Section 440.2 of Part 440 of Title 12 NYCRR is amended to read as follows:

Section 440.2. Definitions

Section 440.2 has added new definitions and renumbered the sections accordingly. 440.2(c), (d), (f), (i)(3)(ii), (n) and (r) are new or substantially changed, and appear below:

(c) "Calculated cost" means the Average Wholesale Price for the national drug code of the prescription drug or medicine on the day it was dispensed plus a dispensing fee. For brand name drugs the Calculated cost shall be AWP minus twelve percent of the Average Wholesale price plus a dispensing fee of four dollars. For generic drugs the Calculated cost shall be AWP minus twenty percent plus a dispensing fee of five dollars.

(d) "Contract price" means the maximum amount that a designated pharmacy (as set forth in section 440.3 of this Part) will pay a pharmacy for generic drugs and brand name drugs that have generic versions available (multi-source brands).

(f) "Formulary" means the New York Workers' Compensation Formulary which is a list of drugs for work-related injuries that is incorporated by reference in section 441.2 of this Part and that must be used to prescribe medication for all Disability events. The Formulary includes medications available in Phase A and B; and, also includes a list of medications available for Perioperative periods that may be prescribed without Prior Authorization during the applicable Phase or Perioperative period.

(g) "Generic drug" means an FDA-approved drug that is therapeutically equivalent to a brand name drug, as determined by the FDA's designation of the drug with the Therapeutic Equivalence Evaluation Code designation as an "A" product in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the Orange Book), irrespective of dosage for the route of administration (oral, topical or systemic) prescribed. A brand name drug may not be dispensed when a generic version of the same active ingredient is commercially available in a different strength/dosage.

(i) "Pharmacy benefit management" means the services provided to a self-insured employer or insurance carrier, directly or through another entity, including:

(3) the administration or management of prescription medicine or drug benefits, including, but not limited to, any of the following:

(i) mail service pharmacy;

(ii) claims processing, New York Pharmacy Formulary administration and prior authorization review, retail network contracting and management, or payment of claims to pharmacies for dispensing prescription medicines or drugs;

(n) "Repackaging" is the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further

manipulation of the drug. Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container when the container does not include other ingredients.

(r) "Usual and Customary price" means the retail price charged to the general public for a prescription drug.

Subdivision (d) of Section 440.3 of Part 440 is amended to add that prior to filing prescribed notice of the decision in a controverted case, the claimant may be prescribed and the carrier/self-insured employer will be responsible for the cost (see section 440.5) of medications from Phase A, B, or Perioperative section the Pharmacy Formulary as applicable.

A new subdivision (g) is added to Section 440.3 of Part 440 to read as follows:

(g) Any rebates or third-party revenue related to drugs dispensed through a contract for pharmacy benefit management and delivered to the designated pharmacy shall be passed through in full to the insurance carrier or self-insured employer in accordance with contract terms that document the methodology for such transactions. Carriers shall offset bills to insured employers by the amount of any passed-through rebate and third-party revenue. Such rebates and third-party revenue shall be reported at least annually to the carrier or self-insured employer and reported by the carrier or self-insured employer to the Chair upon request.

Section 440.5 of Part 440 is amended to read as follows:

Section 440.5. Fee schedule

(a)(1) On or after October 1, 2019, the maximum reimbursement or payment for New York Workers' Compensation Formulary drugs or, when applicable, for drugs that received Prior Authorization in accordance with section 441.4 of this Chapter, including all brand name and generic prescription drugs or medicines, shall be the lesser of the calculated cost, the contract price (for designated pharmacies), or the usual and customary price for the prescription drug or medication.
(2) The maximum reimbursement for prescription drugs or medicines dispensed in controverted cases during the period the case is controverted, including all brand name and generic prescription drugs or medicines, shall be twenty-five per cent more than the calculated cost at the time the prescription drugs or medicines are provided if the case was uncontroverted, plus a

dispensing fee of seven dollars and fifty cents for generic prescription drugs or medicines and six dollars for brand-name prescription drugs or medicines. Prior to the filing of a prescribed notice denying the claim for workers' compensation, the claimant may be prescribed and the insurance carrier or self-insured employer will be responsible for the cost (as set forth in subdivision (a)(1) of this section) of medications from, as applicable, Phase A, B, or the Perioperative section of the Pharmacy Formulary.

