

Section 440.1 of Part 440 of Title 12 NYCRR is amended to read as follows:

This pharmaceutical fee schedule is applicable to prescription drugs or medicines dispensed on or after the most recent effective date of section 440.5 of this part for medical care or treatment of an injured employee, regardless of the date of accident or date of disablement. [The date that the prescription drug or medicine is dispensed shall be the applicable date for reimbursement in accordance with this fee schedule.] Prescription drugs shall be reimbursed in accordance with the fee schedule as set forth section 440.5 in effect on the date the prescription drug is dispensed. [Prescription drugs or medicines dispensed prior to July 11, 2007, shall be reimbursed at the usual and customary rate in the location where the claimant resides. Prescription drugs or medicines dispensed on or after July 11, 2007, but prior to the most recent effective date of section 440.5 of this part, shall be reimbursed pursuant to the fee schedule in section 440.5 of this part in effect on the date the prescription drug or medicine was dispensed.]

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

Section 440.2. Definitions

(a) “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.

(b) “Brand name drug” means a drug for which an application is approved under the Federal Food, Drug, and Cosmetic Act Section 505(c).

(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).

([c]e) “Controlled substance” has the meaning provided in Public Health Law Section 3306.

(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.

([d]g) “Generic drug” means [a drug for which an application is approved under the Federal Food, Drug, and Cosmetic Act Section 505(j)] 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[s] is commercially available in a different strength/dosage.

([e]h) “Independent pharmacy” means a pharmacy (including a remote pharmacy) that is not part of a pharmacy chain.

([f]i) “Insurance carrier” means the State Insurance Fund, stock corporations, mutual corporations or reciprocal insurers with which employers have insured, and any special fund maintained by the Board that is responsible for paying for medical treatment and care of injured workers, including but not limited to, the Special Fund for Reopened Cases created and governed by Workers' Compensation Law Section 25-a and the Uninsured Employers' Fund created and governed by Workers' Compensation Law Section 26-a.

([g]j) “Pharmacy benefit management” means the services provided to a self-insured employer or insurance carrier, directly or through another entity, including:

(1) the negotiation of the amount to be paid for prescription medicine or drugs by the self-insured employer or insurance carrier and the amount paid to an independent pharmacy, pharmacy chain, or remote pharmacy dispensing prescription medicine or drugs;

(2) procurement of prescription medicines or drugs to be dispensed to injured employees; or

(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;

(iii) patient compliance, therapeutic intervention, or generic substitution programs;

(iv) disease management; and

(v) retrospective review.

([h]k) “Pharmacy benefit manager” means any entity that performs pharmacy benefit management for a self-insured employer or insurance carrier.

([i]l) “Pharmacy chain” means any entity that has been designated by a carrier or self-insured employer under section 440.3(a) of this Part that is:

- (1) a group of pharmacies (including remote pharmacies) under common ownership; or
- (2) a group of pharmacies (including remote pharmacies) linked to the same company via franchise agreements.

([j]m) “Pharmacy Processing Agent” means person or entity that contracts with a pharmacy as permitted by law, establishing an agent or assignee relationship, to process claims and act on behalf of the pharmacy under the terms and conditions of a contract related to services being billed. Such contracts may permit the agent or assignee to submit billings, request reconsideration, receive reimbursement, and seek medical dispute resolution for the pharmacy services billed.

([k]n) “Remote pharmacy” means any pharmacy that sells anywhere in New York State by mail, phone and/or Internet.

(o) “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.

([l]p) "Rural area" means counties within the state having a population of less than two hundred thousand, and the municipalities as are found therein, and in counties having a population of two hundred thousand or greater, "rural areas" means towns with population densities of one hundred fifty persons or less per square mile, and the villages and other municipalities as are found therein. For purposes of this Part, a rural area does not include municipalities which are incorporated cities or villages having a population of 2,500 or more.

([m]q) “Self-insured employer” means an employer permitted by the Chair to pay compensation and medical benefits directly under the provisions of Workers' Compensation Law Section 50(3), (3-a) or (4).

([n]r) “Third party payor” means any self-insured employer, insurance carrier, nonprofit hospital service plan, health care service plan, health maintenance organization, or any person or other entity which provides payment for medical and related services.

