

1 AN ACT creating the End Stage Renal Disease Facility Act.

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

26 "Patient" means any individual receiving treatment from  
27 an end stage renal disease facility.

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

30 "Physician" means an individual who is licensed to  
31 practice medicine in all of its branches under the Medical

1 Practice Act of 1987.

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

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

12 (1) a home health agency licensed under the Home Health  
13 Agency Licensing Act;

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

16 (3) the office of a physician.

17 Section 20. Issuance and renewal of license.

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

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

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

28 (d) The Department may grant a temporary initial license  
29 to an applicant. A temporary initial license expires on the  
30 earlier of (i) the date the Department issues or denies the  
31 license or (ii) the date 6 months after the temporary initial

1 license was issued.

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

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

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

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

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

29 Section 30. Minimum standards.

30 (a) The rules adopted pursuant to this Act shall contain  
31 minimum standards to protect the health and safety of a  
32 patient of an end stage renal disease facility, including

1 standards for:

2 (1) the qualifications and supervision of the  
3 professional staff and other personnel;

4 (2) the equipment used by the facility to insure  
5 that it is compatible with the health and safety of the  
6 patients;

7 (3) the sanitary and hygienic conditions in the  
8 facility;

9 (4) quality assurance for patient care;

10 (5) clinical records maintained by the facility;

11 (6) design and space requirements for the facility  
12 to insure safe access by patients and personnel and for  
13 ensuring patient privacy;

14 (7) indicators of the quality of care provided by  
15 the facility; and

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

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

21 Section 35. Training; minimum requirements. An end stage  
22 renal disease facility shall establish and implement a policy  
23 to ensure appropriate training and competency of individuals  
24 employed as dialysis technicians within the licensed  
25 facility. The policy shall, at a minimum, define the acts and  
26 practices that are allowed or prohibited for such employees,  
27 establish how training will be conducted, and illustrate how  
28 initial competency will be established. Proof of initial and  
29 annual competency testing shall be maintained in the  
30 personnel file of each dialysis technician and shall be made  
31 available to the Department upon request. An individual may  
32 not act as a dialysis technician in an end stage renal  
33 disease facility unless that individual has been trained and

1 competency tested in accordance with this Act and the rules  
2 adopted under this Act. Persons training to act as a  
3 dialysis technician must be under the direct supervision of a  
4 physician or an appropriately trained nurse.

5 Section 40. Inspections.

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

11 (b) An inspection conducted under this Section shall be  
12 unannounced.

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

32 (d) The Department shall determine whether a facility is  
33 in violation of this Section no later than 60 days after

1 completion of each inspection, survey, evaluation, or plan of  
2 correction.

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

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

18 Section 50. Plan of correction.

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

27 (b) If the Department rejects a plan of correction, it  
28 shall send notice of the rejection and the reason for the  
29 rejection to the licensee. The facility shall have 10 days  
30 after receipt of the notice of rejection to submit a modified  
31 plan. If the modified plan is not timely submitted, or if  
32 the modified plan is rejected, the facility shall follow a

1 plan of correction imposed by the Department.

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

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

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

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

27 Section 60. Notice of administrative actions; hearing  
28 procedures.

29 (a) Notice of all administrative actions taken under this  
30 Act shall be effected by registered mail, certified mail, or  
31 personal service and shall set forth the particular reasons  
32 for the proposed action and provide the application or

1 licensee with an opportunity to request a hearing. If a  
2 hearing request is not received within 10 days after receipt  
3 of the notice of administrative action, the right to a  
4 hearing is waived.

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

19 (c) The Director or hearing officer shall, upon his own  
20 motion or on the written request of any party to the  
21 proceeding, issue subpoenas requiring the attendance and  
22 testimony of witnesses and subpoenas duces tecum requiring  
23 the production of books, papers, records or memoranda. The  
24 fees of witnesses for attendance and travel shall be the same  
25 as the fees of witnesses before any circuit court of this  
26 State. Such fees shall be paid when the witness is excused  
27 from further attendance. When the witness is subpoenaed at  
28 the instance of the Director or hearing officer, such fees  
29 shall be paid in the same manner as other expenses of the  
30 Department. When the witness is subpoenaed at the instance  
31 of any other party to a proceeding, the Department may  
32 require that the cost of service of the subpoena or subpoena  
33 duces tecum and the fee of the witness be borne by the party  
34 at whose instance the witness is summoned. In such case, the



1 Department, in its discretion, may require a deposit to cover  
2 the cost of such service and witness fees. A subpoena or  
3 subpoena duces tecum issued under this Section shall be  
4 served in the same manner as a subpoena issued by a court.

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

14 (e) The Director or hearing officer, or any party in a  
15 hearing before the Department, may cause the deposition of  
16 witnesses within the State to be taken in the manner  
17 prescribed by law for depositions in civil actions in courts  
18 of this State, and may compel the attendance of witnesses and  
19 the production of books, papers, records, or memoranda.

