Assessment of Public Comment

During the public comment period, the Board received 12 comments.

Several comments expressed general support for the proposal, but many had requests for clarification and other suggestions detailed below.

Several comments requested clarification about the format prescribed by the Chair, whether there will be a new form, what the changes would look like, and when those changes would take effect. One comment expressed general support for the proposal, but requested clarification about the notice requirements and form, and how to satisfy proof of service. The proposal requires that the notice prescribed by the Chair state that it will not be paying for a particular prescription medication pending resolution of the legal objection to payment. The required elements of the notice will be prescribed and the Board will build in time (approximately 30 days) before the regulation takes effect for education and programming efforts.

The comment also suggested that the Board add language specifying the conditions when the notice would be required and response timeframe, etc. The proposal requires the notice when the carrier will not be paying for the prescribed medication pending resolution of the legal objection – before then, the pharmacy must dispense the prescribed medication to the claimant and the carrier (or self-insured employer) is responsible for the cost. There is no particular timeframe – they simply either provide the notice or they do not. If they do not, the pharmacy must dispense the medication and the carrier is responsible for the cost, so no change has been made in response to this comment.

The comment also requested language be added clarifying how a payer could be liable for payment for medications before they've received notice of a new condition or body part. Liability for payment of medication is not triggered by the notice – it is triggered if the medication for that injury or body part is compensable. A carrier could address this in their contract with the designated pharmacy and have a mechanism to deliver the notice contemplated in this regulation at the pharmacy for body parts/conditions that are not part of the established claim. They could also fill pursuant to Phase A in the formulary or do a partial fill until they can analyze the medical evidence, so no change has been made here.

The comment (and two others) also expressed concern about a claimant discontinuing in-network pharmacies if there is a new body part or condition in dispute (where there are medications they are already receiving through the in-network pharmacy) and requested the proposal add language stating that the claimant still has to go in network to fill those medications, and expressed concern about not having knowledge of the new body part or condition until the claimant is trying to fill the prescription. Like the above, the communication to the claimant may contain information about the established body parts/conditions where they must go in network to obtain those medications, but that if it's for another body part or condition that is not yet established, they can go out of network. Accordingly, no change has been made in response to these comments.

The comment also requested the proposal change "failure to dispense" to "failure to authorize" because there is no penalty on the pharmacy for failure to dispense and the payer does not have control over whether the pharmacy dispenses the medication. Another comment mirrored this concern but recommended removing "dispense and" rather than the "failure to authorize" vs. "failure to dispense" language. The Board has made a clarifying change in response to these comments to make explicit that it's the failure *of the designated pharmacy* to dispense such prescribed medications that could result in the penalty.

Several comments supported the proposed change to Section 441.3(b).

Another comment expressed concern about a $2,000 minimum penalty with no upward limit, opining that it is excessive because it may simply be a technical violation. A different comment supported the inclusion of this provision. Timely receipt of medically necessary medication can be a matter of life or death, so a penalty when the carriers do not comply with this notice requirement is necessary to ensure compliance and eliminate unnecessary delays. Therefore, no change has been made here.

This comment disagreed with the inclusion of "legal objection" language in the proposal, opining that it would result in a huge amount of volume and unnecessary hearings. The amendment in section 440.3(d) adds language making clear that the relevant legal objections are those that contend that the medication treats a non-established injury or condition, so no change has been made in response to this comment.

The comment suggested the Board remove reference to "provider" in proposed 440.3(d)(2) because the objection related to a not established site/condition is directed to the claimant, not the provider. The language in this section is not suggesting that the objection is directed to the provider, it is a term of art – the resolution of the objection to the medication is in favor of the provider, but the reimbursement provisions are for the carrier to reimburse the claimant, etc. as follows in the next paragraphs, so no change has been made in response to this comment.

The comment requested that the requirement in section 440.4(c) about re-serving notice be eliminated. This language is necessary to the proposal because it is the section that tells the claimant when they must resume use of the designated pharmacy – without it, the claimant has no knowledge when they must resume use of the designated pharmacy, but the Board has made a clarifying change to remove superfluous references to subdivisions (c) and (d) in the previous sentence.

