



STATE OF NEW YORK  
OFFICE OF MENTAL RETARDATION AND DEVELOPMENTAL DISABILITIES  
44 HOLLAND AVENUE  
ALBANY, NEW YORK 12229-0001  
(518) 473-1997 • TDD (518) 474-3694

## MEMORANDUM

TO: All DDSO Directors  
All Executive Directors of Provider Agencies

FROM: Paul R. Kietzman

DATE: July 19, 2000

SUBJECT: Informed Consent for Medications that Modify or  
Control Maladaptive or Inappropriate Behavior

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This is to inform you of a new directive extending existing requirements for ICF/DDs to obtain informed consent for medications that modify or control maladaptive or inappropriate behavior to all OMRDD licensed or operated residential facilities.

Both federal regulation [42 CFR 483.440(f)(3)] and case law require obtaining informed consent before medications that modify or control maladaptive or inappropriate behavior may be administered to a person residing in an OMRDD facility. Regulatory amendment which will permanently implement this requirement will be promulgated shortly. In the past, in response to the Federal regulatory mandate, OMRDD has required informed consent for such medications for persons residing in ICFs. OMRDD regulations have established a process for obtaining such informed consent for the administration of these medications in ICFs (see 14 NYCRR Section 681.13). Presently, this process should be utilized for persons residing in all OMRDD operated or licensed facilities. In brief, this means that the following rules apply:

- I. Each person for whom medications that modify or control maladaptive or inappropriate behavior are prescribed must be evaluated for his/her ability to give informed consent. Such evaluation must be in writing and documented in the person's clinical record.

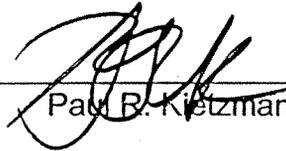
- II. Before any capable person (or a surrogate decision-maker) gives informed consent to such medication, he or she must be told the purposes, risks and benefits of the medication, and any alternatives to the administration of the medication. If the person is considered to have the ability to give informed consent, then such consent must be obtained in writing from the person at that time.
- III. All information must be presented in the language and means of communication the person most clearly and easily understands.
- IV. Informed consent must be freely given, without any undue influence or duress. The person cannot be forced or tricked into consenting.
- V. If a person is 18 years of age or older or is under 18 years old but is married or is the parent of a child (and therefore considered to be an adult) and is capable of consenting on his or her own, consent must be obtained from that person. Medications that modify or control maladaptive or inappropriate behavior may not be administered without the consent of an adult who has the ability to consent.
- VI. If the person is under 18 years of age, consent must be sought from one of the following parties, in the order stated: a court appointed guardian with the authority to give such consent; the person him or herself if he or she is a married person under 18 years of age with the ability to give consent; the person him or herself if he or she is a person under 18 years of age who is the parent of a child and who has the ability to give consent; the person's actively involved adult spouse; the person's actively involved parent; the person's actively involved adult family member; a consent committee created pursuant to 14 NYCRR 681.13(a)(10) or a court of competent jurisdiction.
- VII. If the person is 18 years of age or older or is considered to be an adult, but does not have the ability to consent to the proposed medication, consent must be sought from one of the following parties, in the order stated: a court appointed guardian with the authority to give such consent; the person's actively involved spouse; the person's actively involved adult child; the person's actively involved parent; the person's actively involved family member; the Consumer Advisory Board for a Willowbrook class member that it actively represents; a consent committee created pursuant to 14 NYCRR 681.13(a)(10) or a court of competent jurisdiction.
- VIII. The provider or OMRDD must seek consent from the above parties in the order stated. If the first party on the list is unavailable, consent must be sought from the next party on the list. If the first available party refuses to consent, or if none of the parties listed are available or willing to make a decision, consent must be obtained from a court before the person may be initially administered medication that modifies or controls maladaptive or inappropriate behaviors.

