CHAPTER 64
INTERMEDIATE CARE FACILITIES FOR THE INTELLECTUALLY DISABLED*

481—64.1 Rescinded IAB 7/26/89, effective 7/7/89.

481—64.2(135C) Variances. Variances from these rules may be granted by the director of the department of inspections and appeals for good and sufficient reason when the need for variance has been established; no danger to the health, safety, or welfare of any resident results; alternate means are employed or compensating circumstances exist and the variance will apply only to an individual intermediate care facility for the intellectually disabled. Variances will be reviewed at the discretion of the director of the department of inspections and appeals.

64.2(1) To request a variance, the licensee must:

a. Apply for variance in writing on a form provided by the department;

b. Cite the rule or rules from which a variance is desired;

c. State why compliance with the rule or rules cannot be accomplished;

d. Explain alternate arrangements or compensating circumstances which justify the variance;

e. Demonstrate that the requested variance will not endanger the health, safety, or welfare of any resident.

64.2(2) Upon receipt of a request for variance, the director of the department of inspections and appeals will:

a. Examine the rule from which variance is requested to determine that the request is necessary and reasonable;

b. If the request meets the above criteria, evaluate the alternate arrangements or compensating circumstances against the requirement of the rules;

c. Examine the effect of the requested variance on the health, safety, or welfare of the residents;

d. Consult with the applicant if additional information is required.

64.2(3) Based upon these studies, approval of the variance will be either granted or denied within 120 days of receipt.

[**ARC 0764C**, IAB 5/29/13, effective 7/3/13]

481—64.3(135C) Application for license.

64.3(1) Initial application. In order to obtain an initial intermediate care facility for the intellectually disabled license for an intermediate care facility for the intellectually disabled which is currently licensed, the applicant must:

a. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

b. Make application at least 30 days prior to the change of ownership of the facility on forms provided by the department;

c. Submit a floor plan of each floor of the intermediate care facility, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which room will be put and window and door location;

d. Submit a photograph of the front and side elevation of the intermediate care facility for the intellectually disabled;

e. Submit the statutory fee for an intermediate care facility for the intellectually disabled license;

f. Meet all of the rules, regulations and standards contained in 481—Chapter 64.

g. Comply with federal, state, and local laws, codes, and regulations pertaining to health and safety, including procurement, dispensing, administration, safeguarding and disposal of medications and controlled substances; building, construction, maintenance and equipment standards; sanitation; communicable and reportable diseases; and postmortem procedures;

*See Interpretive Guidelines at end hereof

h. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

64.3(2) In order to obtain an initial intermediate care facility for the intellectually disabled license for a facility not currently licensed as an intermediate care facility for the intellectually disabled, the applicant must:

**a.* Meet all of the rules, regulations, and standards contained in 481—Chapters 61 and 64; exceptions noted in 481—subrule 61.1(2) shall not apply;

*Nullified by 1989 Iowa Acts, SJR 10

b. Submit a letter of intent and a written résumé of the resident care program and other services provided for departmental review and approval;

c. Make application at least 30 days prior to the proposed opening date of the facility on forms provided by the department;

d. Submit a floor plan of each floor of the intermediate care facility for the intellectually disabled, drawn on 8½- × 11-inch paper showing room areas in proportion, room dimensions, room numbers for all rooms, including bathrooms, and designation of the use to which the rooms will be put and window and door locations;

e. Submit a photograph of the front and side elevation of the intermediate care facility for the intellectually disabled;

f. Submit the statutory fee for an intermediate care facility for the intellectually disabled;

g. Comply with federal, state, and local laws, codes, and regulations pertaining to health and safety, including procurement, dispensing, administration, safeguarding and disposal of medications and controlled substances; building, construction, maintenance and equipment standards; sanitation; communicable and reportable diseases; and postmortem procedures;

h. Have a certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations.

64.3(3) Renewal application. In order to obtain a renewal of the intermediate care facility for the intellectually disabled license, the applicant must:

a. Submit the completed application form 30 days prior to annual license renewal date of intermediate care facility for the intellectually disabled license;

b. Submit the statutory license fee for an intermediate care facility for the intellectually disabled with the application for renewal;

c. Have an approved current certificate signed by the state fire marshal or deputy state fire marshal as to compliance with fire safety rules and regulations;

d. Submit appropriate changes in the résumé to reflect any changes in the resident care program or other services.

64.3(4) Licenses are issued to the person or governmental unit which has responsibility for the operation of the facility and authority to comply with all applicable statutes, rules or regulations.

The person or governmental unit must be the owner of the facility or, if the facility is leased, the lessee.

[**ARC 0764C**, IAB 5/29/13, effective 7/3/13]

481—64.4(135C) General requirements.

64.4(1) The license shall be displayed in a conspicuous place in the facility which is viewed by the public. (III)

64.4(2) The license shall be valid only in the possession of the licensee to whom it is issued.

64.4(3) The posted license shall accurately reflect the current status of the intermediate care facility for the intellectually disabled. (III)

64.4(4) Licenses expire one year after the date of issuance or as indicated on the license.

64.4(5) Each citation or a copy of each citation issued by the department for a Class I or Class II violation shall be prominently posted by the facility in plain view of the residents, visitors, and persons inquiring about placement in the facility. The citation or copy of the citation shall remain posted until the violation is corrected to the satisfaction of the department. (III)

64.4(6) The facility shall have in effect a transfer agreement with one or more hospitals sufficiently close to the facility to make feasible the transfer between them of residents and their records. (III) Any facility which does not have such an agreement in effect but has attempted in good faith to enter into such an agreement with a hospital shall be considered to have such an agreement so long as it is in the public interest and essential to ensuring intermediate care facility for the intellectually disabled services for eligible persons in the community.

64.4(7) A resident's personal funds and property shall not be used without the written consent of the resident or the resident's guardian. (II)

64.4(8) A resident's personal funds and property shall be returned to the resident when the funds or property have been used without the written consent of the resident or the resident's guardian. The department may report findings that funds or property have been used without written consent to the audits division or the local law enforcement agency, as appropriate. (II)

64.4(9) A properly trained person shall be charged with the responsibility of administering non-parenteral medications.

a. The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

b. This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

c. A person who is a nursing student or a graduate nurse may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination;

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination;

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating the individual is competent in medication administration.

(4) Successfully complete a department-approved nurse aide competency evaluation.

d. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination.

[**ARC 0764C**, IAB 5/29/13, effective 7/3/13]

481—64.5(135C) Notifications required by the department. The department shall be notified:

64.5(1) Within 48 hours, by letter, any reduction or loss of direct care professional or dietary staff lasting more than seven days which places the staffing ratio of the intermediate care facility for the intellectually disabled below that required for licensing. No additional residents shall be admitted until the minimum staffing requirements are achieved; (III)

64.5(2) Of any proposed change in the intermediate care facility for the intellectually disabled's functional operation or addition or deletion of required services; (III)

64.5(3) Thirty days before addition, alteration, or new construction is begun in the intermediate care facility for the intellectually disabled, or on the premises; (III)

64.5(4) Thirty days in advance of closure of the intermediate care facility for the intellectually disabled; (III)

64.5(5) Within two weeks of any change in administrator; (III)

64.5(6) When any change in the category of license is sought; (III)

64.5(7) Prior to the purchase, transfer, assignment, or lease of an intermediate care facility for the intellectually disabled, the licensee shall:

a. Inform the department of the pending sale, transfer, assignment, or lease of the facility; (III)

b. Inform the department of the name and address of the prospective purchaser, transferee, assignee, or lessee at least 30 days before the sale, transfer, assignment, or lease is completed; (III)

c. Submit a written authorization to the department permitting the department to release all information of whatever kind from the department's files concerning the licensee's intermediate care facility for the intellectually disabled to the named prospective purchaser, transferee, assignee, or lessee. (III)

64.5(8) Pursuant to the authorization submitted to the department by the licensee prior to the purchase, transfer, assignment, or lease of an intermediate care facility for the intellectually disabled, the department shall, upon request, send or give copies of all recent licensure surveys and of any other pertinent information relating to the facility's licensure status to the prospective purchaser, transferee, assignee, or lessee; costs for such copies shall be paid by the prospective purchaser.
[**ARC 0764C**, IAB 5/29/13, effective 7/3/13]

481—64.6(135C) Veteran eligibility.

64.6(1) Within 30 days of a resident's admission to a health care facility receiving reimbursement through the medical assistance program under Iowa Code chapter 249A, the facility shall ask the resident or the resident's personal representative whether the resident is a veteran and shall document the response. If the facility determines that the resident is a potential veteran, the facility shall report the resident's name along with the names of the resident's spouse and any dependent children, as well as the name of the contact person for this information, to the Iowa department of veterans affairs. Where appropriate, the facility may also report such information to the Iowa department of human services.

64.6(2) If a resident is eligible for benefits through the United States Department of Veterans Affairs or other third-party payor, the facility first shall seek reimbursement from the identified payor source before seeking reimbursement from the medical assistance program established under Iowa Code chapter 249A.

64.6(3) The provisions of this rule shall not apply to the admission of an individual as a resident to a state mental health institute for acute psychiatric care. (II, III)

481—64.7(135C) Licenses for distinct parts.

