

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 End  
5 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 fluid  
12 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 that 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" or "ESRDF" means a  
22 facility that provides dialysis treatment or dialysis  
23 training to 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 any individual receiving treatment from  
29 an 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 this  
5 Act, no person shall open, manage, conduct, offer, maintain,  
6 or advertise an end stage renal disease facility without a  
7 valid license issued by the Department. All end stage renal  
8 disease facilities in existence as of the effective date of  
9 this Act shall obtain a valid license to operate within one  
10 year after the adoption of rules to implement 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 Health  
15 Agency Licensing Act;

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

18 (3) the office of a physician.

19 Section 20. Issuance and renewal of license.

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

22 (b) Each application shall be accompanied by a  
23 non-refundable license fee, as established by rule of the  
24 Department.

25 (c) Each application shall contain evidence that there  
26 is at least one physician responsible for the medical  
27 direction of the facility and that each dialysis technician  
28 on staff has completed a training program as required by this  
29 Act.

30 (d) The Department may grant a temporary initial license  
31 to an applicant. A temporary initial license expires on the

1 earlier of (i) the date the Department issues or denies the  
2 license or (ii) the date 6 months after the temporary initial  
3 license was issued.

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

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

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

24 (1) one currently licensed physician, registered  
25 nurse, physician assistant, advanced practice nurse or  
26 licensed practical nurse experienced in rendering end  
27 stage renal disease care is physically present on the  
28 premises to oversee patient care; and

29 (2) adequate staff is present to meet the medical  
30 and non-medical needs of each patient, as provided by  
31 this Act and the rules adopted pursuant to this Act.

32 Section 30. Minimum standards.

1           (a) The rules adopted pursuant to this Act shall contain  
2 minimum standards to protect the health and safety of a  
3 patient of an end stage renal disease facility, including  
4 standards for:

5           (1) the qualifications and supervision of the  
6 professional staff and other personnel;

7           (2) the equipment used by the facility to insure  
8 that it is compatible with the health and safety of the  
9 patients;

10           (3) the sanitary and hygienic conditions in the  
11 facility;

12           (4) quality assurance for patient care;

13           (5) clinical records maintained by the facility;

14           (6) design and space requirements for the facility  
15 to insure safe access by patients and personnel and for  
16 ensuring patient privacy;

17           (7) indicators of the quality of care provided by  
18 the facility; and

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

20           (b) These standards shall be consistent with the  
21 requirements for a supplier of end stage renal disease  
22 services under Titles XVIII and XIX of the federal Social  
23 Security Act.

24           Section 35. Training; minimum requirements. An end stage  
25 renal disease facility shall establish and implement a policy  
26 to ensure appropriate training and competency of individuals  
27 employed as dialysis technicians within the licensed  
28 facility. The policy shall, at a minimum, define the acts and  
29 practices that are allowed or prohibited for such employees,  
30 establish how training will be conducted, and illustrate how  
31 initial competency will be established. Proof of initial and  
32 annual competency testing shall be maintained in the  
33 personnel file of each dialysis technician and shall be made

1 available to the Department upon request. An individual may  
2 not act as a dialysis technician in an end stage renal  
3 disease facility unless that individual has been trained and  
4 competency tested in accordance with this Act and the rules  
5 adopted under this Act. Persons training to act as a  
6 dialysis technician must be under the direct supervision of a  
7 physician or an appropriately trained nurse.

8 Section 40. Inspections.

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

14 (b) An inspection conducted under this Section shall be  
15 unannounced.

16 (c) Upon completion of each inspection, survey, or  
17 evaluation, the appropriate Department personnel who  
18 conducted the inspection, survey, or evaluation shall submit  
19 a copy of their report to the licensee upon exiting the  
20 facility, and shall submit the actual report to the  
21 appropriate regional office. The report shall identify areas  
22 in a facility identified as deficient in compliance with the  
23 requirements of this Act or the standards adopted under this  
24 Act. The report and any recommendation for action by the  
25 Department under this Act shall be sent to the Department's  
26 central office together with a plan of correction from the  
27 facility. The plan of correction may contain related comments  
28 or documentation provided by the licensee that may refute  
29 findings in the report, that explain extenuating  
30 circumstances that the facility could not reasonably have  
31 prevented, or that indicate methods and timetables for  
32 correction of deficiencies described in the report. A  
33 licensee has 10 days after the date of the inspection,

1 survey, or evaluation to submit a plan of correction.

2 (d) The Department shall determine whether a facility is  
3 in violation of this Section no later than 60 days after  
4 completion of each inspection, survey, evaluation, or plan of  
5 correction.

6 (e) The Department shall maintain all inspection,  
7 survey, or evaluation reports for at least 5 years in a  
8 manner accessible to the public.

