
Workers' Compensation Board

NOTICE OF ADOPTION

Impairment Guidelines for Schedule Loss of Use Evaluations

I.D. No. WCB-36-17-00015-A

Filing No. 1120

Filing Date: 2017-12-18

Effective Date: 2018-01-01

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following action:

Action taken: Addition of section 325-1.6 to Title 12 NYCRR.

Statutory authority: Workers' Compensation Law, sections 15(30)(x), 117 and 141

Subject: Impairment Guidelines for Schedule Loss of Use Evaluations.

Purpose: Incorporate by reference Impairment Guidelines.

Text of final rule: A new section 325-1.6 is added to Title 12 NYCRR as follows:

325-1.6 The Impairment Guidelines for Schedule Loss of Use Determinations

a) All evaluations of permanent impairment for use in a schedule loss of use determination shall be performed in accordance with the Workers' Compensation Guidelines for Determining Impairment, First Edition, XXXXXXX, effective January 1, 2018, which is herein incorporated by reference. Such evaluations must be completed in the format prescribed by the Chair.

b) Obtaining the Workers' Compensation Guidelines for Determining Impairment. The Workers' Compensation Guidelines for Determining Impairment incorporated by reference herein 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. Copies may be downloaded from the Board's website or obtained from the Board by submitting a request in writing, with the appropriate fee, identifying the specific guideline requested and the choice of format to Publications, New York State Workers' Compensation Board, 328 State Street, Schenectady, New York 12305-2318. Information about the Workers' Compensation Guidelines for Determining Impairment can be requested by email at GENERAL_INFORMATION@wcb.ny.gov, or by telephone at 1-800-781-2362. The Workers' Compensation Guidelines for Determining Impairment are available on paper or compact disc. A fee of ten dollars will be charged for the guideline requested in paper format, and a fee of five dollars will be charged for a compact disc. Payment of the fee shall be made by check or money order payable to "Chair WCB."

Final rule as compared with last published rule: Nonsubstantive changes were made in section 325-1.6(a).

Revised rule making(s) were previously published in the State Register on November 22, 2017.

Text of rule and any required statements and analyses may be obtained from: Heather MacMaster, Workers' Compensation Board, 328 State Street, Office of General Counsel, Schenectady, NY 12305, (518) 486-9564, email: regulations@wcb.ny.gov

Additional matter required by statute: Workers' Compensation Guidelines for Determining Impairment, First Edition, November 22, 2017, effective January 1, 2018 is incorporated by reference.

Revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement

A revised Regulatory Impact Statement, Regulatory Flexibility Analysis, Rural Area Flexibility Analysis and Job Impact Statement are not required because the changes made to the proposed rule does not necessitate revision to the previously published document. The changes to the text are non-substantive corrections. These changes do not affect the meaning of any statements in the prior document.

Initial Review of Rule

As a rule that requires a RFA, RAFA or JIS, this rule will be initially reviewed in the calendar year 2020, which is no later than the 3rd year after the year in which this rule is being adopted.

Assessment of Public Comment

The Chair and Board received more than 50 formal written comments from Survey Monkey, emailed comments, and regular mail. Additionally, the Chair and Board received more than 150 form letters from individuals.

The Board received approximately 18 form letters opining that the revised proposal was a substantial improvement over the September draft guidelines, but objecting to any reductions in awards for permanent damage to limbs. The Board also received more than 130 form letters from individuals objecting to this proposal in its entirety, specifically any benefit cuts at all. These form letters objected to any revisions at all, and because this is a legislative mandate, the Board must adopt some changes, and no change to the proposal has been made as a result of these form letters.

The Board received a comment from an employee advocate group agreeing with many of the changes from the first proposal to the second, especially the removal of the "cooperation" language.

The Board received several comments from individuals and employee advocate groups objecting to any revisions to the guidelines that would result in benefit cuts for workers, but supported the proposal otherwise.

The Board received a detailed comment from an employee advocacy group that stated that the November proposal is much improved, but objected to several specific sections of the proposed impairment guidelines, including the reduction in some awards, and the change in the thumb measure. The Board did change the thumb measure from 60 degrees in the proposal to 90 degrees.

The Board received a comment from three comments, from individuals and carriers, that the proposals are not based on advancements in modern medicine.

The Board received a comment from a claimant attorney requesting the regulations be amended to include what happens if there are Schedule Loss of Use opinions that remain unresolved prior to the implementation of the final version of the new guidelines, and requesting that existing SLU opinions be "grandfathered in".

The Board received a comment from a carrier attorney suggesting the addition of a note to the impairment guidelines to ensure range of motion is compared to the contralateral side, as well.

