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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 452 Session of 1989

INTRODUCED BY GREENLEAF, BELL, FISHER, SALVATORE, AFFLERBACH, REIBMAN, LYNCH, ANDREZESKI, JONES, WILT AND PORTERFIELD, FEBRUARY 6, 1989

REFERRED TO PUBLIC HEALTH AND WELFARE, FEBRUARY 6, 1989

AN ACT

Prohibiting and restricting the use of certain instruments in connection with renal dialysis; granting rights to renal dialysis patients; and imposing duties on the Department of Health.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Short title.

This act shall be known and may be cited as the Renal Dialysis Patient Protection Act.

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

"Department." The Department of Health of the Commonwealth.

"Hospital." An institution licensed or regulated as a hospital by the Department of Health or the Department of Public Welfare or a facility owned or operated by the Federal Government.

"Renal dialysis facility." A place, other than a hospital or the patient's home, that provides therapeutic care for persons with acute or chronic renal failure through the use of hemodialysis, peritoneal dialysis or any other therapy that clears the blood of substances normally excreted by the kidneys.

Section 3. Reuse of blood tubing or transducer protectors prohibited.

No hospital or renal dialysis facility in this Commonwealth shall reuse blood tubing or transducer protectors.

Section 4. Reuse of hemodialyzer or dialyzer caps.

No hospital or renal dialysis facility in this Commonwealth shall reuse a hemodialyzer or dialyzer caps on a patient unless, prior to the initial treatment, that patient has first signed a written consent form after having been orally advised by a physician of the potential risks, benefits and uncertainties surrounding reuse and the disinfection process. The information conveyed shall consist of a full and fair presentation of representative opinions from those in the medical community who have expressed concerns about reuse practices and from those who support these practices. Any discussion of first-use syndrome shall include information about advances in biocompatible-membrane technology. Treatment shall not be withheld nor shall a patient be otherwise penalized if the patient declines reuse. Hospitals accredited by the Joint Commission on Accreditation of Hospitals are exempt from this section of the act.

Section 5. Rights of dialysis patients.

Dialysis patients shall have the following nonwaivable rights:

(1) To revoke or limit, either orally or in writing, a previously executed reuse consent at any time and for any

reason.

(2) To be informed before each dialysis treatment of the number of times the dialyzer and dialyzer caps have been previously used.

(3) To have documented in their patient care records all consents to reuse, refusals to consent, revocations of consent and limitations placed upon consent.

(4) To have unrestricted access to their patient dialysis care records.

(5) To make the reuse consent decision required under section 4 in an environment devoid of threats, intimidation or retaliation by the facility or its staff.

Section 6. Rules and regulations.

(a) Promulgation by department.--The department shall promulgate rules and regulations applicable to all hospitals not exempt under section 4 and renal dialysis facilities in this Commonwealth with respect to the following:

(1) The labeling, handling, transporting, storage, routine inspection and preventive maintenance of dialysis equipment.

(2) The reprocessing and reuse of hemodialyzers, dialysate port caps and blood port caps.

(3) Water purification and quality.

(4) The flushing of residues from potentially toxic sterilants and disinfectants used during manufacturing or reprocessing.

(5) The responsibility to ensure individualized treatment, including the most appropriate choice of equipment for each patient and, for patients exhibiting hypersensitivity, the use of biocompatible membranes.

(6) The reporting of equipment failures and occurrences of pyrexia, sepsis or bacteremia.

(7) The training, minimum qualifications and supervision of dialysis staff.

(8) The training and support provided to self-dialysis and home dialysis patients.

(b) Minimum standards.--The rules and regulations promulgated under subsection (a) shall not be less stringent than the guidelines set forth in the Recommended Practice for Reuse of Hemodialyzers, published July 28, 1986, by the Association for the Advancement of Medical Instrumentation, and the recommendations of the Centers for Disease Control referenced in those guidelines.

(c) Interim procedures.--Until the rules and regulations promulgated under subsection (a) become effective, hospitals and renal dialysis facilities shall comply with the guidelines set forth in the Recommended Practice for Reuse of Hemodialyzers, except that, where there are recommendations of the Centers for Disease Control, hospitals and renal dialysis facilities shall comply with the Centers for Disease Control recommendations.

Section 7. Effective date.

This act shall take effect in 60 days.