LRB9216063LBprA

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AN ACT concerning health facilities.

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

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

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

7 "Committee" means the End Stage Renal Disease Advisory8 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.

"Dialysis technician" means an individual who is not a registered nurse or physician and who provides dialysis care 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 -2-

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 Health13 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 shall19 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.

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

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

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license was issued. 1

(e) The Department shall issue a license if, after 2 application, inspection, and investigation, it finds the 3 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 Social Security Act as a condition of licensure. 8

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

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

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

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

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Section 30. Minimum standards.

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

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1 standards for: 2 (1) the qualifications and supervision of the professional staff and other personnel; 3 4 (2) the equipment used by the facility to insure that it is compatible with the health and safety of the 5 patients; 6 (3) the sanitary and hygienic conditions in the 7 facility; 8 9 (4) quality assurance for patient care; (5) clinical records maintained by the facility; 10 11 (6) design and space requirements for the facility to insure safe access by patients and personnel and for 12 13 ensuring patient privacy; (7) indicators of the quality of care provided by 14 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 to ensure appropriate training and competency of individuals 23 24 employed dialysis technicians within the licensed as facility. The policy shall, at a minimum, define the acts and 25 practices that are allowed or prohibited for such employees, 26 establish how training will be conducted, and illustrate how 27 initial competency will be established. Proof of initial and 28 29 annual competency testing shall be maintained in the personnel file of each dialysis technician and shall be made 30 available to the Department upon request. An individual may 31 not act as a dialysis technician in an end stage renal 32 disease facility unless that individual has been trained and 33

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

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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.

(c) Upon completion of each inspection, survey, 13 or 14 evaluation, the appropriate Department personnel who 15 conducted the inspection, survey, or evaluation shall submit a copy of their report to the licensee upon exiting 16 the 17 facility, and shall submit the actual report to the 18 appropriate regional office. The report shall identify areas in a facility identified as deficient in compliance with the 19 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 central office together with a plan of correction from the 23 24 facility. The plan of correction may contain related comments or documentation provided by the licensee that may refute 25 findings 26 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 licensee has 10 days after the date of the inspection, 30 survey, or evaluation to submit a plan of correction. 31

32 (d) The Department shall determine whether a facility is33 in violation of this Section no later than 60 days after

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completion of each inspection, survey, evaluation, or plan of
 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.

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

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## Section 50. Plan of correction.

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

(b) If the Department rejects a plan of correction, it shall send notice of the rejection and the reason for the rejection to the licensee. The facility shall have 10 days after receipt of the notice of rejection to submit a modified plan. If the modified plan is not timely submitted, or if the modified plan is rejected, the facility shall follow a 1 plan of correction imposed by the Department.

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

Section 55. Denial, suspension, revocation, or refusal 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.

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

Section 60. Notice of administrative actions; hearingprocedures.

(a) Notice of all administrative actions taken under this
Act shall be effected by registered mail, certified mail, or
personal service and shall set forth the particular reasons
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.

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

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

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

5 (d) Any circuit court of this State, upon the б 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 Director or hearing officer conducting an investigation or 10 11 holding a hearing authorized by this Act, by an attachment 12 for contempt, or otherwise, in the same manner as production of evidence may be compelled before the court. 13

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.

The Director or Hearing Officer shall make findings 20 (f) 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 proper disposition of the matter. When a hearing officer has 24 25 conducted the hearing, the Director shall review the record and findings of fact before rendering a decision. A copy of 26 the findings of fact and decision of the Director shall be 27 served upon the applicant or licensee in 28 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, suspending, or revoking a license shall become final 35 days 31 32 after it is mailed or served, unless the applicant or licensee, within the 35-day period, petitions for review 33 pursuant to Section 70 of this Act. 34

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

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

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

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

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1 ESRDF.

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

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

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

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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.

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

(d) The transferor shall remain liable for all penalties
assessed against the facility that are imposed for violations
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. (a) A facility shall post in plain view of the public 6 7 (i) its current license, (ii) a description of complaint 8 procedures established under this Act provided by the Department, and (iii) the name, address, and telephone number 9 10 of a person authorized by the Department to receive 11 complaints.

(b) A facility shall make the following information ordocuments 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 required23 by this Act; and

(5) a complete copy of the most recent inspection
report of the facility received from the Department. This
information shall not disclose the name of any health
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: -14-

1 (1) 2 members who represent end stage renal disease 2 facilities; (2) 2 members who are physicians licensed 3 to 4 practice medicine in all its branches; member who is a 5 (3) one board-certified nephrologist; 6 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.

(b) Each member shall be appointed for a term of 15 3 16 years, except that of the original members, 4 shall be appointed for a term of 2 years, and 4 shall be appointed for 17 a term of 3 years. The term of office of each of the original 18 19 appointees shall commence on July 1, 2003. A member appointed to fill a vacancy occurring prior to the expiration of the 20 21 term for which his or her predecessor was appointed shall be appointed for the remainder of that term. 22

(c) The Committee shall meet as frequently as the Director deems necessary. Committee members, while conducting the business of the Committee, shall receive actual and necessary travel and subsistence expenses when conducting 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 services under Title XVIII and XIX of the federal Social
 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 this Act, the Department shall consider setting a range of б license and renewal fees based on the number of dialysis 7 8 stations at the end stage renal disease facility, the patient census, and the average costs involved in surveying the 9 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.

Section 135. The State Finance Act is amended by addingSection 5.570 as follows:

19 (30 ILCS 105/5.570 new)
 20 <u>Sec. 5.570. The End Stage Renal Disease Facility</u>
 21 <u>Licensing Fund.</u>

Section 999. Effective date. This Act takes effect uponbecoming law.