

1 AN ACT concerning health facilities.

2 Be it enacted by the People of the State of Illinois,
3 represented in the General Assembly:

4 Section 1. Short title. This Act may be cited as the
5 End Stage Renal Disease Facility Act.

6 Section 5. Definitions. As used in this Act:

7 "Committee" means the End Stage Renal Disease Advisory
8 Committee.

9 "Department" means the Department of Public Health.

10 "Dialysis" means a process by which dissolved substances
11 are removed from a patient's body by diffusion from one
12 fluid compartment to another across a semipermeable membrane.

13 "Dialysis technician" means an individual who is not a
14 registered nurse or physician and who provides dialysis care
15 under the supervision of a registered nurse or physician.

16 "Director" means the Director of Public Health.

17 "End stage renal disease" means the stage of renal
18 impairment that appears irreversible and permanent and that
19 requires a regular course of dialysis or kidney
20 transplantation to maintain life.

21 "End stage renal disease facility" means a facility that
22 provides dialysis treatment or dialysis training to
23 individuals with end stage renal disease.

24 "Licensee" means an individual or entity licensed by the
25 Department to operate an end stage renal disease facility.

26 "Nurse" means an individual who is licensed to practice
27 nursing under the Nursing and Advanced Practice Nursing Act.

28 "Patient" means an individual receiving treatment from an
29 end stage renal disease facility.

30 "Person" means any individual, firm, partnership,
31 corporation, company, association, or other legal entity.

1 "Physician" means an individual who is licensed to
2 practice medicine in all of its branches under the Medical
3 Practice Act of 1987.

4 Section 10. License required. Except as provided by
5 this Act, no person shall open, manage, conduct, offer,
6 maintain, or advertise an end stage renal disease facility
7 without a valid license issued by the Department. All end
8 stage renal disease facilities in existence as of the
9 effective date of this Act shall obtain a valid license to
10 operate within one year after the effective date of this Act.

11 Section 15. Exemptions from licensing requirement. The
12 following facilities are not required to be licensed under
13 this Act:

14 (1) a home health agency licensed under the Home
15 Health Agency Licensing Act that provides dialysis
16 services in the home under the supervision of a nurse;

17 (2) a hospital licensed under the Hospital
18 Licensing Act or the University of Illinois Hospital Act;
19 and

20 (3) the office of a physician, unless the office is
21 used primarily as an end stage renal disease facility.

22 Section 20. Issuance and renewal of license.

23 (a) An applicant for a license under this Act shall
24 submit an application on forms prescribed by the Department.

25 (b) Each application shall be accompanied by a
26 non-refundable license fee, as established by the rules of
27 the Department.

28 (c) Each application shall contain evidence that there
29 is at least one qualified physician responsible for the
30 medical direction of the facility and that each dialysis
31 technician on staff has completed a training program as

1 required by this Act.

2 (d) The Department may grant a temporary initial license
3 to an applicant. A temporary initial license expires on the
4 earlier of (i) the date the Department issues or denies the
5 license or (ii) the date 6 months after the date the
6 temporary initial license was issued.

7 (e) The Department shall issue a license if, after
8 application, inspection, and investigation, it finds that the
9 applicant meets the requirements of this Act and the
10 standards adopted pursuant to this Act. The Department may
11 include participation as a supplier of end stage renal
12 disease services under Titles XVIII and XIX of the federal
13 Social Security Act as a condition of licensure.

14 (f) The license is renewable annually after submission
15 of (i) the renewal application and fee and (ii) an annual
16 report on a form prescribed by the Department that includes
17 information related to quality of care at the end stage renal
18 disease facility. The report must be in the form and
19 documented by evidence as required by the rules adopted by
20 the Department.

21 Section 25. Minimum staffing. An end stage renal
22 disease facility shall be under the medical direction of a
23 qualified physician experienced in renal disease treatment,
24 as required for licensure under this Act. Additionally, at a
25 minimum, every facility licensed under this Act shall ensure
26 that whenever patients are undergoing dialysis all of the
27 following are met:

28 (1) one currently licensed physician, registered
29 nurse, or licensed practical nurse experienced in
30 rendering end stage renal disease care is physically
31 present on the premises to oversee patient care;

32 (2) adequate staff is present to meet the medical
33 and non-medical needs of each patient, as provided by

1 this Act and the rules adopted pursuant to this Act, in a
2 ratio of at least one staff member to every 3 patients
3 receiving end stage renal disease services at the same
4 time; and

5 (3) if the facility offers self-care dialysis
6 training, a qualified nurse is in charge of that
7 training.

