

COUNCIL OF THE DISTRICT OF COLUMBIA

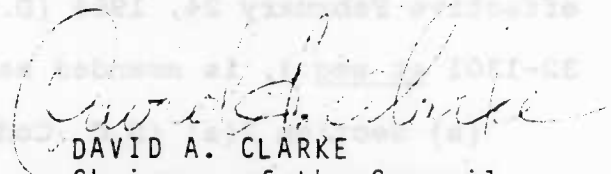
NOTICE

D.C. LAW 6-215

"Renal Dialysis Licensure Amendments Act
of 1986".

Pursuant to Section 412 of the District of Columbia Self-Government and Governmental Reorganization Act, P. L. 93-198, "the Act", the Council of the District of Columbia adopted Bill No. 6-538 on first and second readings, November 25, 1986 and December 16, 1986, respectively. Following the signature of the Mayor on January 8, 1987, this legislation was assigned Act No. 6-275, published in the February 6, 1987, edition of the D.C. Register, (Vol. 34 page 893) and transmitted to Congress on January 13, 1987 for a 30-day review, in accordance with Section 602 (c)(1) of the Act.

The Council of the District of Columbia hereby gives notice that the 30-day Congressional Review Period has expired, and therefore, cites this enactment as D.C. Law 6-215, effective February 28, 1987.


DAVID A. CLARKE
Chairman of the Council

Dates Counted During the 30-day Congressional Review Period:

January 13,14,15,16,20,21,22,23,26,27,28,29,30

February 2,3,4,5,6,9,10,11,17,18,19,20,23,24,25,26,27

AN ACT

D.C. ACT 6 - 275

IN THE COUNCIL OF THE DISTRICT OF COLUMBIA

JAN 08 1987

To amend the Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983 in order to license renal dialysis facilities, require minimum standards and procedures for the performance of dialysis and the reuse of dialyzers and caps, prohibit the reuse of blood tubing and transducer protectors, and make the reuse of dialyzers and caps contingent upon a patient's informed consent.

BE IT ENACTED BY THE COUNCIL OF THE DISTRICT OF COLUMBIA,
That this act may be cited as the "Renal Dialysis Licensure Amendments Act of 1986".

Sec. 2. The Health-Care and Community Residence Facility, Hospice and Home Care Licensure Act of 1983, effective February 24, 1984 (D.C. Law 5-48; D.C. Code, sec. 32-1301 et seq.), is amended as follows:

(a) Section 2(a) (D.C. Code, sec. 32-1301(a)) is amended by adding a new paragraph (9) to read as follows:

D.C. Code, sec.
32-1301 (1987
supp.)

"(9) 'Renal dialysis facility' means any 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."

(b) Section 5(c) (D.C. Code, sec. 32-1304(c)) is amended by inserting the phrase "and renal dialysis facilities" after the phrase "ambulatory surgical facilities".

D.C. Code, sec.
32-1304 (1987
supp.)

(c) A new section 5(i) (D.C. Code, sec. 32-1304(i)) is added to read as follows:

D.C. Code, sec.
32-1304 (1987
supp.)

"(i)(1) As part of the standards for hospitals and renal dialysis facilities required by subsection (a)(3) of this section, the Mayor shall establish standards and procedures with respect to:

"(A) The labeling, handling, transporting, storage, routine inspection, and preventive maintenance of dialysis equipment;

"(B) The reprocessing and reuse of hemodialyzers, dialysate port caps, and blood port caps;

"(C) Water purification and quality;

"(D) The flushing of residues from potentially toxic sterilants and disinfectants used during manufacture or reprocessing;

"(E) The facility's 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;

"(F) The reporting of equipment failures and occurrences of pyrexia, sepsis, or bacteremia;

"(G) The training, minimum qualifications, and supervision of dialysis staff; and

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

"(2) The standards and procedures required by paragraph (1) of this subsection shall not be less stringent than the guidelines set forth in the July 28, 1986, Recommended Practice for Reuse of Hemodialyzers published by the Association for the Advancement of Medical Instrumentation ("AAMI Recommended Practice") and the recommendations of the Centers for Disease Control referenced in those guidelines ("CDC Recommendations").

"(3) Until the standards and procedures required by paragraph (1) of this subsection become enforceable through licensure, hospitals and renal dialysis facilities shall comply with the AAMI Recommended Practice, except that, where there are CDC Recommendations, hospitals and renal dialysis facilities shall comply with the CDC Recommendations.

"(4) No hospital or renal dialysis facility shall reuse blood tubing or transducer protectors.

"(5) No hospital or renal dialysis facility shall reuse a hemodialyzer or dialyzer caps on a patient unless

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 advising physician shall not be a medical director of the facility or dialysis unit, nor shall he or she have a financial interest in the facility. 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 those who support these practices. Any discussion of "first-use syndrome" shall include information about advances in biocompatible-membrane technology.

"(6) Dialysis patients shall have the following nonwaivable rights, to be supplemented by the statement of rights and responsibilities established by the Mayor pursuant to subsection (a)(4) of this section:

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

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

"(C) To have documented in their patient-care records all consents to reuse, refusals to consent, revocations of consent, and limitations placed upon consent;

"(D) To have unrestricted access to their patient-care records;

"(E) To make the reuse-consent decision in an environment devoid of threats, intimidation, or retaliation by the facility or its staff; and

"(F) Except as provided by paragraph (7) of this subsection, to remain at a facility and receive treatments with a new, state-of-the-art dialyzer and new dialyzer caps whenever consent to reuse is refused or revoked or reuse is prohibited by limitations placed upon consent.