20 (f) The Director or Hearing Officer shall make findings  
21 of fact in such hearing and the Director shall render his  
22 decision within 60 days after the termination or waiving of  
23 the hearing unless he or she requires additional time for a  
24 proper disposition of the matter. When a hearing officer has  
25 conducted the hearing, the Director shall review the record  
26 and findings of fact before rendering a decision. A copy of  
27 the findings of fact and decision of the Director shall be  
28 served upon the applicant or licensee in person, by  
29 registered mail or by certified mail in the same manner as  
30 the service of the notice of hearing. The decision denying,  
31 suspending, or revoking a license shall become final 35 days  
32 after it is mailed or served, unless the applicant or  
33 licensee, within the 35-day period, petitions for review  
34 pursuant to Section 70 of this Act.

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

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

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

23           Section 80. Injunctions. The operation or maintenance  
24 of an ESRDF in violation of this Act or of the rules adopted  
25 by the Department is declared a public nuisance inimical to  
26 the public welfare. The Director of the Department, in the  
27 name of the People of the State, through the Attorney General  
28 or the State's Attorney of the county in which the violation  
29 occurs, may, in addition to other remedies herein provided,  
30 bring action for an injunction to restrain such violation or  
31 to enjoin the future operation or maintenance of any such

1 ESRDF.

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

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

18 Section 95. Probationary license. If the applicant has  
19 not been previously licensed or if the facility is not in  
20 operation at the time application is made, the Department  
21 shall issue a probationary license. A probationary license  
22 shall be valid for 120 days unless sooner suspended or  
23 revoked under this Act. Within 30 days prior to the  
24 termination of a probationary license, the Department shall  
25 fully and completely inspect the facility and, if the  
26 facility meets the applicable requirements for licensure,  
27 shall issue a license under this Act. If the Department finds  
28 that the facility does not meet the requirements for  
29 licensure but has made substantial progress toward meeting  
30 those requirements, the license may be renewed once for a  
31 period not to exceed 120 days from the expiration date of the

1 initial probationary license.

2 Section 100. Change of ownership.

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

9 (b) The transferor shall notify the Department at least  
10 30 days prior to final transfer. The transferor shall remain  
11 responsible for the operation of the facility until such time  
12 as a license is issued to the transferee.

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

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

24 Section 105. Access to information. The following  
25 information is subject to disclosure to the public by the  
26 Department:

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

29 (2) complaints and complaint investigation reports,  
30 except that a complaint or complaint investigation report  
31 shall not be disclosed to a person other than the  
32 complainant or complainant's representative before it is

1 disclosed to a facility and except that a complainant's  
2 or patient's name shall not be disclosed. This  
3 information shall not disclose the name of any health  
4 care professionals or employees at the facility.

5 Section 110. Information available for public inspection.

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

7 (i) its current license, (ii) a description of complaint  
8 procedures established under this Act provided by the  
9 Department, and (iii) the name, address, and telephone number  
10 of a person authorized by the Department to receive  
11 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 during the past 5  
16 years;

17 (2) a complete copy of every inspection report of  
18 the facility received from the Department during the past  
19 5 years;

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

22 (4) a copy of the statement of ownership required  
23 by this Act; and

24 (5) a complete copy of the most recent inspection  
25 report of the facility received from the Department. This  
26 information shall not disclose the name of any health  
27 care professionals or employees at the facility.

28 Section 115. End Stage Renal Disease Advisory Committee.

29 (a) The Director shall appoint an End Stage Renal  
30 Disease Advisory Committee to advise and consult with the  
31 Director in the administration of this Act. The Committee  
32 shall be composed of the following members:

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

3           (2) 2 members who are physicians licensed to  
4 practice medicine in all its branches;

5           (3) one member who is a board-certified  
6 nephrologist;

7           (4) one member who represents licensed hospitals;

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

10          (6) one member of the general public who is  
11 currently receiving dialysis. The recommendations of  
12 professional organizations may be considered in selecting  
13 individuals for appointment to the End Stage Renal  
14 Disease Advisory Committee.

15          (b) Each member shall be appointed for a term of 3  
16 years, except that of the original members, 4 shall be  
17 appointed for a term of 2 years, and 4 shall be appointed for  
18 a term of 3 years. The term of office of each of the original  
19 appointees shall commence on July 1, 2001. A member appointed  
20 to fill a vacancy occurring prior to the expiration of the  
21 term for which his or her predecessor was appointed shall be  
22 appointed for the remainder of that term.

23          (c) The Committee shall meet as frequently as the  
24 Director deems necessary. Committee members, while conducting  
25 the business of the Committee, shall receive actual and  
26 necessary travel and subsistence expenses when conducting  
27 such business away from their places of residence.

28          Section 120. Adoption of rules. The Department shall  
29 adopt rules to implement this Act, including requirements for  
30 physical plant standards and for the issuance, renewal,  
31 denial, suspension, and revocation of a license to operate an  
32 end stage renal disease facility. These rules shall be  
33 consistent with the requirements for end stage renal disease

1 services under Title XVIII and XIX of the federal Social  
2 Security Act.

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

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

17 Section 135. The State Finance Act is amended by adding  
18 Section 5.545 as follows:

19 (30 ILCS 105/5.545 new)

20 Sec. 5.545. The End Stage Renal Disease Facility  
21 Licensing Fund.

22 Section 999. Effective date. This Act takes effect upon  
23 becoming law.