SEVEN THINGS TO KNOW ABOUT THE NEW YORK WORKERS' COMP PHARMACY FORMULARY

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Lately, we've received several requests for presentations on the proposed New York Pharmacy Formulary rules and how those rules will impact medical cost containment strategies on claims in that state.

In the past, we've presented on implementation of workers' compensation formularies in Texas, Tennessee, Oklahoma, and California – as well as "formulary-esque" prior authorization requirements in multiple other states. While formularies have been a hot topic within the industry for several years now – particularly as more and more states start to look for ways to deal with the nationwide opioid epidemic – we've gotten an unusually high number of requests for additional information on the formulary proposed by the New York Workers' Compensation Board (WCB). This is likely because the first implementation date for the formulary is currently set for July 1, 2018.

To be clear, this article is just intended to be an overview. It offers a general summary of a few important aspects of the formulary. There's a lot of discussion to be had on how the final rules will impact existing cost-containment strategies in this state, but that's probably better addressed in a more in-depth presentation that takes into account the existing strategies of the payer and the payer's existing relationships with their vendors.

If you'd like a more in-depth presentation on this issue, let us know, but for those who are just looking for some top-level information on the proposed rules as they currently stand, we hope that this piece will help.

1 **Presently, there will be four categories of drugs that will require prior authorization.**

> *"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."* – 12 NYCRR § 441.4(a) (proposed)

> *"…For the purposes of this subchapter, a compound drug shall be treated the same as a Non-Preferred drug…."* – 12 NYCRR § 441.1(d) (proposed)

As currently written, the proposed rules would require prior authorization for four categories of drugs:

- **"Non-Preferred drugs"** (medications that are listed in the formulary with either a "No" under the "NYS WCB Formulary Preferred?" heading, or the absence of a "Yes" under the "Subsequent Prescriptions" heading) in the formulary document;
- **"Unlisted drugs"** (medications that aren't listed in the formulary but are FDA-approved or marketed pursuant to a FDA OTC monograph);
- **"Compound drugs"** (which, as a class, are treated as "Non-Preferred drugs"); and
- Brand-name drugs with generic equivalents.

These categories are similar to those excluded from formularies in other states, but there will be some very important state-specific details (largely owing to the fact that the NY formulary is based on New York's state-specific Medical Treatment Guidelines).

It should also be noted that because this is a state-specific formulary, it may not match up with multistate preauthorization requirements that PBMs are currently using.

There will be exceptions to the prior authorization requirement.

"Special Fill drugs…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." – 12 NYCRR § 441.4(e)(1) (proposed)

"Perioperative Fill drugs…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." – 12 NYCRR § 441.4(e)(2) (proposed)

It's clear that the WCB took some time to research formularies in other states to see what good ideas there were to be borrowed. The "Special Fill" and "Perioperative Fill" exceptions bear a striking resemblance to similar exceptions found in the California formulary rules, but with a few changes (primarily, the removal of any reference to the California Medical Treatment Utilization Schedule).

The timeframes for these exceptions are clearly laid out (another good idea borrowed from the California rules), and they present four easy questions to ask when figuring out whether a dispensed medication qualifies under either exception.

1. Was it dispensed within the "Special Fill" or "Perioperative Fill" timeframe?

2. Does the treating medical provider feel that it is medically necessary? (In most cases, this will be a given.)

3. Is it FDA approved?

It should be noted that the formulary document itself adds a fourth requirement: to qualify as a "Special Fill" or "Perioperative Fill," the fill cannot exceed the number of days' supply indicated on the formulary document for that medication.

Regardless of whether these exceptions remain exactly as they are now in the proposed rules, it's very likely that exceptions of some form will appear in the

formulary rules to address those instances where there may be a clinical basis for not requiring authorization (such as where the medications are prescribed following a surgery).

3 **Failing to request authorization – and failing to respond to a request for authorization – will have consequences.**

"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." – 12 NYCRR § 441.4(d) (proposed)

"A request for prior authorization that is not timely denied shall be deemed approved." – 12 NYCRR § 441.4(b) (proposed)

Any time rules introduce a new obligation, that obligation prompts the question: "Or else what?" For example:

- If new rules require a doctor to request prior authorization for certain treatment, what happens when the doctor doesn't request authorization?

