Washington State Register

WSR 22-15-080 **EMERGENCY RULES** DEPARTMENT OF HEALTH

[Filed July 18, 2022, 12:44 p.m., effective July 26, 2022]

Effective Date of Rule: July 26, 2022.

Purpose: WAC 246-310-806 Kidney disease treatment facilities— Concurrent review cycles. The department of health (department) is adopting an emergency rule to amend WAC 246-310-806(1) as it relates to special and nonspecial circumstances 1 concurrent review cycle. The amendment extends deadlines for kidney disease treatment facility applicants who are submitting applications during concurrent review cycle 1. This adopted emergency rule will extend without change WSR 22-08-028 filed on March 28, 2022. This extension grants flexibility in meeting deadlines due to significant reporting errors in the new End Stage Renal Disease Quality Reporting System (EQRS) database. It was discovered that EQRS, a new Centers for Medicare and Medicaid Services (CMS) reporting system, is not able to correctly process dialysis patients receiving services in coronavirus disease (COVID-19) cohorted facilities and is incorrectly recording death dates or discharge dates. These errors have caused a significant number of counting errors within the reporting system. The department was unable to generate an accurate need methodology for the end stage renal disease (ESRD) providers as required by WAC 246-310-812 due to the incorrect data.

This emergency rule adopts the waived application deadlines for the special and nonspecial circumstances 1 concurrent review cycle. This change allows the dialysis providers to work within EQRS to correct this data and allowed the department to receive reliable data to formulate a reliable need methodology. This emergency rule extension will complete the special and nonspecial circumstances 1 concurrent review cycle.

Citation of Rules Affected by this Order: Amending WAC 246-310-806.

Statutory Authority for Adoption: RCW 70.38.135.

Under RCW 34.05.350 the agency for good cause finds that immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

Reasons for this Finding: The immediate amendment of these existing rules is necessary for the preservation of public health, safety, and general welfare. Allowing an additional month for the kidney disease treatment facility concurrent review start cycle will allow time to receive and generate the data needed by applicants to appropriately fill health care needs in the appropriate areas. Ongoing work to review and revise the certificate of need rules could not be completed in time for this review cycle. This emergency rule has been in effect since March 28, 2022, and this filing will allow for the completion of the impacted cycle. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0. Date Adopted: July 18, 2022.

Kristin Peterson, JD
Deputy Secretary
Policy and Planning
for Umair A. Shah, MD, MPH
Secretary

OTS-2252.1

 $\underline{\text{AMENDATORY SECTION}}$ (Amending WSR 17-04-062, filed 1/27/17, effective 1/1/18)

WAC 246-310-806 Kidney disease treatment facilities—Concurrent review cycles. The department will review kidney dialysis facility applications using the concurrent review cycles described in this section, unless the application was submitted as described in subsection (9) of this section. There are four concurrent review cycles each year.

(1) Applicants must submit applications for review according to the following table:

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
Special Circumstances 1	First working day of ((April)) May of each year.	First working day of ((May)) June of each year.	((May)) June 15 or the first working day thereafter.	((June)) July 15 or the first working day thereafter.	((June)) July 22 or the first working day thereafter.	30-Day Public comment period (including public hearing). Begins ((June)) July 23 or the first working day thereafter.	7-Day Rebuttal period. Applicant and affected party response to public comment.	15-Day Exparte period. Department evaluation and decision.

		Application Submission Period			Department Action	Application Review Period		
Concurrent Review Cycle	Letters of Intent Due	Receipt of Initial Application	End of Screening Period	Applicant Response	Beginning of Review	Public Comment Period (includes public hearing if requested)	Rebuttal Period	Exparte Period
Nonspecial Circumstance Cycle 1	First working day of ((May)) June of each year.	First working day of ((June)) July of each year.	Last working day of ((June)) July.	Last working day of ((July)) August.	((August)) September 5 or the first working day thereafter.	Public comment period (including public hearing). Begins ((August)) September 6 or the first working day thereafter.	30-Day Rebuttal period. Applicant and affected party response to public comment.	75-Day Exparte period. Department evaluation and decision.
Special Circumstances 2	First working day of October of each year.	First working day of November of each year.	November 15 or the first working day thereafter.	December 15 or the first working day thereafter.	December 22 or the first working day thereafter.	30-Day Public comment period (including public hearing). Begins December 23 or the first working day thereafter.	7-Day Rebuttal period. Applicant and affected party response to public comment.	Exparte period. Department evaluation and decision.
Nonspecial Circumstances Cycle 2	First working day of November of each year.	First working day of December of each year.	Last working day of December .	Last working day of January.	February 5 or the first working day thereafter.	Public comment period (including public hearing). Begins February 6 or the first working day thereafter.	30-Day Rebuttal period. Applicant and affected party response to public comment.	75-Day Exparte period. Department evaluation and decision.

- (2) The department should complete a nonspecial circumstance concurrent review cycle within nine months, which begins the first day after letters of intent are due for that particular review cycle. The department should complete the regular review process within six months, which begins the first day after the letters of intent are due for that particular review cycle.
- (3) The department will notify applicants fifteen days prior to the scheduled decision date if it is unable to meet the decision deadline on the applications. In that event, the department will establish and commit to a new decision date.
- (4) When two or more applications are submitted for the same planning area, the department will first evaluate each application independently for meeting the applicable standards described in WAC 246-310-210, 246-310-220, 246-310-230, and 246-310-240. If two or more applications independently meet those four standards, the department will apply the superiority criteria in WAC 246-310-827 to determine the superior application under WAC 246-310-240(1).
- (5) An applicant receiving points for the purposes of the superiority criteria under WAC 246-310-827 (3)(e), (f), or (g) may only apply for station need in one planning area per review cycle.
- (6) An applicant receiving points for purposes of the superiority criteria under WAC 246-310-827 (3) (e), (f), or (g) must operate the

newly awarded stations for a period of time long enough to have a full year of data reporting medicare cost report worksheets and a full year of data reporting the dialysis facility report prior to any future applications.

- (7) The department will not accept new nonspecial circumstance applications for a planning area if there are any nonspecial circumstance applications for which the certificate of need program has not made a decision in that planning area filed under a previous concurrent review cycle. This restriction does not apply if the department has not made a decision on the pending applications within the review timelines of nine months for a concurrent review and six months for a regular review. This restriction also does not apply to special circumstance applications.
- (8) The department may convert the review of a nonspecial circumstance application that was initially submitted under a concurrent review cycle to a regular review process if the department determines that the nonspecial circumstance application does not compete with another nonspecial circumstance application.
- (9) Pending certificate of need applications. Kidney dialysis facility applications submitted prior to the effective date of these rules will be reviewed and action taken based on the rules that were in effect on the date the applications were received.

[Statutory Authority: RCW 70.38.135. WSR 17-04-062, \$ 246-310-806, filed 1/27/17, effective 1/1/18.]