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

441 Formulary

441.1 Definitions.

(a) "Compound drug" means a drug that is created by combining one or more active pharmaceutical ingredients, and/or one or more inactive ingredients, to meet specific patient medical needs that are not met with U.S. Food and Drug Administration ("FDA")-approved prescription drugs, FDA-approved non-prescription drugs, or other drugs commercially available in the marketplace. For the purposes of this Part, a compound drug shall, at all times, be subject to federal law governing compounding, including title 21, United State Code, sections 353a, 353a-1 and 353b. A compound drug that incorporates a drug identified in Phase A, B, or C of the Formulary or FDA-approved non-prescription drug may only be dispensed for the route of administration (oral, topical or systemic) for which it is FDA-approved. Prior authorization is required when a compound includes as an ingredient a prescription or non-prescription drug that is not identified in Phase A, B, or C of the Formulary or is being prescribed for administration by means other than an FDA approved route of administration.

(b) "Disability event" means any accident occurring in the course of employment or any alleged accident that results in personal injury which has caused or will cause a loss of time from regular duties of one day beyond the working day or shift on which the accident or alleged accident occurred, or which has required or will require medical treatment beyond ordinary first aid or more than two treatments by a person rendering first aid; or any disease or alleged disease claimed to have been caused by the nature of the employment and contracted therein.

(c) "Dispense," "dispensed," or "dispensing" means (1) the furnishing of a drug upon a medical prescription, or (2) the furnishing of drugs directly to a patient by a medical provider 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.

(d) "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. for the route of administration (oral, topical or systemic) prescribed.

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

(f) "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[s] is commercially available in a different strength/dosage.

(g) "Carrier's Physician" means a physician, licensed by New York State, or the appropriate state where the professional practices, who is:
    1. employed or contracted by the insurance carrier or self-insured employer; or
    2. is employed by a URAC accredited company retained by the insurance carrier or self-insured employer through a contract to review claims requests for non-formulary agents and advise the insurance carrier or self-insured employer; and
    3. is not employed or contracted by the carrier or self-insured employer's pharmacy benefits network.

(h) "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, B and C; 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.

(i) "Non-Formulary drug" means a drug that does not appear on the Formulary and which is one of the following: an 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. Non-Formulary drugs do not include non-FDA approved drugs and such drugs may not be prescribed. Medical marijuana prescribed and dispensed in accordance with Title V-A of the Public Health Law is not subject to this Part. The use of medical marijuana for work-related injuries will be regulated by the Board pursuant to section 324.3 of this Chapter, regardless of where the medical marijuana was prescribed or dispensed.

(j) "Perioperative Formulary drug" are those drugs listed in the Perioperative Drug Formulary where the drug is prescribed for work-related injuries in accordance with the rules for perioperative fills.

(k) "Phase A drug" are those drugs listed in Phase A of the Formulary. Phase A drugs may be prescribed and dispensed without Prior Authorization and Medical Treatment Guidelines corroboration when prescribed in accordance with subdivision (1) of section 441.4 herein.

(l) "Phase B drug" are those drugs listed in Phase B of the Formulary and may be prescribed and dispensed without Prior Authorization and Medical Treatment Guidelines corroboration when prescribed in accordance with subdivision (2) of section 441.4 herein.

(m) "Phase C drug" are those drugs listed in Phase C of the Formulary. Drugs listed in Phase C may be prescribed and dispensed without Prior Authorization when prescribed consistent with the Medical Treatment Guidelines (as applicable), or when no adopted Medical Treatment Guidelines is applicable, drugs listed in Phase C do not require Prior Authorization when medically necessary for a work-related injury or condition, and when prescribed in accordance with subdivision (3) of section 441.4 herein.

(n) "Prior Authorization process" means the pre-approval review procedure initiated by the medical provider that is conducted prior to the prescribing of an Non-Formulary drug; a

brand-name drug when a Generic drug is available; or a Formulary drug prescribed not in accordance with the Medical Treatment Guidelines (as applicable).

