OFFICE of the INSURANCE COMMISSIONER
WASHINGTON STATE

# Prescription drug substitution timeframes

## Concise Explanatory Statement

## January 12, 2017

**Mike Kreidler**, *Insurance Commissioner*
www.insurance.wa.gov

# Table of contents

# Introduction

The Revised Code of Washington (RCW) 34.05.325(6) requires the Office of Insurance Commissioner (OIC) to prepare a "concise explanatory statement" (CES) prior to filing a rule for permanent adoption. The CES:

1. Identifies the Commissioner's reasons for adopting the rule;

2. Describes the differences between the proposed rule and the final rule (other than editing changes) and the reasons for the difference;

3. Summarizes and responds to all comments that the OIC received regarding the proposed rule during the official public comment period, indicating whether or not the comment resulted in a change to the final rule, or the OIC's reasons for not incorporating the change requested by the comment;

4. Must be distributed to all persons who commented on the rule during the official public comment period and to any person who requests it.

# Reasons for adopting the rule

HHS released the 2017 Notice of Benefit and Payment Parameters setting forth new parameters for a health plan's prescription drug substitution process. 45 CFR §156.122(c) sets forward specific processes that health plans must follow in order to provide enrollees with sufficient access to prescription drugs that are not covered by the plan. Rules are necessary to ensure that state law is consistent with federal requirements. Washington already has a process for consumers to access prescription drugs that aren't on a plan's formulary, but the process did not include a specific timeframe for the plan to follow.

# Rule development process

On July 29, 2016, the OIC filed a Pre-proposal Statement of Inquiry (CR-101) proposing to write a rule to align our prescription drug substitution rules with federal requirements. The comment period on the CR-101 was open until September 15th.

On August 30, 2016, the OIC shared a draft with interested stakeholders. The comment period on the stakeholder draft was open until September 23, 2016.

On November 2, 2016, the OIC filed a CR-102. The agency held a hearing on December 7, 2016. The OIC filed a CR-103P to adopt the rule on January 12, 2017 and the rule went into effect 31 days later.

# Documents reviewed during research

HHS Notice of Benefit and Payment Parameters for 2016
HHS Notice of Benefit and Payment Parameters for 2017, Proposed Rule
HHS Notice of Benefit and Payment Parameters for 2017, Final Rule

# Differences between proposed and final rule

Non-substantive changes were made in WAC 284-43-5080 (3)(b), (3)(c), and (6)(c) to clarify the applicability of the requirements. As a result, proposed. WAC 284-43-5080 (7) was no longer necessary.

Similarly, non-substantive changes were made in WAC 284-43-5110 (6) to clarify the applicability of the requirement. As a result, proposed WAC 284-43-5110 (7) was no longer necessary.

WAC references in WAC 284-43-5110 (1) & (4) were changed to the correct citations.

# Responsiveness summary of comments

The OIC received numerous comments and suggestions regarding this rulemaking. The following information contains a description of the comments, the OIC's assessment of the comments, and information about whether the OIC included or rejected the comments.

The OIC received comments from:

- Premera
- Molina
- Cambia
- Autoimmune Advocacy Alliance
- Northwest Health Law Advocates
- Pharmaceutical Research and Manufacturers of America
- Nancy (last name unknown)

## Comments received

**Comment:** Stakeholders expressed support for protecting the medically stable patient from forced drug replacement. Stakeholders also expressed support for the consumer protection.
**Response:** Thank you for your comments – the Commissioner agrees that patients should have a reasonable pathway to stay on their treatment. That's the reason for these rules.

**Comment:** We appreciate that the timelines align with current Medicare timelines. However, the current Medicare rules state that the clock doesn't start until the supporting statements are received.
**Response:** These rules align with CFR 156.122 regarding commercial coverage, not Medicare. The preamble of the 2016 Payment Notice (80 FR 10818) clarifies that the timeframes begin when the health plan or its designee receives a request and the HHS Notice of Benefit and Payment Parameters for 2017, final rule further clarifies that "the health plan must begin the review following receipt of information sufficient to begin the review."

**Comment:** We believe the use of "substitution" requires additional clarity and defined meaning within this stakeholder draft.
**Response:** No clarification is necessary- the term has been used previously in regulation and no need to define the term further has been identified.

**Comment:** As the drug substitution process described in this draft is similar to the existing Drug Utilization Review Process, we believe that the timeframes imposed in WAC 284-43-5080 (3)(b) & (3)(c)(i) should mirror existing timeframes in WAC 284-43-2020 Drug Utilization Review.
**Response:** The substitution process is unique and separate from prior authorization and therefore has unique timeframes.

