## 92\_HB5906ham001

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- 2 AMENDMENT NO. \_\_\_\_. Amend House Bill 5906 by replacing
- 3 everything after the enacting clause with the following:
- 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
- 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
- 14 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.
- "End stage renal disease facility" or "ESRDF" means a
- 22 facility that provides dialysis treatment or dialysis

- 1 training to individuals with end stage renal disease.
- 2 "Nurse" means an individual who is licensed to practice
- 3 nursing under the Nursing and Advanced Practice Nursing Act.
- 4 "Patient" means any individual receiving treatment from
- 5 an end stage renal disease facility.
- 6 "Person" means any individual, firm, partnership,
- 7 corporation, company, association, or other legal entity.
- 8 "Physician" means an individual who is licensed to
- 9 practice medicine in all of its branches under the Medical
- 10 Practice Act of 1987.
- 11 Section 10. License required. Except as provided by this
- 12 Act, no person shall open, manage, conduct, offer, maintain,
- 13 or advertise an end stage renal disease facility without a
- 14 valid license issued by the Department. All end stage renal
- 15 disease facilities in existence as of the effective date of
- 16 this Act shall obtain a valid license to operate within one
- 17 year after the adoption of rules to implement this Act.
- 18 Section 15. Exemptions from licensing requirement. The
- 19 following facilities are not required to be licensed under
- 20 this Act:
- 21 (1) a home health agency licensed under the Home Health
- 22 Agency Licensing Act;
- 23 (2) a hospital licensed under the Hospital Licensing Act
- or the University of Illinois Hospital Act; and
- 25 (3) the office of a physician.
- Section 20. Issuance and renewal of license.
- 27 (a) An applicant for a license under this Act shall
- submit an application on forms prescribed by the Department.
- 29 (b) Each application shall be accompanied by a
- 30 non-refundable license fee, as established by rule of the
- 31 Department.

- 1 (c) Each application shall contain evidence that there
- 2 is at least one physician responsible for the medical
- 3 direction of the facility and that each dialysis technician
- 4 on staff has completed a training program as required by this
- 5 Act.
- 6 (d) The Department may grant a temporary initial license
- 7 to an applicant. A temporary initial license expires on the
- 8 earlier of (i) the date the Department issues or denies the
- 9 license or (ii) the date 6 months after the temporary initial
- 10 license was issued.
- 11 (e) The Department shall issue a license if, after
- 12 application, inspection, and investigation, it finds the
- 13 applicant meets the requirements of this Act and the
- 14 standards adopted pursuant to this Act. The Department may
- 15 include participation as a supplier of end stage renal
- 16 disease services under Titles XVIII and XIX of the federal
- 17 Social Security Act as a condition of licensure.
- 18 (f) The license is renewable annually after submission
- of (i) the renewal application and fee and (ii) an annual
- 20 report on a form prescribed by the Department that includes
- 21 information related to quality of care at the end stage renal
- 22 disease facility. The report must be in the form and
- documented by evidence as required by Department rule.
- 24 Section 25. Minimum staffing. An end stage renal disease
- 25 facility shall be under the medical direction of a physician
- 26 experienced in renal disease treatment, as required for
- 27 licensure under this Act. Additionally, at a minimum, every
- 28 facility licensed under this Act shall ensure that whenever
- 29 patients are undergoing dialysis all of the following are
- 30 met:
- 31 (1) one currently licensed physician, registered
- nurse, or licensed practical nurse experienced in
- rendering end stage renal disease care is physically

