

Assessment of Public Comment

The Chair and the Board received approximately 16 unique written comments in response to the revised proposed adoption of Part 441 of 12 NYCRR and the Formulary incorporated by reference therein. The public comment period remained open through May 17, 2019.

Multiple commenters commended the Board on the proposed Formulary.

One medical provider was generally opposed to the implementation of the Formulary. In response, the Board notes that it is statutorily required to implement a comprehensive drug formulary, pursuant to Workers' Compensation Law section 13-p.

441.3 Applicability, Effective Dates and Notice

One claims management group requested that the Board avoid mandating disclosure of any unnecessary protected health information under section 441.3(f), specifically when the information relates to medications prescribed and conditions treated, to protect a claimant's privacy. Notifications pursuant to this section are only sent to parties who are legally entitled to this information, the claimant and the prescribing medical provider. Accordingly, no change have been made as a result of this comment.

One TPA requested that the Formulary apply to medications that are not dispensed by a pharmacy. The regulations set forth specific rules regarding physician and hospital dispensing (see section 441.3[d]). Accordingly, no changes are made due to this comment.

441.4 Application of Formulary

One medical provider argued that Phases A, B, and the Perioperative Formulary are arbitrary and impractical. In comparison, several commenters commended the Board on this and the prior draft of the Formulary, both of which incorporated a three-phase approach. Therefore, on balance, the Board declines to make changes because of this comment.

One medical provider and one claimant opposed the seven-day supply limit for controlled substances and muscle relaxants on the Formulary. The Board declines to make changes pursuant to these comments, as it finds that the 7-day supply limit best protects a claimant's health, and the Prior Authorization process set forth in section 441.5 exists where a greater supply is medically necessary.

One medical provider asked that a seven-day supply of opioids be pre-authorized in both Phase A and Phase B when medically necessary. In response, the Board notes that section 441.4 specifies that controlled substances may not exceed a single seven-day supply; such medications are indicated on Phase A of the Formulary as "1" in the "Special Considerations" column. Pursuant to section 441.5, if the treating medical provider believes that medication that is not pre-authorized in the Formulary is medically necessary, he or she may submit a request for Prior Authorization. As such, the Board declines to make changes as a result of this comment.

441.5 Prior Authorization Process

One claims management group commended the Board's treatment of compound medications.

One claimant requested that language be added to the regulations expressing that use beyond the maximum period is acceptable in some cases. As set forth in section 441.5, if a claimant's medical provider believes that medication that is not pre-authorized in the Formulary is medically necessary, he or she may submit a request for Prior Authorization. As such, the Board declines to make changes as a result of this comment.

One medical provider disagreed with the multiple review levels set forth in the Prior Authorization process. However, several other commenters commended the Board on this draft of the Formulary, which included the Prior Authorization process. Therefore, on balance, the Board declines to make changes because of this comment.

One medical provider opined that the regulations should require claimants or a claimant's representative to seek Prior Authorization, not only medical providers. The Board declines to make the requested change, as it finds that requiring medical providers to initiate first- and second-level Prior Authorization requests best protects claimants, as medical providers are in the best position to supply evidence in support of the Prior Authorization request.

One claims management group asked that nurse practitioners also be permitted to review Prior Authorization requests relating to schedule II, III, IV, and V controlled substances, as nurse practitioners are authorized to prescribe such medications. The Board declines to make this change, as it finds that requiring licensed physicians to review second-level Prior Authorization requests best protects claimants.

One claims management group suggested amending section 441.5(b) such that Prior Authorization need not be obtained prior to prescribing, only requested beforehand, in order to prevent delays. The Board declines to make the requested change. Prior authorization must be both sought and obtained before prescribing and dispensing. The Formulary contains drugs from all therapeutic categories; therefore, there should be medications that can be used until a Prior Authorization is reviewed. Additionally, Prior Authorization would not necessitate another visit to the doctor; after the Prior Authorization is obtained, the provider can electronically prescribe the medication and the claimant would then collect it from his or her pharmacy.

One commenter asked that the regulations include specific provisions prohibiting retrospective review of medications. Nothing in the regulations, particularly in sections 441.5 or 441.6, permits retrospective review of medications. Accordingly, the Board does not believe that a change to the regulations is necessary.

One insurance carrier requested that the regulations specifically state that Prior Authorization is required for brand name versions of time-released drugs where a generic drug with the same

active ingredient and therapeutic efficacy is available. The regulations specify rules for generic drugs, as set forth in sections 441.1 and 441.5; as such, no change has been made as a result of this comment.

One insurance carrier asked that carriers be permitted to list a general designated phone number and email address for the regulation's designated contact requirement. The Board believes the proposed regulations provide a sufficient process to ensure that drugs are prescribed and dispensed correctly, and as such has not made any changes as a result of this comment. However, the Board has made a clarifying change to section 441.5(c) to clarify that the names and contact information of designated contacts will not be posted on the Board's website. Instead, medical providers requesting Prior Authorization electronically will be automatically directed to the carrier's designated contact.