- IX. The person or the surrogate decision-maker must be told that he or she may withdraw consent to the administration of medication that modifies or controls maladaptive or inappropriate behavior. Once the person or the surrogate decision-maker withdraws consent the administration of such medication is to be stopped (subject to paragraph XI below). If the immediate cessation of the administration of medication would be harmful or dangerous to the person, then the medication shall be withdrawn in accordance with accepted medical practice. If the DDSO or the Agency determines that the administration of the medication is in the person's best interests, then the DDSO or the Agency must obtain a court order allowing the administration of the medication.
- X. If the person refuses medication that modifies or controls maladaptive or inappropriate behavior, either initially, or after informed consent has been given to the administration of such medication, then: (1) The administration of that medication must be suspended (subject to paragraph XI below) and: (2) If the provider or the DDSO believes that the administration of such medication is in the person's best interests, the provider or the DDSO must petition the courts for a hearing which will determine the person's ability to refuse the medication. If the person has been judicially determined not to have the ability to refuse the proposed medication, the court will then look to the issue of whether the medication is, indeed, in the person's best interests. If the person is determined to have the ability to refuse the medication, then, in general, such medication may not be administered over that person's refusal. This type of judicial hearing has been called a "Rivers" hearing from the court's opinion in a case called Rivers v. Katz.
- XI. Use of "emergency" medication: Medication that modifies or controls inappropriate or maladaptive behavior may be administered over the objection of the person or the objecting authorized party when: (1) The person's behavior constitutes a significant danger to the person or others, or; (2) The person is engaging in destructive conduct in the facility, or (3) When, in a physician's judgement, an emergency exists creating an immediate need for the administration of such medication, and an attempt to secure informed consent would result in delay of treatment which would increase the risk to the person's life or health. The administration of such medication may only continue for as long as the above condition(s) exists.
- XII. If an "emergency" medication is used more than 2 times in a 30 day period, or four times in a six month period, then there shall be a comprehensive review of the situation by the program planning team within 5 days of the second medication administration. The team then discusses if there needs to be a behavior management plan to address the noted and medicated behavior, or if there is a need to modify an existing plan, or to determine the criteria that will be used to decide if a plan will be needed in the future. If the need for the "emergency"

medication is more than twice in a 30 day period (or four times in a six month period), then the team will immediately write a plan that will deal with the administration of medications for the observed dangerous behavior, get the plan approved, and get consent, even if it means going to court.

Attached to this memorandum is a copy of 14 NYCRR 681.13 and 14 NYCRR 681.99 (Glossary). These are OMRDD's regulations which contain the rules and procedures stated in this memorandum. At the present time, these regulations should be consulted when obtaining consent for medications that modify or control maladaptive or inappropriate behavior.

If you have any questions about this memorandum, please feel free to call me at (518) 474-7700.



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Paul R. Kietzman

PRK/PRG/js  
Attachments

cc: Kathy Broderick  
Peter Pezzolla

(ii) From July 1, 1996 to December 31, 1996, facilities will be reimbursed operating costs that will result in a full annual trend factor of 2.92 percent for the rate period. On January 1, 1997, the trend factor for the previous rate period shall be deemed to be the 2.92 percent full annual trend.

(11) 5.23 percent for 1996-1997.

(12) 2.88 percent for 1997 to 1998.

(c) Where appropriate, the commissioner shall use some combination in whole or in part of the yearly components to project cost data into the appropriate rate period.