- 1 present on the premises to oversee patient care; and
- 2 (2) adequate staff is present to meet the medical
- 3 and non-medical needs of each patient, as provided by
- 4 this Act and the rules adopted pursuant to this Act.
- 5 Section 30. Minimum standards.
- 6 (a) The rules adopted pursuant to this Act shall contain
- 7 minimum standards to protect the health and safety of a
- 8 patient of an end stage renal disease facility, including
- 9 standards for:
- 10 (1) the qualifications and supervision of the
- 11 professional staff and other personnel;
- 12 (2) the equipment used by the facility to insure
- 13 that it is compatible with the health and safety of the
- 14 patients;
- 15 (3) the sanitary and hygienic conditions in the
- 16 facility;
- 17 (4) quality assurance for patient care;
- 18 (5) clinical records maintained by the facility;
- 19 (6) design and space requirements for the facility
- 20 to insure safe access by patients and personnel and for
- 21 ensuring patient privacy;
- 22 (7) indicators of the quality of care provided by
- 23 the facility; and
- 24 (8) water treatment and reuse by the facility.
- 25 (b) These standards shall be consistent with the
- 26 requirements for a supplier of end stage renal disease
- 27 services under Titles XVIII and XIX of the federal Social
- 28 Security Act.
- 29 Section 35. Training; minimum requirements. An end stage
- 30 renal disease facility shall establish and implement a policy
- 31 to ensure appropriate training and competency of individuals
- 32 employed as dialysis technicians within the licensed

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

- 14 Section 40. Inspections.
- 15 (a) The Department, whenever it deems necessary, may 16 conduct an inspection, survey, or evaluation of an end stage 17 renal disease facility to determine compliance with licensure 18 requirements and standards or a plan of correction submitted 19 as a result of deficiencies cited by the Department.
- 20 (b) An inspection conducted under this Section shall be 21 unannounced.
- 22 Upon completion of each inspection, survey, or appropriate Department personnel 23 evaluation, the who 24 conducted the inspection, survey, or evaluation shall submit 25 a copy of their report to the licensee upon exiting the shall submit the actual report to 26 facility, and the appropriate regional office. The report shall identify areas 27 in a facility identified as deficient in compliance with the 28 29 requirements of this Act or the standards adopted under this The report and any recommendation for action by the 30 Act. Department under this Act shall be sent to the Department's 31 central office together with a plan of correction from the 32 33 facility. The plan of correction may contain related comments

- 1 or documentation provided by the licensee that may refute
- 2 findings in the report, that explain extenuating
- 3 circumstances that the facility could not reasonably have
- 4 prevented, or that indicate methods and timetables for
- 5 correction of deficiencies described in the report. A
- 6 licensee has 10 days after the date of the inspection,
- 7 survey, or evaluation to submit a plan of correction.
- 8 (d) The Department shall determine whether a facility is
- 9 in violation of this Section no later than 60 days after
- 10 completion of each inspection, survey, evaluation, or plan of
- 11 correction.
- 12 (e) The Department shall maintain all inspection,
- 13 survey, or evaluation reports for at least 5 years in a
- 14 manner accessible to the public.
- 15 Section 45. Notice of violation. When the Department
- 16 determines that a facility is in violation of this Act or of
- 17 any rule promulgated hereunder, a notice of violation shall
- 18 be served upon the licensee. Each notice of violation shall
- 19 be prepared in writing and shall specify the nature of the
- violation and the statutory provision or rule alleged to have
- 21 been violated. The notice shall inform the licensee of any
- 22 action the Department may take under the Act, including the
- 23 requirement of a plan of correction under Section 50, or
- 24 licensure action under Section 60. The Director or his
- 25 designee shall also inform the licensee of the right to a
- hearing under Section 60.
- 27 Section 50. Plan of correction.
- 28 (a) Each facility served with a notice of violation
- 29 under Section 45 of this Act shall file with the Department a
- 30 written plan of correction, which is subject to approval of
- 31 the Department, within 10 days after receipt of such notice.
- 32 The plan of correction shall state with particularity the

