Section 440.2 of Title 12 of NYCRR is amended to add a new subdivision (g) as follows:

(g) Any rebates delivered to the designated pharmacy shall be passed through in full to the insurance carrier or self-insured employer to ensure savings to the overall cost of the program. Such rebates shall be reported annually to the carrier or self-insured employer and reported to the Chair upon request.

Subchapter M of Chapter V of Title 12 of NYCRR is amended to add a new Part 441 as follows:

441 Pharmacy Formulary

441.1 Definitions.

(a) “Preferred drug” means a drug on the New York Pharmacy Formulary that does not require prior authorization. The Preferred status of a drug is designated in the column with the heading labeled “Preferred/Non-Preferred”.

(b) “Non-Preferred drug” means a drug on the New York Pharmacy Formulary that requires prior authorization by the insurance carrier or self-insured employer before dispensing. The Non-Preferred status of a drug is designated in the column with the heading labeled “Preferred/Non-Preferred”.

(c) “Unlisted drug” means a drug that does not appear on the New York Pharmacy Formulary and which is one of the following: a Federal Drug Administration (FDA) approved prescription drug; an FDA-approved nonprescription drug; or a nonprescription over the counter drug that is marketed pursuant to an FDA OTC Monograph.

(d) “Compound drug” means a drug that is created by combining one or more active pharmaceutical ingredients, and one or more inactive ingredients, to meet specific patient medical needs that presumably cannot be met with FDA-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace. For the purposes of this subchapter, a compound drug shall be treated the same as a Non-Preferred drug but at all times shall be subject to federal law governing compounding, including title 21, United State Code, sections 353a, 353a-1, 353b.

(e) “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).

(f) “New York Pharmacy Formulary” or “Pharmacy Formulary” means the drug list incorporated by reference in section 441.3 of this Part.

(g) “Dispense” or “dispensed” means (1) the furnishing of a drug upon a prescription from a physician or other health care provider acting within the scope of his or her practice, or (2) the furnishing of drugs directly to a patient by a physician acting within the scope of his or her practice and pursuant to the dispensing limitations set forth in section 6807(2) of the Education Law.

(h) “Special Fill policy” means the policy set forth in subparagraph (a) of paragraph (5) of subdivision (d) of this section, allowing dispensing of identified Non-Preferred drugs without obtaining prior authorization where the drug is dispensed at the initial treatment visit following a workplace injury, where the visit occurs within seven days of the date of injury.

(i) “Perioperative Fill policy” means the policy set forth in paragraph (2) of subdivision (e) of section 441.4 of this Part, allowing dispensing of identified Non-Preferred drugs without obtaining prior authorization where the drug is prescribed within the perioperative period and meets specified criteria. Perioperative period refers to the four days before and four days after the
patient goes into the hospital, clinic, or doctor's office for surgery; with the day of surgery being day zero.

(j) “FDA-approved drug” means a prescription or nonprescription drug that has been approved by the FDA under the federal Food, Drug, and Cosmetic Act, title 21, United States Code, section 301 et seq.

(k) “FDA OTC Monograph” means a data standards manual (DSM) established by the FDA setting forth acceptable ingredients, doses, formulations, and labeling for a class of over the counter drugs.

(l) “Prior Authorization” means the review procedure conducted prior to the dispensing of a Non-Preferred drug, or a drug prescribed that is not in accordance with the Medical Treatment Guidelines.

441.2 Applicability of the New York Pharmacy Formulary.

(a) On or after July 1, 2018, every new prescription shall be dispensed consistent with the Pharmacy Formulary regardless of the date of accident or disablement unless prior authorization is received to dispense a non-preferred or unlisted drug.

(b) On or after December 31, 2018, every refill and renewal prescription shall be dispensed consistent with the Pharmacy Formulary regardless of the date of accident or disablement unless prior authorization is received to dispense a non-preferred or unlisted drug.

