Regulatory Analysis for

Rules and Regulations for the Licensing of Kidney Disease Treatment Centers

216-RICR-40-10-12

July 25, 2023

Background

The Rhode Island Department of Health (RIDOH) is proposing to revise § 12.5.8(C) of the *Rules and Regulations for the Licensing of Kidney Disease Treatment Centers (216-RICR-40-10-12)* to align more closely with the Regulatory Requirements and Interpretive Guidelines of the Centers for Medicare and Medicaid Services ("CMS"). CMS aligns the number, timing, and frequency of home visits with the individual needs of patients receiving in-home dialysis treatment. When RIDOH surveyors inspect and respond to complaints associated with home kidney dialysis facilities, they hold the facilities accountable to the CMS Regulatory Requirements and Interpretive Guidelines. Home kidney dialysis facilities are aware of this expectation as they have all participated in RIDOH inspections. Home kidney dialysis facilities also adhere to other standards established by other recognized organizations as well as the latest research findings to provide quality care to their patients. According to IPRO End-Stage Renal Disease (ESRD) Network 1, there are currently 144 home kidney dialysis patients in Rhode Island (as of July 12, 2023).

These amendments are being promulgated in response to a petition for regulatory action from a member of the public which was received by RIDOH on November 7, 2022. The petitioner asked that RIDOH amend RIDOH's current regulatory requirement that patients on a home dialysis program be visited no less than every 3 months by the professional staff of the facility to assess and review the patient care plan and to observe the patient and the patient's helper carry out dialysis treatment. The petitioner requested that RIDOH amend the wording to align the frequency of visits with patient needs as required by CMS. The petitioner, who is employed by a home dialysis facility, noted that it was extremely challenging to carry out this requirement during the COVID-19 pandemic, although they were able to accomplish them through telehealth visits. Now that the pandemic is over, there is interest in amending this requirement to allow patients to receive the optimal level of care while allowing them to continue to work and live a more normal life while dealing with a chronic medical condition.

RIDOH reviewed the current promulgated regulation and determined that there is no clinical justification for the requirement that patients on a home dialysis program be visited no less than every 3 months by the professional staff of the facility to assess and review the patient care plan and to observe the patient and the patient's helper carry out dialysis treatment since the patients are already receiving home visits based on their needs in accordance with CMS requirements. As a result, the requirement cannot be justified. The required visits have no connection with the patient's clinical needs. This results in an unnecessary burden on the patients and their families. For example, a patient and their family member may have to take time out of work to receive these clinically unnecessary home visits. In addition, the current rules require staff to provide unnecessary visits during a significant workforce shortage. Their time would be better utilized serving other patients based on their needs. In addition, the current regulations require facilities to provide these home visits beyond the point of mastery of dialysis as provided by the patient and their helper. For example, the patient may require 1 visit to demonstrate to facility staff that they have achieved competency, but the current regulation required the facility to provide a clinically unnecessary visit 4 times each year until the patient is no longer a patient of the facility.

Outdated and superfluous, or vague rules, such as the current requirement for patients to be visited every three months impose unnecessary costs and burdens on regulated entities. The current rule imposes an undue burden upon those persons or entities who must comply with the rule; is not relevant or up to date; not based on sound, reasonably available scientific, technical, economic, and other relevant information; does not achieve the regulatory objective in a cost-effective manner; does not avoid negative business, employment, and overall economic impact; does not encourage existing businesses to expand and grow. The current rule does not serve the public interest. As such, RIDOH fully expects that there will be no opposition to the proposed amendment by either home kidney dialysis facilities or patients and their families.

Proposed Amendments

Under 12.5.2 (Patient Care Plans), the following new sentence is proposed: The frequency of home visits, if applicable, will be noted in the patient's care plan and based on each individual patient's needs. The wording in 12.5.8 (C) (Home Dialysis) has been changed from:

Patients on a home dialysis program shall be visited no less than every 3 months by the facility's professional staff to assess and review a patient care plan and to observe a patient and "helper" carry out dialysis.

The proposed new wording is:

Patients on a home dialysis program shall be visited by facility professional staff of the facility to assess and review a patient's care plan and to observe a patient's care plan and to observe a patient and "helper" perform dialysis. The frequency of such visits shall be determined by facility professional staff, applying clinical judgment to the specifics of a patient's case.

Regulatory Analysis

RIDOH has prepared the following regulatory analysis in accordance with R.I. Gen. Laws § 42-35-2.9. In the analysis, RIDOH attempts to quantify the costs and benefits to all parties of the proposed regulatory change to the greatest extent possible. The level of analysis is proportional to the significance of the rule.