- 1 method by which the facility intends to correct each
- 2 violation and shall contain a stated date by which each
- 3 violation shall be corrected.
- 4 (b) If the Department rejects a plan of correction, it
- 5 shall send notice of the rejection and the reason for the
- 6 rejection to the licensee. The facility shall have 10 days
- 7 after receipt of the notice of rejection to submit a modified
- 8 plan. If the modified plan is not timely submitted, or if
- 9 the modified plan is rejected, the facility shall follow a
- 10 plan of correction imposed by the Department.
- 11 (c) If a facility desires to contest any Department
- 12 action under this Section it shall send a written request for
- 13 a hearing under Section 60 to the Department within 10 days
- 14 of receipt of the notice of the contested action. The
- 15 Department shall commence the hearing as provided in Section
- 16 60. Whenever possible, all actions of the Department under
- 17 this Section arising out of a single violation shall be
- 18 contested and determined at a single hearing. Issues decided
- 19 as the result of the hearing process may not be reheard at
- 20 subsequent hearings under this Act, but such determinations
- 21 may be used as grounds for other administrative action by the
- 22 Department pursuant to this Act.
- 23 Section 55. Denial, suspension, revocation, or refusal
- 24 to renew a license; suspension of a service.
- 25 (a) When the Director determines that there is or has
- 26 been a substantial or continued failure to comply with this
- 27 Act or any rule promulgated hereunder, the Department may
- issue an order of license denial, suspension, revocation, or
- refusal to renew a license in accordance with subsection (a)
- 30 of Section 60 of this Act.
- 31 (b) When the Director determines that a facility has
- 32 failed to demonstrate the capacity to safely provide one or
- 33 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.
- 3 Section 60. Notice of administrative actions; hearing
- 4 procedures.
- 5 (a) Notice of all administrative actions taken under this
- 6 Act shall be effected by registered mail, certified mail, or
- 7 personal service and shall set forth the particular reasons
- 8 for the proposed action and provide the application or
- 9 licensee with an opportunity to request a hearing. If a
- 10 hearing request is not received within 10 days after receipt
- 11 of the notice of administrative action, the right to a
- 12 hearing is waived.
- 13 (b) The procedure governing hearings authorized by this
- 14 Section shall be in accordance with rules promulgated by the
- 15 Department consistent with this Act. A hearing shall be
- 16 conducted by the Director or by an individual designated in
- 17 writing by the Director as hearing officer. A full and
- 18 complete record shall be kept of all proceedings, including
- 19 notice of hearing, complaint, and all other documents in the
- 20 nature of pleadings, written motions filed in the
- 21 proceedings, and the report and orders of the Director and
- 22 hearing officer. All testimony shall be reported but need
- 23 not be transcribed unless the decision is appealed pursuant
- 24 to Section 70 of this Act. Any interested party may obtain a
- 25 copy or copies of the transcript on payment of the cost of
- 26 preparing such copy or copies.
- 27 (c) The Director or hearing officer shall, upon his own
- 28 motion or on the written request of any party to the
- 29 proceeding, issue subpoenas requiring the attendance and
- 30 testimony of witnesses and subpoenas duces tecum requiring
- 31 the production of books, papers, records or memoranda. The
- 32 fees of witnesses for attendance and travel shall be the same
- 33 as the fees of witnesses before any circuit court of this

- 1 State. Such fees shall be paid when the witness is excused 2 from further attendance. When the witness is subpoenaed at the instance of the Director or hearing officer, such fees 3 4 shall be paid in the same manner as other expenses of the 5 Department. When the witness is subpoenaed at the instance 6 of any other party to a proceeding, the Department may 7 require that the cost of service of the subpoena or subpoena duces tecum and the fee of the witness be borne by the party 8 9 at whose instance the witness is summoned. In such case, the Department, in its discretion, may require a deposit to cover 10 11 the cost of such service and witness fees. A subpoena or subpoena duces tecum issued under this Section shall be 12 served in the same manner as a subpoena issued by a court. 13
- (d) Any circuit court of this 14 State, t.he application of the Director or the application of any other 15 16 party to the proceeding, may, in its discretion, compel attendance of witnesses, the production of books, papers, 17 18 records or memoranda, and the giving of testimony before 19 Director or hearing officer conducting an investigation or 20 holding a hearing authorized by this Act, by an attachment 2.1 for contempt, or otherwise, in the same manner as production 22 of evidence may be compelled before the court.

