# PROPOSED RULE MAKING

## CR-102 (December 2017)
## (Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

**CODE REVISER USE ONLY**

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 24, 2020
TIME: 10:24 AM

WSR 20-10-010

**Agency:** Health Care Authority

☒ **Original Notice**

☐ **Supplemental Notice to WSR _____**

☐ **Continuance of WSR _____**

☒ **Preproposal Statement of Inquiry was filed as WSR** 20-05-090 **; or**

☐ **Expedited Rule Making--Proposed notice was filed as WSR _____; or**

☐ **Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or**

☐ **Proposal is exempt under RCW _____.**

**Title of rule and other identifying information:** (describe subject) WAC 182-501-0165 Medical and dental coverage – fee-for-service (FFS) prior authorization – Determination process for payment

**Hearing location(s):**

| **Date:** | **Time:** | **Location:** (be specific) | **Comment:** |
|---|---|---|---|
| June 9, 2020 | 10:00 AM | Health Care Authority<br>Cherry Street Plaza<br>Sue Crystal Conf. Rm. 106A<br>626 8th Ave, Olympia WA 98504 | Metered public parking is available street side around building. A map is available at: https://www.hca.wa.gov/assets/program/Driving-parking-checkin-instructions.pdf or directions can be obtained by calling: (360) 725-1000 |

**Date of intended adoption:** Not sooner than June 10, 2020 (Note: This is **NOT** the **effective** date)

**Submit written comments to:**

Name: HCA Rules Coordinator
Address: PO Box 42716, Olympia WA 98504-2716
Email: arc@hca.wa.gov
Fax: (360) 586-9727
Other:
By (date) June 9, 2020

**Assistance for persons with disabilities:**

Contact Amber Lougheed
Phone: (360) 725-1349
Fax: (360) 586-9727
TTY: Telecommunication Relay Services (TRS): 711
Email: amber.lougheed@hca.wa.gov
Other:
By (date) May 29, 2020

**Purpose of the proposal and its anticipated effects, including any changes in existing rules:** The agency (HCA) is updating this rule to further implement full integration of behavioral health in HCA's Medicaid program by replacing the term "mental health" with "behavioral health." This change will ensure clarity that clients receiving behavioral health services under HCA's Medicaid fee-for-service program receive appropriate notices and opportunities for hearings based on adverse benefit decisions resulting from prior authorization.

**Reasons supporting proposal:** See Purpose above.

**Statutory authority for adoption:** RCW 41.05.021, RCW 41.05.160

**Statute being implemented:** RCW 41.05.021, RCW 41.05.160

**Is rule necessary because of a:**

| | | |
|---|---|---|
| Federal Law? | ☐ Yes | ☒ No |
| Federal Court Decision? | ☐ Yes | ☒ No |
| State Court Decision? | ☐ Yes | ☒ No |

If yes, CITATION:

**Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:** N/A

**Name of proponent:** (person or organization) Health Care Authority

☐ Private
☐ Public
☒ Governmental

**Name of agency personnel responsible for:**

| | Name | Office Location | Phone |
|---|---|---|---|
| Drafting: | Melinda Froud | PO Box 42716, Olympia WA 98504-2716 | 360-725-1408 |
| Implementation: | Josh Morse | PO Box 42712, Olympia, WA 98504-2712 | 360-725-0839 |
| Enforcement: | Josh Morse | PO Box 42712, Olympia, WA 98504-2712 | 360-725-0839 |

**Is a school district fiscal impact statement required under RCW 28A.305.135?** ☐ Yes ☒ No

If yes, insert statement here:
N/A

The public may obtain a copy of the school district fiscal impact statement by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

**Is a cost-benefit analysis required under RCW 34.05.328?**

☐ Yes: A preliminary cost-benefit analysis may be obtained by contacting:
Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

☒ No: Please explain: RCW 34.05.328 does not apply to Health Care Authority rules unless requested by the Joint Administrative Rules Review Committee or applied voluntarily.

**Regulatory Fairness Act Cost Considerations for a Small Business Economic Impact Statement:**

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see chapter 19.85 RCW). Please check the box for any applicable exemption(s):

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.061 because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

☐ This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by RCW 34.05.313 before filing the notice of this proposed rule.

☐ This rule proposal, or portions of the proposal, is exempt under the provisions of RCW 15.65.570(2) because it was adopted by a referendum.