**Comment:** We believe that additional verbiage needs to be added to WAC 284-43-5080 (6)(b) to clarify that a carrier is required to provide coverage of the non-formulary drug in the event that the substitution request is approved. If the intent is that a carrier must cover the nonformulary drug in cases other than when approval is granted, we may have additional concerns.
**Response:** The requirement has been clarified.

**Comment:** These rules should provide a standardized review period for all exceptions and a uniform submission form for the "standard exceptions" or "prior authorization" of prescription drugs. We support changing the draft to encompass a shortened decision timeframe to 48 hours or 2 business days from the time of the request. Patients awaiting new therapies should never be forced to wait more than 48 hours to find out whether they can receive the treatment their physician orders.
**Response:** The substitution process is unique and separate from prior authorization and therefore has unique timeframes.

**Comment:** Automatic approval of a prior authorization or "standard" exceptions request is essential for patients that have epilepsy or take orphan drugs.
**Response:** This is outside the scope of this rulemaking.

**Comment:** Please clarify that the exceptions process only applies to prescriptions that are not on the formulary. Enrollees have access to the plan's appeal process for any adverse benefit determination, which could include coverage for a formulary drug that was denied because the enrollee had not completed a required step therapy protocol, for example. This denial would not be eligible for the exceptions process under the federal rule and should not apply to your substitution rule.
**Response:** We have offered clarification.

**Comment:** When the stakeholder draft was released, a comment was submitted that suggested the OIC's reading of the federal rule was mistaken. The federal requirements do not allow an external review in addition to the appeals process that follows an adverse benefit determination.
**Response:** The OIC contacted HHS after the stakeholder draft was released to clarify their intent. The OIC made significant changes to clarify that consumers will have access to an external review only once. The consumer seeking an alternative drug will only be able to go through the drug substitution process or the appeals process (depending on the circumstances), not both if the consumer desires it.

**Comment:** Do not allow carriers the option to deny consumers a request for an external review.
**Response:** The federal rule clearly states that carriers must have a process for a consumer to request an external review. The rules do not state that the request must be granted. Given that the scope of the rule is limited to maintaining consistency of state law with federal law, the rule clarifies, but does not go beyond the changes in federal law.

# Implementation plan

## Implementation and enforcement of the rule

The OIC intends to implement and enforce the rule through the Rates and Forms Division and Market Conduct Oversight Unit, which is part of the Company Supervision Division. Using existing resources, OIC staff will continue to work with carriers, providers, and interested parties in complying with the requirements of these rules.

## How the agency will inform and educate affected persons about the rule

After the agency files the permanent rule and adopts it with the Office of the Code Reviser:

- Policy staff will distribute copies of the final rule and the Concise Explanatory Statement (CES) to all interested parties through US mail, post to its standard rule making listserv and email to stakeholder participants.

- The Rules Coordinator will post the CR-103 documents on the Office of Insurance Commissioner's website

- OIC staff will address questions as follows:

| Type of Inquiry | Division |
|---|---|
| **Consumer assistance** | **Consumer Protection Division** |
| **Rule content** | **Rates and Forms** |
| **Authority for rules** | **Policy and Legislative Affairs** |
| **Enforcement of rule** | **Legal Division** |
| **Market Compliance** | **Company Supervision** |

## How the agency intends to promote and assist voluntary compliance for this rule

The steps listed under implementation will inform and educate affected persons on the changes and help promote voluntary compliance. Prior to the rule, the Rates and Forms Division issued a universal objection for the Plan Year 2017 individual and small group filings, so the industry is already aware of the Commissioner's intention to follow federal law.

## How the agency intends to evaluate whether the rule achieves the purpose for which it was adopted

The OIC will work closely with carriers, providers, and other interested parties to evaluate the effectiveness of the rule as well as monitor consumer complaints and to monitor plans for non-compliance.

# Appendix A – Hearing Summary

**Summarizing Memorandum**

**To:** **Mike Kreidler, Insurance Commissioner**

**From:** **Bianca Stoner, presiding official for rule hearing**

**Matter:** **Rule 2016-22**

**Topic:** **Prescription drug substitution timeframe rule**

This memorandum summarizes the hearing on the above-named rulemaking, which was held on December 6, 2016 at 10:30 a.m. in Tumwater. I presided over this hearing in your place.

The hearing began at 10:30 a.m.

In attendance but did not testify:

- Jessica Fortescue, Abbvie

The hearing was adjourned.

*SIGNED this 6th day of December, 2016*

*Bianca Stoner, Presiding Official*