmaceutical care to claimants in New York's workers' compensation system continues to be a challenge. Similar to other states, New York is challenged by the utilization of pharmaceutical products with questionable efficacy and increasing cost.

The Board should work with Stakeholders to establish a comprehensive pharmacy benefit plan that will insure the availability high-quality, cost-effective medications for claimants, mitigate the limitations of the current benefit structure and increase agility in evaluating new drugs and responding to new pharmaceutical issues or concerns as they arise.