Washington State Office of the Insurance Commissioner

Mike Kreidler-*Insurance Commissioner*

As required by

The Washington State Administrative Procedures Act

Chapter 34.05 RCW

Matter No. **[R 2014-13]**

CONCISE EXPANATORY STATEMENT; RESPONSIVENESS SUMMARY; RULE DEVELOPMENT PROCESS; AND IMPLEMENTATION PLAN

Relating to the adoption of

Prior authorization of pharmacy benefits

November 25, 2015

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Section 1: Introduction

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 shall:

1. Identify the Commissioner's reason’s for adopting the rule;
2. Describe differences between the proposed rule and the final rule (other than editing changes) and the reasons for the differences; and
3. Summarize and respond to all comments 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 Commissioner's reasoning in not incorporating the change requested by the comment; and
4. Be distributed to all persons who commented on the rule during the official public comment period and to any person who requests it.

Section 2: Reasons for Adopting the Rule

ESSB 6511 passed the Legislature in 2014 (Chapter 141, Laws of 2014). The bill created a work group to examine the prior authorization process and make recommendations to streamline the process. The authorizing legislation requires the OIC to adopt rules to implement the recommendations of the workgroup.

Section 3: Rule Development Process

The OIC worked closely with OneHealthPort, the convener of the work group authorized by ESSB 6511, to develop the rule. In addition, the OIC worked closely with interested parties to understand the content of the rule.

In addition:
The CR-101 was released November 3, 2014
A stakeholder draft was released June 10, 2015
The rules team held a stakeholder meeting on June 29, 2015
The CR-102 draft was released September 23, 2015
The CR-102 hearing was held November 2, 2015.

Section 4: Differences Between Proposed and Final Rule

In WAC 284-43-325, “billing pharmacies” was changed to “billing pharmacies” to improve consistency and readability. This change occurred twice in this section.

In WAC 284-43-420 (5)(a)(i)(A), “if a prior authorization number is required” was added to clarify that an authorization number is only required to be transmitted if they are used by an issuer.

Section 5: Responsiveness Summary

General comments

Comment: *Use the OIC's independent authority to streamline and standardize prior authorization requirements more broadly, including for medical benefits.*
Response: Per the authorizing legislation, the scope of these rules are limited to the recommendations of the OneHealthPort work group.

Comment: *Seek input from patient and consumer organizations. They were left out of the work group discussions.*
Response: The Commissioner appreciates the input of all stakeholders, including patient and consumer organizations.

Comment: *If the current and "future state" proposals are to apply to state public sector payers, as well as private sector health plans, the requirements would need to comply with federal Medicaid requirements under Title XIX of the Social Security Act and federal ACA requirements.*
Response: The recommendations from the OneHealthPort work group are limited to regulated plans.

Comment: *Please promote continuity of coverage by requiring plans to provide a temporary supply of any non-formulary drug (or one subject to utilization management) for new enrollees in a plan at any time within the first 90 days of coverage. The amount of fill should be at a minimum, the lesser of a 30 day supply or the amount as prescribed.*
Response: This suggestion is outside the scope of this rule.

Comment: *Consumers need access to up-to-date, detailed information about a plan's formulary and provider network. We support the development of a common website for prescribers and pharmacies to access pharmacy benefits, formularies, and prior authorization information. Website functionality should allow for searching a medication by a generic or brand name, determining if the medication is covered (and whether through the medical or pharmacy benefit), tiering (if any), the applicable deductible (if any), and any dispensing constraints. We also support requiring that formulary information be made electronically available for loading into e-prescribing applications.*
Response: This suggestion is outside the scope of this rule.

Comment: *New or revised processes should be closely examined to avoid unnecessary complexity or confusion for either providers or enrollees.*
Response: Thank you for your comments.

Comment: *Please allow a significant amount of time to implement the rules once finalized because they will require system changes or process changes. If possible, please allow for an alternative mechanism to show compliance, such as sharing this information online or as an update to provider handbooks.*
Response: The Commissioner agrees with this comment and will provide significant time for implementation.

Comment: *To ensure the best application of the recommendations, we suggest the adoption of standards/penalties for failure to comply. We believe this is a better option than patients or providers filing complaints with the OIC.*
Response: The OneHealthPort work group recommendations have been put into rules in such a way that enforcement is possible. All regulations are subject to OIC enforcement.

Comment: *Please create a standardized form. We believe that the specific data points in electronic prescribing applications be used to adopt a standard form used by all plans.*
Response: This comment is outside the scope of this rule.

