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THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 933 Session of 2001

INTRODUCED BY GREENLEAF, COSTA, BOSCOLA, FUMO AND O'PAKE, JUNE 7, 2001

REFERRED TO PUBLIC HEALTH AND WELFARE, JUNE 7, 2001

AN ACT

Prohibiting and limiting the use of certain instruments in connection with renal dialysis; establishing certain rights for 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 in this Commonwealth.

"Patient." A person who is in need of renal dialysis.

"Renal dialysis facility." A facility in this Commonwealth, other than a hospital or a 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.

"Treatment." The provision of renal dialysis.

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

No hospital or renal dialysis facility may reuse blood tubing or transducer protectors.

Section 4. Reuse of hemodialyzer or dialyzer caps limited.

(a) Reuse consent required.--No hospital or renal dialysis facility may reuse a hemodialyzer or dialyzer caps on a patient unless, prior to the initial treatment:

(1) The patient has been orally advised by a physician of the potential risks, benefits and uncertainties surrounding reuse and the disinfection process.

(2) The patient has signed a written consent form for treatment with reuse of a hemodialyzer or dialyzer caps.

(b) Contents of physician advice.--The advice from the physician shall consist of a full and fair presentation of representative opinions from the medical community that express concern about and support reuse practices. Any discussion with the patient of first-use syndrome shall include information about advances in biocompatible-membrane technology.

(c) Effect of declined reuse.--Treatment shall not be withheld nor shall a patient be otherwise penalized by a hospital or renal dialysis facility if the patient declines

reuse.

Section 5. Rights of dialysis patient.

A dialysis patient 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 the patient's care records all consents to reuse, refusals to consent, revocations of consent and limitations placed upon consent.

(4) To have unrestricted access to the patient's 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 and renal dialysis facilities 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.

(9) The nonwaivable dialysis patients' rights enumerated under section 5.

(b) Minimum standards.--The rules and regulations promulgated under subsection (a) shall not be less stringent than the guidelines set forth in the most current edition of the Recommended Practice for Reuse of Hemodialyzers published 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, each hospital and renal dialysis facility shall comply with the guidelines set forth in the Recommended Practice for Reuse of Hemodialyzers, except that, where there are recommendations relating to reuse of hemodialyzers from the Centers for Disease Control, a hospital and renal dialysis facility shall comply with those recommendations.

Section 7. Effective date.

This act shall take effect in 60 days.