W124

(Rev. 135, Issued: 02-27-15, Effective: 04-27-15, Implementation: 04-27-15)

§483.420(a)(2) Inform each client, parent (if the client is a minor), or legal guardian, of the client's medical condition, developmental and behavioral status, attendant risks of treatment, and of the right to refuse treatment;

Guidance §483.420(a)(2)

Clients, their families or legal guardians are promptly informed of any change in the client's medical or behavioral needs that requires immediate alteration to programmatic or medical intervention. Promptly is defined by the level of severity of the alteration. In each case, they must also be informed of the attendant risks of any recommended treatments or interventions and of their right to refuse treatment, training or services.

If parents or legal guardians wish for other members of the client's family to be informed of such changes, they must put this permission in writing.

The communication of this information must be provided in the manner and language understood by the client or their family or legal guardian (language boards, sign language, etc.).

The term "attendant risks of treatment" describes the risk vs. risk and risk vs. benefit associated with the treatment. These risks include possible side effects, other complications from treatments including medical and drug therapy, unintended consequences of treatment, other behavioral or psychological ramifications arising from treatment, etc.

The facility actively attempts to engage clients who refuse to participate in active treatment. While the regulation recognizes the client's right to refuse treatment, persistent refusal that impacts the health and safety of the client and/or others, or the ability to provide overall active treatment, may result in facility's consideration of alternative placements for the client. It is expected, however, that the facility has assessed the reason for refusal, and developed and implemented all possible interventions to engage the client in active treatment programs prior to referring the client to another therapeutic setting.

A client, his or her family member, or legal guardian who refuses a particular treatment (e.g., a behavior control, seizure control medication or a particular intervention strategy) must be offered information about acceptable alternatives to the treatment, if acceptable alternatives are available. The client's preference about alternatives should be elicited and considered in deciding on the course of treatment. If the client, family member, or legal guardian also refuses the alternative treatment, or if no alternative exists to the treatment refused, the facility must consider the effect this refusal may have on other clients, the client himself or herself, and if they can continue to provide services to the client consistent with these regulations.

If the facility is unable to provide services to a client due to consistent refusal to participate, they must weigh all options including an involuntary discharge. Involuntary discharge must be for good cause (see 483.440(b)(4)(i)).

When a client is considered for participation in experimental research the client, his/her family and/or legal guardian must be fully informed of the nature of the experiment (e.g., what medications or physical interventions will be utilized, the length of the research, any possible side effects and how the information from the research will be utilized). Information regarding the possible consequences of participating or not participating must be provided to the client, family member or legal guardian. The written consent of the client, his/her family or legal guardian must be received prior to participation. For a client who is a minor or who has been adjudicated as incompetent, the written informed consent of the parents of the minor or the legal guardian is required. The signed, informed consent documentation must be in compliance with HHS Guidelines for Research Involving Human Subjects. The signed consent must also include a clear discussion of what treatments will be included in the research, the time limits for the research and should clearly inform the client, family member or legal guardian that the client may end participation at any time without fear of recrimination. If the research protocol indicates that clients receive compensation, then clients are compensated per the protocol.

Any research must be reviewed and approved by the Specially Constituted Committee. See W263.