64.7(1) Separate licenses may be issued for distinct parts of a health care facility which are clearly identifiable, containing contiguous rooms in a separate wing or building or on a separate floor of the facility and which provide care and services of separate categories.

64.7(2) The following requirements shall be met for a separate licensing of a distinct part:

a. The distinct part shall serve only residents who require the category of care and services immediately available to them within that part; (III)

b. The distinct part shall meet all the standards, rules, and regulations pertaining to the category for which a license is being sought;

c. The distinct part must be operationally and financially feasible;

d. A separate staff with qualifications appropriate to the care and services being rendered must be regularly assigned and working in the distinct part under responsible management; (III)

e. Separately licensed distinct parts may have certain services such as management, building maintenance, laundry, and dietary in common with each other.

481—64.8 to **64.16** Rescinded IAB 7/26/89, effective 7/7/89.

481—64.17(135C) Contracts. Each party shall receive a copy of the signed contract. (III) Each contract for residents shall:

64.17(1) State the rate or scale per day or per month for services included in the rate or scale and method of payment; (III)

64.17(2) Contain a complete schedule of all offered services for which a fee may be charged in addition to the base rate. (III) Furthermore, the contract shall:

a. Stipulate that no further additional fees shall be charged for items not contained in complete schedule of services as set forth in this subrule; (III)

b. State the method of payment of additional charges; (III)

c. Contain an explanation of the method of assessment of such additional charges and an explanation of the method of periodic reassessment, if any, resulting in changing such additional charges; (III)

d. State that additional fees may be charged to the resident for nonprescription drugs, other personal supplies, and services by a barber, beautician, etc.; (III)

64.17(3) Contain an itemized list of those services, with the specific fee the resident will be charged and method of payment, as related to the resident's current condition, based on a preadmission evaluation assessment which is determined in consultation with the administrator; (III)

64.17(4) Include the total fee per day to be charged to the resident; (III)

64.17(5) State the conditions whereby the facility may make adjustments to its overall fees for resident care as a result of changing costs. (III) Furthermore, the contract shall provide that the facility shall give:

a. Written notification to the resident, or responsible party when appropriate, of changes in the overall rates of both base and additional charges, at least 30 days prior to effective date of such changes; (III)

b. Notification to the resident, or responsible party when appropriate, of changes in charges, based on a change in the resident's condition. Notification must occur prior to the date such revised charges begin. If notification is given orally, subsequent written notification must also be given within a reasonable time, not to exceed one week, listing specifically the adjustments made; (III)

64.17(6) State the terms of agreement in regard to refund of all advance payments in the event of transfer, death, voluntary or involuntary discharge; (III)

64.17(7) State the terms of agreement concerning the holding and charging for a bed in the event of temporary absence of the resident; such terms shall include, at a minimum, the following provisions:

a. If a resident has a temporary absence from a facility for medical treatment, the facility shall ask the resident or responsible party if they wish the bed held open. This shall be documented in the resident's record including the response. Upon request of the resident/responsible party, the facility shall hold the bed open for at least ten days during the resident's absence and the facility shall receive payment for the absent period in accordance with provisions of the contract. (II)

b. If a resident has a temporary absence from a facility for therapeutic reasons as approved by a physician or qualified intellectual disabilities professional, the facility shall ask if the resident or responsible party wishes that the bed be held open. This request shall be documented in the resident's record, including the response. The bed shall be held open at least 30 days per year, and the facility shall receive payment for the absent periods in accordance with the provisions of the contract. The required holding during temporary absences for therapeutic reasons is limited to 30 days per year. (II)

c. For Title XIX residents the department of social services shall continue funding for the temporary absence as provided under paragraphs *"a"* and *"b"* and in accordance with department of social services guidelines.

d. Private pay residents shall have a negotiated rate stated in the signed contract relating to these provisions. (II)

64.17(8) State the conditions under which the involuntary discharge or transfer of a resident would be effected; (III)

64.17(9) State the conditions of voluntary discharge or transfer; (III)

64.17(10) Set forth any other matters deemed appropriate by the parties to the contract. No contract or any provision thereof shall be drawn or construed so as to relieve any facility of any requirement or obligation imposed upon it by this chapter or any standards or rules in force pursuant to this chapter. (III)
[**ARC 0764C**, IAB 5/29/13, effective 7/3/13]

481—64.18(135C) Records.

64.18(1) *Resident record.* The licensee shall keep a permanent record about each resident, with all entries current, dated, and signed. (II) The record shall include:

a. Name and previous address of resident; (III)

b. Birth date, sex, and marital status of resident; (III)

c. Church affiliation of resident; (III)

d. Physician's name, telephone number, and address; (III)

e. Dentist's name, telephone number, and address; (III)

f. Name, address, and telephone number of resident's next of kin or legal representative; (III)

g. Name, address, and telephone number of the person to be notified in case of emergency; (III)

h. Funeral director's telephone number and address; (III)

i. Pharmacy's name, telephone number and address; (III)

j. Certification by the physician that the resident requires no higher level of care than the facility is licensed to provide; (III)

k. Physician's orders for medication and treatments in writing, which shall be signed by the physician quarterly, and diet orders, which shall be renewed yearly; (III)

l. A notation of the resident's yearly or other visits to physician or other professionals and all consultation reports and progress notes; (III)

m. Documentation describing any change in the resident's condition; (II, III)

n. A notation describing the resident's condition on admission, transfer, and discharge; (III)

o. In the event of a resident's death, notations in the resident's record shall include the date and time of the resident's death, the circumstances of the resident's death, the disposition of the resident's body, and the date and time that the resident's family and physician were notified of the resident's death; (III)

p. A copy of instructions given to the resident, the resident's legal representative, or receiving facility in the event of the resident's discharge or transfer; (III) and

q. Disposition of personal property. (III)

64.18(2) *Confidentiality of resident records.* The facility shall have policies and procedures providing that each resident shall be ensured confidential treatment of all information, including information contained in an automated data bank. The resident's or the resident's legal guardian's written informed consent shall be required for the release of information to persons not otherwise authorized under law to receive it. (II)

A release of information form shall be used which includes to whom the information shall be released, the reason for the release of the information, how the information is to be used, and the period of time for which the release is in effect. A third party not requesting the release shall witness the signing of the release of information form. (II)

a. The facility shall limit access to any resident records to staff and consultants providing professional service to the resident. Information shall be made available to staff only to the extent that the information is relevant to the staff person's responsibilities and duties. (II)

Only those personnel concerned with financial affairs of the residents may have access to the financial information. This paragraph is not meant to preclude access by representatives of state or federal regulatory agencies. (II)

b. The resident, or the resident's legal guardian, shall be entitled to examine all information and shall have the right to secure full copies of the record at reasonable cost upon request, unless the physician or qualified mental health professional determines the disclosure of the record or certain information contained in the record is contraindicated in which case the information will be deleted before the record is made available to the resident. This determination and the reasons for it must be documented in the resident's record by the physician or qualified mental health professional in collaboration with the resident's interdisciplinary team. (II)

64.18(3) *Incident records.* Each facility shall maintain an incident record report and shall have available incident report forms. (II, III)

a. The report of every incident shall be in detail on a printed incident report form. (II, III)

b. The person in charge at the time of the incident shall oversee the preparation of the report and sign the report. (III)

c. The facility shall maintain a copy of the incident report as part of the facility's administrative records and shall make the record available for review. (III)

64.18(4) *Retention of records.* A resident's records shall be retained in the facility for five years following termination of services to the resident even when there is a change of ownership of the facility. (III)

When the facility ceases to operate, the resident's records shall be released to the receiving facility. If no transfer occurs, the records shall be released to the resident's physician. (III)

481—64.19 to **64.32** Reserved.

481—64.33(235B) Separation of accused abuser and victim. Upon a claim of dependent adult abuse of a resident being reported, the administrator of the facility shall separate the victim and accused abuser immediately and maintain the separation until the abuse investigation is completed. (I, II)

481—64.34(135C) Employee criminal record checks, child abuse checks and dependent adult abuse checks and employment of individuals who have committed a crime or have a founded abuse. The facility shall comply with the requirements found in Iowa Code section 135C.33 as amended by 2013 Iowa Acts, Senate File 347, and rule 481—50.9(135C) related to completion of criminal record checks, child abuse checks, and dependent adult abuse checks and to employment of individuals who have committed a crime or have a founded abuse. (I, II, III)
[**ARC 0903C**, IAB 8/7/13, effective 9/11/13]

481—64.35(135C) Care review committee. Each facility shall have a care review committee in accordance with Iowa Code section 135C.25, which shall operate within the scope of the rules for care review committees promulgated by the department of elder affairs. (II)

64.35(1) Role of committee in complaint investigations.

a. The department shall notify the facility's care review committee of a complaint from the public. The department shall not disclose the name of a complainant.

b. The department may refer complaints to the care review committee for initial evaluation or investigation by the committee pursuant to rules promulgated by the department of elder affairs. Within ten days of completion of the investigation, the committee shall report to the department in writing the results of the evaluation of the investigation.

c. When the department investigates a complaint, upon conclusion of its investigation, it shall notify the care review committee and the department of elder affairs of its findings, including any citations and fines issued.

d. Results of all complaint investigations addressed by the care review committee shall be forwarded to the department within ten days of completion of the investigation.