8 Section 30. Minimum standards.

9 (a) The rules adopted pursuant to this Act shall contain
10 minimum standards to protect the health and safety of a
11 patient of an end stage renal disease facility, including
12 standards for:

13 (1) the qualifications and supervision of the
14 professional staff and other personnel;

15 (2) the equipment used by the facility to insure
16 that it is compatible with the health and safety of the
17 patients;

18 (3) the sanitary and hygienic conditions in the
19 facility;

20 (4) quality assurance for patient care;

21 (5) clinical records maintained by the facility;

22 (6) design and space requirements for the facility
23 to insure safe access by patients and personnel and to
24 insure patient privacy;

25 (7) indicators of the quality of care provided by
26 the facility; and

27 (8) water treatment and reuse by the facility.

28 (b) The standards described in item (8) of subsection
29 (a) of this Section shall apply only (i) to a facility that
30 initiates the provision of end stage renal disease services
31 on or after January 1, 2003 or (ii) to the area of a facility
32 affected by design and space modifications or renovations
33 completed after January 1, 2004.

1 Section 35. Training; minimum requirements. An end
2 stage renal disease facility shall establish and implement a
3 policy to ensure appropriate training and competency of
4 individuals employed as dialysis technicians within the
5 licensed facility. The policy shall, at a minimum, define
6 the acts and practices that are allowed or prohibited for
7 such employees, establish how training will be conducted, and
8 illustrate how initial competency will be established. Proof
9 of initial and annual competency testing shall be maintained
10 in the personnel file of each employee and shall be made
11 available to the Department upon request. An individual may
12 not act as a dialysis technician in an end stage renal
13 disease facility unless that individual has been trained and
14 competency tested in accordance with this Act and the rules
15 adopted thereunder. Persons training to act as dialysis
16 technicians must be under the direct supervision of a
17 physician or an appropriately trained nurse.

18 Section 40. Inspections.

19 (a) The Department, whenever it deems necessary, may
20 conduct an inspection, survey, or evaluation of an end stage
21 renal disease facility to determine compliance with licensure
22 requirements and standards or a plan of correction submitted
23 as a result of deficiencies cited by the Department.

24 (b) An inspection conducted under this Section shall be
25 unannounced.

26 (c) Areas in a facility identified as deficient in
27 compliance with the requirements of this Act or the standards
28 adopted under this Act shall be presented to the facility.

29 (d) Upon completion of each inspection, survey, or
30 evaluation, the appropriate Department personnel who
31 conducted the inspection, survey, or evaluation shall submit
32 a copy of their report to the licensee upon exiting the
33 facility, and shall submit the actual report to the

1 appropriate regional office. The report and any
2 recommendation for action by the Department under this Act
3 shall be sent to the Department's central office together
4 with a plan of correction from the facility. The plan of
5 correction may contain related comments or documentation
6 provided by the licensee that may refute findings in the
7 report, explain extenuating circumstances that the facility
8 could not reasonably have prevented, or indicate methods and
9 timetables for correction of deficiencies described in the
10 report. A licensee has 10 days to submit a plan of
11 correction.

12 (e) Violations shall be determined under this Section no
13 later than 60 days after completion of each inspection,
14 survey, evaluation, or plan of correction.

15 (f) The Department shall maintain all inspection,
16 survey, or evaluation reports for at least 5 years in a
17 manner accessible to the public.

18 Section 45. Civil penalties.

19 (a) The license of a facility that is in violation of
20 this Act or any rule adopted thereunder may be subject to the
21 penalties or fines levied by the Department as specified in
22 this Section.

23 (b) A Class I violation is one that the Department
24 determines presents an imminent danger to the patients of the
25 facility or a substantial probability that death or serious
26 physical harm could result therefrom. A physical condition
27 or one or more practices, means, methods, or operations in
28 use in a facility may constitute such a violation. The
29 condition or practice constituting a Class I violation shall
30 be abated or eliminated immediately unless a fixed period of
31 time, as stipulated by the Department, is required for
32 correction. Each day such a violation exists after
33 expiration of the stipulated time shall be considered a

1 subsequent violation. The civil penalty for a Class I
2 violation is as follows:

3 (1) \$1,500 for a first violation within a 24 month
4 period;

5 (2) \$3,000 for a second violation within a 24 month
6 period;

7 (3) \$5,000 for a third violation within a 24 month
8 period; and

9 (4) \$10,000 for a fourth or subsequent violation
10 within a 24 month period.

