OFFICE of the INSURANCE COMMISSIONER
WASHINGTON STATE

Prescription drug coverage disclosures (R 2016-16)

Concise Explanatory Statement
December 15, 2016

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

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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

The existing regulations regarding prescription drug benefit disclosures are confusing. The rule clarifies the requirements for disclosures related to prescription drug benefits so that consumers are fully aware of the prescription drug coverage of the plan they purchase.

Background

Consumers are increasingly concerned about the prescription drug coverage offered by their health insurance policies. Existing regulations regarding prescription drug disclosures are incomplete, confusing, and do not generally contribute to consumer awareness of their complete prescription drug coverage. The rule builds off HHS guidance offered in the 2016 Notice of Benefit and Payment Parameters to ensure the prescription drug benefit is easily understood by consumers.

Rule development process

On May 31, 2016, the OIC filed a Pre-proposal Statement of Inquiry (CR-101) proposing to write a rule on prescription drug coverage disclosures. The comment period on the CR-101 was open until July 15th.

On June 10, 2016, the OIC shared a draft with interested stakeholders. The comment period on the stakeholder draft was open until June 30, 2016.

On October 18, 2016, the OIC filed a CR-102. The agency held a hearing on Nov 22, 2016.

The OIC will file a CR-103P to adopt the rule by December 21, 2016 and portions of the rule will go into effect as follows:

- WAC 284-43-0160: July 1, 2017
- WAC 284-43-5170: 31 days after filing.
- WAC 284-43-5040: Repeal is effective December 31, 2017

Differences between proposed and final rule

No differences.

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:

- American Cancer Society, Cancer Action Network
- Arthritis Foundation
- Alliance for Patient Access
- Cambia Health Solutions
- Molina Health Care
- Northwest Health Law Advocates
- PhRMA
- Premera Blue Cross/ Lifewise Health Plan of WA
- Robert E. Parker, PhD
- Vertex
- Washington State Medical Association
- Washington State Podiatric Medical Association

Comments regarding the CR-101 and CR-102

Comment: Stakeholders expressed both support and opposition for the clarification regarding the definition of "formulary," stating that it include drugs covered under the medical benefit.
Response: The Commissioner believes that drugs covered under the medical benefit are important aspect for consumers who are inquiring about covered benefits. Including drugs covered under the medical benefit is an important protection for consumers who may want to know about these benefits.

Comment: Commenters expressed support for a requirement that estimated out of pocket costs be added to formularies. Consumers need access to additional information to compare the cost of prescriptions under various plans.
Response: This is outside the scope of this rulemaking.

Comment: Please clarify WAC 284-43-5170 (1)(d) to state that carriers may offer formularies that do not have drugs that move between tiers during a plan year. This is an important disclosure.

Response: Thank you for your comment – we have made this clarification.

Comment: Comments were made both for and against the revisions to the disclosures. Some stakeholders stated that the existing disclosure requirements in a pose-and-response format serve consumers sufficiently well and do not need modification. They also said that information should be made available to consumers prior to the purchase of a health plan. Another stakeholder appreciated the elimination of the pose-and-response requirements and the clarification of all prescription drug related disclosures. A stakeholder also asked that the cost of a drug be required to be disclosed to consumers under this section.
Response: The Commissioner appreciates these comments. The existing disclosures requirements already allow deviation from the pose-and-response format. Clarification is necessary as disclosure requirements currently exist throughout a number of sections and do not sufficiently ensure that clear information is presented to consumers. Furthermore, we believe eliminating redundancies in requirements will be more efficient to administer while maintaining existing consumer protections. The disclosures are related to coverage and limits; disclosures related to cost are covered by other consumer protections.

Comment: A stakeholder urged the disclosure of "pay-to-prescribe" measures whereas consumers would be made aware of increased provider reimbursement for following certain clinical pathways.
Response: This is outside the scope of this rule.

Comment: Stakeholders requested that consumers be allowed to continue coverage on their medication when they change health plans.
Response: This is outside the scope of this rule. This rule is related to disclosure, not mandating specific coverage requirements for carriers.

