

75197 Informed Consent

(a)

The patient or his or her legal guardian or conservator may execute written consent for the reuse of hemodialysis filters. Non-execution shall indicate the patient chooses not to participate in a reuse program.

(b)

The written consent form shall include, but not be limited to, the following statements: (1) The patient's name, the dialysis facility name, and the name of the staff person who explained the facility's reuse program and process. (2) A statement that the reuse process has been fully explained to the patient and that the facility's written policies and reuse procedures are available upon request. (3) A statement that a reused dialyzer will only be used by the same patient again. (4) A statement that single-use dialyzers are recommended by the dialyzer manufacturer for one-time use only. (5) A list of the advantages and disadvantages associated with reuse which shall include, but not be limited to: (A) Entry of a residual amount of (name of the disinfectant chemical), the long-term effect of which is unknown. (B) The increased possibility of infection and/or fever producing reactions if procedures are not correctly followed at this dialysis facility. (C) A lower incidence of back and chest pain, cramps, fever, sweating, blood pressure problems, nausea, and/or vomiting often associated with the initial use of a dialyzer in hypersensitive patients. (6) A list of patient rights regarding the

reuse of dialyzers which shall be adhered to by the facility and include: (A) The right to ask questions at any time about dialysis reuse and reprocessing procedures, and to receive answers which fully, fairly, and understandably respond to such questions. (B) The right to withdraw authorization for dialysis reuse by oral request, followed by a written notice, to the supervising practitioner for any reason. (C) The right to file a written complaint with the dialysis facility and the Department of Health Services' Licensing and Certification Division, and expect a resolution of that complaint by the dialysis facility. (D) The right to expect safe and effective reprocessing of the dialyzer. (E) The right to know the number of times the dialyzer has been reprocessed prior to each dialysis treatment. (F) The right not to participate in the dialysis facility's reuse program without abridgement of any service of the facility.

(1)

The patient's name, the dialysis facility name, and the name of the staff person who explained the facility's reuse program and process.

(2)

A statement that the reuse process has been fully explained to the patient and that the facility's written policies and reuse procedures are available upon request.

(3)

A statement that a reused dialyzer will only be used by the same patient again.

(4)

A statement that single-use dialyzers are recommended by the dialyzer manufacturer for one-time use only.

(5)

A list of the advantages and disadvantages associated with reuse which shall include, but not be limited to: (A) Entry of a residual amount of (name of the disinfectant

chemical), the long-term effect of which is unknown. (B) The increased possibility of infection and/or fever producing reactions if procedures are not correctly followed at this dialysis facility. (C) A lower incidence of back and chest pain, cramps, fever, sweating, blood pressure problems, nausea, and/or vomiting often associated with the initial use of a dialyzer in hypersensitive patients.

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A lower incidence of back and chest pain, cramps, fever, sweating, blood pressure problems, nausea, and/or vomiting often associated with the initial use of a dialyzer in hypersensitive patients.

(6)

A list of patient rights regarding the reuse of dialyzers which shall be adhered to by the facility and include: (A) The right to ask questions at any time about dialysis reuse and reprocessing procedures, and to receive answers which fully, fairly, and understandably respond to such questions. (B) The right to withdraw authorization for dialysis reuse by oral request, followed by a written notice, to the supervising practitioner for any reason. (C) The right to file a written complaint with the dialysis facility and the Department of Health Services' Licensing and Certification Division, and expect a resolution of that complaint by the dialysis facility. (D) The right to expect safe and effective reprocessing of the dialyzer. (E) The right to know the number of times the dialyzer has been reprocessed prior to each dialysis treatment. (F) The right

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(B)

The right to withdraw authorization for dialysis reuse by oral request, followed by a written notice, to the supervising practitioner for any reason.

(C)

The right to file a written complaint with the dialysis facility and the Department of Health Services' Licensing and Certification Division, and expect a resolution of that complaint by the dialysis facility.

(D)

The right to expect safe and effective reprocessing of the dialyzer.

(E)

The right to know the number of times the dialyzer has been reprocessed prior to each dialysis treatment.

(F)

The right not to participate in the dialysis facility's reuse program without abridgement of any service of the facility.

(c)

A copy of the executed form shall be given to the patient or legal guardian or conservator.

(d)

A patient shall be treated with a new dialyzer if consent for reuse is denied, withdrawn, or not executed.

(e)

All executed informed consent forms and withdrawal notices shall be included in the patient's medical records.