11 (c) A Class II violation is one that the Department
12 determines has a direct or immediate relationship to the
13 health, safety, or security of the facility's patients, but
14 is not a Class I violation. The citation for a Class II
15 violation shall specify the time within which the violation
16 is required to be corrected. Each day such a violation
17 exists after the expiration of the specified time shall be
18 considered a subsequent violation. The civil penalty for a
19 Class II violation is as follows:

20 (1) \$250 for a first violation within a 24 month
21 period;

22 (2) \$500 for a second violation within a 24 month
23 period;

24 (3) \$1,000 for a third violation within a 24 month
25 period;

26 (4) \$2,500 for a fourth violation within a 24 month
27 period; and

28 (5) \$5,000 for a fifth or subsequent violation
29 within a 24 month period.

30 (d) A Class III violation is one that is not classified
31 as serious by the Department or that is against the best
32 practices as interpreted by the Department. The citation of
33 a Class III violation shall specify a time within which the
34 violation is required to be corrected. Each day such a

1 violation exists after the expiration of the specified time
2 shall be considered a subsequent violation. A civil penalty
3 shall not be assessed for a first violation within a 24 month
4 period. The civil penalty for a Class III violation is as
5 follows:

6 (1) \$200 for a second violation within a 24 month
7 period;

8 (2) \$500 for a third violation within a 24 month
9 period;

10 (3) \$750 for a fourth violation within a 24 month
11 period; and

12 (4) \$1,000 for a fifth or subsequent violation
13 within a 24 month period.

14 (e) For purposes of assessing fines under this Section,
15 a repeat violation is a violation that has been cited during
16 one inspection of a facility for which an accepted plan of
17 correction was not complied with. A new citation is not a
18 repeat violation unless the licensee is not substantially
19 addressing the issue routinely throughout the facility.

20 Section 50. Department access to and reproduction of
21 documents. The Department shall have access to and may
22 reproduce or photocopy at its cost any books, records, and
23 other documents maintained by the facility to the extent
24 necessary to carry out the purposes of this Act and the rules
25 promulgated under this Act. The Department shall not divulge
26 or disclose the identity of any patient or other information
27 prohibited from disclosure by the laws of this State.

28 Section 55. Refusal to allow inspections. Any licensee,
29 applicant for a license, or person operating what may be an
30 end stage renal disease facility shall be deemed to have
31 given consent to any authorized officer, employee, or agent
32 of the Department to enter and inspect the facility in

1 accordance with this Act. Refusal to permit such entry or
2 inspection shall constitute grounds for denial, nonrenewal,
3 or revocation of a license.

4 Section 60. Denial, suspension, or revocation of
5 license.

6 (a) The Department may deny, suspend, or revoke a
7 license for a violation of this Act or a rule adopted
8 pursuant to this Act.

9 (b) The denial, suspension, or revocation of a license
10 by the Department and the appeal from that action are
11 governed by the Illinois Administrative Procedure Act.

12 (c) Immediately upon the denial, suspension, or
13 revocation of a license, the Department shall notify the
14 applicant or licensee in writing. Notice of the denial,
15 suspension, or revocation shall include a statement of the
16 violations of the Act or rules on which the denial is based
17 and notice of the opportunity for a hearing under the
18 Illinois Administrative Procedure Act. If the applicant
19 desires to contest the Department's action, a written request
20 for a hearing shall be provided to the Department within 10
21 days after receipt of the Department's notice.

22 Section 65. Probationary license. If the applicant has
23 not been previously licensed or if the facility is not in
24 operation at the time application is made, the Department
25 shall issue a probationary license. A probationary license
26 shall be valid for 120 days unless sooner suspended or
27 revoked under this Act. Within 30 days prior to the
28 termination of a probationary license, the Department shall
29 fully and completely inspect the facility and, if the
30 facility meets the applicable requirements for licensure,
31 shall issue a license under this Act. If the Department
32 finds that the facility does not meet the requirements for

1 licensure but has made substantial progress toward meeting
2 those requirements, the license may be renewed once for a
3 period not to exceed 120 days from the expiration date of the
4 initial probationary license.

5 Section 70. Change of ownership.

6 (a) Whenever ownership of a facility is transferred from
7 the person named in the license to any other person, the
8 transferee must obtain a new probationary license. The
9 transferee shall notify the Department of the transfer and
10 apply for a new license at least 30 days prior to final
11 transfer.

12 (b) The transferor shall notify the Department at least
13 30 days prior to final transfer. The transferor shall remain
14 responsible for the operation of the facility until such time
15 as a license is issued to the transferee.

16 (c) The license granted to the transferee shall be
17 subject to any plan of correction submitted by the previous
18 owner and approved by the Department and any conditions
19 contained in a conditional license issued to the previous
20 owner. If there are outstanding violations and no approved
21 plan of correction has been implemented, the Department may
22 issue a conditional license and plan of correction as
23 provided in this Act.