(o) "Prior Authorization" means the carrier's approval of a Prior Authorization request initiated by the medical provider.

(p) "URAC" means the Washington DC-based non-profit organization of that name that helps promote health care quality through the accreditation of organizations involved in medical care services.

441.2 New York Workers' Compensation Formulary

The New York Workers' Compensation Formulary, 1st edition (September 26, 2018), incorporated by reference herein, identifies drugs using four lists: 1) Phase A for prescriptions within the first seven days following a Disability event; 2) Phase B for prescriptions from day eight to day 30 following a Disability event; 3) Phase C for prescriptions after, the sooner of, the first 30 days following a Disability event or acceptance or establishment of the claim; and 4) Perioperative for use during the Perioperative period. 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 Formulary can be requested by email at GENERAL_INFORMATION@wcb.ny.gov, or by telephone at 1-800-781-2362.

441.3 Effective Dates and Notice.

The Formulary shall apply to all prescriptions following a Disability event regardless of the date of accident or disablement and regardless of where the claimant lives. The Formulary shall not apply to drugs when such drugs are administered in a hospital or medical provider's office. The Formulary shall be subject to the following:

(a) Effective Dates

1. New Prescriptions. Six months from the effective date of this Part, every new prescription shall be prescribed consistent with the Formulary and this Part regardless of the date of accident or disablement and subject to any required Prior Authorization.
2. Refill and Renewal Prescriptions. 12 months from the effective date of this Part, every refill and renewal prescription shall be prescribed and dispensed consistent with the Formulary and this Part regardless of the date of accident or disablement and subject to any required Prior Authorization.
3. The Formulary shall apply to prescriptions for Disability events that are controverted by the insurance carrier or self-insured employer.
4. The Pharmacy Fee Schedule set forth in Part 440 of this Subchapter remains in effect and includes pricing for prescriptions including Compound Drugs, the rules

governing use of pharmacy networks and payments for prescriptions when the claim is controverted.

(b) Notice. Within six months of the effective date of this Part, the insurance carrier or self-insured employer shall identify all claimants with current prescriptions for Non-Formulary drugs and provide written notification to the claimant and to the prescribing medical provider. Notice to the prescribing medical provider shall contain patient name, date of birth, date of accident, workers' compensation number and carrier case number as well as the following information: (1) the effective date and applicability of the Formulary and (2) a process for determining an equivalent Formulary drug (or a Generic drug subject to subparagraph [5] of subdivision [a] of section 441.5 herein); and (3) the process to request Prior Authorization for a non-Formulary drug. Notice to the claimant shall be in the format prescribed by the Chair.

441.4 Application of Formulary.

Formulary sets forth drugs in four lists identified as follows:

1. Phase A: The drugs on this list may be prescribed and dispensed without obtaining Prior Authorization when (i) the supply does not exceed seven days or, if an antibiotic or post-exposure medications, the course of treatment, (ii) the drug is prescribed at the initial treatment visit following a Disability event when such initial treatment is within seven days following a Disability event, and (iii) the dispensing occurs within seven days of the date of initial treatment. A thirty-day supply of Phase A drugs that are also Phase B drugs may be prescribed and dispensed during the first seven days following a disability event. Phase A drugs may be prescribed in the absence of a denial of the claim, without acceptance or establishment of the claim or reference to the adopted Medical Treatment Guidelines. Prior Authorization is required for any Phase A drug that is not prescribed in accordance with this subdivision.
2. Phase B: The drugs on this list may be prescribed and dispensed without obtaining Prior Authorization within the eighth and thirtieth day following a Disability event when (i) the supply does not exceed thirty days, (ii) the drug is prescribed at an initial or follow-up/second treatment, (iii) the case has not been accepted by the carrier or established by the Board, and (iv) the dispensing occurs within seven days of the date of treatment. Phase B drugs may be prescribed and dispensed in accordance with subparagraphs (i), (ii) and (iii) herein, up to a 30-day supply, in the absence of a denial of the claim, without acceptance or establishment of the claim or reference to the adopted Medical Treatment Guidelines. Following the carrier or self-insured employer's acceptance of the injury or illness with or without liability, or establishment by the Board, all drugs must be prescribed and dispensed consistent with Phase C.
3. Phase C: The drugs on this list may be prescribed and dispensed, up to a 90- day supply, without obtaining Prior Authorization after 30 days following a Disability event. When a body part or illness has been accepted (with or without liability) or established, drugs must also be prescribed in accordance with, as applicable, the