#### Historical Note

Sec. filed Jan. 31, 1980; repealed, new filed July 20, 1982; amds. filed: April 4, 1983; July 19, 1983; Oct 28, 1983; March 30, 1984; Sept. 20, 1984; March 19, 1985 as emergency measure, expired 60 days after filing; June 4, 1985; March 28, 1986; March 31, 1987; Sept. 30, 1987; Dec. 29, 1987 as emergency measure; Feb. 23, 1988; Feb. 24, 1988 as emergency measure, expired 60 days after filing; June 28, 1988 as emergency measure; June 28, 1988; Dec. 30, 1988 as emergency measure; March 14, 1989; June 13, 1989; Oct. 3, 1989; Dec. 29, 1989 as emergency measure; March 13, 1990; Dec. 31, 1990 as emergency measure; March 29, 1991 as emergency measure; April 26, 1991 as emergency measure; May 24, 1991 as emergency measure; June 18, 1991; June 28, 1991 as emergency measure; July 2, 1991; Sept. 3, 1991; Dec. 31, 1991 as emergency measure; Jan. 16, 1992 as emergency measure; March 10, 1992; March 31, 1992; April 15, 1992 as emergency measure; June 23, 1992; Aug. 18, 1992; Dec. 31, 1992 as emergency measure; March 16, 1993; Dec. 31, 1993 as emergency measure; March 15, 1994; Dec. 30, 1994 as emergency measure; March 14, 1995; June 1, 1995 as emergency measure; Aug. 8, 1995; Dec. 29, 1995 as emergency measure; March 12, 1996; April 4, 1996 as emergency measure; May 1, 1996 as emergency measure; May 7, 1996 as emergency measure; June 11, 1996; June 24, 1996 as emergency measure; July 1, 1996 as emergency measure; July 16, 1996; Aug. 20, 1996 as emergency measure; Aug. 20, 1996; Sept. 10, 1996; Dec. 31, 1996 as emergency measure; March 28, 1997 as emergency measure; May 23, 1997 as emergency measure; July 1, 1997 as emergency measure; July 18, 1997 as emergency measure; Aug. 26, 1997; Sept. 9, 1997; Dec. 31, 1997 as emergency measure; March 30, 1998 as emergency measure; May 12, 1998; Dec. 8, 1998; Dec. 31, 1998 as emergency measure; March 30, 1999 as emergency measure; April 1, 1999 as emergency measure; April 30, 1999 as emergency measure eff. April 30, 1999. Amended (c)(10)(iii).

### § 681.13 Informed consent for service plans which involve untoward risk to an individual's protection or rights when the individual is a resident of an ICF/DD.

(Please note that this section is presented in a principles of compliance [see glossary, section 681.99 of this Part] and standards of certification [see glossary, section 681.99 of this Part] format.)

(a) *Principles of compliance.* (1) Principles of compliance represent those requirements with which an agency/facility must comply, but against which the agency/ facility will not be routinely surveyed for recertification purposes. However, evidence of failure to comply with the principles may be the basis for decertification in accordance with article 16 of the Mental Hygiene Law.

(2) No service plan (see glossary, section 681.99 of this Part) which involves an untoward risk to an individual's protection or rights, including those designed to manage inappropriate behavior and inclusive of those employing medication for such purposes, shall be implemented until informed consent is obtained in conformance with this section.

(3) Nothing in this section shall be deemed to limit the availability of medical, dental, health, and hospital services, which may be rendered to an individual of any age without seeking informed consent when, in the physician's judgment, an emergency exists creating an immediate need for attention.

(4) Nothing in this section shall be deemed to limit the necessity for informed consent for professional medical treatment as required by section 633.11 of this Title.

(5) Determining whether a service plan constitutes an untoward risk to an individual's protection or rights (see glossary, section 681.99 of this Part), and committee approval of such plans:

(i) An individual's interdisciplinary team shall review each service plan developed to determine whether the proposed plan constitutes an untoward risk to the individual's protection and rights.

(ii) If an interdisciplinary team considers that a proposed service plan constitutes an untoward risk to an individual's protection or rights, the plan shall be referred to the specially constituted committee charged with the responsibility for reviewing programs that may involve untoward risks to an individual's protection or rights pursuant to the provisions of 42 CFR 483.440(f)(3).

(iii) The specially constituted committee, upon receipt of a service plan referred to it from an interdisciplinary team, shall determine whether or not the service plan constitutes an untoward risk to an individual's protection or rights.

(iv) If the specially constituted committee determines that a service plan constitutes an untoward risk to an individual's protection or rights, it shall approve or disapprove the implementation of the plan and, if approved, ensure that the requirements of this Part are met.

(6) Role of the facility when obtaining informed consent for a proposed service plan that constitutes an untoward risk to an individual's protection or rights:

(i) The administrator shall ensure the obtaining of written informed consent by or on behalf of an individual whose service plan is under consideration. As it is the intent of this section to ensure an individual's participation in granting or withholding informed consent for any service plan affecting him or her, it is, therefore, necessary to ensure that the presentation to the individual be in terms and a manner that will most easily facilitate understanding by that individual.

(a) In every case it shall be the duty of the administrator to ensure that the individual is personally afforded an appropriate explanation of the proposed service plan.