"(7) A hospital or renal dialysis facility may transfer or decline to admit a patient on account of that patient's refusal to consent to the reuse of hemodialyzers or dialyzer caps only if:

(A) The Mayor certifies that the facility is currently in full compliance with this subsection and all other District of Columbia laws that regulate, either directly or indirectly, the reprocessing and reuse of hemodialyzers and dialyzer caps;

(B) The facility, in cooperation with a patient-care ombudsman designated by the Mayor, identifies and secures a permanent placement for the patient in an alternative facility within the District of Columbia where that patient will be provided the option of receiving each

treatment with a new, state-of-the-art dialyzer and new dialyzer caps; and

(C) The patient-care ombudsman designated by the Mayor finds that the patient can obtain equally reliable transportation to and from the alternative facility without suffering extreme physical, psychological, or financial hardship.

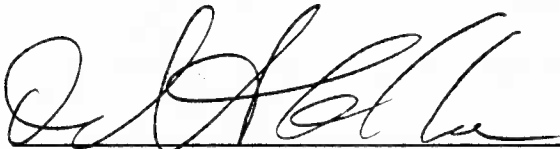
"(8) Paragraphs (3) through (7) of this subsection shall be applicable and enforceable with respect to all hospitals and renal dialysis facilities, whether licensed or temporarily exempt from licensure under section 3(c), immediately upon the effective date of the Renal Dialysis Licensure Amendments Act of 1986."

(d) Section 10(c) (D.C. Code, sec. 32-1309(c)) is amended by striking the phrase "any provision in section 8 of this act" and inserting in its place the phrase "any provision of this act or rule issued pursuant to this act".

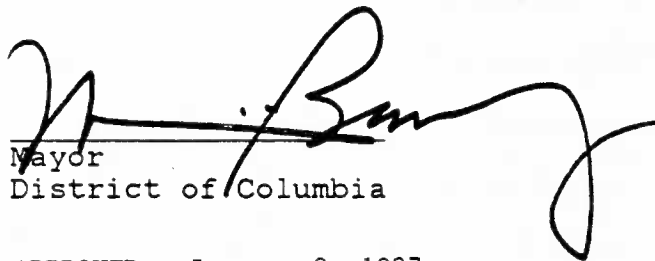
D.C. Code, sec.
32-1309 (1987
supp.)

Sec. 3. This act shall take effect after a 30-day period of Congressional review following approval by the Mayor (or in the event of veto by the Mayor, action by the Council of the District of Columbia to override the veto) as provided in section 602(c)(1) of the District of Columbia Self-Government and Governmental Reorganization Act,

approved December 24, 1973 (87 Stat. 813; D.C. Code, sec.
1-233(c)(1)).



Chairman
Council of the District of Columbia



Mayor
District of Columbia

APPROVED: January 8, 1987



COUNCIL OF THE DISTRICT OF COLUMBIA
Council Period Six — Second Session

RECORD OF OFFICIAL COUNCIL VOTE

DOCKET NO: B6-538

Item on Consent Calendar

ACTION & DATE: Adopted First Reading, 11-25-86

VOICE VOTE: Unanimous

Recorded vote on request

Absent: Schwartz

ROLL CALL VOTE: — RESULT _____

COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.
CHMN. CLARKE					MASON					SPAULDING				
SMITH, JR.					RAY					WILSON				
CRAWFORD					ROLARK					WINTER				
JARVIS					SCHWARTZ									
KANE					SHACKLETON									

X — Indicates Vote A.B. — Absent N.V. — Present, not voting

CERTIFICATION RECORD

Russell S. Galt
 Secretary to the Council

11/25/86
 Date

Item on Consent Calendar

ACTION & DATE: Adopted Final Reading, 12-16-86

VOICE VOTE: Unanimous

Recorded vote on request

Absent: all present

ROLL CALL VOTE: — RESULT _____

COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.
CHMN. CLARKE					MASON					SPAULDING				
SMITH, JR.					RAY					WILSON				
CRAWFORD					ROLARK					WINTER				
JARVIS					SCHWARTZ									
KANE					SHACKLETON									

X — Indicates Vote A.B. — Absent N.V. — Present, not voting

CERTIFICATION RECORD

Russell S. Galt
 Secretary to the Council

12/16/86
 Date

Item on Consent Calendar

ACTION & DATE: _____

VOICE VOTE: _____

Recorded vote on request

Absent: _____

ROLL CALL VOTE: — RESULT _____

COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.	COUNCIL MEMBER	AYE	NAY	N.V.	A.B.
CHMN. CLARKE					MASON					SPAULDING				
SMITH, JR.					RAY					WILSON				
CRAWFORD					ROLARK					WINTER				
JARVIS					SCHWARTZ									
KANE					SHACKLETON									

X — Indicates Vote A.B. — Absent N.V. — Present, not voting

CERTIFICATION RECORD

 Secretary to the Council

 Date