adopted Medical Treatment Guidelines. Phase C drugs designated as "2nd" Drugs may be prescribed and dispensed without Prior Authorization, following a trial of a first line drug prescribed in accordance with Phase C and, as applicable, the adopted Medical Treatment Guidelines.

4. Perioperative Formulary Drugs. Drugs listed as Perioperative Formulary drugs may be prescribed without Prior Authorization when prescribed during the perioperative period. The 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. Perioperative Formulary drugs may not be prescribed or dispensed outside of such perioperative period without Prior Authorization unless such drug is identified for the applicable Phase.

441.5 Prior Authorization Process

(a) A medical provider must obtain Prior Authorization before prescribing or dispensing:

1. Phase A formulary drugs (including compound drug ingredients) other than as set forth in subdivision (1) of section 441.4 herein;
2. Phase B formulary drugs (including compound drug ingredients) other than as set forth in subdivision (2) of section 441.4 herein
3. Phase C formulary drugs (including compound drug ingredients) other than as set forth in subdivision (3) of section 441.4 herein; or,
4. Perioperative formulary drugs other than as set forth in subdivision (4) of section 441.4 herein.
5. Brand name drugs for a generically available formulary drug.
6. Non-Formulary drugs;
7. Compound drugs with any Non-Formulary drug ingredient and/or for Formulary drugs being prescribed for other than an FDA approved route of administration.
8. Formulary drugs prescribed in a manner not consistent with the adopted Medical Treatment Guidelines (other than Phase A and Phase B drugs).

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

(c) Insurance carriers and self-insured employers shall provide the Chair or his or her designee in the manner prescribed by the Chair with the name and contact information for the point(s) of contact for the First level and Second level review within 30 days of the effective date of this paragraph. Such contact information shall include the contacts' direct telephone number(s), facsimile number(s), and email address(es). If the designated point(s) of contact changes at any time for any reason, the insurance carrier or self-insured employer shall notify the Chair or his or her designee of such change in the manner prescribed by the Chair. The list of designated points of contact for each insurance carrier and self-insured employer shall be posted on the Board's website. Any change in the designated contact shall not be effective until the designated contact information has been updated on the Board's website.

(d) Insurance carriers and self-insured employers shall provide two levels of review as Prior Authorization process.

(e) First level review. To initiate the Prior Authorization process, the medical provider shall submit a request for Prior Authorization to the insurance carrier, self-insured employer, or when designated by section 440.3 of this Subchapter, the pharmacy network, to the designated contact for First level review as described in subdivision (c) herein. Such request shall be submitted in the manner prescribed by the Chair.

1. A Prior Authorization request for an Non-Formulary drug may include the requested length of time that the Prior Authorization or the quantity prescribed and the number of refills. If the requested length of time for the Prior Authorization is not stated, the default shall be 30 days. In no event may a Prior Authorization request exceed 365 days.
2. The carrier, self-insured employer, or pharmacy benefits manager shall approve, partially approve or deny a Prior Authorization request within four days of submission by provider.
    i. A partial approval authorizes the requested drug but limits the length of time, quantity prescribed or number of refills from that requested by the medical provider.
    ii. A request for Prior Authorization that is not timely denied or partially approved shall be deemed approved for a period of 30 days.
3. A partial approval or denial of a request for Prior Authorization must:
    i. Provide a specific reason for the denial or partial approval with reference to the specific Prior Authorization request made by the medical provider.
    ii. Provide information regarding how to request review of the denial from the Carrier's Physician.