64.35(2) The care review committee shall, upon department request, be responsible for monitoring correction of substantiated complaints.

64.35(3) When requested, names, addresses and telephone numbers of family members shall be given to the care review committee, unless the family refuses. The facility shall provide a form on which a family member may refuse to have the member's name, address or telephone number given to the care review committee.

This rule is intended to implement Iowa Code section 135C.25.

481—64.36(135C) Involuntary discharge or transfer.

64.36(1) A facility shall not involuntarily discharge or transfer a resident from a facility except: for medical reasons; for the resident's welfare or that of other residents; for nonpayment for the resident's stay (as contained in the contract for the resident's stay), except as prohibited by Title XIX of the Social Security Act, 42 U.S.C. 1396 to 1396k by reason of action pursuant to Iowa Code chapter 229; by reason of negative action by the Iowa department of human services; and by reason of negative action by the professional review organization. A resident shall not be transferred or discharged solely because the cost of the resident's care is being paid under Iowa Code chapter 249A, or because the resident's source of payment is changing from private support to payment under chapter 249A. (I, II)

a. "Medical reasons" for transfer or discharge are based on the resident's needs and are determined and documented in the resident's record by the attending physician. Transfer or discharge may be required to provide a different level of care. In the case of transfer or discharge for the reason that the resident's condition has improved so that the resident no longer needs the level of care being provided by the facility, the determination that medical reason exists is the exclusive province of the professional review organization or utilization review process in effect for residents whose care is paid in full or in part by Title XIX. (II)

b. "Welfare" of a resident or that of other residents refers to their social, emotional, or physical well-being. A resident might be transferred or discharged because the resident's behavior poses a continuing threat to the resident (e.g., suicidal) or to the well-being of other residents or staff (e.g., the resident's behavior is incompatible with their needs and rights). Evidence that the resident's continued presence in the facility would adversely affect the welfare of the resident or that of other residents shall be made by the administrator or designee and shall be in writing and shall include specific information to support this determination. (II)

c. Involuntary transfer or discharge of a resident from a facility shall be preceded by a written notice to the resident or responsible party at least 30 days in advance of the proposed transfer or discharge. The 30-day requirement shall not apply in any of the following instances:

(1) If an emergency transfer or discharge is mandated by the resident's health care needs and is in accord with the written orders and medical justification of the attending physician. Emergency transfers or discharges may also be mandated to protect the health, safety, or well-being of other residents and staff from the resident being transferred. (II)

(2) If the transfer or discharge is subsequently agreed to by the resident or the resident's responsible party, and notification is given to the responsible party, physician, and the person or agency responsible for the resident's placement, maintenance, and care in the facility. (II)

(3) If the discharge or transfer is the result of a final, nonappealable decision by the department of human services or the professional review organization.

d. The notice required by 64.36(1)*"c"* shall contain all of the following information:

(1) The stated reason for the proposed transfer or discharge. (II)

(2) The effective date of the proposed transfer or discharge. (II)

(3) A statement in not less than 12-point type (elite), which reads: "You have a right to appeal the facility's decision to transfer or discharge you. If you think you should not have to leave this facility, you may request a hearing in writing or verbally with the Iowa state department of inspections and appeals (hereinafter referred to as "department") within 7 days after receiving this notice. You have a right to be represented at the hearing by an attorney or any other individual of your choice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department and you will not be transferred prior to a final decision. Provision may be made for extension of the 14-day requirement upon request to the department of inspections and appeals designee in emergency circumstances. If you lose the hearing, you will not be transferred before the expiration of 30 days following receipt of the original notice of the discharge or transfer, or no sooner than 5 days following final decision of such hearing. To request a hearing or receive further information, call the department at (515)281-4115 or you may write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319." (II)

e. A request for a hearing made under 64.36(1)*"d"*(3) shall stay a transfer or discharge pending a hearing or appeal decision. (II)

f. The type of hearing shall be determined by a representative of the department. Notice of the date, time, and place of the hearing shall be sent by certified mail or delivered in person to the licensee, resident, responsible party, and Iowa department of elder affairs long-term care ombudsman of record not later than five full business days after receipt of the request. This notice shall also inform the licensee, resident or responsible party that they have a right to appear at the hearing in person or be represented by their attorneys or other individual. The hearing shall be dismissed if neither party is present or represented at the hearing. If only one party appears or is represented, the hearing shall proceed with one party

present. The Iowa department of elder affairs long-term care ombudsman shall have the right to appear at the hearing.

g. The hearing shall be heard by a department of inspections and appeals designee pursuant to Iowa Code chapter 17A. (The hearing shall be public unless the resident or the resident's representative requests in writing that it be closed.) The licensee or a designee shall have the opportunity to present to the representative of the department any oral testimony or written materials to show by a preponderance of the evidence just cause why a transfer or discharge may be made. The resident and responsible party shall also have an opportunity to present to the representative of the department any oral testimony or written material to show just cause why a transfer or discharge should not be made. In a determination as to whether a transfer or discharge is authorized, the burden of proof rests on the party requesting the transfer or discharge.

h. Based upon all testimony and material submitted to the representative of the department, the representative shall issue, in accordance with Iowa Code chapter 17A, written findings of fact and conclusions of law and issue a decision and order in respect to the adverse action. This decision shall be mailed by certified mail to the licensee, resident, responsible party, and department of elder affairs long-term care ombudsman within 10 working days after the hearing has been concluded. The representative shall have the power to issue fines and citations against the facility in appropriate circumstances.

A request for review of a proposed decision in which the department is the final decision maker shall be made within 15 days of issuance of the proposed decision, unless otherwise provided by statute. Requests shall be mailed or delivered by either party to the Director, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319-0083. Failure to request review will preclude judicial review unless the department reviews a proposed decision upon its own motion within 15 days of the issuance of the decision.

i. A copy of the notice required by 64.36(1)*"c"* shall be personally delivered to the resident and a copy placed in the resident's record. A copy shall also be transmitted to the department, the resident's responsible party, physician, the person or agency responsible for the resident's placement, maintenance, and care in the facility, and the department of elder affairs long-term care ombudsman.

j. If the basis for an involuntary transfer or discharge is the result of a negative action by the Iowa department of human services or the professional review organization (Iowa Foundation for Medical Care), appeals shall be filed with those agencies as appropriate. Continued payment shall be consistent with rules of those agencies.

k. If nonpayment is the basis for involuntary transfer or discharge, the resident shall have the right to make full payment up to the date that the discharge or transfer is to be made and then shall have the right to remain in the facility. (II)

l. The involuntary transfer or discharge shall be discussed with the resident, the resident's responsible party, and the person or agency responsible for the resident's placement, maintenance, and care in the facility within 48 hours after notice of discharge has been received. The explanation and discussion of the reasons for involuntary transfer or discharge shall be given by the facility administrator or other appropriate facility representative as the administrator's designee. The content of the discussion and explanation shall be summarized in writing and shall include the names of the individuals involved in the discussions and made a part of the resident's record. (II)

m. The resident shall receive counseling services before (by the sending facility) and after (by the receiving facility) the involuntary transfer to minimize the possible adverse effects of the involuntary transfer. Counseling shall be documented in the resident's record. (II)

(1) Counseling shall be provided by a qualified individual who meets one of the following criteria:

1. Has a bachelor's or master's degree in social work from an accredited college. (II)

2. Is a graduate of an accredited four-year college and has had at least one year of full-time paid employment in a social work capacity with a public or private agency. (II)

3. Has been employed in a social work capacity for a minimum of four years in a public or private agency. (II)

4. Is a licensed psychologist or psychiatrist. (II)

5. Is any other person of the resident's choice. (II)

(2) The facility shall develop a plan to provide for the orderly and safe transfer or discharge of each resident to be discharged or transferred. (II)

(3) The receiving health care facility of a resident involuntarily discharged or transferred shall immediately formulate and implement a plan of care which takes into account possible adverse effects the transfer may cause. (II)

n. In the case of an emergency transfer or discharge as outlined in 64.36(1)*"c"*(1), the resident must still be given a written notice prior to or within 48 hours following transfer or discharge. A copy of this notice must be placed in the resident's file and it must contain all the information required by 64.36(1)*"d"*(1) and (2). In addition, the notice must contain a statement in not less than 12-point type (elite), which reads: "You have a right to appeal the facility's decision to transfer or discharge you on an emergency basis. If you think you should not have to leave this facility, you may request a hearing in writing or verbally with the Iowa state department of inspections and appeals within 7 days after receiving this notice. If you request a hearing, it will be held no later than 14 days after receipt of your request by the department. You may be transferred or discharged before the hearing is held or before a final decision is rendered. If you win the hearing, you have the right to be transferred back into the facility. To request a hearing or receive further information, call the department at (515)281-4115 or you may write to the department to the attention of: Administrator, Division of Health Facilities, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319." A hearing requested pursuant to this subrule shall be held in accordance with 64.36(1)*"f," "g,"* and *"h."* (II)

o. Residents shall not have the right to a hearing to contest an involuntary discharge or transfer resulting from the revocation of the facility's license by the department of inspections and appeals. In the case of a facility voluntarily closing, a period of 30 days must be allowed for an orderly transfer of residents to other facilities.