☐ This rule proposal, or portions of the proposal, is exempt under RCW 19.85.025(3). Check all that apply:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☐ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ RCW 34.05.310 (4)(g) ((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

☐ This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of exemptions, if necessary:

**COMPLETE THIS SECTION ONLY IF NO EXEMPTION APPLIES**

If the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

☒ No Briefly summarize the agency's analysis showing how costs were calculated. This rule does not impose any costs on businesses

☐ Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses, and a small business economic impact statement is required. Insert statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name:
Address:
Phone:
Fax:
TTY:
Email:
Other:

| | |
|---|---|
| **Date:** April 24, 2020 | **Signature:**  |
| **Name:** Wendy Barcus | |
| **Title:** HCA Rules Coordinator | |

AMENDATORY SECTION (Amending WSR 15-15-053, filed 7/9/15, effective 8/9/15)

**WAC 182-501-0165 Medical and dental coverage—Fee-for-service (FFS) prior authorization—Determination process for payment.** (1) This section applies to fee-for-service (FFS) requests for medical or dental services and medical equipment that:

(a) Are identified as covered services or early and periodic screening, diagnosis, and treatment services; and

(b) Require prior authorization by the medicaid agency.

(2) The following definitions and those found in chapter 182-500 WAC apply to this section:

**"Controlled studies"** - Studies in which defined groups are compared with each other to reduce bias.

**"Credible evidence"** - Type I-IV evidence or evidence-based information from any of the following sources:

- Clinical guidelines
- Government sources
- Independent medical evaluation (IME)
- Independent review organization (IRO)
- Independent technology assessment organizations
- Medical and hospital associations
- Policies of other health plans
- Regulating agencies (for example, the Federal Drug Administration or Department of Health)
- Treating provider
- Treatment pathways

**"Evidence-based"** - The ordered and explicit use of the best evidence available (see "hierarchy of evidence" in subsection (6)(a) of this section) when making health care decisions.

**"Health outcome"** - Changes in health status (mortality and morbidity) which result from the provision of health care services.

**"Institutional review board (IRB)"** - A board or committee responsible for reviewing research protocols and determining whether:

(1) The rights and welfare of human subjects are adequately protected;

(2) The risks to people are minimized and are not unreasonable;

(3) The risks to people are outweighed by the potential benefit to them or by the knowledge to be gained; and

(4) The proposed study design and methods are adequate and appropriate in the light of stated study objectives.

**"Independent review organization (IRO)"** - A panel of medical and benefit experts intended to provide unbiased, independent, clinical, evidence-based reviews of adverse decisions.

**"Independent medical evaluation (IME)"** - An objective medical examination of the client to establish the medical facts.

**"Provider"** - The person who is responsible for diagnosing, prescribing, and providing medical, dental, or ((~~mental~~)) behavioral health services to agency clients.

(3) The agency authorizes, on a case-by-case basis, requests described in subsection (1) of this section when the agency determines the service or equipment is medically necessary as defined in WAC 182-500-070. The process the agency uses to assess medical necessity is based on:

(a) The evaluation of submitted and obtainable medical, dental, or ((~~mental~~)) behavioral health evidence as described in subsections (4) and (5) of this section; and

(b) The application of the evidence-based rating process described in subsection (6) of this section.

(4) The agency reviews available evidence relevant to a medical, dental, or ((~~mental~~)) behavioral health service or equipment to:

(a) Determine its efficacy, effectiveness, and safety;

(b) Determine its impact on health outcomes;

(c) Identify indications for use;

(d) Evaluate pertinent client information;

(e) Compare to alternative technologies; and

(f) Identify sources of credible evidence that use and report evidence-based information.

(5) The agency considers and evaluates all available clinical information and credible evidence relevant to the client's condition. The provider responsible for the client's diagnosis, or treatment, or both, must submit with the request credible evidence specifically related to the client's condition including, but not limited to:

(a) A physiological description of the client's disease, injury, impairment, or other ailment;

(b) Pertinent laboratory findings;

(c) Pertinent X-ray and/or imaging reports;

(d) Individual patient records pertinent to the case or request;

(e) Photographs, or videos, or both, if requested; and

(f) Objective medical/dental/((~~mental~~)) behavioral health information such as medically/dentally acceptable clinical findings and diagnoses resulting from physical or ((~~mental~~)) behavioral health examinations.