Comment: *Please require disclosure of pay to prescribe/pay for performance measures as we believe they do not take into account patient preferences or a physician's own experience and judgment.*
Response: This comment is outside the scope of this rule.

Comment: *Encourage the OIC to focus on pharmacy prior authorization, rather than also medical services. If the OIC determines that additional changes are needed for medical prior authorization time frames, encourages a separate rulemaking to address those concerns.*
Response: The Commissioner appreciates this comment. The rule is focused exclusively on pharmacy prior authorization with additional rulemaking on medical prior authorization to follow.

Comment: *The rule discusses the NCPDP Formulary and Benefit standard transaction and the Telecommunication Standard transaction and then adds a list of five additional data elements. Not all issuers use the same software. Adding*

additional components beyond a standard transaction could create technical challenges for implementing, especially for issuers who share common software across multiple states.
Response: The Commissioner appreciates the comment, but the authorizing legislation requires the full adoption of the work group recommendations. The specific elements were named by the work group as being necessary for transparency and processing prior authorizations.

WAC 284-43-325

Comment: *We support coverage of emergency fills of prescription medication. The proposed changes, however, refer to "dispensing pharmacist" without any clarifying language regarding the network status of the pharmacy. The underlying OneHealthPort best practice says that an emergency fill will not be paid at a non-contracted pharmacy however this concept does not carry over to the suggested regulation text. It is important for the regulation to be able to stand on its own, and we recommend that the concept of contracted or network pharmacies be included in the regulation text.*
Response: The Commissioner appreciates this comment and has made the suggested clarification.

Comment: *We recommends that the Commissioner clarify that the minimum amount of the emergency fill be enough medication to last through the prior authorization process, rather than the workgroup recommendation of at minimum, the minimum packaging size, or the lesser of a 7 day supply or the amount as prescribed.*
Response: This comment is outside the scope of this rule.

Comment: *We believe the proposed definition of "emergency fill" may be confusing and could be read to suggest that a health plan may not always be required to cover the emergency fill. We recommend that you revise the definition to clarify that while a health plan may determine that a patient does not meet the prior authorization for a medication and would not be covered for subsequent fills, a health plan is required to cover an emergency fill as described for as long as the prior authorization process lasts*
Response: This comment is outside the scope of this rule.

Comment: *We believes that excluding certain expensive medications for chronic conditions from "immediate therapeutic needs" implies an inappropriate categorical exclusion of drugs that are critical for serious chronic conditions. We urge clarification that the determination of a patient's "immediate therapeutic need" for a particular medication be made by the prescribing provider on a case*

by case basis. We also urge the Commissioner to confirm that the recommendation does not negate the requirement that health plans cover a drug that has been removed from a formulary while an enrollee goes through the "substitution process" to request continuation of coverage for the drug.
Response: This comment is outside the scope of this rule.

Comment: *The original work group recommendations requiring the availability of NCPDP telecommunication standards appears to be misplaced. It is unclear why this additional information would need to appear in the actual provider contract. If further clarification is needed for the content of a claims denial notice, we recommend that the language be in a separate section of the regulation that would not trigger all provider contracts to be amended and re-filed.*
Response: The Commissioner appreciates this comment. The work group recommendations have been edited for appropriate inclusion into regulations.

Comment: *For the claims denial notice content, we recommend that the regulation limit the data elements to those that are required by the NCPDP Telecommunications standard transaction and not require additional data elements. To date, Washington has been successful in having issuers voluntarily adopt best practices that often entail providing information beyond a standard dataset. We encourage the Commissioner to continue the best practice model for administrative simplification instead of writing the best practice data elements into regulation.*
Response: The authorizing legislation for this rule requires that the Commissioner fully implement the OneHealthPort work group recommendations.

Comment: *We urge the Commissioner to consider adopting a process for deeming "approval" of a complete prior authorization request for a given medication if an issuer fails to respond to a complete request within the specified time frame. Such criteria for deeming approval would encourage plans to respond to requests more promptly.*
Response: This comment is outside the scope of this rule.

Comment: *As mentioned at the meeting, we believe it would make sense to examine how the new requirement for synchronization of medications would fit into the prior authorization process and this rulemaking. We suggest that the interaction between prior authorization requirements and changes in refill timing resulting from synchronization be clarified.*
Response: The Commissioner appreciates this comment. The scope of this rulemaking is limited by its authorizing legislation.

Comment: *Please define "immediate therapeutic need" in WAC 284-43-130.*
Response: The Commissioner appreciates this comment and made the change.