(c) No later than October 1, 2018, the insurance carrier or self-insured employer shall identify all claims that have been prescribed for an unlisted or Non-Preferred drug and provide written notification to the injured employee and Treating Medical Provider, which contains the following information: (a) the notice of the impending date and applicability of the New York Pharmacy Formulary and (b) a process for determining an equivalent preferred drug as well as the process to request prior authorization for a Non-preferred or unlisted drug.

441.3 Incorporation by Reference.

The New York Pharmacy Formulary incorporated by reference herein, lists the drug ingredient, preferred status, and drug class. Copies of the formulary may be downloaded from the Board's website free of charge. The formulary may be examined at the office of the Department of State, 99 Washington Avenue, Albany, New York, 12231, the Legislative Library, the libraries of the New York State Supreme Court, and the district offices of the Board, or obtained from the Board by submitting a request in writing, with a fee of five dollars, to the New York State Workers' Compensation Board, 328 State Street, Schenectady, New York 12305-2318. Payment of the fee shall be made by check or money order payable to "Chair WCB." Information about the New York Pharmacy Formulary can be requested by email at GENERAL_INFORMATION@wcb.ny.gov, or by telephone at 1-800-781-2362.
441.4 Prior Authorization (Utilization Review) for Non-Preferred or Unlisted Drugs.

(a) When a medical provider determines that a Non-Preferred drug or unlisted drug, or a brand-name drug with a generic equivalent, is appropriate for the claimant and medically necessary, the medical provider shall seek prior authorization prior to prescribing or dispensing.

(b) The medical provider may request a prior authorization from the insurance carrier or self-insured employer. The request may be made orally or in writing. The carrier or self-insured employer shall approve or deny this request within four calendar days. A request for prior authorization that is not timely denied shall be deemed approved.

(c) If the carrier or self-insured employer denies the request, the medical provider may seek review by the Board through the medical director’s office or, when requested, through the conciliation process.

(d) Prior authorization must be sought and obtained prior to the time that the drug is dispensed. The carrier or self-insured employer may deny payment when prior authorization was not obtained prior to dispensing the drug.

(e) Exceptions to Prior Authorization Requirement:

(1) Special Fill drugs. The New York Pharmacy Formulary identifies drugs that are subject to the Special Fill policy. Under this policy, a drug that usually requires prior authorization because it is non-Preferred may be dispensed when: (i) The drug is prescribed at the initial treatment visit following a work related injury or illness, provided that the initial visit is within 7 days of the date of injury or disablement, with the day after the date of injury counting as “day one”; (ii) The prescription is medically necessary in the opinion of the treating medical provider; and (iii) The prescription for the Special Fill-eligible drug is for an FDA-approved drug.

(2) Perioperative Fill drugs. The New York Pharmacy Formulary identifies drugs that are subject to the Perioperative Fill policy. Under this policy, the drug identified as a Perioperative Fill drug may be dispensed when: (i) The drug is prescribed during the perioperative period, which is defined as the period from four days prior to surgery to four days after surgery, with the day of surgery as “day zero”; and (ii) The prescription is medically necessary in the opinion of the treating medical provider; and (iii) The prescription for the Perioperative Fill - eligible drug is for an FDA-approved drug.

441.5 Changes to the New York Pharmacy Formulary.

(a) The New York Pharmacy Formulary shall be updated not less than annually to account for changes to medications available on the market.
(b) The Medical Director, or his or her designee, shall review any drugs recommended for addition or removal from the preferred drugs list, and assess public petitions regarding drugs included and/or excluded from the Pharmacy Formulary. If the position of medical director of the Board shall become vacant, the Chair shall appoint a competent person to temporarily assume the authority and duties of the Medical Director to review such additions and removals, and to review and assess such public petitions, until such time as the position of medical director of the Board is filled. Written documentation of the review and assessment of changes to the Pharmacy Formulary shall be maintained by the Board and posted on the Board’s website.