Comment: It is unclear what "intellectual services" refers to. If it is considered medication therapy management or disease management, these serves may or may not be provided by a carrier (and typically at no cost to the consumer), and it is unclear why these services must be disclosed.
Response: All services covered by a health plan must be disclosed to consumers under RCW 48.43.510.

Comment: A stakeholder asked for disclosure of whether any medications with no alternative in the same drug class are placed on the tier with the highest patient cost-sharing.
Response: This is outside the scope of this rulemaking. Information about cost-sharing is already required.

Comment: A commenter asked for disclosure so that consumers would know if experts in a disease area are consulted in coverage determinations for rare disease medications.
Response: The Commissioner believe a general description of the process for developing coverage standards is sufficient to inform consumers. Additional specificity may not cover the necessary information relevant to all drugs.

Comment: A stakeholder asked that health plans be required to include contact information for agents acting on behalf of carriers, such as pharmacy benefit managers.

Response: Carriers are ultimately responsible for delivering benefits and thus should be the starting place for consumers inquiring about their benefits.

Comment: A stakeholder expressed support for a provision stating that mid-year formulary changes should only occur in very limited situations as allowing mid-year changes is unfair to consumers. Mid-year changes to tiering may result in changes to cost-sharing, which is often an important consideration for consumers when choosing a plan.
Response: The Commissioner believes that consumers should be aware that the formularies may change during a plan year, but issuers have the option to keep a formulary static if they choose. Most importantly, consumers are to be notified if changes occur. Changes to cost-sharing is outside of the scope of this rule. It may not always be in the consumer's best interest to require drugs in the same tier throughout a plan year.

Comment: A stakeholder expressed concern for the potential of the rule to allow generics-only benefits, which were withdrawn from the market several years ago at the Commissioner's direction.
Response: Thank you for this comment. The Commissioner clarified that relevant provision as we do not want to imply that generics-only benefits are permissible.

Comment: A stakeholder expressed support for requirements that align with federal guidance, both in the CMS Notice of Benefit and Payment Parameters and Medicare Part D requirements.
Response: The Commissioner reserves the right to be more stringent regarding consumer protections than the federal government. Many of these requirements are long-standing.

Comment: A stakeholder asked that the effective date reflect a realistic implementation timeframe, especially given that plans were filed earlier in the spring.
Response: The Commissioner appreciates this concern and has adjusted the effective date of the requirements.

Comment: A stakeholder asked that carriers be allowed to put this information online rather than putting these disclosures into the certificate of coverage.
Response: The Commissioner believes these disclosures are important enough to justify their existence in the certificate of coverage rather than online.

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.

The new disclosure requirements in WAC 284-43-5170 will apply to contracts issued on or after January 1, 2018. Any plans filed with the OIC during 2017 with effective dates on or after January 1, 2018 should follow the new requirements in WAC 284-43-5170. The existing disclosure requirements in WAC 284-43-5040 will continue to apply to plans with effective dates on or before December 31, 2017 and be repealed on December 31, 2017.

The new requirement expanding the definition of formulary to include drugs covered under the medical benefit will become effective July 1, 2017, meaning formularies filed with the OIC quarterly (per WAC 284-43-5640 (6)(f)(i)) must meet this new requirement starting with the submission of third quarter 2017 formulary filings. Copies of formularies available to consumers under disclosure and formulary transparency requirements must meet this requirement as of the effective date of the rule, July 1, 2017.

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 posting to its standard rule making listserv.

- 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.

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: **Jim Freeburg, presiding official for rule hearing**

Matter: **Rule 2016-16**

Topic: **Prescription drug disclosures rule**

This memorandum summarizes the hearing on the above-named rulemaking, which was held on November 22, 2016 at 3:00 p.m. in Tumwater. I presided over this hearing in your place.

The hearing began at 3:00 p.m.

In attendance but did not testify:

- Matt Miller, Millter, Malone & Tellefson
- Nancy Heley, Retired Public Employees Council of Washington

No one offered testimony during the hearing.

The hearing was adjourned.

SIGNED this 22th day of November, 2016

Jim Freeburg, Presiding Official