



FRESENIUS MEDICAL CARE

June 3, 2024

Ross Valore, Executive Director
Eric Hernandez, Manager
Certificate of Need Program
CNrulemaking@doh.wa.gov

RE: [WSR 24-10-089](#), CR-102 for ESRD Rules to Implement SSB 5569

Dear Mr. Valore and Mr. Hernandez,

Fresenius Medical Care (“FMC”) appreciates the Department of Health distributing on May 6th the CR-102 for ESRD temporary emergency situation exemption rules related to kidney dialysis facilities.

Please find attached as FMC’s written comments on the rules proposed in the CR-102.

If you have any questions or need additional information, please do not hesitate to contact me at maria.c.garcia@freseniusmedicalcare.com or 707.246.2773.

Sincerely,

Maria Garcia
Senior Director, State Government Affairs
Fresenius Medical Care

Fresenius Medical Care

Written comments regarding CR-102 filed for ESRD temporary emergency situation exemption rules

Fresenius Medical Care (“FMC”) appreciates the Department of Health (“Department”) distributing on May 6th the CR-102 for ESRD temporary emergency situation exemption rules related to kidney dialysis facilities.

FMC Supports the Proposed CR-102

Overall, FMC is very supportive of the proposed rules. The proposed rules reflect the considerable amount of thought, effort, and collaboration among various stakeholders and the Department over the course of multiple rulemaking sessions held this past year.

Additional Comments

In our review of the proposed rules submitted with the CR-102, FMC noticed the following two sections (“section (4)”, “section (7)”) from the final version of draft rules sent for public review released on January 16th were removed in the proposed rules distributed on May 6th:

[January 16, 2024 Release] Department of Health – Certificate of Need Program
Final Version of Draft Certificate of Need Rules for Comment: Temporary Emergency Situation Exemption for Kidney Disease Treatment Centers (SSB 5569)

WAC 246-310-825

...

(4) The department will make reasonable efforts to issue a decision within three working days of receipt of a facility’s complete written request for temporary emergency stations, as described in subsection (3).

...

(7) The department will publish on its website all written requests and department decisions related to kidney disease treatment center requests for additional dialysis stations due to a temporary emergency situation. The information will also include a list of affected facilities.

Section (4). FMC recognizes that a binding number of working days to issue a decision, such as the “three working days” in proposed (4), might not be feasible in all circumstances. For example, FMC understands that the Department may need additional time to review and ask follow up questions on complicated cases. Further, there may be times when there are limited staff available (e.g. designated State holidays) where a decision may not reasonably be able to be rendered. However, section (4) only stated “reasonable efforts” would need to be made by the Department. This “reasonable efforts” language provided broad flexibility for the Department so it was not held to an inflexible, binding number of working days to issue a decision.

Section (7). FMC finds it unfortunate that section (7) was also removed. There was general consensus among the rulemaking workshop participants to include section (7), and we are unaware of any comments submitted following the final draft January 16th rules that called for its removal. We respectfully request the Department consider reinserting section (7).

FMC believes section (7) is a fair and reasonable proposal that did not place a significant burden on the Department. Having the temporary emergency information publicly posted on the Department's website would have provided a central, transparent source of information for all stakeholders. This transparency is vital given the potential impact on whether a temporary emergency request could lead to a planning area being open or closed to new applications. In addition, including section (7) would help mitigate costly litigations that can arise if information is siloed and not readily available. Further, including section (7) could increase efficiency by saving CN staff from having to duplicate efforts to respond to individual requests for this information.

FMC believes that the Department will likely publish this information on its website even if section (7) is not included in the final rules. Therefore, many of the practical considerations raised above may be addressed. Yet, given how the temporary exemptions are now linked to the nonspecial need methodology in WAC 246-310-812, we believe the inclusion of section (7) would make the overall ESRD planning process more robust by ensuring transparency now and in the future.

FMC requests the Department consider re-inserting sections (4) and (7). If these sections are not re-inserted, we request the Department provide comments to these requests in its review of rulemaking comments related to the CR-102