(3) Nothing in this section shall bar a self-insured employer or insurance carrier from providing a lower reimbursement rate or dispensing fee pursuant to a written agreement with any independent pharmacy, pharmacy chain, or pharmacy benefit manager.

(4) The maximum reimbursements or payments for prescription drugs or medicines set forth in this subdivision shall be the maximum payment any individual or entity may receive from any claimant, individual, entity, self-insured employer, insurance carrier, or third party in connection with a claim for workers' compensation benefits.

(b) Fees for pharmacy benefit management shall be established by agreement between the self-insured employer or insurance carrier and the independent pharmacy, pharmacy chain, or pharmacy benefit manager. Fees to a pharmacy processing agent shall be established by agreement between the independent pharmacy, pharmacy chain, or pharmacy benefit manager and the pharmacy processing agent. The Chair may audit agreements from time to time for the purpose of ensuring compliance with this Part.

(c) Notwithstanding any other provision of this Part, if a prescription drug or medicine has been repackaged, the Average Wholesale Price used to determine the maximum reimbursement shall be the Average Wholesale Price of the underlying drug product, as identified by its national drug code (or NDC), of the underlying drug product used in the drug packaging. If the NDC is not supplied with the bill for the prescription drug or medicine, the self-insured employer or insurance carrier may identify the NDC of the underlying drug product to calculate reimbursement. While a pharmacy may engage in repackaging by removing a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different (often smaller container), the pharmacy may not charge a fee that exceeds the AWP for the container in which the finished drug product was distributed by the original manufacturer prior to any repackaging.

(d) Compound drug, as defined in subdivision (a) of section 441.1, shall be reimbursed at the ingredient level, with each ingredient identified using the applicable NDC of the drug product, and the corresponding quantity. Ingredients with no NDC are not separately reimbursable. When a compound drug is prescribed and dispensed in accordance with subdivision (a) of section 441.1 or pursuant subdivision (m) of section 441.1 (Prior Authorization), payment shall be based upon

a sum of the allowable fee for each NDC ingredient(s) plus a single dispensing fee of six dollars per compound drug.
(e) The fee schedule created by this section shall not apply to prescription drugs or medicines provided as part of treatment governed by the medical and hospital fee schedule issued pursuant to Workers' Compensation Law Section 13.

Section 440.6 of Part 440 is amended to read as follows:

Section 440.6. Prescription drugs or medicines

(a) When a brand name drug is prescribed to treat an injury for which a self-insured employer or insurance carrier is liable pursuant to Workers' Compensation Law Section 13, a generic drug equivalent, if a generic equivalent is available, shall be provided unless the prescribing physician obtains Prior Authorization pursuant to subdivision (m) of section 441.1.
(b) A billing statement submitted to a self-insured employer or carrier for a prescription drug that has been dispensed shall include the national drug code number of the prescription drug as listed in the national drug code directory maintained by the federal Food and Drug Administration and shall state separately the price of the prescription drug and the dispensing fee.

Subdivisions (a) and (b) of Section 440.8 of Part 440 are amended to read as follows:

(a) Upon receipt of a bill or reimbursement request for prescription medicine, the self-insured employer or insurance carrier shall pay or reimburse the claimant, pharmacy, pharmacy benefit manager, pharmacy processing agent or third party within forty-five days of receipt of the bill or reimbursement request in accordance with section 440.5 of this Part, unless:
(1) The drug was not prescribed consistent with Part 441 of this Chapter (New York Workers' Compensation Formulary); or
(2) The insurance carrier or self-insured employer has denied the claim in accordance with Workers' Compensation Law section 25 (2), and section 300.22 of this Chapter.
(b) Where the self-insured employer or insurance carrier denies payment of all or a portion of a pharmacy bill pursuant to subdivision 1 herein, it shall pay any undisputed amount of the bill or reimbursement request and notify the claimant, the claimant's representative, if any, as well as the pharmacy, or pharmacy benefit manager, pharmacy processing agent, or third party which submitted the bill or reimbursement request, as appropriate. A notice to the pharmacy, pharmacy benefits manager, pharmacy processing agent, or third party must be made for each claim; denial of multiple claims in a single notice are not in compliance with this Section. Such notice shall be made to all parties on the same day within forty-five days of receipt of the claim or

reimbursement request and shall state that the claim is not being paid and the reason for non-payment of the claim.