64.36(2) Intrafacility transfer.

a. Residents shall not be relocated from room to room within a licensed health care facility arbitrarily. (I, II) Involuntary relocation may occur only in the following situations and such situation shall be documented in the resident's record.

(1) Incompatibility with or disturbing to other roommates, as documented in the resident's record.

(2) For the welfare of the resident or other residents of the facility.

(3) For medical, nursing or psychosocial reasons, as documented in the resident's record, as judged by the attending physician, nurse or social worker in the case of a facility which groups residents by medical, nursing or psychosocial needs.

(4) To allow a new admission to the facility which would otherwise not be possible due to separation of roommates by sex.

(5) In the case of a resident whose source of payment was previously private, but who now is eligible for Title XIX assistance, the resident may be transferred from a private room to a semiprivate room or from one semiprivate room to another.

(6) Reasonable and necessary administrative decisions regarding the use and functioning of the building.

b. Unreasonable and unjustified reasons for changing a resident's room without the concurrence of the resident, or responsible party include:

(1) Change from private pay status to Title XIX, except as outlined in 64.36(2)*"a"*(5). (II)

(2) As punishment or behavior modification (except as specified in 64.36(2)*"a"*(1). (II)

(3) Discrimination on the basis of race or religion. (II)

c. If intrafacility relocation is necessary for reasons outlined in 64.36(2)*"a,"* the resident shall be notified at least 48 hours prior to the transfer and the reason therefor shall be explained. The responsible party shall be notified as soon as possible. The notification shall be documented in the resident's record and signed by the resident or responsible party. (II)

d. If emergency relocation is required to protect the safety or health of the resident or other residents, the notification requirements may be waived. The conditions of the emergency shall be

documented. The family or responsible party shall be notified immediately or as soon as possible of the condition requiring emergency relocation and notification shall be documented. (II)

This rule is intended to implement Iowa Code sections 135C.2(3) and 135C.14(8).

481—64.37 to **64.58** Rescinded IAB 7/26/89, effective 7/7/89.

481—64.59(135C) County care facilities. Rescinded **ARC 0764C**, IAB 5/29/13, effective 7/3/13.

481—64.60(135C) Federal regulations adopted—conditions of participation. Regulations in 42 CFR Part 483, Subpart D, Sections 410 to 480 effective October 3, 1988, are adopted by reference and incorporated as part of these rules. A copy of these regulations is available on request from the Health Facilities Division, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

Classification of violations is I, II, and III, determined by the division using the provisions in 481—Chapter 56, "Fining and Citations," to enforce a fine to cite a facility.

This rule is intended to implement Iowa Code section 135C.2(3).

481—64.61(135C) Federal regulations adopted—rights. Regulations in 42 CFR Part 483, Subpart B, Sections 10, 12, 13, and 15 effective August 1, 1989, are adopted by reference and incorporated as part of these rules. Section 10 governs resident rights; Section 12, admission, transfer or discharge rights; Section 13, resident behavior and facility practices; and Section 15, quality of life. Classification of violations for all of these regulations is I and II. A copy is available on request from the Health Facilities Division, Department of Inspections and Appeals, Lucas State Office Building, Des Moines, Iowa 50319.

NOTE: The federal interpretive guidelines are printed immediately following 481—Chapter 64.

This rule is intended to implement Iowa Code section 135C.14(8).

481—64.62(135C) Another business or activity in a facility. A facility is allowed to have another business or activity in a health care facility or in the same physical structure of the facility, if the other business or activity is under the control of and is directly related to and incidental to the operation of the health care facility, or the business or activity is approved by the department and the state fire marshal.

To obtain the approval of the department and the state fire marshal, the facility must submit to the department a written request for approval which identifies the service(s) to be offered by the business and addresses the factors outlined in paragraphs *"a"* through *"j"* of this rule. (I, II, III)

64.62(1) The following factors will be considered by the department in determining whether a business or activity will interfere with the use of the facility by residents, interfere with services provided to residents, or be disturbing to residents:

a. Health and safety risks for residents;

b. Compatibility of the proposed business or activity with the facility program;

c. Noise created by the proposed business or activity;

d. Odors created by the proposed business or activity;

e. Use of entrances and exits for the business or activity in regard to safety and disturbance of residents and interference with delivery of services;

f. Use of the facility's corridors or rooms as thoroughfares to the business or activity in regard to safety and disturbance of residents and interference with delivery of services;

g. Proposed staffing for the business or activity;

h. Sharing of services and staff between the proposed business or activity and the facility;

i. Facility layout and design; and

j. Parking area utilized by the business or activity.

64.62(2) Approval of the state fire marshal shall be obtained before approval of the department will be considered.

64.62(3) A business or activity conducted in a health care facility or in the same physical structure as a health care facility shall not reduce space, services or staff available to residents below minimums required in these rules. (I, II, III)

481—64.63(135C) Respite care services. Respite care services means an organized program of temporary supportive care provided for 24 hours or more to a person in order to relieve the usual caregiver of the person from providing continual care to the person. A facility which chooses to provide respite care services must meet the following requirements related to respite care services and must be licensed as a health care facility.

64.63(1) A facility which chooses to provide respite care services is not required to obtain a separate license or pay a license fee.

64.63(2) Rules regarding involuntary discharge or transfer rights do not apply to residents who are being cared for under a respite care contract.

64.63(3) The facility shall have a contract with each resident in the facility. When the resident is there for respite care services, the contract shall specify the time period during which the resident will be considered to be receiving respite care services. At the end of that period, the contract may be amended to extend that period of time. The contract shall specifically state the resident may be involuntarily discharged while being considered as a respite care resident. The contract shall meet other requirements for contracts between a health care facility and resident, except the requirements concerning the holding and charging for a bed when a resident is hospitalized or leaves the facility temporarily for recreational or therapeutic reasons.

64.63(4) Respite care services shall not be provided by a facility to persons requiring a level of care which is higher than the level of care the facility is licensed to provide.

These rules are intended to implement Iowa Code sections 10A.202, 10A.402, 135C.2(6), 135C.6(1), 135C.14, 135C.14(8), 135C.25, 135C.25(3), 135C.32, 135C.36, 227.4, 235B.1(6), and 235B.3(11).

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◊ Two or more ARCs
1 See IAB, Inspections and Appeals Department.
2 Two ARCs

INTERPRETIVE GUIDELINES*

These guidelines are included in the Iowa Administrative Code pursuant to Iowa Code section 135C.2(3)*"d"* and are not subject to the rule-making provisions in Iowa Code sections 17A.4 and 17A.5.

440.150(c) The statutory and regulatory use of the word "institution" includes settings that serve four or more people with mental retardation and/or related conditions.

See §435.1009 for definition of "persons with related conditions."

The presence or absence of an individual requiring a medical care plan, as defined at W320, is not salient in the determination of whether a facility is eligible to participate in the ICF/MR program.

483.410(a)(1) The responsibility for direction includes areas such as health, safety, sanitation, maintenance and repair, and utilization and management of staff, especially when problems in these areas are of a serious or recurrent nature. Condition level deficiencies (other than the Governing Body Condition) or repeat, pervasive patterns of deficiencies at the Standard level may be an indication that the governing body is not providing sufficient operating direction over the facility. When a pattern of serious or repeated deficiencies is identified during the survey, interview the administrator or review the minutes of governing body meetings, if available, to determine whether or not the governing body has identified and addressed the problem.

Staff who have been trained, but are not implementing programs or are inappropriately deployed (e.g., there are enough staff but they are assigned to duties like record keeping which prevents them from delivering needed services), may indicate a failure of the governing body to adequately direct the staff's activities.

483.410(b) Licenses, permits, and approvals of the facility must be available to you upon request. Current reports of inspections by State and/or local health authorities are on file, and notations are made of action taken by the facility to correct deficiencies.

Some State or local laws are more stringent or prescriptive than the Federal Medicaid requirement on the same issue. Failure of the facility to meet a Federal (i.e., non- Medicare or Medicaid), State or local law may be cited only when the authority having jurisdiction (AHJ) has both made a determination of non-compliance and has taken a final adverse action.

An adverse action is defined as any procedure that goes beyond the approval of a plan of correction, such as a civil money penalty, ban on admissions, denial of payment, or loss of license, and is not under appeal by the provider. The AHJ is the public official(s) having authority to make a determination of noncompliance, and is responsible for signing correspondence notifying the facility of the adverse action.

If you believe you have identified a situation indicating the provider may not be in compliance with a Federal, State or local law, refer that information to the AHJ for follow-up action. If a final adverse action results, then the facility could be found to not meet §483.410(b).

483.410(c)(1) The structure and content of the individual's record must be an accurate, functional representation of the actual experience of the individual in the facility. This should be identified through interviews with staff and, when possible, with individuals being served, as well as through observations.

The regulations do not specify that all information about an individual be located in the individual program plan (IPP) document, only that information explicitly identified in the regulations. The regulations do not prescribe the manner, form or where in the individual's record this information is to be recorded.

483.410(c)(2) "Keep confidential" means safeguarding the content of information including video, audio, and/or computer stored information from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian, and consistent with the advocate's right of access, as required in the Developmental Disabilities Act. Facility staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to the individual.