(b) If an individual with the ability to give consent (see glossary, section 681.99 of this Part), gives his or her informed consent, and does not object, one of the following parties, in the order of priority stated, shall be informed of the proposed service plan before implementation:

(1) an individual's actively involved (see glossary, section 681.99 of this Part) adult spouse;

(2) an individual's actively involved parent;

(3) an individual's actively involved adult child;

(4) an individual's actively involved adult family member (see glossary, section 681.99 of this Part); and

(5) the consumer advisory board for the Willowbrook class (for a class member only).

(c) The party receiving notice as listed above shall be informed of the right to appeal service plan decisions pursuant to section 633.12 of this Title.

(ii) Obtaining informed consent for service plans that constitute an untoward risk to an individual's protection and rights if the individual is less than 18 years of age:

(a) Consent shall be sought from the parties listed below, in the order stated:

(1) an individual's court appointed guardian (see glossary, section 681.99 of this Part);

(2) a married individual with the ability to give consent;

(3) an individual's actively involved adult spouse;

(4) an individual's actively involved parent;

(d) If no party is available and the agency/facility considers implementation of the service plan to be in the best interest of the individual, application shall be made to a court of competent jurisdiction.

(e) If a party or parties on the list is either unwilling to consent to or object to the proposed service plan, application may be made to subsequent parties on the list; if no party is willing to give consent and the agency/facility considers implementation to be in the best interest of the individual, application shall be made to a court of competent jurisdiction.

(iii) Obtaining informed consent for service plans that constitute an untoward risk to an individual's protection and rights if an individual is 18 years of age or older and has the ability to understand appropriate disclosures regarding a proposed service plan:

(a) Such service plan shall be initiated only with the individual's informed consent.

(b) In the absence of a determination to the contrary (e.g., appointment of a guardian, or a determination in accordance with paragraph [8] of this subdivision), it shall be presumed that the individual has the ability to understand appropriate disclosure regarding the proposed treatment.

(c) If an individual should object at any time to the administration of medication as part of a behavior management plan, regardless of his or her ability to give informed consent, the provisions of paragraph (9) of this subdivision shall apply.

(iv) Obtaining informed consent for service plans that constitute an untoward risk to an individual's protection and right if an individual is 18 years of age or older and a determination of insufficient capacity has been made by a court of competent jurisdiction:

(a) Consent shall be secured pursuant to the terms of the order of said court.

(b) If a legal guardian has been appointed pursuant to section 17-A of the Surrogate's Court Procedure Act, consent shall be sought from said guardian except as provided for in subparagraph (10) (ii) of this subdivision.

(v) Obtaining informed consent for service plans that constitute an untoward risk to an individual's protection and rights if an individual is 18 years of age or older and a determination of insufficient ability to give informed consent has been made pursuant to paragraph (8) of this subdivision.

(a) Consent shall be sought from the parties listed below, in the order stated:

(1) an individual's actively involved adult spouse;

(2) an individual's actively involved adult child;

(3) an individual's actively involved parent;

(4) an individual's actively involved adult family member;

(5) the consumer advisory board for the Willowbrook class (for a class member only); and

(6) a consent committee pursuant to paragraph (10) of this subdivision.

(b) When an individual has been determined to lack the ability to consent, but the first party on the above list disagrees with that determination, and the agency/facility considers implementation in the best interest of the individual, the plan shall only be implemented after application to a court of competent jurisdiction; notice of such application shall be given to the party who disagreed with the determination.

(c) If the first available party on this list objects to the proposed service plan, and the agency/facility considers implementation to be in the best interest of the individual, application shall be made to a court of competent jurisdiction; notice of such application shall be given to the objecting party.

(d) If no party is available and the agency/facility considers implementation of the service plan to be in the best interest of the individual, application shall be made to a court of competent jurisdiction.

(e) If a party or parties on this list is either unwilling to consent to or object to the proposed service plan, application may be made to subsequent parties on the list; if no party is willing to give consent and the agency/facility considers implementation to be in the best interest of the individual, application shall be made to a court of competent jurisdiction.