9 Section 45. Notice of violation. When the Department  
10 determines that a facility is in violation of this Act or of  
11 any rule promulgated hereunder, a notice of violation shall  
12 be served upon the licensee. Each notice of violation shall  
13 be prepared in writing and shall specify the nature of the  
14 violation and the statutory provision or rule alleged to have  
15 been violated. The notice shall inform the licensee of any  
16 action the Department may take under the Act, including the  
17 requirement of a plan of correction under Section 50, or  
18 licensure action under Section 60. The Director or his  
19 designee shall also inform the licensee of the right to a  
20 hearing under Section 60.

21 Section 50. Plan of correction.

22 (a) Each facility served with a notice of violation  
23 under Section 45 of this Act shall file with the Department a  
24 written plan of correction, which is subject to approval of  
25 the Department, within 10 days after receipt of such notice.  
26 The plan of correction shall state with particularity the  
27 method by which the facility intends to correct each  
28 violation and shall contain a stated date by which each  
29 violation shall be corrected.

30 (b) If the Department rejects a plan of correction, it  
31 shall send notice of the rejection and the reason for the  
32 rejection to the licensee. The facility shall have 10 days

1 after receipt of the notice of rejection to submit a modified  
2 plan. If the modified plan is not timely submitted, or if  
3 the modified plan is rejected, the facility shall follow a  
4 plan of correction imposed by the Department.

5 (c) If a facility desires to contest any Department  
6 action under this Section it shall send a written request for  
7 a hearing under Section 60 to the Department within 10 days  
8 of receipt of the notice of the contested action. The  
9 Department shall commence the hearing as provided in Section  
10 60. Whenever possible, all actions of the Department under  
11 this Section arising out of a single violation shall be  
12 contested and determined at a single hearing. Issues decided  
13 as the result of the hearing process may not be reheard at  
14 subsequent hearings under this Act, but such determinations  
15 may be used as grounds for other administrative action by the  
16 Department pursuant to this Act.

17 Section 55. Denial, suspension, revocation, or refusal  
18 to renew a license; suspension of a service.

19 (a) When the Director determines that there is or has  
20 been a substantial or continued failure to comply with this  
21 Act or any rule promulgated hereunder, the Department may  
22 issue an order of license denial, suspension, revocation, or  
23 refusal to renew a license in accordance with subsection (a)  
24 of Section 60 of this Act.

25 (b) When the Director determines that a facility has  
26 failed to demonstrate the capacity to safely provide one or  
27 more of its services to patients, the Department may issue an  
28 order of service suspension in accordance with subsection (a)  
29 of Section 60 of this Act.

30 Section 60. Notice of administrative actions; hearing  
31 procedures.

32 (a) Notice of all administrative actions taken under this

1 Act shall be effected by registered mail, certified mail, or  
2 personal service and shall set forth the particular reasons  
3 for the proposed action and provide the applicant or licensee  
4 with an opportunity to request a hearing. If a hearing  
5 request is not received within 10 days after receipt of the  
6 notice of administrative action, the right to a hearing is  
7 waived.

8 (b) The procedure governing hearings authorized by this  
9 Section shall be in accordance with rules promulgated by the  
10 Department consistent with this Act. A hearing shall be  
11 conducted by the Director or by an individual designated in  
12 writing by the Director as administrative law judge. A full  
13 and complete record shall be kept of all proceedings,  
14 including notice of hearing, complaint, and all other  
15 documents in the nature of pleadings, written motions filed  
16 in the proceedings, and the report and orders of the Director  
17 and administrative law judge. All testimony shall be  
18 reported but need not be transcribed unless the decision is  
19 appealed pursuant to Section 70 of this Act. Any interested  
20 party may obtain a copy or copies of the transcript on  
21 payment of the cost of preparing such copy or copies.

22 (c) The Director or administrative law judge shall, upon  
23 his own motion or on the written request of any party to the  
24 proceeding, issue subpoenas requiring the attendance and  
25 testimony of witnesses and subpoenas duces tecum requiring  
26 the production of books, papers, records or memoranda. The  
27 fees of witnesses for attendance and travel shall be the same  
28 as the fees of witnesses before any circuit court of this  
29 State. Such fees shall be paid when the witness is excused  
30 from further attendance. When the witness is subpoenaed at  
31 the instance of the Director or administrative law judge,  
32 such fees shall be paid in the same manner as other expenses  
33 of the Department. When the witness is subpoenaed at the  
34 instance of any other party to a proceeding, the Department



1 may require that the cost of service of the subpoena or  
2 subpoena duces tecum and the fee of the witness be borne by  
3 the party at whose instance the witness is summoned. In such  
4 case, the Department, in its discretion, may require a  
5 deposit to cover the cost of such service and witness fees.  
6 A subpoena or subpoena duces tecum issued under this Section  
7 shall be served in the same manner as a subpoena issued by a  
8 court.

