

for inclusion in a national ESRD medical information system and in compilations relevant to program administration, including claims processing and reimbursement. Such information is treated as confidential when it pertains to individual patients and is not disclosed except as authorized by Department regulations on confidentiality and disclosure (see 45 CFR parts 5, 5b, and part 401 of this chapter).

[53 FR 6548, Mar. 1, 1988]

**§ 405.2134 Condition: Participation in network activities.**

Each facility must participate in network activities and pursue network goals.

[51 FR 30362, Aug. 26, 1986]

**§ 405.2135 Condition: Compliance with Federal, State and local laws and regulations.**

The ESRD facility is in compliance with applicable Federal, State and local laws, and regulations.

(a) *Standard: licensure.* Where State or applicable local law provides for the licensing of ESRD facilities, the facility is:

- (1) Licensed pursuant to such law; or
- (2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.

(b) *Standard: licensure or registration of personnel.* Each staff member is currently licensed or registered in accordance with applicable law.

(c) *Standard: conformity with other laws.* The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.

**§ 405.2136 Condition: Governing body and management.**

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the pa-

tients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

(a) *Standard: disclosure of ownership.* The ESRD facility supplies full and complete information to the State survey agency (§ 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 percent or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;

(2) Each officer and director of the corporation, if the facility is organized as a corporation; and

(3) Each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) *Standard: Operational objectives.* The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.