(vi) The administrator shall furnish an individual, and/or other parties, committee, or court reviewing an individual's ability to understand treatment and considering consent thereto, with all necessary information, including medical risks, benefits, and alternatives to a proposed service plan.

(vii) Documentation of consent shall be included in an individual's record.

(viii) Whenever consent is sought from other than an authorized guardian or the parents of a minor (see glossary, section 681.99 of this Part), for individual's who are residents of a developmental center or those on conditional release from a developmental center, the Mental Hygiene Legal Service shall be notified.

(7) Role of the individual, party, or committee giving consent.

(i) ~~When~~ an actively involved spouse, actively involved parent, actively involved adult child, actively involved adult family member, the consumer advisory board for the Willowbrook class (for class members only), or a consent committee reviews a request to give informed consent, the party or committee:

(a) shall review the ability of the individual to understand appropriate disclosures regarding the proposed service plan and, if appropriate, a range of related alternative treatment approaches; as well as the individual's ability to give or withhold consent thereto;

(1) may seek the services of an outside consultant to advise them on the individual's ability to give informed consent; and

(2) if such party or committee disagrees with a determination that an individual lacks the ability to give informed consent, no further action shall be taken until application is made to a court of competent jurisdiction; notice of such application shall be given to the party or committee who disagreed with the determination;

(b) shall, to the extent practicable, discuss a proposed service plan with the individual;

(c) shall, to the extent practicable, ensure that the individual's opinions, beliefs, and wishes are represented in the decision to consent or object to the proposed service plan; and

(d) shall consent to the proposed service plan only if the individual lacks the ability to give or withhold consent and the proposed service plan is determined to be in the individual's best interest.

(ii) When a court appointed guardian reviews a request to give informed consent, the guardian shall:

(a) to the extent practicable, discuss a proposed plan with the individual;

(b) to the extent practicable, ensure that the individual's opinions, beliefs, and wishes are represented in the guardian's decision to consent or object to the proposed service plan; and

(c) consent to the proposed service plan only if it is determined to be in the individual's best interest.

(iii) The individual, court appointed guardian, party or committee giving consent shall, based on the information provided by the interdisciplinary team, indicate the duration of the consent.

→(a) Duration of consent shall not exceed one year from the date of decision.

- (b) Any change to a service plan beyond the designated span of adjustments, or the development of a new service plan (even one using those proposed for consideration on a contingent basis) requires the informed consent of the appropriate party.
- (iv) Consent may be withdrawn by an individual, court appointed guardian, party, or committee giving it, at anytime, in writing. Consent may be withdrawn by an individual in the same manner as originally given. Such withdrawal of consent shall be included in the individual's record.
- (8) Determination of ability to give informed consent for individual's who do not have a guardian appointed pursuant to section 17-A of the Surrogate's Court procedure Act.
- (i) Given the complexity and interrelated elements when determining an individual's ability to understand his or her treatment and give informed consent thereto, the interdisciplinary team may prepare a plan with a span of interventions, with specific limitations, should adjustment be necessary. It may also present, for consideration on a contingent basis, a range of related treatment approaches. However, all such interventions and/or related treatment approaches shall have been described to the individual in terms and manner that would be most easily understood.
- (ii) In those instances when an individual's interdisciplinary team considers, beyond any reasonable doubt, that the individual does not have the ability to give informed consent:
- (a) The team, through its member having coordination responsibility, shall enter a written opinion and detailed analysis as to why it considers the individual to be unable to provide informed consent.
- (b) The opinion and analysis of the team shall be reviewed by a New York State licensed psychologist, or a New York State licensed physician who is board certified or eligible to be certified as a psychiatrist, who is not a member of the individual's interdisciplinary team, and who may or may not be an employee of the agency/facility. Such professional shall review the material provided and, in writing, provide an opinion as to whether the individual has the ability to give informed consent. If the professional disagrees with the team, the requirements of subparagraph (iii) of this paragraph shall be followed.
- (iii) If it is not clear to the interdisciplinary team that an individual does not have the ability to give informed consent, it shall be the responsibility of the administrator to comply with the requirements listed below. The administrator shall:
- (a) obtain from the individual's interdisciplinary team, its written opinion and analysis of the individual's ability to understand the proposed service plan, and of the individual's ability to give or withhold informed consent thereto;
- (b) obtain from a New York State licensed psychologist, or New York State licensed physician who is board certified or eligible for certification as a psychiatrist, a written opinion and analysis of the individual's ability to understand the proposed service plan, and of the individual's ability to give inform consent thereto. Said professional shall not have any ownership, employment relationship, or other interest in the agency/facility which would compromise his or her objectivity in decisionmaking;
- (c) after considering the opinion of the interdisciplinary team and the psychologist or psychiatrist, determine whether it is appropriate to obtain consent from a party duly recognized by this section, and whether to proceed in accordance with the other provisions of this section; and
- (d) ensure that the opinions of the interdisciplinary team and the psychologist or psychiatrist, and the decision of the administrator, are documented in the individual's record and communicated to that individual and to his or her actively involved adult spouse, parent, adult child, or adult family member; unless the individual is an adult who has been determined to have the ability to give informed consent, objects to such notice being made.