(6) The agency uses the following processes to determine whether a requested service described in subsection (1) is medically necessary:

(a) **Hierarchy of evidence - How defined.** The agency uses a hierarchy of evidence to determine the weight given to available data. The weight of medical evidence depends on objective indicators of its validity and reliability including the nature and source of the evidence, the empirical characteristics of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The hierarchy (in descending order with Type I given the greatest weight) is:

(i) Type I: Meta-analysis done with multiple, well-designed controlled studies;

(ii) Type II: One or more well-designed experimental studies;

(iii) Type III: Well-designed, quasi-experimental studies such as nonrandomized controlled, single group pre-post, cohort, time series, or matched case-controlled studies;

(iv) Type IV: Well-designed, nonexperimental studies, such as comparative and correlation descriptive, and case studies (uncontrolled); and

(v) Type V: Credible evidence submitted by the provider.

(b) **Hierarchy of evidence - How classified.** Based on the quality of available evidence, the agency determines if the requested service is effective and safe for the client by classifying it as an **"A," "B," "C,"** or **"D"** level of evidence:

(i) **"A" level evidence:** Shows the requested service or equipment is a proven benefit to the client's condition by strong scientific literature and well-designed clinical trials such as Type I evidence

or multiple Type II evidence or combinations of Type II, III or IV evidence with consistent results (An "A" rating cannot be based on Type III or Type IV evidence alone).

(ii) **"B" level evidence:** Shows the requested service or equipment has some proven benefit supported by:

(A) Multiple Type II or III evidence or combinations of Type II, III or IV evidence with generally consistent findings of effectiveness and safety (A **"B"** rating cannot be based on Type IV evidence alone); or

(B) Singular Type II, III, or IV evidence in combination with agency-recognized:

(I) Clinical guidelines;

(II) Treatment pathways; or

(III) Other guidelines that use the hierarchy of evidence in establishing the rationale for existing standards.

(iii) **"C" level evidence:** Shows only weak and inconclusive evidence regarding safety, or efficacy, or both. For example:

(A) Type II, III, or IV evidence with inconsistent findings; or

(B) Only Type V evidence is available.

(iv) **"D" level evidence:** Is not supported by any evidence regarding its safety and efficacy, for example that which is considered investigational or experimental.

(c) **Hierarchy of evidence - How applied.** After classifying the available evidence, the agency:

(i) Approves **"A"** and **"B"** rated requests if the service or equipment:

(A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment; and

(B) Is not more costly than an equally effective alternative treatment.

(ii) Approves a **"C"** rated request only if the provider shows the requested service is the optimal intervention for meeting the client's specific condition or treatment needs, and:

(A) Does not place the client at a greater risk of mortality or morbidity than an equally effective alternative treatment;

(B) Is less costly to the agency than an equally effective alternative treatment; and

(C) Is the next reasonable step for the client in a well-documented tried-and-failed attempt at evidence-based care.

(iii) Denies **"D"** rated requests unless:

(A) The requested service or equipment has a humanitarian device exemption from the Food and Drug Administration (FDA); or

(B) There is a local institutional review board (IRB) protocol addressing issues of efficacy and safety of the requested service that satisfies both the agency and the requesting provider.

(7) Within fifteen days of receiving the request from the client's provider, the agency reviews all evidence submitted and:

(a) Approves the request;

(b) Denies the request if the requested service is not medically necessary; or

(c) Requests the provider submit additional justifying information. The agency sends a copy of the request to the client at the same time.

(i) The provider must submit the additional information within thirty days of the agency's request.

(ii) The agency approves or denies the request within five business days of the receipt of the additional information.

(iii) If the provider fails to provide the additional information, the agency will deny the requested service.

(8) When the agency denies all or part of a request for a covered service or equipment, the agency sends the client and the provider written notice, within ten business days of the date the information is received, that:

(a) Includes a statement of the action the agency intends to take;

(b) Includes the specific factual basis for the intended action;

(c) Includes reference to the specific WAC provision upon which the denial is based;

(d) Is in sufficient detail to enable the recipient to:

(i) Learn why the agency's action was taken; and

(ii) Prepare an appropriate response.

(e) Is in sufficient detail to determine what additional or different information might be provided to challenge the agency's determination;

(f) Includes the client's administrative hearing rights;

(g) Includes an explanation of the circumstances under which the denied service is continued or reinstated if a hearing is requested; and

(h) Includes examples(s) of "lesser cost alternatives" that permit the affected party to prepare an appropriate response.

(9) If an administrative hearing is requested, the agency or the client may request an independent review organization (IRO) or independent medical examination (IME) to provide an opinion regarding whether the requested service or equipment is medically necessary. The agency pays for the independent assessment if the agency agrees that it is necessary, or an administrative law judge orders the assessment.