Comment: *We recommend that you clarify the newly added definition for "emergency fill" to state expressly that emergency fills are applicable only for medications that are otherwise covered under the enrollee's health benefit plan.*
Response: Emergency fill is a short-term dispensed amount of medication that allows time for the processing of a pre-authorization request. The emergency fill medication will be approved and paid regardless of whether the prior authorization will be approved. If the patient requires medication past the emergency fill, then a determination will be made regarding its covered status under the prior authorization process.

Comment: *Proposed WAC 284-43-325(2) requires issuers providing notice of a pharmacy claim rejection to follow NCPDP guidelines and include specified information. We suggest that subsections (d) and (e), with respect to instructions for accessing additional information if needed through a website and telephone number, be further streamlined. The two could be combined to allow for the provision of either a phone number or information directing the submitting pharmacy to a website with more specific contract information (including phone numbers). Plans may have multiple phone numbers for different populations and jurisdictions; a more streamlined approach would reduce the administrative burden by allowing the plan to maintain to one website where all pharmacies can find the phone number or other contact information that they are looking for.*
Response: We decline to make this change. We believe that instructions and a phone number are necessary for providers to obtain necessary information regarding a claim.

Comment: *We urge you to reconsider the inclusion of specific prior authorization information into provider agreements. This would add a level of complexity to the implementation process that would likely prolong it and make it unnecessarily burdensome. Amending all provider agreements, and especially pharmacy contracts (typically done via the pharmacy benefits manager, which holds the agreements with each of the pharmacies), is an effort that requires significant lead time. The workgroup had not intended for such contract changes to be included in the rule, and did not suggest them in its recommendations. We believe there are other, more practical and more effective, avenues to ensure that details regarding prior authorization are disclosed. Our preferred alternative would be to accomplish this by using what we have in place today already, namely website information, which prescribers and pharmacies are accustomed to accessing and using on a regular basis. Alternatively, please only require this new language upon subsequent contract renewal.*

Response: The provider needs to know the rights that are available to them. The only way we can enforce these provisions are via the provider contract.

Comment: *We appreciate the attempt to include all data necessary to provide increased transparency to the notification process. However, we request clarification on the data necessary for each transaction. What is the justification for requesting information listed in parts (a) through (e) in addition to those required in the NCPDP Telecommunications Standards? Additionally, the language "to the extent supported by the transaction" seems vague in terms of application and enforcement. We suggest that this language be clarified so that all parties can prepare for any necessary changes and adjust their systems accordingly. It appears that these additional data elements, if provided for each prior authorization request, would increase transparency which we are supportive of; however, we want to ensure that these regulations, if implemented, would not lead to duplicative requests for information.*
Response: The specific elements were agreed upon by the OneHealthPort work group as being necessary to dispense a prescription.

Comment: *Sufficient information to facilitate the processing of a prior authorization request only needs to be provided by the issuer to the organization that is requesting the pre-authorization.*
Response: The Commissioner appreciates this comment and made the necessary clarification.

Comment: *Please require that authorization numbers be transmitted to the billing pharmacy upon their receipt of a claim after the request has been approved.*
Response: The Commissioner appreciates this comment and made the necessary change.

WAC 284-43-410

Comment: *To provide for further consistency among the regulations, we request that the term (and definition) "nonurgent review request" in WAC 284-43-420(1)(b) be revised to read "nonurgent preservice review request" as defined in WAC 284-43-410(1)(c).*
Response: We respectfully decline. We feel the terms apply to unique circumstances.

WAC 284-43-420

Comment: *We support attempts to clarify appropriate staffing of utilization review programs. In addition to the requirements set out in section (4) regarding staff qualifications, we request that language is added to require that the utilization review programs established by issuers are overseen by a Medical Director or a Pharmacist-in-Charge with appropriate licensure. We believe that this will ensure that review criteria and procedures support current medical practice, and would contribute to the implementation of "explicit written clinical review criteria and review procedures" as required by this section.*
Response: This recommendation is outside the scope of this rule as it was not recommended by OneHealthPort's work group. The criteria in WAC 284-43-420 were pulled from WAC 284-43-410. Only the criteria relevant to pharmacy were included. Utilization review programs are still required to meet national accreditation standards.