- If new rules require a payer to perform utilization review, what happens when the payer doesn't perform utilization review?

For those who are familiar with the "closed formulary" in Texas, there's a temptation to assume that all workers' compensation formularies work in the same way – that they all have enforceable prior authorization requirements with clear consequences for payers who ignore a request for authorization.

In reality, different states – even those that initially tried to recreate the Texas formulary – have gone in slightly different directions. For example:

- While some states have formulary rules that explicitly permit denial of certain medications that are dispensed without authorization, other states require the payer to take an extra step before an unauthorized fill can be denied. Some states even require a formal review of medical necessity regardless of whether the medication requires authorization or not. (We most recently saw this in earlier proposed versions of California's formulary rules – which only allowed payers to deny an unauthorized drug that required authorization if it was "determined upon retrospective review that the drug treatment was not medically necessary.")

- Additionally, while some states automatically deem treatment to be authorized if the payer doesn't respond to a request in a timely manner, others deem a non-response to be an effective denial, and others consider it a "no response" – neither an approval nor a denial. In some states, an untimely response triggers an automatic right to an independent peer review process; in others, an untimely response forces any dispute over medical necessity of that treatment to be handled by a workers' compensation judge.

While all formulary states have different approaches to answering the "Or else what?" question, not all formulary states offer that answer as clearly as New York does in its proposed formulary rules.

The proposed New York rules indicate that payers should expect to be held accountable for complying with their prior authorization process, and providers should expect to be held accountable for requesting authorization.

Payers will need to proactively notify healthcare providers (but the timetable for this will likely change).

As a very broad generalization, most workers' compensation formularies follow a timetable that goes something like this:

- **Date 1: Notice Deadline** – Payers are required to notify prescribers about upcoming formulary prior authorization requirement.

- **Date 2: Implementation** – Payers can start requiring prior authorization for new fills.

The idea is fairly simple: before payers can require a provider to obtain prior authorization, the provider needs to be told (1) that prior authorization will be required, and (2) **how** to request prior authorization.

Some states (like Texas), had two formulary implementation dates (one for newer claims and one for older claims) with a separate notice deadline prior to each implementation date, but the idea was the same: notice first, implementation second.

The current New York proposed rules offer something of a mix: they have two implementation dates (one for new fills and then a later one for refills and renewals), but they only have one notice deadline…and it falls **after** one of the implementation dates.

Here's what that looks like:

- July 1, 2018 – Prior authorization requirement applied to new prescriptions.

- October 1, 2018 – Deadline for payers to notify providers about prior authorization requirement. Deadline for payers to tell providers how to request prior authorization.

- December 31, 2018 – Prior authorization requirement applied to refills and renewals.

As written, this would suggest that payers could require prior authorization in July but not get around to telling providers how to obtain prior authorization until October. In reality, it's very unlikely that this was the intent of the rules. We can likely expect to see this clarified before the rules are finalized.

Payers will need to develop a formulary prior authorization process.

"No later than October 1, 2018, the insurance carrier or self-insured employer shall… provide written notification to the injured employee and Treating Medical Provider which contains…the process to request prior authorization for a Non-preferred or unlisted drug." — 12 NYCRR § 441.2(c) (proposed)

The proposed rules are clear that payers have a deadline by which to explain to providers how to request prior authorization, but they don't offer much guidance as to how providers should submit a request for prior authorization or how payers should evaluate a request.

Currently, providers for New York claims use the C-4AUTH form to request authorization for special services that require prior authorization under the state's treatment guidelines; however, the form doesn't currently address medications, and the review timeframe for a C-4AUTH form is typically 30-days — much longer than the time contemplated for a review of medications under the proposed formulary rules. The proposed rules currently state that a request that is not timely denied "shall be deemed approved," so ensuring a timely delivery will be of the utmost importance.

Additionally, since the proposed rules would allow any denial of a request for a medication under the formulary rules to be appealed to the Medical Director of the Workers' Compensation Board, payers will want to ensure that any denials have a substantial basis so that they can survive appeal.