*Editor's Note: Verbatim from federal regulations—neither the Department nor the Administrative Code Editors have attempted to correct inconsistencies in numbering, spelling or grammar.

Confidentiality applies to both central records and information kept at dispersed locations. If there is information considered too confidential to place in the record used by all staff (e.g., identification of the family's financial assets, sensitive medical data), it may be retained in a secure place in the facility (e.g., social worker's locked desk). A notation must be made in the record of the location of confidential information (e.g., "Family information is available from the social worker").

The sharing of individual specific information with members of the "specially constituted committee" required by §483.450(f)(3), who are not affiliated with the agency, does not violate an individual's right to have information about him or her kept confidential. The committee needs to know relevant information to function properly.

The facility is allowed the flexibility to work out arrangements with its members to maintain confidentiality.

483.410(c)(3) Although one facet of the requirement is that the facility must decide how this is to be accomplished (i.e., policies and procedures), the surveyor's primary focus should be on the second part of the requirement, i.e., the facility's implementation or "outcome" that consent is obtained prior to the release of any individual information (e.g., records, photographs, interviews, or other means of exposure to public view or identification).

The following guidance is provided to assist in determining whether informed consent for release of information is adequate:

1. Was the confidential information to be released specifically identified?
2. Was the person or agency to whom the information was to be released identified to the consenting party?
3. Was the consent time-limited (i.e., include the date the consent was given, and the date which the specific consent would be invalid)?
4. Was the person giving consent legally able to give consent?

Information regarding an individual's HIV status may not be released without specific consent and may not be in the record if that consent has not been given. Staff are expected to use universal precautions when dealing with all individuals, therefore, it is unnecessary to routinely share information about HIV status with all staff. Under some conditions, knowledge may be shared with those directly involved in the care of infected persons. Surveyors should be familiar with State law requirements.

483.410(c)(4) In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable.

Given the large number of entries that are made in individual's records, this requirement is cited only when a systemic problem is identified.

483.410(c)(6) "Appropriate" means those parts of each individual's record most likely (or known) to be needed by the residential staff to carry out the individual's active treatment program in the unit, to alert staff to health risks and other aspects of medical treatment, to support the psychosocial needs of the individual, and anything else necessary to the staff's ability to work on behalf of the individual.

483.410(d)(1) Federal statute (P.L. 94-142) requires all school-aged children to receive a free and appropriate school education. Therefore, a written agreement between ICFs/MR and public schools is not necessary.

483.410(d)(2)(ii) Outside providers of day services would not have to meet certain requirements relating to physical environment under §§483.470 (a)-(g), (j), and (k) unless that source also provides living quarters for ICF/MR individuals. Outside sources must, of course, meet any applicable State and local requirements.

The facility's responsibility includes assuring that any restrictive techniques proposed for use by outside service providers are used only when warranted and with the required safeguards and approvals.

483.410(d)(3) "Assure" means that the facility's staff actively participate with staff in outside programs in the assessment process and in development of objectives and intervention strategies. For example, if a public school is implementing a manual communication system with an individual, the direct care staff in the individual's living unit should have instructions to implement the program in the residential environment. Likewise, if the facility is implementing a behavior management program

for the individual, it should be shared with and implemented as needed by the outside program. This communication is often difficult, but nevertheless essential to the provision of active treatment.

483.410(d)(4) Even though the facility's premises may be rented from a landlord, the facility must ensure that the requirements for physical environment are met, either through arrangement with the landlord or through the facility's own services.

483.420 A citation of W127 or W150, which require that individuals are not subjected to verbal, sexual, or psychological abuse or punishment, is sufficient justification that the facility has failed to comply with the most fundamental of protections and, therefore, does not comply with this Condition of Participation.

483.420(a) "Ensure" means that the facility actively asserts the individual's rights and does not wait for him or her to claim a right. This obligation exists even when the individual is less than fully competent and requires that the facility is actively engaged in activities which result in the pro-active assertion of the individual's rights, e.g., guardianship, advocacy, training programs, use of specially constituted committee, etc.

483.420(a)(1) The obligation to inform requires that the facility present information in a manner and form which can be understood, e.g., use of print materials, specialized programs to inform individuals who are deaf or blind, use of interpreters, etc.

483.420(a)(2) The term "attendant risks of treatment" refers to all treatment, including medical treatment. An individual 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 being refused, if acceptable alternatives are available. The individual's preference about alternatives should be elicited and considered in deciding on the course of treatment. If the individual 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 individuals, the individual himself or herself and the facility, and if it can continue to treat the individual consistent with these regulations. Thus, every effort must be made to assist the individual to understand and cooperate in the legitimate exercise of the IPP.

An individual being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating or not participating. The individual's written consent must be received prior to participation. For an individual who is a minor or who has been adjudicated as incompetent, the written informed consent of parents of the minor or the legal guardian is required.

The determination as to whether the individual was sufficiently "informed" is based on the following:

1. Was the individual aware of the proposed program or treatment, the procedures to be followed, and the identification of the person who will perform the treatment activity?
2. Was the individual aware of the intended outcome or benefits of the proposed program or treatment?
3. Was the individual aware of the possible risks, including side effects and attendant discomfort of the proposed program or treatment, and the steps to be taken to minimize risk?
4. Was the individual aware of the ramifications if he or she decided not to participate, and of the alternatives to the proposed activity, particularly alternatives offering less risk or adverse effects?
5. Did the individual participate voluntarily? Did the individual have the opportunity to have questions about the activity answered?
6. Was the information about the activity presented in language that could be readily understood by the individual?

Additionally, for experimental, invasive or potentially harmful treatment, activities or procedures for which written informed consent is recommended, if not otherwise required by State or Federal law:

1. Was the consent time-limited (i.e., include the date the consent was signed and the date it becomes invalid)?
2. Did the individual realize that consent to participate could be withdrawn at any time without risk of punitive action?
3. Was the person who gave consent the legally appropriate party to do so for the individual?

483.420(a)(3) The facility must ensure protection of the individual from any form of reprisal or intimidation as a result of a complaint or grievance reported by an individual.

As long as there are no decisions or circumstances which require action by a legally-appointed surrogate, a spokesperson or advocate could assist the individual in exercising his or her rights as a citizen of the United States and as a person residing in the facility. Some examples might include assisting the individual to express his/her needs, wants and interests, to utilize community resources or to file a complaint. A spokesperson might also express opinions regarding situations in which consent by the beneficiary, parent of a minor, or legal guardian is required in order to bring to the attention of the facility potential concerns or problems.

The extent to which any person can act on behalf of another individual who has been assessed as needing a guardian, however, is entirely dependent upon the needs of the individual client and upon the laws and regulations of the State in which that individual resides. The facility and surveyor must be familiar with the laws and regulations of the State in which the facility is located. It is inappropriate for the facility to unofficially delegate the individual's rights to others (e.g., parents, family, advocacy groups, etc.). To the extent that the individual is able to make decisions for himself or herself, it is inappropriate to delegate the person's rights to others.

Individuals who need guardianship or advocacy, and do not have this need addressed, are not prepared to exercise their rights as citizens of the United States. The facility's failure to ensure guardianship or advocacy for those who need it should be cited. Further deficiencies may also be cited under W123, W124, W143, and W263, depending upon the survey findings.

483.420(a)(4) Since the use of money is a right, determine if the facility demonstrated, based on objective data, that the individual was unable to be taught how to use money before the decision was made to restrict that right.

483.420(a)(5) The facility is responsible to organize itself in such a manner that it proactively assures individuals are free from serious and immediate threat to their physical and psychological health and safety. Citing of this requirement indicates that there is a high probability that abuse to individuals could occur at any time, or already has occurred and may well occur again, if the individuals are not effectively protected from the serious physical or psychological harm or injury, or if the threat is not removed. A citation of this requirement, therefore, must result in a determination of Condition level non-compliance due to immediate and serious threat. Cross reference W122 for additional guidance.

"Threat," as used in this guideline, is any condition/situation which could cause or result in severe, temporary or permanent injury or harm to the mental or physical condition of individuals, or in their death.

"Abuse" refers to the ill-treatment, violation, revilement, malignment, exploitation and/or otherwise disregard of an individual, whether purposeful, or due to carelessness, inattentiveness, or omission of the perpetrator.

"Physical abuse" refers to any physical motion or action, (e.g., hitting, slapping, punching, kicking, pinching, etc.) by which bodily harm or trauma occurs. It includes use of corporal punishment as well as the use of any restrictive, intrusive procedure to control inappropriate behavior for purposes of punishment. Observe individuals to see if they are bruised, cut, burned (cigarettes, etc.).

"Verbal abuse" refers to any use of oral, written or gestured language by which abuse occurs. This includes pejorative and derogatory terms to describe persons with disabilities.

"Psychological abuse" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation, sexual coercion, intimidation, whereby individuals suffer psychological harm or trauma.

Individuals must not be subjected to abuse by anyone (including, but not limited to, facility staff, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, other individuals, or themselves).

Since many individuals residing in ICFs/MR are unable to communicate feelings of fear, humiliation, etc., the assumption must be made that any actions that would usually be viewed as psychologically or verbally abusive by a member of the general public, is also viewed as abusive by the individual residing in the ICF/MR, regardless of that individual's perceived ability to comprehend the nature of the incident.