(f) Second level review by carrier or self-insured employer's physician (Carrier's Physician). Within 10 days of a denial or partial approval of a Prior Authorization request, the medical provider may request review of such denial or partial approval by the Carrier's Physician. Such request shall be made to the designated contact for Second level review as described in subparagraph (c) herein. Such physician shall approve, partially approve or deny a Prior Authorization request within four days.

441.6 Review by the Board of a Prior Authorization Denial.

(a) If the Carrier's Physician issues a denial or a partial approval, the medical provider may seek review by the Board's Medical Director's Office. The medical provider may not seek review by the Board's Medical Director's Office unless the medical provider has received a denial or partial approval by the Carriers' Physician.

(b) All requests for review of denials or partial approvals of a Prior Authorization request shall be submitted to the Medical Director's Office in the format prescribed by the Chair. The Chair or Medical Director may designate private entities to evaluate such requests for review of denials by a Carrier's Physician provided that the entity has:

1. the appropriate URAC accreditation or such accreditation/certification as designated by the Chair,
2. other demonstrated expertise and criteria established by the Board; and

3. no conflict of interest exists in resolving the subject dispute.

(c) When a prescribing medical provider wishes to request review of a denial or partial approval of a Prior Authorization request, the medical provider shall submit the request to the Medical Director's Office in the format prescribed by the Chair within 10 days of the denial date together with all documentation submitted in support of its First and Second level carrier review, and the denial or partial approval issued following such First and Second level reviews.

(d) A decision by the Medical Director's Office (or designated accredited entity) is final and binding on the medical provider, the carrier, self-insured employer or pharmacy network. Such decision shall be binding and not appealable under Workers' Compensation Law section 23.

(e) Notwithstanding paragraph (d) herein, a claimant may request review of a Medical Director's Office decision, by filing a Request for Further Action, that demonstrates that such drug is medical necessary and denial or Prior Authorization adversely impacts the claimant's interests. The Board may respond to such requests for review by letter or by referral to adjudication, as appropriate in the discretion of the Chair or his or her designee. Such decisions shall be binding and not appealable under Workers' Compensation Law section 23.

(f) In the event that a Prior Authorization request is denied on the merits, the medical provider may not submit a request for Prior Authorization for the same prescription unless he or she submits evidence that there has been a change in the claimant's medical condition that renders the denial of the request for Prior Authorization no longer applicable to the claimant's current medical condition.

(g) All communications regarding Prior Authorization shall be by the means of electronic delivery as the receiving party or the Chair has designated for this purpose, unless the prescribing medical provider has sent a certification to the Board's Medical Director's Office that it is not equipped to send or receive Prior Authorization requests by electronic means. Such certifications must include an attestation that the prescribing medical provider is unable to send or receive Prior Authorization requests by electronic means.

441.7 Changes to the Formulary.

(a) The Formulary shall be updated not less than annually to account for changes to medications available on the market.

(b) The Medical Director and/or Chair, or his or her designees, shall review any drugs recommended for addition or removal from the Formulary, and assess requests regarding drugs included and/or excluded from the Formulary. Written documentation of the review and assessment of changes to the Formulary shall be maintained by the Board and posted on the Board's website. Decisions regarding changes to the Formulary shall be binding and not appealable under Workers' Compensation Law section 23.

441.8 Medical Treatment Guidelines and Formulary.

In the event that a conflict exists between the Board's medical treatment guidelines and the New York Formulary, the provisions of the medical treatment guidelines shall prevail, unless the drug was prescribed in accordance with Phase A or Phase B of Formulary.