Mike Kreidler- Insurance commissioner

As required by

The Washington State Administrative Procedures Act

Chapter 34.05 RCW

Matter No. **R 2024-05**

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

Relating to the adoption of

Consolidated Health Care

November 27, 2024

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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 reasons 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

Consolidated rulemaking is required due to the passage of health insurance related legislation and other changes in law. This rulemaking will aid in implementing enacted legislation, including: Chapter 325, Laws of 2023, concerning continuity of coverage for prescription drugs prescribed for the treatment of behavioral health conditions, Chapter 215, Laws of 2024, establishing a uniform standard for creating an established relationship for the purposes of coverage of audio-only telemedicine services, and Chapter 314, Laws of 2024, preserving coverage of preventive services without cost sharing.

The Commissioner is adopting consolidated health care regulations due to the passage of health insurance related legislation, as outlined above. Currently multiple provisions of health insurance-related regulations in the Washington Administrative Code need to be updated by the Commissioner to be consistent with legislation passed and codified in the Revised Code of Washington, as well as recent federal law changes. These rules will facilitate implementation of the new laws by ensuring that all affected health care and insurance entities understand their legal rights and obligations under the enacted legislation.

This effort includes but is not limited to: clarifying prescription drug coverage for behavioral health treatment; updating the definition of “established relationship” as applied to coverage of audio-only telemedicine services; and clarifying coverage and cost sharing requirements for preventive health care services. This rulemaking impacts the following authorities: WAC 284-170-130, 284-43-0120, 284-43-0160, 284-43-5080, 284-43-5110, 284-43-5642, 284-43-5800, and 284-43-5980.

Section 3: Rule Development Process

The CR-101 (Preproposal Statement of Inquiry) for this rulemaking was filed with the Washington State Register (WSR) on June 4, 2024 (WSR 24-12-075). The comment period for the CR-101 was open for approximately one month, closing on July 5, 2024. Two written comments were received in response to the CR-101.

A prepublication draft for this rulemaking was published on August 9, 2024, with a two-week comment period ending on August 23, 2024. No written comments were received in response to the prepublication draft.

The CR-102 (Proposed Rule Making) was filed with the Office of the Code Reviser on October 1, 2024 (WSR 24-20-133). The Commissioner accepted comments through Friday, November 8, 2024. Five written comments were received in response to the CR-102.

The Commissioner held a public hearing on the proposed rule text on Thursday, November 7, 2024, at 9:00 AM; the public hearing was administered by Policy Analyst, Delika Steele, as a virtual meeting. No public testimony or comments were provided at the public hearing.

The CR-103 (Rule-Making Order) was submitted to the Office of the Code Reviser on Wednesday, November 27, 2024, for agency adoption.

Section 4: Differences Between Proposed and Final Rule

There are no differences between the proposed and final rule.

Section 5: Responsiveness Summary

General Comments	**Agency Considerations and Responses**
WACs 284-43-0160 and 284-43-5080	

Although "serious mental illness" is defined in RCW 48.43.0961, we are concerned about the consistent implementation of this definition. Carriers cannot systematically program this definition for claims adjudication because they do not have the insight through claims, or codes used on claims, whether a behavioral diagnosis results in a functional impairment. Carriers would need a manual pending and review process to confirm with a prescriber that a patient is experiencing a functional impairment because of their diagnosis. This will delay cases. Without clarification the definition will be applied inconsistently especially as it relates to "other drugs prescribed to treat a serious mental illness." OIC should clarify and specifically list all relevant drug categories. Carriers cannot determine from a prescription whether a physician has established that a patient has a "serious mental illness." Prescriptions prescribed for a mental health condition may have off-label usage and there may be no underlying mental health condition.	Thank you for your written comments. The Commissioner considered these comments and made no changes to the rule language. RCW 48.43.0961 addresses coverage of refills for specified types or classes of prescription drugs. RCW 48.43.0961 states that *"…a health carrier or its health care benefit manager may not require the substitution of a nonpreferred drug with a preferred drug in a given therapeutic class, or increase an enrollee's cost-sharing obligation mid-plan year for the drug, <u>if the prescription is for a refill of an antipsychotic, antidepressant, antiepileptic, or other drug prescribed to the enrollee to treat a serious mental illness</u>, the enrollee is medically stable on the drug, and a participating provider continues to prescribe the drug."* RCW 48.43.0961 further defines "serious mental illness" as *"…a mental disorder, as defined in the most recent edition of the diagnostic and statistical manual of mental disorders published by the American psychiatric association, that results in serious functional impairment that substantially interferes with or limits one or more major life activities."* OIC does not employ pharmacists and does not have the clinical capacity to identify every possible drug that may be prescribed to treat a serious mental illness nor every drug category or drug class to which the law applies. This would be better addressed using the clinical resources of carriers in consultation with the expertise of prescribing providers. These comments request changes requiring legislation to amend the relevant statutes.
<u>WAC 284-43-5800</u>	