The facility must take whatever action is necessary to protect the individuals residing there. For example, if a facility is forced by court order or arbitration rulings to retain or reinstate an employee believed to be abusive, the facility may need to take other measures (such as assigning the employee to an area where there is no contact with beneficiaries, providing increased supervision and additional training for the employee, appealing the arbitration or court decision or pursuing formal criminal charges) in order to ensure beneficiary safety.

483.420(a)(6) The chronic use of restraints may indicate one or more of the following: the individual's developmental and/or behavioral needs are not being met and the appropriateness of placement should be questioned; staff behavior may be prompting behaviors in individuals which result in the chronic use of physical restraints and drugs to control behavior; staff may have inadequate training and/or experience to provide active treatment and employ preventive measures that reduce the levels of behaviors judged to require physical restraints and drugs to control behavior; and restraints may be applied to behaviors which are, in fact, not threatening to the health and welfare of the individual or other individuals and staff.

483.420(a)(7) The facility must have a method of arranging for privacy of visits between individuals with significant relationships, if they do not both reside at the facility.

483.420(a)(7) The facility must examine and treat individuals in a manner that maintains the privacy of their bodies. Only employees directly involved in the treatment are present when treatments are given. Some method or mechanism which ensures privacy (such as a closed door, a drawn curtain or systematically implemented training for an individual to use their own methods) must be employed to shield the individual from passers-by. People not involved in the care of the individual should not be present without their consent while they are being examined or treated.

If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy. There is no prohibition, however, on staff to work with individuals of the opposite sex.

Exercise special attention to ensure that your behavior, during onsite observations in the individual's home, does not violate an individual's right to privacy during treatment and care of personal needs.

483.420(a)(8) "Work," as used in the regulation, means any directed activity, or series of related activities which results in benefit to the economy of the facility or in a contribution to its maintenance, or in the production of a salable product. In deciding whether a particular activity constitutes "work" as defined above, the key determinant is if an individual was unavailable to perform the particular activity or function, would the facility be required to hire additional full or part-time staff (or pay overtime to existing staff) in order to properly maintain the facility or to provide necessary care services to individuals, in order to carry out its assigned mission?

Individuals are not to be used to provide a source of labor for a facility against their will or in opposition to the objectives of the IPP.

Seriously question any situation in which an individual is observed or reported to be "volunteering" to do real work that benefits the facility, or its maintenance without compensation. Interview such individuals to determine if they have given informed consent to such practices and understand that by providing employable services they are able to be compensated. This does not preclude an individual from helping out a friend or being kind to others. Self-care activities related to the care of one's own person are not considered "work" for purposes of compensation.

Regular participation in the domiciliary activities of maintaining one's own immediate household or residential living unit which can lead to the individual's greater functional ability to perform independent household tasks is also not considered "work" for the facility. Shared duties are common and appropriate. Included in, but not limited to, these domiciliary tasks are:

- Meal planning, food purchasing, food preparation, table setting, serving, dishwashing, etc.;
- Household cleaning, laundry;
- Clothes repair;
- Light yard and house maintenance (painting, simple carpentry, etc.); and
- General household shopping, including clothing.

In general, participation in any household task which promotes greater independent functioning (and which the individual has not yet learned) is permitted as long as tasks are included in the IPP in written behavioral and measurable terms. This participation must be supervised, and indices of performance should be available. No task may be performed for the convenience of staff (e.g., supervising individuals, running personal errands) or which has no relationship to the individual's IPP.

As individuals become widely competent and independent in household tasks, they must not be used in those capacities and represented as "in training" and serious consideration should be given to the individual's potential for even less restrictive residential environments. (See also §§483.440(a)(2) and (b)(1).) However, it is acceptable for individuals to engage in household tasks which are in common with other individuals, all sharing the total household tasks commonly shared in nuclear family units. The test in this regard is:

The expectation is that tasks are the general responsibility of the individual, and that the duties rotate to the maximum extent possible; and/or

The individual can assume control in performing the responsibility given (e.g., John has until Thursday at 8 p.m. to clean the living and dining rooms), thereby adding to the development of internal controls and assumption of responsibility by individuals.

Work performed by the individual which no other individual is required or expected to do, or is not a regular part of running the household, must be compensated.

"Compensated" means the receipt of money or other forms of negotiable compensation for work (including work performed in an occupational training program) which is available to the individual, to be used at his or her discretion in determining the benefits to be derived therefrom.

"Prevailing wage" refers to the wage paid to non-disabled workers in nearby industry or the surrounding community for essentially the same type, quality and quantity of work or work requiring comparable skills.

A working individual must be paid at least the prevailing minimum wage except when an appropriate certificate has been obtained by the facility in accordance with current regulations and guidelines issued under the Fair Labor Standards Act, as amended.

Any individual performing work, as defined above, must be compensated in direct proportion to his or her productivity as measured in work equivalents of a regular employee's output. For example, if an individual's productivity for a particular work activity or function is determined to be 30 percent of normal output for an average non-disabled worker, and the prevailing wage is $4.00 an hour, then the individual should be compensated in money at a rate of one dollar and twenty cents per hour (.30 x $4.00 =$1.20). If a piece rate can be determined for a particular job, an individual is paid based on the number of pieces he or she produces. An individual's pay is not dependent on the production of other individuals when he or she works in a group.

When the individual's active treatment program includes assignment to occupational or vocational training or work, specific work objectives of anticipated progress should be included in the IPP along with reasons for the assignments. If the training of individuals on particular occupational activities or functions involves "real work" to be accomplished for the facility, the individuals must be compensated based on ability. For example, if in the process of work training activities involved with learning to clean a floor, the floor for a particular building is cleaned and does not require further janitorial cleanup, then the individual must be compensated for this activity.

483.420(a)(9) Space must be provided for individuals to receive visitors in reasonable comfort and privacy.

483.420(a)(9) Assistance must be provided to individuals who require help in reading or sending mail. Refer to W145.

483.420(a)(11) Outdoor and out of home activities are planned for all individuals on a regular basis.

483.420(a)(12) All individual possessions regardless of their apparent value to others must be treated with respect, for what they are and for what they may represent to the individual. The facility should encourage individuals to use or display possessions of his or her choice in a culturally normative manner. Appropriate personal possessions includes personal care and hygiene items. Individuals should not be without personal possessions because of the behavior of others with whom they live. If a method

for identifying personal effects is used, it should be inconspicuous and in a manner that will assist the individual to identify them.

"Appropriate" clothing means a supply of clothing that is sufficient, in good repair, accounts for a variety of occasions and seasons, and appropriate to age, size, gender, and level of activity. Modification or adaptation of clothing fasteners should be considered based on the needs of an individual with a physical disability to be independent.

As appropriate, each individual's active treatment program maximizes opportunities for choice and self-direction with regard to choosing and shopping for clothing which enhances his or her appearance, and selecting daily clothing in accordance with age, sex and cultural norms. Individuals are permitted to keep personal clothing and possessions for their use while in the facility. Determine how the facility both ensures the safety of personal possessions while at the same time providing individual access to them when the individual chooses.

Individuals are provided the opportunity, encouraged, and trained to use age-appropriate materials. The term "age-appropriate" refers to anything that reinforces recognition of the individual as a person of a certain chronological age. The facility's environment must be furnished with materials and activities that will enhance opportunities for growth. Determine whether the failure of an individual to achieve functional, adaptive skills, or to have opportunities to make informed choices, or to achieve any positive outcomes is a result of the constant use of materials or participation in activities that are age-inappropriate.

483.420(b)(1)(i) A "full and complete accounting for personal funds" does not need to document accounting for incidental expenses or "pocket money," funds a capable individual handles without assistance, funds dispensed to an individual under a program to train the individual in money management, and funds that are not entrusted to the facility (e.g., funds paid directly to the individual's representative payee).

483.420(b)(1)(ii) Although prudent to do so, there is no Federal requirement to maintain individuals' personal funds in financial institutions in interest bearing accounts, or in accounts separate from other individual accounts. However, if the facility elects to pool individuals' funds in an interest bearing account, including common trust accounts, it is expected to know the interest separately accrued by each individual, as part of its required accounting of funds. Interest accumulated to an individual's account belongs to the individual, not the facility.

483.420(b)(2) Parents or other family members should not have automatic access to the financial records of adult individuals. It is not necessary that a facility be required to furnish an annual financial statement to the individual or the individual's family, since the facility is already required to make the financial record available at any time upon request. The individual, in turn, is free to choose to make his or her financial record available to anyone else.

483.420(c)(1) "Unobtainable," as used in this standard, means that the facility has made a bonafide effort to seek parental or guardian participation in the process, even though the effort may ultimately be unsuccessful (for example, the parent may be impossible to locate or may prove unwilling or unable to participate).

"Inappropriate" as used in this standard means that the parent or legal guardian's behavior is so disruptive or uncooperative that others cannot effectively participate; the individual does not wish his or her parent to participate, and the individual is competent to make this decision; or there is strong evidence that the parent or guardian is not acting on the individual's behalf or in the individual's best interest. In the case of the latter, determine what the facility has done to bring effective resolution to the problem.