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- (e) The Director or hearing officer, or any party in a hearing before the Department, may cause the deposition of witnesses within the State to be taken in the manner prescribed by law for depositions in civil actions in courts of this State, and may compel the attendance of witnesses and the production of books, papers, records, or memoranda.
- (f) The Director or Hearing Officer shall make findings of fact in such hearing and the Director shall render his decision within 60 days after the termination or waiving of the hearing unless he or she requires additional time for a proper disposition of the matter. When a hearing officer has conducted the hearing, the Director shall review the record

- 1 and findings of fact before rendering a decision. A copy of
- 2 the findings of fact and decision of the Director shall be
- 3 served upon the applicant or licensee in person, by
- 4 registered mail or by certified mail in the same manner as
- 5 the service of the notice of hearing. The decision denying,
- 6 suspending, or revoking a license shall become final 35 days
- 7 after it is mailed or served, unless the applicant or
- 8 licensee, within the 35-day period, petitions for review
- 9 pursuant to Section 70 of this Act.
- 10 Section 65. Receiving and investigating complaints. The
- 11 Department shall establish by rule a procedure for receiving
- 12 and investigating complaints regarding any ESRDF, consistent
- 13 with federal complaint procedures.
- 14 Section 70. Judicial review. Whenever the Department
- 15 refuses to grant or decides to revoke or suspend a license to
- open, conduct, or maintain an ESRDF, the applicant or
- 17 licensee may have such decision judicially reviewed. The
- 18 provisions of the Administrative Review Law and the rules
- 19 adopted pursuant thereto shall apply to and govern all
- 20 proceedings for the judicial review of final administrative
- 21 decisions of the Department hereunder. The term
- 22 "administrative decisions" is defined as in Section 3-101 of
- 23 the Code of Civil Procedure.
- Section 75. Fines. Any person opening, conducting, or
- 25 maintaining an ESRDF without a license issued pursuant to
- 26 this Act shall be guilty of a business offense punishable by
- 27 a fine of \$5,000 and each day's violation shall constitute a
- 28 separate offense. Any person opening, conducting, or
- 29 maintaining an ESRDF who violates any other provision of this
- 30 Act shall be guilty of a business offense punishable by a
- fine of not more than \$5,000.

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

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

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

Section 95. Probationary license. If the applicant has not been previously licensed or if the facility is not in operation at the time application is made, the Department shall issue a probationary license. A probationary license shall be valid for 120 days unless sooner suspended or

- 1 revoked under this Act. Within 30 days prior to the
- 2 termination of a probationary license, the Department shall
- 3 fully and completely inspect the facility and, if the
- 4 facility meets the applicable requirements for licensure,
- 5 shall issue a license under this Act. If the Department finds
- 6 that the facility does not meet the requirements for
- 7 licensure but has made substantial progress toward meeting
- 8 those requirements, the license may be renewed once for a
- 9 period not to exceed 120 days from the expiration date of the
- 10 initial probationary license.
- 11 Section 100. Change of ownership.
- 12 (a) Whenever ownership of a facility is transferred from
- 13 the person named on the license to any other person, the
- 14 transferee must obtain a new probationary license. The
- 15 transferee shall notify the Department of the transfer and
- 16 apply for a new license at least 30 days prior to final
- 17 transfer.
- 18 (b) The transferor shall notify the Department at least
- 19 30 days prior to final transfer. The transferor shall remain
- 20 responsible for the operation of the facility until such time
- 21 as a license is issued to the transferee.
- (c) The license granted to the transferee shall be
- 23 subject to any plan of correction submitted by the previous
- 24 owner and approved by the Department and any conditions
- 25 contained in a conditional license issued to the previous
- owner. If there are outstanding violations and no approved
- 27 plan of correction has been implemented, the Department may
- 28 issue a conditional license and plan of correction as
- 29 provided in this Act.
- 30 (d) The transferor shall remain liable for all penalties
- 31 assessed against the facility that are imposed for violations
- 32 occurring prior to transfer of ownership.