6 Payers will need to work with prescribers to safely implement the formulary.

This is more of a point of common sense than an administrative rule; however, it does also make an appearance in the proposed MTG formulary document:

"Finally, if the claimant requires a refill of a prescription(s) which was the first fill of a preferred drug and subsequent fill criteria for the applicable body part is not met, it is the carrier's responsibility to:

1. *Contact the prescriber to discuss:*
   (a) changing the prescription to a preferred drug for that body part / condition, or
   (b) submitting a prior authorization request for the non-preferred medication.

2. *Continue to authorize payment for the medication until the prescriber has either:*
   (a) changed to a preferred drug for the applicable body part, or
   (b) received the denial of the prior authorization request."

Oddly, this language appears in the formulary document (the actual list of drugs) rather than in the proposed regulations; however, it offers a clear picture of the WCB's expectations for claims where a patient is being treated with a "Preferred Drug" that isn't actually "preferred" beyond the initial fill.

While not explicitly stated, this expectation likely also applies where the patient has been on a course of "Non-Preferred" or "Unlisted" drugs for some time, and the payer is attempting to transition treatment in that claim to the formulary by the implementation date (currently, December 1, 2018 for refills/renewals).

Other than giving a later implementation date, the proposed rules currently don't offer much guidance as to how payers are to facilitate transition from ongoing use of a "Non-Preferred" or "Unlisted" drug to a "Preferred" drug under the formulary. Until this is clarified in the rules, the best guidance may come from the formulary document itself and observation as to how the WCB has applied its Medical Treatment Guidelines in the past.

With that in mind, it's unlikely that payers will be permitted to suddenly implement a "hard and fast" prior authorization requirement for continuing use of "Non-Preferred" or "Unlisted" drugs, particularly where doing so could put the patient at risk.

Working with prescribers early-on to prepare for implementation of the formulary will be essential. It will certainly be easier in some claims than in others. Some patients will need additional time to transition. Some patients will not be able to transition completely (and will require on-going authorization). Some prescribers will ignore the formulary altogether.

In these instances, documenting good-faith attempts to work with the provider to meet the patient's needs within the formulary rules will be an absolute necessity

7 **Payers should start preparing now. Details within the proposed rules may change; the core concepts will not.**

Shortly after the proposed rules were announced, PRIUM received multiple requests for implementation outlines and process flows for each stage of implementation, as delineated by the notice and implementation dates in the proposed rules.

One of the questions that came up was, "What happens if the Workers' Compensation Board (WCB) changes the deadlines?"

That's a smart question, and it's one that should be kept in mind.

Should payers and PBMs be preparing for the formulary? Absolutely.

Should they be crafting detailed implementation processes that hinge on specific details of the proposed rules that are currently subject to change? Probably not.

The initial comment period ended on February 28, and the WCB is currently evaluating the submitted comments. Depending on what (if any) changes the WCB makes to the proposed rules, an additional comment period may be held.

Certain aspects of the rules – such as implementation dates – may need to be changed if there is an extended comment period (since stakeholders would effectively have less time to prepare for implementation). It's also possible that more substantive aspects of the formulary rules – or even the formulary itself – will be changed as the WCB evaluates submitted comments.

That said, while certain aspects of the final rules may be changed prior to approval, the core concepts underlying the formulary will likely remain.

These core concepts – such as requiring prior authorization for certain medications, requiring payers to abide by a prior authorization process with strict timeframes, and requiring payers to work with prescribers to ease transition into the formulary – will likely still appear in the final rules, even if some of the details are changed.

Working with vendors to make sure that they are prepared for implementing the formulary is a good idea, but, until the rules are finalized, that preparation may have to be general rather than specific.

For example:

- Confirming that your PBM is aware of the proposed formulary;
- Confirming that your PBM will be able to implement the final formulary (as published in the final rules) by the implementation deadlines (as published in the final rules);

- Confirming that your peer review/UR vendor has a prior authorization process that meets or exceeds the requirements of the proposed rules and can, if necessary, adapt to meet changes added in the final rules.

- Developing a plan to ensure notification of prescribers prior to enforcement of the formulary, and developing notification templates (with the understanding that the dates may be changed prior to finalization).

- Developing a plan with your vendors to assist prescribers in transitioning to the formulary.

We'll continue to keep an eye on the rules as they progress, and we'll continue to work with you and your other vendors to implement strategic changes in this – and any – state.

If you'd like more information on this topic, let us know at compliance@prium.net.

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