The Board received approximately five comments from health care providers suggesting the addition of various other medical conditions, including spine injuries and tinnitus among others, as well as several small specific suggestions for changes to the guidelines.

The Board received several comments from carriers, third party administrators, self-insured employers, and businesses objecting to the most recent proposal, citing unfairness to employers and preferring the September proposal, especially the "loss of earning power" factor. The Board received many comments from the last round of proposals objecting on behalf of employees, and the most recent proposal takes those comments into account. No change to the proposal has been made in response to this comment.

The Board received several comments from health care providers and claimant attorneys supporting the fairness of this revised proposal as a whole.

Changes to the Proposal

• Section 2.4: The Board changed the thumb measure from 60 degrees to 90 degrees.

PROPOSED RULE MAKING NO HEARING(S) SCHEDULED

Establishment of Prescription Drug Formulary

I.D. No. WCB-52-17-00021-P

PURSUANT TO THE PROVISIONS OF THE State Administrative Procedure Act, NOTICE is hereby given of the following proposed rule:

Proposed Action: Addition of section 440.2(g) and Part 441 to Title 12 NYCRR.

Statutory authority: Workers' Compensation Law, sections 13-p, 117 and 142

Subject: Establishment of Prescription Drug Formulary.

Purpose: Establishment of a drug formulary that includes high-quality and cost-effective preauthorized medication.

Text of proposed rule: 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 States 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.

Text of proposed rule and any required statements and analyses may be obtained from: Heather MacMaster, Workers' Compensation Board, Office of General Counsel, 328 State Street, Schenectady, NY 12305-2318, (518) 486-9564, email: regulations@wcb.ny.gov

Data, views or arguments may be submitted to: Same as above.

Public comment will be received until: 60 days after publication of this notice.

Additional matter required by statute: The drug formulary is posted for review at: wcb.ny.gov/drug-formulary-regulation

Regulatory Impact Statement

1. **Statutory authority:** Workers' Compensation Law (WCL) § 117 authorizes the Chair of the Workers' Compensation Board (Board) to adopt reasonable rules consistent with the provisions of the WCL. Chapter 59 of the Laws of 2017 added Section 13-p to the WCL mandating that the Chair adopt a prescription drug formulary.

2. **Legislative objectives:** These proposed regulations incorporate by reference a prescription drug formulary that includes high-quality and cost effective drugs. Additionally, these proposed regulations set forth the process for obtaining prior authorization and administrative review of a pre-authorization denial for non-preferred drugs.

3. **Needs and benefits:** Chapter 59 of the Laws of 2017 added Section 13-p. WCL section 13-p mandates that the Chair of the Workers' Compensation Board establish a prescription drug formulary on or before December 31, 2017. The legislation specifically states: "The prescription drug formulary shall include a tiered list of high-quality, cost-effective medications that are pre-approved to be prescribed and dispensed, as well as additional non-preferred drugs that can be prescribed with prior approval. Such prescription drug formulary, shall include but not be limited to implementation of a pharmacy reimbursement strategy, administration of a prescription drug rebate program for formulary drugs, a pre-approval program, drug utilization review, and limitations on the prescribing of compounded medications and compounded topical preparations." Accordingly, the proposed rule incorporates a drug formulary by reference and sets forth the procedure for use of preferred and non-preferred drugs. The prescription drug formulary will benefit carriers, medical providers, pharmacies, and claimants by providing uniform guidelines for prescribing drugs.

4. **Costs:** The proposal will not impose costs on parties of interest in the workers' compensation system. The New York Pharmacy Formulary can be downloaded free of cost from the Board's website. Additionally, it is expected that there will be costs savings for all parties. By having a defined list of preferred drug, which have been selected based on their medical efficacy, many claimants may have lower prescription drug costs and there will be fewer fee disputes necessitating hearings before the Workers' Compensation Board.

5. **Local government mandates:** The proposed regulation does not impose any program, service, duty, or responsibility upon any county, city, town, village, school district, fire district, or other special district. However, a municipality or governmental agency that is self-insured is required to comply with the same rules required of insurance carriers, including reviewing prior authorization requests and approving or denying the request within four days. Although this review process may impose minor administrative costs on self-insured municipalities and governmental agencies, it is the option of municipalities and governmental agencies to self-insure, and self-insurance guidelines are set by statute. Moreover, it is expected that the proposed regulation will actually reduce costs by reducing fee disputes.

6. **Paperwork:** The proposal does not impose any new reporting requirements.

7. **Duplication:** There is no duplication.