483.420(c)(2) Where possible, randomly select a family or guardian to validate the quality, nature and frequency of the communications between the facility and families or guardians (but only with their consent). There is no requirement that each contact with family and friends be documented.

483.420(c)(3) Any limitations of visitors are recorded by the interdisciplinary team with reason and time limits given. Decisions to restrict a visitor must be reviewed and re-evaluated each time the IPP is reviewed or at the individual's request. If you find broad restrictions, review general facility access policies.

The facility should have arrangements available to provide privacy for families and others when visiting with individuals.

483.420(c)(5) It is not acceptable for a facility to sponsor or allow individuals to take a particular type of trip that is contraindicated. For example, in the situation of an individual subject to abuse by a parent, the facility obviously is not required to permit such a trip. However, as with any right that may need to be modified or limited, the individual should be provided with the least restrictive and most appropriate alternative available.

483.420(c)(6) "Significant" incidents or changes in the individual's condition refers to any type of occurrence or event, that is perceived to have some level of importance to the individual, family or guardian. Examples include, but are not limited to, allegations of mistreatment, psychological trauma experienced by the individual, loss or change of a program service or staff person, entry or placement in new programs or agencies, day-to-day events on which family members express interest to be informed, etc.

483.420(d)(1) "Mistreatment" as used in this standard, includes behavior or facility practices that result in any type of individual exploitation such as financial, sexual, or criminal.

"Neglect" means failure to provide goods or services necessary to avoid physical or psychological harm.

See W127 for definitions related to "abuse."

483.420(d)(1)(i) See W127, Facility Practices, as related specifically to staff of the facility.

A citation of this requirement indicates that abuse to an individual by staff of the facility is highly likely to occur or has already occurred and may well occur again if the individual is not effectively protected. A citation of this requirement, therefore, must result in Condition-level non-compliance due to immediate and serious threat. Cross reference W122 and W127.

483.420(d)(1)(ii) Cross-reference W465.

483.420(d)(1)(iii) This regulation applies to the hiring of new employees on or after October 3, 1988. The facility is required to screen potential employees for a prior employment history of child or client abuse, neglect or mistreatment, as well as for any conviction based on those offenses. The abuse, neglect or mistreatment must be directed toward a child or an individual who is a client (resident, patient) in order for the prohibition of employment to apply.

This requirement also applies to acts of abuse, neglect or mistreatment committed by a current ICF/MR employee outside the jurisdiction of the ICF/MR (e.g., in the community or in another health care facility). A substantiated allegation of abuse, neglect or mistreatment which occurred after October 3, 1988, (regardless of the date of the person's employment in the ICF/MR), and which resulted in the termination of that person's employment from another health care facility, becomes a part of the person's employment history and the ICF/MR is prohibited from continuing to employ the individual. For example, an individual who abused a resident in a nursing facility and as a result, is barred from employment in the nursing home setting would also be prohibited from employment in the ICF/MR. While facilities are not required to periodically screen existing employees, if the facility becomes aware that such action has been taken against an employee, the facility is required to prohibit continued employment. This is also true of any conviction in a court of law for child or client (resident, patient) abuse, neglect or mistreatment. Therefore, conviction for abusing one's own child is also a reason employment would be prohibited.

The definition of "mistreatment" under the guideline at W153 includes financial exploitation. Therefore, if an employee was convicted or had a prior employment history of theft of an individual's funds, that would also be a reason employment would be prohibited.

Access other information, as appropriate, including information contained in "closed" records, in order to adequately evaluate compliance.

483.420(d)(2) The facility is responsible for reporting any injuries of unknown origin and any allegations of mistreatment to an individual residing in the facility regardless of who is the perpetrator (e.g., facility staff, parents, legal guardians, volunteer staff from outside agencies serving the individual, neighbors, or other individuals, etc.).

483.420(d)(3) The facility is responsible for investigating all injuries of unknown origin and must prevent further potential abuse while the investigation is in progress.

483.420(d)(4) Some States require that allegations of abuse must be reported to the police. CMS cannot regulate the activities of the police. However, if the police take longer than five working days for their investigation, the facility is still required to complete an internal investigation report of findings within the five day timeframe. "Working days" means Monday through Friday, excluding State and Federal holidays.

483.420(d)(4) This requirement refers to corrective action taken based upon findings of investigations of incidents which have occurred within the jurisdiction of the facility. It requires that the seriousness of infractions be weighed in the determination of what action is necessary by the facility to correct the situation appropriately. In cases of abuse, neglect or mistreatment by staff, where extenuating circumstances exist and dependent on the nature of the infraction, a remedy that is consistent with appropriate progressive disciplinary measures may be acceptable. When the intentional action or inaction of a staff person has resulted in abuse, neglect or mistreatment which poses a serious and immediate threat to individuals' health and safety, termination of employment is the only acceptable corrective action.

Appropriate corrective action is also required for findings of abuse, neglect or mistreatment by other individuals residing in the facility, staff of outside agencies, parents or any other person, and for injuries to individuals resulting from controllable environmental factors.

Appropriate corrective action is defined as that action which is reasonably likely to prevent the abuse, neglect, mistreatment or injury from recurring.

When an employee appeals a finding of abuse by the facility, whether through arbitration or in a court of law, the decision of the arbitrator or the court of law is then considered the final finding. If the arbitrator found that the charges lacked substance, the allegation would be considered unsubstantiated. The facility, however, is still required to ensure that individuals residing in the facility are not subjected to physical, verbal, sexual or psychological abuse or punishment by W127.

An arbitrator may find that the allegation of abuse is substantiated, but impose a lesser penalty than that which was sought by the facility. For example, the facility may seek termination of employment as the appropriate corrective action but the arbitrator determines that a 10 day suspension is more appropriate. The facts of the situation will have to be evaluated by the surveyor and a judgment made regarding appropriateness. Therefore, while the facility is permitted by the regulation to exercise judgment regarding appropriate corrective action, the surveyor must also exercise judgment and may determine that the corrective action is NOT reasonably likely to prevent the abuse from recurring.

483.430(a) View the person serving in the QMRP role as pivotal to the adequacy of the program the individual receives, since it is this role that is intended to ensure that the individual receives those services and interventions necessary by competent persons capable of delivering them. The paramount importance of having persons competent to judge and supervise active treatment issues cannot be overstated.

An individual's IPP may be coordinated and monitored by more than one QMRP or by other staff persons who perform the QMRP duties. There must, however, be one QMRP who is assigned primary responsibility and accountability for the individual's IPP and the QMRP function.

The regulations do not specify if the person designated as QMRP must do the duties of a QMRP exclusively, or is allowed to perform other professional staff duties in addition. The facility has the flexibility to allocate staff resources in whatever manner it believes is necessary as long as it ensures that the QMRP function is performed effectively for each individual.

The test of whether the number of QMRPs is adequate rests with the ability of the facility to provide the services described in §483.430(a) in an effective manner. The number will vary depending on such factors as the number of individuals the facility serves, the complexity of needs manifested by these individuals, the number, qualifications and competencies of additional professional staff members, and whether or not other duties are assigned to the QMRP function.

483.430(b)(1) For an active treatment program to be responsive to the individual's unique needs, there must be a foundation of competent professional knowledge that can be drawn upon in the implementation

of the interdisciplinary team process. Individuals with developmental deficits will require initial, temporary, or ongoing services from professional staff, knowledgeable about contemporary care practices associated with these areas. A special mention needs to be made that individuals should not be provided with services that are not needed (e.g., if an individual is basically healthy and not on medication, then the individual should not be provided extensive health and health-related services).

The needs identified in the initial comprehensive functional assessment, as required in §483.440(c)(3)(v), should guide the team in deciding if a particular professional's further involvement is necessary and, if so, to what extent professional involvement must continue on a direct or indirect basis.

Since such needed professional expertise may fall within the purview of multiple professional disciplines, based on overlapping training and experience, determine if the facility's delivery of professional services is adequate by the extent to which individuals' needs are aggressively and competently addressed. Some examples in which professional expertise may overlap include:

- Physical development and health: nurse (routine medical or nursing care needs that do not interfere with participation in other programs); physician, physician assistant, nurse practitioner (acute major medical intervention, or the treatment of chronic medical needs which will be dependent upon an individual's success or failure in other treatment programs).
- Nutritional status: nurse (routine nutritional needs that do not affect participation in other programs); nutritionist or dietitian (chronic health problems related to nutritional deficiencies, modified or special diets).
- Sensorimotor development: physical educators, adaptive physical educators, recreation therapists, (routine motor needs involving varying degrees of physical fitness or dexterity); special educators or other visual impairment specialists (specialized mobility training and orientation needs); occupational therapist, physical therapist, physiatrist (specialized fine and gross motor needs caused by muscular, neuromuscular, or physical limitations, and which may require the therapeutic use of adaptive equipment or adapted augmentative communication devices to increase functional independence); dietitians to increase specialized fine and gross motor skills in eating.
- Affective (emotional) development: special educators, social workers, psychologists, psychiatrists, mental health counselors, rehabilitation counselors, behavior therapists, behavior management specialists.
- Speech and language (communication) development: speech-language pathologists, special educators for people who are deaf or hearing impaired.
- Auditory functioning: audiologists (basic or comprehensive audiologic assessment and use of amplification equipment); speech-language pathologists (like audiologists, may perform aural rehabilitation); special educators for individuals who are hearing impaired.
- Cognitive development: teacher (if required by law, i.e., school aged children, or if pursuit of GED is indicated), psychologist, speech-language pathologist.
- Vocational development: vocational educators, occupational educators, occupational therapists, vocational rehabilitation counselors, or other work specialists (if development of specific vocational skills or work placement is indicated).
- Social Development: teachers, professional recreation staff, social workers, psychologists (specialized training needs for social skill development).
- Adaptive behaviors or independent living skills: Special educators, occupational therapists.