(iv) The administrator shall ensure that these procedures for determining ability to give informed consent are also followed whenever:

(a) there is a significant departure from the material considered in relation to determining an individual's ability to understand the proposed treatment (*i.e.*, the service plan or originally proposed alternative treatment approaches);

(b) when a totally new service plan with a different approach is proposed;

(c) when there has been a change in the diagnosis of the individual; or

(d) when there has been a change in the determination of an individual's ability to give informed consent by the individual's interdisciplinary team or a psychologist.

*Note:* Once ability to give informed consent has been determined, it is not necessary to reevaluate such ability unless one of the above four conditions occur.

(9) Objections to the medication component of a plan designed to manage inappropriate behavior may be made.

(i) Such objections may be made:

(a) by an individual 18 years of age or older who does not have a guardian lawfully empowered to give medical consent; or by an individual under the age of 18 where consent has not been derived from a lawfully empowered guardian or parent;

(b) irrespective of a judgement about the individual's ability to understand appropriate disclosures regarding a proposed service plan; and

(c) by conveying the objection in whatever manner is typically utilized by an individual to communicate a meaningful decision (which does not include stereotypic actions, reactions, or responses).

(ii) If all reasonable attempts to resolve the issue have not resulted in agreement to proceed with the use of medication, then the medication component of a service plan shall not be administered without an order of a court of competent jurisdiction. Notification of the individual's objection to medication shall be given to the party or committee having initially given consent.

(10) Consent committee.

(i) This committee need not be a "standing" committee. It may be a committee convened on an as-needed basis with appropriate representation for the purpose of reviewing a request(s) for informed consent.

(ii) Informed consent may be obtained from a committee convened for that purpose, for service plans, including ones designed to manage inappropriate behavior, and inclusive of those employing medication for such purpose, where such service plans constitute an untoward risk to the individual's protection or rights, if a duly appointed guardian or other parties authorized by this section to give informed consent are unavailable to do so.

(iii) Each B/DDSO shall arrange for the creation of a committee. Services of a committee may be made available to community-based facilities, whether State or voluntary agency operated.

(iv) Voluntary agencies/facilities may arrange for the creation of their own committee(s) or, if available, use the one provided by the B/DDSO.

(v) When a consent committee meeting is convened, it shall:

(a) consist of at least three individuals or parties, with a majority having no ownership, employment relationship or other interest in the agency/facility which would compromise his or her objectivity in decisionmaking.

(b) have at least one QMRP; and

(c) not include anyone who is involved in the care and treatment of an individual whose service plan is under review.

(vi) Membership shall be drawn from the following groups:

- (a) staff members;
- (b) staff members of another agency/facility;
- (c) individuals receiving services from OMRDD-operated or certified facilities;
- (d) parents, court appointed guardians, or family members of those with developmental disabilities who have demonstrated sensitivity to issues surrounding the treatment of those with such disabilities;
- (e) advocates of those with developmental disabilities who have demonstrated sensitivity to issues surrounding the treatment of those with developmental disabilities; and
- (f) parties who have either experience or training in contemporary practices to change inappropriate behavior.