9 (d) Any circuit court of this State, upon the  
10 application of the Director or the application of any other  
11 party to the proceeding, may, in its discretion, compel the  
12 attendance of witnesses, the production of books, papers,  
13 records or memoranda, and the giving of testimony before the  
14 Director or administrative law judge conducting an  
15 investigation or holding a hearing authorized by this Act, by  
16 an attachment for contempt, or otherwise, in the same manner  
17 as production of evidence may be compelled before the court.

18 (e) The Director or administrative law judge, or any  
19 party in a hearing before the Department, may compel the  
20 attendance of witnesses and the production of books, papers,  
21 records, or memoranda.

22 (f) The Director or administrative law judge shall make  
23 findings of fact in such hearing and the Director shall  
24 render his decision within 60 days after the termination or  
25 waiving of the hearing unless he or she requires additional  
26 time for a proper disposition of the matter. When a  
27 administrative law judge has conducted the hearing, the  
28 Director shall review the record and findings of fact before  
29 rendering a decision. A copy of the findings of fact and  
30 decision of the Director shall be served upon the applicant  
31 or licensee in person, by registered mail or by certified  
32 mail in the same manner as the service of the notice of  
33 hearing. The decision denying, suspending, or revoking a  
34 license shall become final 35 days after it is mailed or

1 served, unless the applicant or licensee, within the 35-day  
2 period, petitions for review pursuant to Section 70 of this  
3 Act.

4 Section 65. Receiving and investigating complaints. The  
5 Department shall establish by rule a procedure for receiving  
6 and investigating complaints regarding any ESRDF, consistent  
7 with federal complaint procedures.

8 Section 70. Judicial review. Whenever the Department  
9 refuses to grant or decides to revoke or suspend a license to  
10 open, conduct, or maintain an ESRDF, the applicant or  
11 licensee may have such decision judicially reviewed. The  
12 provisions of the Administrative Review Law and the rules  
13 adopted pursuant thereto shall apply to and govern all  
14 proceedings for the judicial review of final administrative  
15 decisions of the Department hereunder. The term  
16 "administrative decisions" is defined as in Section 3-101 of  
17 the Code of Civil Procedure.

18 Section 75. Fines. Any person opening, conducting, or  
19 maintaining an ESRDF without a license issued pursuant to  
20 this Act shall be guilty of a business offense punishable by  
21 a fine of \$5,000 and each day's violation shall constitute a  
22 separate offense. Any person opening, conducting, or  
23 maintaining an ESRDF who violates any other provision of this  
24 Act shall be guilty of a business offense punishable by a  
25 fine of not more than \$5,000.

26 The Department shall adopt rules for determining the  
27 fines for violations.

28 Section 80. Injunctions. The operation or maintenance  
29 of an ESRDF in violation of this Act or of the rules adopted  
30 by the Department is declared a public nuisance inimical to

1 the public welfare. The Director of the Department, in the  
2 name of the People of the State, through the Attorney General  
3 or the State's Attorney of the county in which the violation  
4 occurs, may, in addition to other remedies herein provided,  
5 bring action for an injunction to restrain such violation or  
6 to enjoin the future operation or maintenance of any such  
7 ESRDF.

8 Section 85. Department access to and reproduction of  
9 documents. The Department shall have access to and may  
10 reproduce or photocopy at its cost any books, records, and  
11 other documents maintained by the facility to the extent  
12 necessary to carry out the purposes of this Act and the rules  
13 adopted under this Act. The Department shall not divulge or  
14 disclose the identity of any patient or other information  
15 prohibited from disclosure by the laws of this State.

16 Section 90. Refusal to allow inspections. Any licensee,  
17 applicant for a license, or person operating what may be an  
18 end stage renal disease facility shall be deemed to have  
19 given consent to any authorized officer, employee, or agent  
20 of the Department to enter and inspect the facility in  
21 accordance with this Act. Refusal to permit such entry or  
22 inspection shall constitute grounds for denial, nonrenewal,  
23 or revocation of a license.

24 Section 95. Probationary license. If the applicant has  
25 not been previously licensed or if the facility is not in  
26 operation at the time application is made, the Department  
27 shall issue a probationary license. A probationary license  
28 shall be valid for 120 days unless sooner suspended or  
29 revoked under this Act. Within 30 days prior to the  
30 termination of a probationary license, the Department shall  
31 fully and completely inspect the facility and, if the

1 facility meets the applicable requirements for licensure,  
2 shall issue a license under this Act. If the Department finds  
3 that the facility does not meet the requirements for  
4 licensure but has made substantial progress toward meeting  
5 those requirements, the license may be renewed once for a  
6 period not to exceed 120 days from the expiration date of the  
7 initial probationary license.