Comment: *To ensure that notification occurs whether a request is approved or denied, we suggest adding language to part (b)(i) to be consistent with part (b)(ii). Currently, notification of an approval or denial for prior authorizations occurs primarily when the pharmacist or requesting pharmacy calls the issuer back repeatedly to check on progress. Adding language from subsection (ii) would apply the same standards of notification methods to requesting providers to ensure that information is provided through reasonable methods. If amended, the suggested language in part (b)(i) would then read: "Information about whether a request was approved must be made available to the provider by one or more of the following methods; phone, fax, and/or secure electronic notification, and the covered person in writing or via secure electronic* notification."
Response: We decline to make this change. Clear standards are needed to clarify delivery methods only when an issuer issues a denial. The request would result in additional administrative burdens.

Comment: *We believe that subsection WAC 284-43-420 (5)(a)(i)(A) needs to be clarified in order to be consistent both with proposed WAC 284-43-325(5)(b) and with existing issuer practices (which vary), namely that not all issuers require or use an authorization number.*
Response: Thank you for your comment. We have made the change to clarify our intent.

Comment: We are c*oncerned that allowing too much time to pass before a plan is required to process a prior authorization request may jeopardize enrollees' ability to timely access the medications they need. We urge a shortened*

response time for prior authorization to 24 hours (rather than 48 hours) for urgent care and to 72 hours (rather than 5 days) for standard requests.
Response: This comment is outside the scope of this rule. The authorizing legislation requires us to adopt the work group recommendations.

Comment: *Information regarding the rejection of any prior authorization request should be required to go the prescribing provider in addition to the pharmacy and the enrollee. If not feasible, consider requiring a pharmacy to make the rejection information available to the patient who can contact the provider.*
Response: Notification of a prior authorization rejection will be transmitted to the prescriber and the consumer.

WAC 284-43-818

Comment: *We want to express support for the changes included in section (4), which would improve system coordination and ultimately, allow our pharmacists to provide better care to patients through the increased transparency that would result from inclusion of this information.*
Response: Thank you for your comments.

Comment: *We work with a number of health plan clients who design the prescription drug benefit for each of their offerings. As such, we manage thousands of formularies and benefit designs for our clients. When patients are comparing plans, they are looking to the plan website to provide all of the information. It will create mass confusion for patients if they are required to move between the plan and the PBM websites to compare benefits. The formulary information should be posted on the plan's website, not the PBM.*
Response: Issuers are required to post their formulary information online. It can be posted on either the issuer's website or that of the pharmacy benefit manager. This was a recommendation from the work group and as such, cannot be deviated from.

Section 6: Implementation Plan

A. Implementation and enforcement of the rule.

The Commissioner has worked closely with the work group submitting the recommendations to ensure that the rules align with their recommendations. Issuers actively contributed to the development of the recommendations and have had significant lead time to start complying with the rules.

B. How the Agency intends to inform and educate affected persons about the rule.

The Commissioner has worked closely with all stakeholders during the rulemaking process. Significant outreach has been done to both the issuer and provider community to ensure that they are aware of these changes.

Type of Inquiry	Division
Consumer assistance	None
Rule content	Policy
Authority for rules	Policy
Enforcement of rule	Rates and Forms
Market Compliance	Company Supervision

C. How the Agency intends to promote and assist voluntary compliance for this rule.

The Commissioner will continue to work with OneHealthPort and individual issuers to ensure they are aware of the contents of the rule and assist with questions related to implementation as necessary.

D. How the Agency intends to evaluate whether the rule achieves the purpose for which it was adopted.

The Commissioner will maintain close contact with OneHealthPort and its work groups to ensure that the rules have their intended effect.

Appendix A

CR-102 Hearing Summary

Summarizing Memorandum

To: Mike Kreidler
Insurance Commissioner

From: Jim Freeburg
Presiding Official, Hearing on Rule-making

Matter No. R 2014-13

Topic of Rule-making: Prior authorization of pharmacy benefits

This memorandum summarizes the hearing on the above-named rule making, held on November 2, 2015 over which I presided in your stead.

The following agency personnel were present:
Mandy Weeks, staff attorney
Dan Halpin, compliance analyst

In attendance and testifying:
Waltraut Lehman, Premera (only person in attendance)

Contents of the presentations made at hearing:
Though Premera supports the rule, Waltraut made three requests. First, clarify that emergency fills will only apply to covered medications. Allow significant lead time for allow for implementation of the new requirements. And clarify that an authorization number only needs to be transmitted to a provider if an issuer uses such a system (Premera does not).

The hearing was adjourned.

SIGNED this 2nd day of November, 2015

_ Jim Freeburg_____
[NAME], Presiding Official