24 (d) The transferor shall remain liable for all penalties
25 assessed against the facility that are imposed for violations
26 occurring prior to transfer of ownership.

27 Section 75. Access to information. The following
28 information is subject to disclosure to the public by the
29 Department:

30 (1) records of license inspections, surveys, and
31 evaluations of facilities; and

32 (2) complaints and complaint investigation reports,

1 except that a complaint or complaint investigation report
2 shall not be disclosed to a person other than the
3 complainant or complainant's representative before it is
4 disclosed to a facility and except that a complainant's
5 or patient's name shall not be disclosed.

6 Section 80. Information available for public inspection.

7 (a) A facility shall post in plain view of the public

8 (i) its current license, (ii) a description, provided by the
9 Department, of complaint procedures established under this
10 Act, and (iii) the name, address, and telephone number of a
11 person authorized by the Department to receive complaints.

12 (b) A facility shall make the following information or
13 documents available upon request for public inspection:

14 (1) a copy of any order pertaining to the facility
15 issued by the Department or a court;

16 (2) a complete copy of every inspection report of
17 the facility received from the Department during the past
18 5 years;

19 (3) a copy of every order pertaining to the
20 facility issued by the Department or a court during the
21 past 5 years;

22 (4) a description of the services provided by the
23 facility and the rates charged for those services;

24 (5) a copy of the statement of ownership required
25 by this Act;

26 (6) a record of personnel employed or retained by
27 the facility who are licensed, certified, or registered
28 by the Department of Professional Regulation; and

29 (7) a complete copy of the most recent inspection
30 report of the facility received from the Department.

31 Section 85. End Stage Renal Disease Advisory Committee.

32 (a) The Director shall appoint an End Stage Renal

1 Disease Advisory Committee to advise and consult with the
2 Director in the administration of this Act. The Committee
3 shall be composed of the following members:

4 (1) 3 members who represent end stage renal disease
5 facilities, one of whom shall represent not-for-profit
6 facilities, one of whom shall represent for-profit
7 facilities, and one of whom shall represent
8 institution-based facilities;

9 (2) 2 members who are physicians licensed to
10 practice medicine in all its branches;

11 (3) one member who is a board-certified
12 nephrologist;

13 (4) one member who represents licensed hospitals;

14 (5) one member who is a registered professional
15 nurse with experience treating end stage renal disease;

16 (6) 3 members of the general public, one of whom is
17 currently receiving dialysis.

18 The recommendations of professional organizations may be
19 considered in selecting individuals for appointment to the
20 End Stage Renal Disease Advisory Committee.

21 (b) Each member shall be appointed for a term of 3
22 years, except that of the original members, 3 shall be
23 appointed for a term of one year, 4 shall be appointed for a
24 term of 2 years, and 4 shall be appointed for a term of 3
25 years. The term of office of each of the original appointees
26 shall commence on July 1, 2002. A member appointed to fill a
27 vacancy occurring prior to the expiration of the term for
28 which his or her predecessor was appointed shall be appointed
29 for the remainder of that term.

30 (c) The Committee shall meet as frequently as the
31 Director deems necessary. Committee members, while serving
32 on business of the Committee, shall receive actual and
33 necessary travel and subsistence expenses while so serving
34 away from their places of residence.

1 Section 90. Adoption of rules. The Department shall
2 adopt rules to implement this Act, including requirements for
3 physical plant standards and for the issuance, renewal,
4 denial, suspension, and revocation of a license to operate an
5 end stage renal disease facility.

6 Section 95. Fees. The Department may establish and
7 collect fees in amounts reasonable and necessary to defray
8 the cost of administering this Act. In setting fees under
9 this Act, the Department shall consider setting a range of
10 license and renewal fees based on the number of dialysis
11 stations at the end stage renal disease facility, the patient
12 census, and the average costs involved in surveying the
13 facility.

14 Section 100. Deposit of fees and penalties. Fees and
15 penalties collected under this Act shall be deposited into
16 the End Stage Renal Disease Facility Licensing Fund, which is
17 hereby created as a special fund in the State treasury.
18 Moneys in the Fund may be used, subject to appropriation, by
19 the Department for the administration of this Act.

20 Section 105. The State Finance Act is amended by adding
21 Section 5.545 as follows:

22 (30 ILCS 105/5.545 new)

23 Sec. 5.545. The End Stage Renal Disease Facility
24 Licensing Fund.

25 Section 999. Effective date. This Act takes effect
26 January 1, 2002.