We request that expanded screening for syphilis and all components of Latent Tuberculosis Infection (LTBI) screening and treatment be included as preventative services and not subject to cost-sharing. Washington's syphilis epidemic is growing and causing long-term health consequences and deaths that are preventable. The number of reported cases increased between 2019-2021 and in 2021 the legislature funded an advisory group which produced policy recommendations that included health coverage for syphilis prevention services without cost-sharing. In 2022, two counties and the state Department of Health updated their syphilis recommendations to include screening for some cisgender women and men who have sex with women. The United States Preventative Services Task Force (USPSTF) recommends syphilis screening for pregnant women and "others who are at increased risk for infection." The USPSTF recommendations are vague and may be a barrier to consistent access to syphilis testing without cost-sharing. We request that OIC use detailed language so that individuals are not billed for syphilis testing. Washington state had 211 cases of tuberculosis (TB) in 2023, and it is estimated that many more have LTBI. The USPSTF has issued a Grade B recommendation for LTBI screening in populations at increased risk and has noted that it is important for LTBI patients to receive follow up and treatment. Chest x-rays and treatment for LTBI are not routinely covered without cost-sharing and this can be a barrier to TB prevention. ESHB 1957 authorizes OIC to adopt rules related to "any future preventive services recommendations and guidelines issued by the United States preventive services task force, the advisory committee on immunization practices of the centers for disease control and prevention, and the health resources and services administration or related federal rules or guidance." We ask the commissioner to consider including specific recommendations for syphilis testing and LTBI screening in the Consolidated Health Care rulemaking.	Thank you for your written comments. The Commissioner considered these comments and made no changes to the rule. Under WAC 284-43-5800, the proposed rule language explains that *"[a]n issuer may not require cost-sharing for preventive services as defined in RCW 48.43.047, delivered by network providers."* RCW 48.43.047 provides that *"[a] nongrandfathered health plan must provide coverage for…preventive services…consistent with federal rules and guidance related to coverage of preventive services in effect on January 8, 2024."* This includes *"[e]vidence-based items or services that have a rating of A or B in the current recommendations of the United States preventive services task force with respect to the enrollee."* Services such as screenings that have a grade A or B rating from the USPSTF are preventive services and are required to be covered without cost sharing. As of 2022, screening for syphilis in nonpregnant adolescents and adults with an increased risk for infection has a grade A rating from USPSTF, and as of 2023, screening for LTBI for populations at increased risk has a grade B rating. The OIC does not employ clinicians and so cannot determine which individuals may be at "increased risk" for specific conditions. The recommendations include some clinical guidance related to populations that would be considered "at risk" for these illnesses. In addition, the USPSTF recommendations for syphilis and LTBI note that clinicians should assess a patient's risk based on the prevalence of the condition within their community and rely on information provided by state and local health departments.

	Under RCW 48.43.047, the Legislature requires coverage for preventive services based on specific federal recommendations or guidelines in effect on January 8, 2024. To incorporate new recommendations and guidelines adopted after that date, the law gives OIC authority to update existing or adopt new rules.
WAC 284-170-130	
Multiple sclerosis (MS) is an unpredictable disease of the central nervous system and has no cure. An estimated 1 million people with M.S. live in the U.S. and early diagnosis and treatment are critical to minimizing disability. While we strongly recommend that initial meetings be in-person, there are access considerations that make telehealth a necessary option for many. We advocate for individuals and providers to have the flexibility to come to medical decisions that are in the best interest of the patient. The revisions to WAC 284-170-130 "established relationship" align with these flexibilities and remove any differentiation between physical, behavioral, and other health care services. We applaud OIC's work in facilitating public participation and ensuring continued access to telehealth for all Washingtonians.	Thank you for your written comments. The Commissioner appreciates these comments.

Section 6: Implementation Plan

A. Implementation and enforcement of the rule.

After the permanent rule is adopted and filed with the Office of the Code Reviser:

- Policy staff will distribute copies of the final rule and the CES to all interested parties through the State's GovDelivery electronic mail system.
- The CR-103 documents and adopted rule will be posted on the OIC's website.

Questions about the new regulations will be addressed by OIC staff as follows:

Type of Inquiry	Division
Consumer assistance	Consumer Protection
Rule content	Legal Affairs
Authority for rules	Policy
Enforcement of rule	Company Supervision

Market Compliance	Company Supervision

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

The agency will answer inquiries, hold meetings upon request, and provide assistance to all affected parties including but not limited to insurers, producers, consumers, or other regulators.

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

Policy staff will distribute copies of the final rule and the CES to all interested parties through the State's GovDelivery electronic mail system.

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

The Insurance Commissioner will monitor the frequency and impact of consumer complaints, investigations and enforcement actions to evaluate whether the rule achieves its intended purpose.

Appendix A

CR-102 Hearing Summary

Summarizing Memorandum

To: Mike Kreidler
Insurance Commissioner
From: Health Policy Analyst, Delika Steele
Presiding Official, Hearing on Rulemaking

Matter No. R 2024-05

Topic of Rulemaking: Consolidated Health Care

This memorandum summarizes the hearing on the above-named rule making, held on Thursday, November 7, 2024, at 9:00 a.m. Pacific Standard Time, virtually via Zoom meetings, over which I presided in your stead.

The following agency personnel were present:

Wendy Conway, Sr. Health Forms Compliance Analyst (FPA 4)
Julia Hinrichs, Sr. Health Forms Compliance Analyst (FPA 4)
Jennifer Kreitler, Provider Network Oversight Program Manager
Darren Dezutter, Senior Provider Contract Analyst
Ryan Bowen, Functional Program Analyst 3
Rocky Patterson, Actuary (3)
Robert Solano, Function Program Analyst 4
Kim Tocco, Attorney Manager
Mary Tedders-Young, Functional Program Analyst 3
Tracy Thornburg, Administrative Assistant

In attendance:

Jane Douthit, Cambia Health Solutions
Thalia Cronin, Community Health Plan of Washington
Melissa Saiz, Molina Health Care
Kate Deiters, Quest Analytics
Kerrie Fowler, Centene
Jillian Caughey, United Health Care

No testimony or comments were provided at the public hearing.

Contents of the presentations made at hearing: None.

The hearing was adjourned.

SIGNED this 7th day of November 2024.
Delika Steele, Presiding Official