8. **Alternatives:** Based upon the mandate of the Legislature to establish a prescription drug formulary, the Chair is required to promulgate regulations in order to ensure the orderly implementation of the formulary incorporated by reference in the proposed regulation. To fail to promulgate the proposed regulations, which set forth clear criteria for the use of the prescription drug formulary, would violate the statutory mandate and cause confusion for parties that anticipate the adoption of a drug formulary. The Workers' Compensation Board also had discussions about the content of the regulations with other states, such as California, to garner information about their experience with adopting a drug formulary.

9. **Federal standards:** There are no applicable Federal Standards.

10. **Compliance schedule:** The proposed regulation is mandatory. All affected medical providers, carriers, and self-insured employers will have to refer to the New York Pharmacy Formulary incorporated by reference in the proposed regulation.

Regulatory Flexibility Analysis

1. **Effect of rule:**

This proposed rule applies to all medicines prescribed to workers' compensation claimants. The proposed regulation establishes a drug formulary that provides a list of pre-authorized high-quality and cost-effective drugs, and sets forth the procedure for receiving authorization for drugs that are not listed in the drug formulary. The rule will have no effect on local governments.

2. Compliance requirements:

Under this new rule, all prescriptions in workers' compensation cases must be made in accordance with the drug formulary and accompanying regulations.

3. Professional services:

The Board believes that no professional services will be needed to comply with this rule. This new rule simply proposes establishment of a drug formulary listing authorized medications.

4. Compliance costs:

This proposal does not involve any new compliance costs. It is anticipated that use of the drug formulary will simplify compliance with the workers' compensation law.

5. Economic and technological feasibility:

No implementation or technology costs are anticipated for small businesses and local governments for compliance with the proposed rule. Therefore, it will be economically and technologically feasible for small businesses and local governments affected by the proposed rule to comply with the rule.

6. Minimizing adverse impact:

The Board does not anticipate any increased costs or adverse impact. The new rule simply establishes a formulary for use in prescribing and dispensing medication to workers' compensation claimants.

7. Small business and local government participation:

The Chair proposes this regulation pursuant to a legislative mandate. Due to the fact that no impact is anticipated on small businesses or local governments, the Chair has not engaged in consultation.

Rural Area Flexibility Analysis

1. Types and estimated numbers of rural areas:

The proposed rule applies to all carriers, employers, self-insured employers, third party administrators and pharmacies in rural areas. This includes all municipalities in rural areas.

2. Reporting, recordkeeping and other compliance requirements:

Medical providers in all areas of the state, including rural areas, will be required to prescribe and dispense drugs in accordance with the New York Pharmacy Formulary, which is incorporated by reference in the proposed regulation. Additionally, carriers and self-insured employers throughout the state, including rural areas, will be required to timely approve or deny prior authorization requests for the use of non-preferred or unlisted drugs within four calendar days.

3. Costs:

This proposal will impose minimal compliance costs on carriers and employers across the state, including rural areas, which will be more than offset by the savings afforded by the Pharmacy Formulary. Particularly, the Board anticipates that all regulated parties will experience cost savings as a result of the formulary incorporated by reference in the proposed regulations, insofar as the formulary sets forth clear guidance as to the preferred status of drugs, which should result in fewer fee disputes.

4. Minimizing adverse impact:

This proposed rule is designed to minimize adverse impacts on all regulated parties. The proposed rule will provide a benefit to all parties, including claimants, carriers and self-insured employers, and medical providers, by setting forth clear, uniform guidelines as to the preferred status of drugs. Under the proposed regulation, all regulated parties will be able to easily assess whether a prescription drug is preferred, and in the event the drug is non-preferred or unlisted, medical providers will understand the process for requesting to prescribe or dispense such a drug. Ultimately, the Board expects that the proposed regulation will result in fewer fee disputes and claimants receiving more effective and timely prescription drug treatment.

5. Rural area participation:

The Board is statutorily required under Workers' Compensation Law section 13-p to adopt a prescription drug formulary by December 31, 2017. Given the deadline, the Board has not yet had an opportunity to consult with rural areas about the adoption of this regulation. However, the Board will duly assess all comments received by representatives of rural areas during the public comment period.

Job Impact Statement

1. Nature of Impact

The drug formulary proposed in these rules is not expected to have any impact on jobs in New York State. These guidelines simply create a list of high-quality, cost effective drugs that are pre-authorized for treatment of workers' compensation claimants.

2. Categories and Numbers Affected

The drug formulary is not expected to have any adverse impact on jobs.

3. Regions of Adverse Impact

The drug formulary does not affect any region specifically.

4. Minimizing Adverse Impact

The proposed rule provides drug formulary for use in workers' compensation cases. There is not expected to be any impact on jobs with use of the drug formulary.