- **Analysis of the benefits and costs of a reasonable range of regulatory alternatives reflecting the scope of discretion provided by the statute authorizing the proposed rule.**

The proposed regulatory change is discretionary. RIDOH has no historical context for the current regulation. The proposed change would not impact the number of patients receiving four visits per year or those receiving more than four visits per year as they are already receiving four or more visits based on their clinical needs per CMS regulations and guidelines. As such, these visits are excluded from this analysis. This analysis is based on the patients who may receive fewer than four visits per year because of the proposed change. These would be the patients not already being seen in accordance with CMS requirements.

RIDOH conducted an extensive literature search and found that there is no definitive conclusion that identifies the ideal frequency of home visits to prevent and reduce adverse events. RIDOH also reviewed Massachusetts and Connecticut regulations related to kidney dialysis home visits.

Neither of these regulations specifically addresses what is included in Rhode Island's current regulations, which is to both assess and review a patient care plan and to observe a patient and "helper" carry out dialysis four times a year. As a result, RIDOH does not believe that the Massachusetts and Connecticut regulations can be compared with RIDOH's proposed amendments.

RIDOH consulted with a public health physician from another state who concluded that the regulation, at first glance, appears to be stricter than needed. The physician asked if the current regulatory requirement is truly protecting the public. Given that the healthcare professional workforce is in short supply, the physician questioned if the current requirement represents the best use of limited healthcare workforce staff. The physician also noted that the interval, whether every 3, 4, 6, or 9 months appears to be subjective and that although these patients are vulnerable, they are in constant contact with their healthcare team.

RIDOH conducted an extensive literature search to find the information that RIDOH could be used for the regulatory analysis and came up empty-handed as the data needed to determine the number of visits that would be reduced is not collected due to it being a regulatory requirement only in Rhode Island. RIDOH reached out to a kidney dialysis center located in Massachusetts to try to obtain information that would help RIDOH with the regulatory analysis and it referred us to the IPRO ESRD Network 1, which provided us with the current number of patients in Rhode Island. They did not provide RIDOH with data related to the number of visits as they are unable to do so. We reached out to CMS Dialysis Data for reimbursement data, and they referred us to the ESRD Payment Program. CMS's ESRD Payment Program informed RIDOH that CMS pays a bundled payment to ESRD providers. That means any home visits would be included in the bundle and CMS does not have a broken-out cost per home visit. However, CMS shared that, in Rhode Island, the average bundled payment per dialysis treatment is roughly $300.00.

Medicare Part B covers at-home kidney dialysis training (See: Medicare coverage of dialysis and kidney transplant services). A patient may qualify for training if the patient thinks he or she will benefit from home dialysis patients and his or her doctor approves. Training is limited to a maximum number of training sessions. Medicare makes a single payment per dialysis treatment to the facility for all dialysis-related services, including equipment and supplies. Dialysis facilities pay third-party suppliers from this single payment amount. Most people pay a monthly premium for Part B. The standard Part B premium for 2023 is $164.90 per month, although it may be higher based on the patient's income. Premium rates can change yearly.

If a patient has original Medicare, after they pay the Part B yearly deductible, they will continue to pay a 20% co-insurance of the Medicare-approved amount for all covered dialysis-related services. Medicare will pay the remaining 80%. The dollar amount of the co-insurance may vary, depending on the patient's plan. Original Medicare pays the patient's kidney doctor to supervise home dialysis training. After the patient pays the Part B yearly deductible ($226.00 in 2023),

Medicare pays 80% of the fee and the patient pays the remaining 20%. Medicare does not pay for any lost income to the patient or the patient's helper during home dialysis training.

RIDOH then reached out to a home dialysis facility in Rhode Island, and it estimates that each new patient would have about one home visit in Year One to assess and review the patient care plan and to observe the patient and the patient's helper carry out dialysis treatment, but these visits would continue to take place under current CMS requirements. This leaves three visits per year per patient (three visits x 144 patients = 432 visits) that are currently clinically unnecessary in Year One and four visits per year thereafter per patient (four visits x 144 patients = 576 visits) until the patient is no longer a patient with the facility. For the above-noted reasons, RIDOH has concluded that there is no risk to the patients that would receive fewer visits since the visits were clinically unnecessary, to begin with.

