

- SUBJECT:** Regulating end stage renal disease facilities
- COMMITTEE:** Public health — committee substitute recommended
- VOTE:** 7 ayes — Berlanga, Hirschi, Coleman, Glaze, Janek, Maxey, Rodriguez
0 nays
2 absent — Delisi, McDonald
- WITNESSES:** For — Alfred Gilchrist, Texas Medical Association
Against — none
On — Linda Wiegman, Julia Beechinor, Glenda Payne, Texas Department of Health
- BACKGROUND:** End stage renal disease is a disease in which the kidneys cease to function and is usually caused by severe or untreated diabetes. Persons with end stage renal disease require either a kidney transplant or treatment in which their blood (or body fluid through the abdominal cavity) is filtered several times a week through a dialysis machine to remove toxins.
- DIGEST:** CSHB 1023 would amend the Health and Safety Code to license and regulate end stage renal disease (ESRD) facilities. The act would take effect September 1, 1995. Licensing and dialysis technician requirements would take effect September 1, 1996.

Licensing

A ESRD facility could not be operated without a license unless it was a licensed home and community service agency, a licensed hospital that provides dialysis to inpatients only or a physician's office that was not primarily a ESRD facility.

Applicants for licenses would be required to show evidence that there was at least one qualified physician on the staff of the facility and each dialysis technician had completed the required training program.

The department would be required to adopt rules governing the minimum standards for ESRD facilities, including qualifications and supervision of staff, equipment used, quality assurance, sanitary conditions, recordkeeping, management and organizational structure and water treatment and reuse.

The license would be renewed annually upon submission of the required fee and annual report. A medical review board would review the quality of care information on the report and could recommend appropriate corrective action or other enforcement proceedings. Quality of care information and medical review board recommendations would be confidential.

Dialysis technicians

The board of health would be required to establish minimum standards for the curricula, training, competency determination and practice authorization of dialysis technicians.

Inspections

The department would be authorized to conduct announced and unannounced inspections to determine compliance with the act.

It would be an offense intentionally, knowingly or recklessly to disclose the date or time of an unannounced inspection to an authorized person. The offense would be a Class B misdemeanor (maximum penalty 180 days in jail and a \$2,000 fine). A convicted person also would not be eligible for state employment.

Enforcement

Corrective actions. The department would be required to consider whether a corrective action would be appropriate before taking an enforcement action. A level one corrective action plan would be appropriate for facilities that did not have serious or life-threatening violations and would require the department to monitor the progress of the facility implementing an approved action plan.

A level two corrective plan would be for violators that failed to comply with a level one plan, and the department would supervise the facility's implementation of the plan. A level three corrective plan could be imposed on violators who fail to comply with a level two action plan and would allow the department to seek the appointment of a temporary manager.

Administrative penalties. The department could impose an administrative penalty not to exceed \$1,000 per day of violation against a person who violates the act. All administrative penalty proceedings would be subject to the Texas Administrative Procedures Act. The department would be required to give written notice of the violation to the person committing the violation. The person notified would have 20 days to accept the determination and recommended penalty or to request a hearing.

CSHB 1023 includes provisions relating to hearing officer findings and conclusions, payment of the penalty, judicial review contesting the violation and penalty and stays of enforcement while the case is under judicial review and department recovery of administrative hearing costs.

Other penalties. The department could deny, suspend or revoke a license for violation of the act or rule under the Texas Administrative Procedure Act for contested case hearings. The department could also petition a district court for a temporary restraining order if the violation posed an immediate threat to patients' health and safety. Venue could be in the county in which the facility is located or in Travis County.

It would be a criminal offense, punishable by a Class C misdemeanor (a maximum penalty of \$500) to operate a non-exempt facility without a license or work as a dialysis technician without training. Each day of violation would constitute a separate offense.

A person who knowingly violated a rule under the bill would be liable for a civil penalty of not more than \$1,000 for each violation if the violation threatened the health and safety of ESRD patients. Each day of violation would constitute a separate offense.

A civil or administrative penalty would be deposited to the general revenue fund.

Temporary managers

A person with a controlling interest in an ESRD facility could request from the department appointment of a temporary manager to ensure adequate and safe patient services.

The department could request the attorney general to bring action on behalf of the state for the appointment of a temporary manager if the ESRD facility was operating without a valid license, if an imminent or immediate threat to patient health and safety exists or if the facility was closing and arrangements for the care of patients have not been made before closure.

A temporary manager would be entitled to a reasonable fee as determined by the court that would be paid by the facility.

NOTES:

The committee substitute added to the original version provisions relating to medical review board review of quality of care, corrective action plans and appointment of temporary managers. The committee substitute removed provisions relating to exempting specified professionals from dialysis training requirements and required unannounced inspections.