One insurance carrier opined that reviewing Prior Authorization requests in 4 calendar days is too burdensome. The Board consulted with stakeholders in drafting the proposed regulation and finds that 4 calendar days is an appropriate amount of time to decide Prior Authorization requests. Accordingly, no changes are made as a result of this comment.

One third-party administrator (TPA) asked that the regulations clarify whether TPAs are included when the terms "carrier and self-insured employer" are used in the regulation. Pursuant to section 441.5, Prior Authorization shall be submitted in the manner prescribed by the Chair. When the Chair designates the form and manner by which to request Prior Authorization, he or she may, at that time, permit the carrier's agent, including a TPA, to view Prior Authorization requests. Therefore, no changes will be made to the regulation as a result of this comment.

Several commenters opined that the Prior Authorization process is unclear. Because these commenters have not expressed specific changes to sections 441.5 or 441.6, and a number of other commenters commended the Board on this version of the Formulary regulation, including the Prior Authorization process prescribed therein, the Board declines to make changes to these sections as a result of these comments. It should be noted that the Board is developing the electronic process and solution for the Prior Authorization process and will make this solution available to stakeholders available in the process. Additionally, the Board is available as a resource should stakeholders have specific questions, and the Board may develop Frequently Asked Questions on its website should repeat questions arise.

One law firm asked that section 441.5(d)(3)(ii) impose a 30-day deadline for issuing an Order of the Chair. The Board expects any Orders of the Chair to be issued in a timely manner.

441.6 Review by the Board of a Prior Authorization Denial

Several commenters expressed confusion as to whether the electronic delivery provisions set forth in section 441.6(g) apply to all Prior Authorization requests, or only Board-level review of Prior Authorization requests. As a result, the Board has clarified that former section 441.6(g), now section 441.5(f), applies to all levels of Prior Authorization review. Additionally, the Board has amended this provision to clarify that, in the event a prescribing medical provider is not

equipped to send or receive Prior Authorization requests by electronic means, he or she must send a certification to the Board's Medical Director's Office in accordance with 12 NYCRR 324.3(a)(3).

One insurance carrier asked that medical providers be required to appeal a Prior Authorization denial or partial approval in 4 days, rather than 10 days. The commenter contended that a 4-day appeal timeline is more equitable because the carrier must review a Prior Authorization request within 4 calendar days under section 441.5. The Board declines to make the requested change, as a carrier's decision timeline differs in purpose from the timeframe by which to appeal a decision.

One insurance carrier opined that claimants should not be permitted to appeal a decision by the Medical Director's Office because the decision is binding on all other parties. The Board declines to make any changes as a result of this comment, as it finds that the currently-drafted regulation is necessary to best protect a claimant's due process interests.

441.8 Medical Treatment Guidelines and Formulary

One medical provider requested that the regulations clearly state that the Medical Treatment Guidelines are controlling in the event of a contradiction with the Formulary. In response, the Board notes that section 441.8 clearly sets forth when the Medical Treatment Guidelines control in the event of a conflict.

Formulary

One commenter expressed that the "2nd" category on the Formulary is confusing. As is described in the Formulary, medications may only be prescribed for the body parts identified with a Yes or as a 2nd line prescription when indicated by a 2nd. When there is no such indicator for the body party, the drug may not be prescribed without prior authorization.

One commenter recommended that the Formulary and instructions that accompany it be updated to include the specific NCCI or ICD-10 codes associated with each of the diagnosis categories listed on the formulary table. This suggestion is beyond the scope of the Formulary. Accordingly, no changes have been made to the revised proposed regulations as a result of this comment.

One pharmacy asked whether all formulations of a given medication are included when the drug formulation is not specified, or whether the PBM may determine an appropriate formulation. The Board is unclear on this commenter's question, and therefore no changes have been made to the Formulary as a result of this comment. However, all stakeholders are welcome to contact the Board directly for clarifying questions such as these, and the Board may develop Frequently Asked Questions on its website should repeat questions arise.

Many stakeholders requested that specific drugs be included in the Formulary. The Board is interested in adopting the final Formulary regulations as soon as possible, in order to bring clarity to all stakeholders and begin the educational and implementation process. Therefore, no changes have been made to the Formulary at this time to incorporate the suggested drugs.

However, to the extent that these drugs have been requested for inclusion for the first time, the Board will review them for inclusion at a later date. To the extent that several of these drugs have been requested for inclusion in past versions of the Formulary regulation, the Board previously reviewed these drugs and declined to include them, and no new evidence has been provided regarding the drugs' efficacy. Stakeholders should also be mindful that the Formulary is intended to be dynamic, and the Board will continue to monitor requests for additions to or deletions from the Formulary pursuant to section 441.7.