1	Section	105	. Access	to	informatio	on.	Tł	ne f	ol	low	ing
2	information	is	subject	to	disclosure	to	the	publi	c k	oy	the
3	Department:										

- (1) records of license inspections, surveys, and evaluations of facilities; and
- (2) complaints and complaint investigation reports, 6 7 except that a complaint or complaint investigation report not be disclosed to a person other than the 8 9 complainant or complainant's representative before it is disclosed to a facility and except that a complainant's 10 11 or patient's name shall not be disclosed. This information shall not disclose the name of any health 12 care professionals or employees at the facility. 13
- 14 Section 110. Information available for public inspection.
- (a) A facility shall post in plain view of the public (i) its current license, (ii) a description of complaint procedures established under this Act provided by the Department, and (iii) the name, address, and telephone number of a person authorized by the Department to receive
- 20 complaints.

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- 21 (b) A facility shall make the following information or 22 documents available upon request for public inspection:
- 23 (1) a copy of any order pertaining to the facility 24 issued by the Department or a court during the past 5 25 years;
- (2) a complete copy of every inspection report of
  the facility received from the Department during the past
  5 years;
- 29 (3) a description of the services provided by the 30 facility and the rates charged for those services;
- 31 (4) a copy of the statement of ownership required 32 by this Act; and
- 33 (5) a complete copy of the most recent inspection

- 1 report of the facility received from the Department. This
- 2 information shall not disclose the name of any health
- care professionals or employees at the facility. 3
- Section 115. End Stage Renal Disease Advisory Committee. 4
- 5 The Director shall appoint an End Stage Renal
- 6 Disease Advisory Committee to advise and consult with the
- in the administration of this Act. The Committee 7 Director
- 8 shall be composed of the following members:
- (1) 2 members who represent end stage renal disease 9
- facilities; 10

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- (2) 2 members who are physicians licensed to practice medicine in all its branches;
- (3) one member is a 13 who board-certified 14 nephrologist;
  - (4) one member who represents licensed hospitals;
    - (5) one member who is a registered professional nurse with experience treating end stage renal disease;
- 18 (6) one member of the general public who is currently receiving dialysis. The recommendations of 20 professional organizations may be considered in selecting 21 individuals for appointment to the End Stage Renal 22 Disease Advisory Committee.
- (b) Each member shall be appointed for a term of 23 24 years, except that of the original members, 4 shall be appointed for a term of 2 years, and 4 shall be appointed for 25 a term of 3 years. The term of office of each of the original 26 appointees shall commence on July 1, 2003. A member appointed 27 28 to fill a vacancy occurring prior to the expiration of the 29 term for which his or her predecessor was appointed shall be appointed for the remainder of that term. 30
- 31 The Committee shall meet as frequently as (C) t.he Director deems necessary. Committee members, while conducting 32 33 the business of the Committee, shall receive actual and

- 1 necessary travel and subsistence expenses when conducting
- 2 such business away from their places of residence.
- 3 Section 120. Adoption of rules. The Department shall
- 4 adopt rules to implement this Act, including requirements for
- 5 physical plant standards and for the issuance, renewal,
- 6 denial, suspension, and revocation of a license to operate an
- 7 end stage renal disease facility. These rules shall be
- 8 consistent with the requirements for end stage renal disease
- 9 services under Title XVIII and XIX of the federal Social
- 10 Security Act.
- 11 Section 125. Fees. The Department may establish and
- 12 collect fees in amounts reasonable and necessary to defray
- 13 the cost of administering this Act. In setting fees under
- 14 this Act, the Department shall consider setting a range of
- 15 license and renewal fees based on the number of dialysis
- 16 stations at the end stage renal disease facility, the patient
- 17 census, and the average costs involved in surveying the
- 18 facility.
- 19 Section 130. Deposit of fees and penalties. Fees and
- 20 penalties collected under this Act shall be deposited into
- 21 the End Stage Renal Disease Facility Licensing Fund, which is
- 22 hereby created as a special fund in the State treasury.
- 23 Moneys in the Fund may be used, subject to appropriation, by
- the Department for the administration of this Act.
- 25 Section 135. The State Finance Act is amended by adding
- 26 Section 5.570 as follows:
- 27 (30 ILCS 105/5.570 new)
- 28 <u>Sec. 5.570. The End Stage Renal Disease Facility</u>
- 29 <u>Licensing Fund.</u>

- Section 999. Effective date. This Act takes effect upon 1
- 2 becoming law.".