(vii) The Mental Hygiene Legal Services may represent the interests of individuals before the committee where the individual is a resident of a developmental center or is on conditional release therefrom, and shall be notified of any committee meetings where the service plans of such individuals will be under consideration.

(viii) The committee shall reach its decision within 14 days of receiving an application for consent.

(ix) The committee's decision shall be by majority vote.

(11) All information required to be conveyed by the requirements of this section shall be communicated in whatever language or method is appropriate to ensure understanding by the individual and/or the individual's parent, guardian, spouse, adult child, or other adult family member. That is, the agency/facility personnel responsible for obtaining informed consent shall use the language, whether spoken or written, that the individual/party is most comfortable using and most clearly understands. Examples of acceptable forms of communication include, but are not limited to, sign language, a communications board, a computer-assisted technology, Braille, etc. There shall be agency/facility policies/procedures to implement this process as well as the process whereby individuals can be made aware of and understand, to the extent possible, the rights to which they are entitled pursuant to this section.

(b) *Standards of certification.* (1) Standards of certification represent those criteria which specify the basis of documenting compliance with the requirements for the operation of an ICF/DD. The basis of documentation may include facility specific records; specified forms or reports; specified contents of records, report or forms; and/or other means of assessing compliance such as interviews with individuals residing in the facility, employees or volunteers, and/or on-site observation of activities and the environment.

(2) When it has been determined, by a specially constituted committee charged with the responsibility, that a service plan involves untoward risk to an individual's protection or rights, OMRDD shall verify (see glossary, section 681.99 of this Part) that written informed consent has been obtained from:

(i) the individual, if the individual has the ability to give informed consent and is either 18 years of age or older or is under the age of 18 and is married; or

(ii) if the individual is 18 years of age or older but does not have the ability to give informed consent, OMRDD shall verify that such consent has been obtained from a court appointed guardian; an actively involved spouse, adult child, parent, or adult family member; the consumer advisory board for the Willowbrook class (for class members only); a consent committee; or a court of competent jurisdiction; or

(iii) if the individual is under the age of 18 and unmarried or married and unable to give informed consent, OMRDD shall verify that such consent has been obtained from a court appointed guardian; an actively involved spouse, parent, or adult family member; the consumer advisory board for the Willowbrook class (for class members only); a consent committee; or a court of competent jurisdiction.

(3) OMRDD shall further verify that the signed consent document is in the written language that the individual or party giving consent is most comfortable using and most clearly understands, or through the written verification of a witness that the individual understood and agreed to the document before signing or putting his or her mark thereon.

Historical Note

Sec. filed Jan. 31, 1980; ams. filed: April 1, 1985; Aug. 27, 1985 as emergency measure, expired 60 days after filing; Oct. 30, 1985; Dec. 31, 1985; repealed, new filed Feb. 28, 1989; renum. 681.99, new filed July 24, 1990 eff. Aug. 8, 1990.

§ 681.99 Glossary.

(a) *Administrator.* The person designated by the governing body to be responsible and accountable for the daily operation of the intermediate care facility. The administrator shall be:

- (1) a qualified mental retardation professional as defined in 42 CFR 483 with a minimum of two years of administrative experience in a developmental disability program;
- (2) a person licensed by the State of New York as a nursing home administrator; or
- (3) a person with at least a bachelor's degree in administration if the administrative staff of the intermediate care facility includes a person meeting the qualifications described in either paragraph (1) or (2) of this subdivision.

(b) *Agency, sponsoring.* A unit of government, a voluntary agency or any other person or organization which intends to establish or operate a community residential facility for persons who are developmentally disabled.

(c) *Capacity.* The maximum number of individuals who may reside in the intermediate care facility. This is specified on the operating certificate.

(d) *Standards of certification.* Those criteria which OMRDD specifies as necessary to be met in order for an agency/facility to demonstrate that the facility can and does provide the appropriate environment to adequately address the matters of quality of care and the welfare of individuals admitted to the facility, rights, safety, and/or fiscal accountability. Surveys in community based ICF/DD's are conducted for the purpose of documenting conformity with standards of certification, and such conformance is the basis for issuing an operating certificate and/or renewing an operating certificate.

(e) *Commissioner.* The Commissioner of the New York State Office of Mental Retardation and Developmental Disabilities.