(s) “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 read as follows:

(d) In any claim controverted by the self-insured employer or insurance carrier pursuant to Workers' Compensation Law Section 25(2), where the self-insured employer or insurance carrier will not reimburse the designated independent pharmacy, pharmacy chain, or pharmacy benefits manager for prescription medicines dispensed to the claimant until the controversy is resolved and the claim established, even under the provisions of Workers' Compensation Law Section 21-a, the self-insured employer or insurance carrier shall provide notice of this decision to the claimant with the notice that the right to compensation is controverted. Such notice shall be in the form prescribed by the Chair, and shall state that the self-insured employer or insurance carrier does not intend to reimburse the independent pharmacy, pharmacy chain, or pharmacy benefit manager it has designated while the claim is controverted and until it is established, and the claimant may elect to use a pharmacy not designated pursuant to this Part during the period that the claim is controverted. Prior to the filing of such prescribed notice, the claimant may be prescribed and dispensed and the insurance carrier or self-insured employer will be responsible for the cost (as set forth in section 440.5 of this Part) of medications from, as applicable, Phase A, B or the Perioperative section of the Pharmacy Formulary. In the event the claimant prevails on his or her claim, the self-insured employer or insurance carrier shall reimburse either:

- (1) the claimant, the pharmacy processing agent, or other third party that has made payment for such medication; or
- (2) the pharmacy from which the claimant has obtained such medication where the pharmacy has not received payment from the claimant, the pharmacy processing agent, or any third party. Such reimbursement shall not exceed the maximum amount set by the fee schedule for controverted claims in section 440.5 of this Part. In the event the self-insured employer or insurance carrier prevails, it shall have no obligation to reimburse the claimant, the pharmacy processing agent, or any third party that paid for such medication, or pharmacy. Nothing in these regulations shall bar the pharmacy or pharmacy processing agent or other third-party payor from seeking payment or reimbursement from the claimant if the claim is not established as otherwise permitted by law.

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) (i) Prior to October 1, 2019, t[T]he maximum reimbursement or payment for prescription drugs or medicines in uncontroverted cases, including all brand name and generic prescription drugs or medicines, shall be the Average Wholesale Price for the national drug code for the prescription drug or medicine on the day it was dispensed minus twelve percent of the Average Wholesale price plus a dispensing fee of four dollars for brand name drugs or medicines, minus twenty percent of the Average Wholesale Price plus a dispensing fee of five dollars for generic drugs or medicines.

(ii) On or after October 1, 2019, the maximum reimbursement or payment for New York Workers' Compensation Formulary drugs or when applicable, 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 dispensed 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 maximum reimbursement must be calculated using the AWP for the container in which the finished drug product was distributed by the original manufacturer prior to any repackaging.

(d) Compound[ed medications] 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), [P] payment shall be based upon a sum of the allowable fee for each NDC ingredient(s) a set forth in this section, plus a single dispensing fee of six dollars per compound drug. Compound drugs with any Non-Formulary drug ingredient and/or for Formulary drugs being prescribed for other than an FDA approved route of administration are not reimbursable.

(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 [specifically provides otherwise on the prescription in accordance with New York Education Law Section 6810(6)].

(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] maximum reimbursement (as set forth in subdivision [a] of section 440.5 herein) of the prescription drug and the dispensing fee as applicable.

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 liability of the self-insured employer or insurance carrier for the claim has not been established] The drug was not prescribed consistent with Part 441 of this Chapter (New York Workers' Compensation Formulary); or

(2) [the prescribed medicine is not for a causally related condition; or] 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.

[(3) the prescribed medicine was not prescribed consistent with the medical treatment guidelines set forth in section 342.2 (a) of Part 342 of this Title.]

(b) Where the [liability of the self-insured employer or insurance carrier for the claim has not been established, or the prescribed medicine is not for a causally related condition, or the prescribed medicine was not prescribed consistent with the medical treatment guidelines set forth in section 342.2 of this title, 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[:

(1)]that the claim is not being paid and the reason for non-payment of the claim[; or

(2) that additional information is needed to reasonably determine the self-insured employer's or insurance carrier's liability for the claim, whether the medicine is causally related to the injury, or whether the prescribed medicine was prescribed in accordance with the medical treatment guidelines and to request such information Upon receipt of the information reasonably requested by this paragraph, the self-insured employer or insurance carrier shall have twenty days to pay the bill or reimbursement request or provide a written explanation why the bill is not being paid, with copies of the additional information requested attached to the explanation to support the determination. The written explanation shall be sent by the self-insured employer or insurance carrier to the claimant, pharmacy, pharmacy benefit manager, pharmacy processing agent or third party that submitted the bill or reimbursement request, the claimant's legal representative, if any, and the Board on the same day].