8 Section 100. Change of ownership.

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

15 (b) The transferor shall notify the Department at least  
16 30 days prior to final transfer. The transferor shall remain  
17 responsible for the operation of the facility until such time  
18 as a license is issued to the transferee.

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

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

30 Section 105. Access to information. The following  
31 information is subject to disclosure to the public by the  
32 Department:

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

3           (2) complaints and complaint investigation reports,  
4           except that a complaint or complaint investigation report  
5           shall not be disclosed to a person other than the  
6           complainant or complainant's representative before it is  
7           disclosed to a facility and except that a complainant's  
8           or patient's name shall not be disclosed. This  
9           information shall not disclose the name of any health  
10          care professionals or employees at the facility.

11          Section 110. Information available for public inspection.

12          (a) A facility shall post in plain view of the public  
13          (i) its current license, (ii) a description of complaint  
14          procedures established under this Act provided by the  
15          Department, and (iii) the name, address, and telephone number  
16          of a person authorized by the Department to receive  
17          complaints.

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

20                 (1) a copy of any order pertaining to the facility  
21                 issued by the Department or a court during the past 5  
22                 years;

23                 (2) a complete copy of every inspection report of  
24                 the facility received from the Department during the past  
25                 5 years;

26                 (3) a description of the services provided by the  
27                 facility and the rates charged for those services;

28                 (4) a copy of the statement of ownership required  
29                 by this Act; and

30                 (5) a complete copy of the most recent inspection  
31                 report of the facility received from the Department. This  
32                 information shall not disclose the name of any health  
33                 care professionals or employees at the facility.

1 Section 115. End Stage Renal Disease Advisory Committee.

2 (a) The Director shall appoint an End Stage Renal  
3 Disease Advisory Committee to advise and consult with the  
4 Director in the administration of this Act. The Committee  
5 shall be composed of the following members:

6 (1) 2 members who represent end stage renal disease  
7 facilities;

8 (2) 2 members who are physicians licensed to  
9 practice medicine in all its branches;

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

12 (4) one member who represents licensed hospitals;

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

15 (6) one member of the general public who is  
16 currently receiving dialysis. The recommendations of  
17 professional organizations may be considered in selecting  
18 individuals for appointment to the End Stage Renal  
19 Disease Advisory Committee.

20 (b) Each member shall be appointed for a term of 3  
21 years, except that of the original members, 4 shall be  
22 appointed for a term of 2 years, and 4 shall be appointed for  
23 a term of 3 years. The term of office of each of the original  
24 appointees shall commence on July 1, 2003. A member appointed  
25 to fill a vacancy occurring prior to the expiration of the  
26 term for which his or her predecessor was appointed shall be  
27 appointed for the remainder of that term.

28 (c) The Committee shall meet as frequently as the  
29 Director deems necessary. Committee members, while conducting  
30 the business of the Committee, shall receive actual and  
31 necessary travel and subsistence expenses when conducting  
32 such business away from their places of residence.

33 Section 120. Adoption of rules. The Department shall

1 adopt rules to implement this Act, including requirements for  
2 physical plant standards and for the issuance, renewal,  
3 denial, suspension, and revocation of a license to operate an  
4 end stage renal disease facility. These rules shall be  
5 consistent with the requirements for end stage renal disease  
6 services under Title XVIII and XIX of the federal Social  
7 Security Act.

8 Section 125. Fees. The Department may establish and  
9 collect fees in amounts reasonable and necessary to defray  
10 the cost of administering this Act. In setting fees under  
11 this Act, the Department shall consider setting a range of  
12 license and renewal fees based on the number of dialysis  
13 stations at the end stage renal disease facility, the patient  
14 census, and the average costs involved in surveying the  
15 facility.

16 Section 130. Deposit of fees and penalties. Fees and  
17 penalties collected under this Act shall be deposited into  
18 the End Stage Renal Disease Facility Licensing Fund, which is  
19 hereby created as a special fund in the State treasury.  
20 Moneys in the Fund may be used, subject to appropriation, by  
21 the Department for the administration of this Act.

22 Section 135. The State Finance Act is amended by adding  
23 Section 5.570 as follows:

24 (30 ILCS 105/5.570 new)

25 Sec. 5.570. The End Stage Renal Disease Facility  
26 Licensing Fund.

27 Section 999. Effective date. This Act takes effect July  
28 1, 2003.