

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 101

Session of
1983

INTRODUCED BY BURNS, GALLAGHER, MAIALE, REINARD, J. L. WRIGHT
AND CLYMER, JANUARY 31, 1983

REFERRED TO COMMITTEE ON HEALTH AND WELFARE, JANUARY 31, 1983

AN ACT

1 Amending the act of July 19, 1979 (P.L.130, No.48), entitled "An
2 act relating to health care; prescribing the powers and
3 duties of the Department of Health; establishing and
4 providing the powers and duties of the State Health
5 Coordinating Council, health systems agencies and Health Care
6 Policy Board in the Department of Health, and State Health
7 Facility Hearing Board in the Department of Justice;
8 providing for certification of need of health care providers
9 and prescribing penalties," providing for hemodialysis
10 services.

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

13 Section 1. The act of July 19, 1979 (P.L.130, No.48), known
14 as the Health Care Facilities Act, is amended by adding a
15 section to read:

16 Section 806.1. Hemodialysis services.

17 (a) It is the intent of this section that a hemodialysis
18 patient be fully informed about his or her therapy, including
19 the possibility of reuse of single use hemodialyzers, and that
20 the patient have full freedom of choice regarding the reuse of
21 such dialyzers.

1 (b) The department shall adopt by April 1, 1984 regulations
2 establishing such specific protocol for the reprocessing and
3 reuse of disposable hemodialysis filters as it determines is
4 reasonably necessary for the protection of the health and safety
5 of hemodialysis patients.

6 (c) Every hemodialysis clinic or hospital providing
7 hemodialysis services shall submit to the department for
8 approval its protocol for dialyzer reprocessing and reuse within
9 three months after the effective date of the department's
10 protocol. The department shall approve each protocol which the
11 department determines provides protection to hemodialysis
12 patients which is equal to or greater than the protection
13 provided by the department's protocol. If a dialysis facility
14 does not submit a protocol to the department within three months
15 after the department has established the protocol, such dialysis
16 facility shall automatically be subject to the department's
17 protocol.

18 (d) The protocol shall include, but not be limited to, the
19 following:

20 (1) A patient when receiving dialysis treatment at a
21 dialysis facility for the first time after July 1, 1984 shall
22 execute a written consent for the reuse of disposable
23 hemodialysis filters. The consent form shall be approved by
24 the department and shall inform the patient of the risks and
25 the possible benefits of reuse. The signature of the patient
26 shall appear at the bottom of the form containing such
27 information. The form shall be inserted in the patient's
28 medical file at the dialysis facility.

29 (2) The patient shall be informed that he or she is not
30 required to reuse a dialyzer.

1 (3) The patient may reject reuse of a dialyzer at any
2 time and, upon rejection, shall be supplied a new dialyzer.

3 (4) No patient shall be denied treatment at a dialysis
4 facility because he or she refuses to reuse a dialyzer.

5 (5) Prior to a dialysis treatment, a patient who chooses
6 to reuse the filter shall be informed of how many times the
7 filter has previously been used.

8 (e) The protocol shall contain specific requirements and
9 standards for the reprocessing of such disposable dialyzers
10 which shall include, but not be limited to, the following:

11 (1) Require that a dialysis facility utilize department
12 approved methods in the rinsing, cleansing, sterilizing,
13 storing and labeling of such dialyzers.

14 (2) Require that the dialysis facility utilize the most
15 effective methods, as determined by the department for
16 detecting the presence of cleansing agents on the dialyzer
17 filter.

18 (3) Prohibit the reuse of a dialyzer when tests indicate
19 the presence of formaldehyde or other impurities following
20 cleansing.

21 (4) Establish specific standards for each type of
22 single-use dialyzer and prohibit reuse upon a specific
23 reduction of total capacity for each type of dialyzer.

24 (f) This section may be enforced by the department pursuant
25 to sections 811(1), 813, 814, 815, 817 and 818.

26 Section 2. This act shall take effect in 60 days.