The Board received a comment in support of the bill A1219A/S1974 that the Governor vetoed in 2024 and opined that the proposed regulation was not sufficient for injured workers with established cases trying to access medications. Another comment expressed similar concerns, opining that this proposal excludes most scenarios where injured workers lose access to medications. One comment also opined that the regulation is insufficient because it does not address a failure by the employer, carrier, or network pharmacy to timely respond to authorization/reauthorization for established cases, denials because medical reports haven't been filed, carrier claims MMI has been reached, case is being settled, and several other similar scenarios. The referenced vetoed pharmacy legislation provided for a select number of scenarios

under which the injured worker can go out of network. These specific scenarios would inevitably result in litigation over factual disputes concerning whether the opt-out criteria was met. This proposal goes much further than the legislation by permitting the injured worker to go out of network whenever the pharmacy fails to dispense the medication. The regulation also provides for a significant payment surcharge when the medication is found compensable as well as a penalty to the payer who has not provided the injured worker with timely notice of the right to go out of network, neither of which were part of the vetoed legislation. The Board anticipates this regulation will go a long way toward ensuring injured workers have timely access to necessary prescription medication, and regulations can be amended in the future as necessary. Therefore, no change has been made in response to these comments.

Two comments requested clarification about whether the proposed rule would allow a pharmacy to dispense a medication in the instances described in the regulation without risk of denial or recoupment. Section 440.3(d) of the proposal language states that "prior to the filing of [the] prescribed notice and service upon the claimant, the pharmacy must dispense the prescribed medication to the claimant *and the insurance carrier or self-insured employer will be responsible for the cost*" so no change has been made here.

One comment expressed general support for the proposed regulation and the intent of the regulation but expressed concern that the pharmacies would not be willing to dispense medications that are disputed by a carrier. The regulation addresses this situation by allowing the injured worker to go out of network to get necessary medication and providing that the insurance carrier will be responsible for the cost, including the 25% surcharge, after the filing of the notice. If the pharmacy fails to dispense or the carrier fails to pay for such prescribed medications prior to the notice, they will be subject to a penalty as set forth in the regulation, so no change has been made.

The comment also opined that the regulation should not only apply where there is controversy on causal relationship, but rather the entity should pay bills and be reimbursed later. The regulation requires the notice in this proposal when there is a new body part or condition, but this does not mean the claimant cannot go out of network if the pharmacy refused to dispense medication. The surcharge would still apply and any C-8.1B objection found in favor of the provider.

The comment also expressed concerns about ongoing issues with medications preauthorized under the Medical Treatment Guidelines and Drug Formulary being denied. A different comment expressed concern that the proposed regulation does not address injured workers being denied post-operative pain medications, antibiotics, already authorized medications, etc. These concerns are not within the scope of this regulatory proposal, so no change has been made in response to this comment, and it is noted that in-network denial allows claimant to go out of network to obtain necessary prescription medications, and if successful the carrier will be responsible for bill and 25% surcharge as set forth in 12 NYCRR 440.5(a)(2), if there was in fact an improper denial.

The comment expressed concern that this regulatory proposal would be abused by carriers. The regulation provides for a clear path for the claimant to obtain their necessary medication and provides for the 25% surcharge as well as penalties if the regulation is not complied with, so no change has been made to the proposal here. The Board also encourages communication of knowledge of any carrier habitually abusing the system, not complying with regulations, etc. so it can be properly investigated.

The comment disagreed with using 114-a(3) as the basis of the penalty, opining that the penalties should be paid to the injured worker. The Board does not have statutory authority to pay the penalty to the injured worker, so no change has been made here.

One comment from a claims examiner opined that the regulatory proposal "is not rational or reality-based" and places too much burden on businesses, and that there are other ways this can be done. The comment did not provide any alternative suggestions to consider; no change has been made in response.

One comment from a carrier suggested this proposal was not necessary and does not address any serious concern, opining the status quo is preferable. The goal of the regulation is for injured workers to get their required prescription medications as quickly as possible – this regulation addresses serious issues for claimants being denied prescription medications at in-network pharmacies with no explanation, no clear path for communication from the carrier about how to remedy the situation, and no clear guidance about what to do when the in-network pharmacy refuses to dispense prescribed medication, among others. The regulation addresses these serious impediments to claimants receiving necessary medication in a timely manner, so no change has been made in response to this comment.

Changes made:

- Allowing approximately 30 days from adoption before regulation takes effect for education, guidance, and programming efforts associated with the notice, etc. (The RIS outlined that the regulation would be effective upon publication of the Notice of Adoption in the State Register).
- Clarifying language added to 440.3(d)(1) to clarify that failure to dispense medication would be the failure of the *designated pharmacy* to dispense medication, and that the failure to pay for such prescribed medications refers to the failure of the *self-insured employer or insurance carrier* to do so.
- Clarifying change to remove superfluous references to subdivisions (c) and (d) in 440.4(c).