RIDOH, however, believes that all four visits per year, would be eliminated since all four are clinically unnecessary to begin with and that any clinically necessary visits are taking place in accordance with CMS regulations and guidelines. All four visits, taken at face value, are clinically unnecessary. Four visits per year per patient equals four visits x 144 patients = 576 visits). Again, for the above-noted reasons, RIDOH has concluded that there is no risk to the patients that would receive fewer visits since the visits were clinically unnecessary, to begin with.

The reader is cautioned not to interpret these numbers as a comprehensive accounting of all costs and benefits. The lack of available data prevents RIDOH from calculating the full economic impacts related to the benefits associated with the proposed regulatory change. As noted, RIDOH's current regulations require four visits per year *to assess and review a patient care plan* and *to observe a patient and "helper" carry out dialysis.*

CMS regulations state:

V519 (d) Standard: Patient reassessment: In accordance with the standards specified…a comprehensive reassessment of each patient and a revision of the plan of care must be conducted – (1) at least annually for stable patients; and V520: (2) at least monthly for unstable patients…

V582 (a) Standards: Training: The…team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis…and when home dialysis caregiver or home dialysis modality changes.

V589: Services include, but are not limited to, the following: (i) Periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel in accordance with the patient's plan of care.

RIDOH believes that it is just not possible to know in advance how many patients would be impacted by the proposed regulatory change because the number of patients impacted by the proposed change would vary based on the patient mix and their clinical needs at the time the regulation went into effect and because the proposed regulatory change would impact two types of visits at the same time (reassessment and observation visits).

However, RIDOH believes that the costs related to the risks to patients are clear – there are no risks associated with the proposed removal of clinically unnecessary home visits.

RIDOH considered changing the currently required annual visits to one annual visit, but it rejected this idea as an alternative because it would place RIDOH in the same position, which is to require a clinically unnecessary visit, which would continue to be a burden to the patients, families, and the facilities. As noted by the public health consultant from another state with whom RIDOH consulted, any interval, whether every 3, 4, 6, or 9 months appears to be subjective, and, although these patients are vulnerable, they are in constant contact with their healthcare team as required by CMS regulations and guidelines.

Based on this information, there is only one other alternative, which is to maintain the status quo. Patients would continue to receive four clinically unnecessary home visits that are not aligned with CMS requirements until they were no longer patients. Patients would continue to spend time receiving these unnecessary visits (and paying for them) and facility staff would be required to continue to provide these clinically unnecessary visits during a healthcare workforce shortage when their time would be better spent with patients with clinical needs. On average, home dialysis RNs make about $55/hour and most home visits take about three hours. This amounts to $71,280.00 in Year One and $95,040.00 in Year Two and beyond. $95,040.00 would be saved in Year One and beyond if all four visits were addressed in Year One. The proposed regulatory change would free up several days per month that the RNs could better spend on such services as training new patients at home, educating in-center hemodialysis (ICHD) patients at home, and focusing on clinical outcomes (i.e., working to reduce hospitalizations and peritonitis rates, etc.).

The average reimbursement amount that facilities receive is proprietary information. However, looking at costs using Medicare's bundled rate of $300.00 per home visit, the costs of the clinically unnecessary home visits in Year One would be $129,600.00 and, in Year Two, it would be $172,800.00. $172,800.00 would be saved in Year One and beyond if all four visits were addressed in Year One. Again, the proposed regulatory change would free up several days per month that would be better used providing home kidney dialysis services to patients with clinically justifiable needs. The proposed change would also save the patient money in co-insurance costs. Additionally, if the status quo were maintained, the facilities would remain unaligned with CMS regulations and guidelines.

- **Demonstration that there is no alternative approach among the alternatives considered during the rulemaking proceeding which would be as effective and less burdensome to affected private persons as another regulation. This standard requires that an agency proposing to write any new regulation must identify any other state regulation which is overlapped or duplicated by the proposed regulation and justify any overlap or duplication.**

Based on the above information, there is no alternative approach among the alternatives considered during the rulemaking proceeding which would be as effective and less burdensome to affected private persons as another regulation.

- **Determination whether:**

  - **The benefits of the proposed rule justify the costs of the proposed rule.**

Based on the above information, RIDOH has determined that the proposed rule justifies the costs since the only costs related to the change are cost savings.

- **The proposed rule will achieve the objectives of the authorizing statute in a more cost-effective manner, or with greater net benefits, than other regulatory alternatives.**

  - Based on the above information, RIDOH has determined that the proposed rule will achieve the objectives of the authorizing statute in a more cost-effective manner, and with greater net benefits, than the other regulatory alternative, which is the status quo.