(f) *Principles of compliance.* Identified required expectations and areas of concern to be addressed by an agency/facility. This includes both philosophically based parameters of operation and administration which have emanated from experience as being relevant to the efficient and effective delivery of quality care; and those items for which OMRDD considers agencies/facilities must be responsible, but over which they shall have discretion and flexibility as to how any administrative solution will be designed and implemented as long as it is in accordance with the applicable sections of this Part. The policies/procedures developed by the agency/facility shall reflect such solutions to achieve the principles of compliance as set forth in regulations of the commissioner. Principles of compliance are, in fact, requirements of participation as a certified facility. While OMRDD expects and assumes compliance, and reserves the right to monitor compliance at any time pursuant to the responsibilities of the commissioner under the Mental Hygiene Law, facilities will not routinely be examined against principles of compliance at surveys for recertification.

(g) *Individual with the ability to give consent.* As used in section 681.13 of this Part, a person:

- (1) who has not been determined to lack capacity by a court of competent jurisdiction;
- (2) who is not a minor, unless married;
- (3) who understands and appreciates the nature and consequences of a proposed service plan and its span of interventions, as well as a range of related treatment approaches, if such have been prepared on a contingent basis;

- (4) who understands and appreciates the benefits and significant risks, and alternatives, thereto; and
- (5) who can make a decision in a knowing and voluntary manner, based on the information provided.
- (h) *Developmental disability.* A disability of a person which:
- (1) is attributable to mental retardation, cerebral palsy, epilepsy, neurological impairment, or autism;
  - (2) is attributable to any other condition of a person found to be closely related to mental retardation because such condition results in similar impairment of general intellectual functioning or adaptive behavior to that of persons with mental retardation or requires treatment and services similar to those required for such persons;
  - (3) is attributable to dyslexia resulting from a disability described in subparagraph (1) or (2) of this paragraph;
  - (4) originates before such person attains age 22;
  - (5) has continued or can be expected to continue indefinitely; and
  - (6) constitutes a substantial handicap to such person's ability to function normally in society.
- (i) *Guardian.* As used in section 681.13 of this Part, a party (or parties) appointed by a court of competent jurisdiction to make personal care decisions for an individual determined to have insufficient capacity to make said decisions for himself or herself.
- (j) *Actively involved.* Significant and ongoing involvement in an individual's life so as to have sufficient knowledge of the individual's needs.
- (k) *Actively involved adult family member.* Someone 18 years of age or older who is related to a person in a facility and who has demonstrated, in the opinion of the interdisciplinary team, significant and ongoing involvement in the individual's life, as well as sufficient knowledge of the individual's needs.
- (l) *Minor.* Anyone under the age of 18, unless that individual is married.
- (m) *OMRDD.* The Office of Mental Retardation and Developmental Disabilities.
- (n) *Person.* For purposes of this Part, a child or adult with a diagnosis of developmental disability, who has been or is being served by a State, private or voluntary operated facility certified by OMRDD. For the purposes of this Part, this shall include children or adults who have applied to or have been screened for services and for whom a clinical record is maintained or possessed by such a facility.
- (o) *Service plan.* That portion of an individual program plan that states an objective necessary to meet an individual's identified need(s) and the planned sequence of methods or interventions for meeting that objective. The service plan can include a span of interventions, with specific limitations, should adjustment of that plan be necessary.
- (p) A service plan constitutes an untoward risk to an individual's protection or rights. As used in section 681.13 of this Part, plans, including those designed to manage inappropriate behavior, which may impact negatively upon the rights or protection afforded individuals in an ICF/DD, including, but not limited to, the use of time-out rooms, physical restraints, medication, and the application of painful or noxious stimuli. Such "risks" do not include those typically associated with participation in normal activities; or those that are reasonable, foreseeable, and appropriate in relation to a service plan.
- (q) *Verify.* Any means, including, but not limited to, observation, interview, and the written word that provides OMRDD with a basis for being reasonably assured that a requirement is met.

**Historical Note**

Sec. added by renum. and amd. 681.13, filed July 24, 1990; amd. filed Jan. 29, 1991 eff. March 1, 1991. Amended (h).