483.430(b)(1) There are some individuals in ICFs/MR who can often have their needs effectively met without having direct contact with professional staff on a daily basis. The intent of the requirement is not to require that professionals work directly with individuals on a daily basis, but only as often as an individual's needs indicate that professional contact is necessary. The amount and degree of direct care that professionals must provide will depend on the needs of the individual and the ability of other staff to train and direct individuals on a day-to-day basis.

483.430(b)(2) If there is sufficient evidence that para- and non-professional staff demonstrate the needed competencies to carry through with intervention strategies, you may be satisfied there is sufficient professional staff to carry out the active treatment program. However, if the professional's expertise is

not demonstrable at the para- and non-professional staff level, question both the numbers of professional staff and the effectiveness of the transdisciplinary training of para- and non-professional staff.

483.430(b)(3) "Participate" means providing input through whatever means is necessary to ensure that the individual's IPP is responsive to the individual's needs. The purpose of the interdisciplinary team process is to provide team members with the opportunity to review and discuss information and recommendations relevant to the individual's needs, and to reach decisions as a team, rather than individually, on how best to address those needs. Therefore, determine whether or not there is a pattern of active treatment based on professional participation in the process.

Without a negative outcome to demonstrate that professional involvement in any aspect of the active treatment process (e.g., comprehensive functional assessment, IPP development, program implementation, etc.) was insufficient or inaccurate, the facility is allowed the flexibility to use its resources in a manner that works in behalf of the client, in accordance with the regulations.

483.430(b)(4) "Participate" means both seeking out self-training and provision of training to others.

483.430(b)(5)(i)-(ix) The introductory phrase "to be designated as…" means that a provider is allowed to represent him or herself as a professional provider in that discipline, only if the provider meets State licensing requirements, or if the particular discipline does not fall under State licensure requirements, the provider meets the qualifications specified in §§483.430(b)(5)(i)-(ix). A person who is not qualified, for example, as a social worker, may not be referred to as a social worker per se. Nevertheless, such a person may be able to provide social services in an ICF/MR if there is no conflict with State law, and as long as the individuals' needs are met.

483.430(b)(5)(ix) The Commission on Dietetic Accreditation of the American Dietetic Association is the organization to whom the American Dietetic Association delegates this responsibility.

483.430(b)(5)(x) The intent for including a "human services professional" category is to expand the number and types of persons who could qualify as QMRPs, while still maintaining acceptable professional standards.

"Human services field" includes all the professional disciplines stipulated in §§483.430(a)(3)(i)(ii) and §§483.430(b)(5)(i)-(ix), as well as any related academic disciplines associated with the study of: human behavior (e.g., psychology, sociology, speech communication, gerontology etc.), human skill development (e.g., education, counseling, human development), humans and their cultural behavior (e.g., anthropology), or any other study of services related to basic human care needs (e.g., rehabilitation counseling), or the human condition (e.g., literature, the arts).

An individual with a "bachelors degree in a human services field" means an individual who has received: at least a bachelor's degree from a college or university (master and doctorate degrees are also acceptable) and has received academic credit for a major or minor coursework concentration in a human services field, as defined above. Although a variety of degrees may satisfy the requirements, majors such as geology and chemical engineering are not acceptable.

Taking into consideration a facility's needs, the types of training and coursework that a person has completed, and the intent of the regulation, the facility and you can exercise wide latitude of judgment to determine what constitutes an acceptable "human services" professional. Again, the key concern is the demonstrated competency to do the job.

483.430(c)(1) Volunteers may provide supplementary services. The facility may not rely on volunteers to fill required staff positions and perform direct care services.

Examine closely the adequacy of staffing when individuals served are engaged in the care, training, treatment or supervision of other individuals, either as part of training, "volunteer work," or normal daily routines. (See W131-W132 for additional interpretation of productive work done as a "volunteer" or as part of the individual's active treatment program.) The test of adequacy is whether or not there is sufficient staff to accomplish the job in the absence of the individual's work. Work done as part of an active treatment training program requires that the staff are monitoring and teaching new skills as part of the IPP.

483.430(c)(2) The test of adequacy about "awake" staffing is how well the facility has organized itself to detect and react to potential emergencies, such as fire, injuries, health emergencies described in the

medical care plan (e.g., aspiration, cardiac or respiratory failure, uncontrolled seizures) and behavioral crises described in the IPP.

483.430(c)(3) The intent of the regulation is that at all times a staff person is in a position to help if individual needs arise. For purposes of this provision, "on duty" staff need not be awake during normal bedtime hours.

Facilities sending some or all of the individuals to out of home or off grounds active treatment programs for a majority of the day need not provide a full complement of direct care staff in the residence during their absence. However, a minimum of one staff person must be on duty, if even one individual is present.

483.430(c)(4) "Support staff" include all personnel hired by the facility that are not either direct care staff or professional staff. For example, support staff include, but are not limited to, secretaries, clerks, housekeepers, maintenance and laundry personnel.

Direct care staff should be utilized at their highest level of competence, but they may assume other roles as long as their ability to exercise their primary direct care duties is not diluted. For example, direct care staff may serve as aides in a training program during the hours individuals are away from the living unit.

483.430(d)(1) "Sufficient" direct care staff means the number of staff, over and above the ratios specified in §483.430(d)(3), necessary to implement active treatment, as dictated by the individual's active treatment needs.

Do not look at numbers alone. The facility is responsible for organizing and evaluating its individual appointments, programming schedules, activities, materials, equipment, grouping assignments and available staff in such a way that maximizes benefit to the individual. During the course of the onsite survey, you should be able to observe behavioral evidence of such organization. Evaluate this data in light of the success or failure observed relevant to providing active treatment, and come to a judgment about the adequacy of the facility's staffing.

483.430(d)(2) "Direct care staff" are those personnel whose daily responsibility it is to manage, supervise and provide direct care to individuals in their residential living units. This staff could include professional staff (e.g., registered nurses, social workers) or other support staff, if their primary assigned daily shift function is to provide management, supervision and direct care of individuals' daily needs (e.g., bathing, dressing, feeding, toileting, recreation and reinforcement of active treatment objectives) in their living units. However, professional staff who simply work with individuals in a living unit on a periodic basis cannot be included. Also, supervisors of direct care staff can be counted only if they share in the actual work of the direct care of individuals. Supervisors whose principal assigned function is to supervise other staff cannot be included.

483.430(d)(3) The minimum ratios in this standard indicate the minimum number of direct-care staff that must be present and on duty, 24 hours a day, 365 days a year, for each discrete living unit. It does not include anyone functioning as direct care staff. For example, to calculate the minimum number of living unit staff that must be present and on duty in a discrete living unit serving 16 individuals with multiple disabilities: divide the number of individuals "16," by the number corresponding to the regulation "3.2," the result equals "5." Therefore, the facility must determine how many staff it must hire to ensure that at least 5 staff will be able to be present and on duty during the 24 hour period in which those individuals are present.

Using the living unit described above, "calculated over all shifts in a 24-hour period" means that there are present and on duty every day of the year: one direct care staff for each eight individuals on the first shift (1:8), one direct care staff for each eight individuals on the second shift (1:8), and one direct care staff for each 16 individuals on the third shift (1:16). Therefore, there are five (5) direct care staff present and on duty for each twenty-four hour day, for 16 individuals. The same calculations are made for the other ratios, whichever applies. Determine if absences of staff for breaks and meals results in a pattern of prolonged periods in which present and on-duty staff do not meet the ratios.

483.430(e)(2) View in-service training as a dynamic growth process. It is predicated on the view that all levels of staff can share competencies which enable the individual to benefit from the consistent, wide-spread application of the interventions required by the individual's particular needs.

In the final analysis, the adequacy of the in-service training program is measured in the demonstrated competencies of all levels of staff relevant to the individual's unique needs as well as in terms of the "affective" characteristics of the caregivers and the personal quality of their relationships with the individuals. Observe the staff's knowledge by observing the outcomes of good transdisciplinary staff development (i.e., in the principles of active treatment) in such recommended competencies as:

- Respect, dignity, and positive regard for individuals (e.g., how staff refers to individuals, refer to W150);
- Use of behavioral principles in training interactions between staff and individuals;
- Use of developmental programming principles and techniques, e.g., functional training techniques, task analysis, and effective data keeping procedures;
- Use of accurate procedures regarding abuse detection and prevention, restraints, medications, individual safety, emergencies, etc.;
- Use of adaptive mobility and augmentative communication devices and systems to help individuals achieve independence in basic self-help skills; and
- Use of positive behavior intervention programming.

483.430(e)(3) Observe staff interactions with individuals to see if the specific interventions, techniques and strategies to change inappropriate behavior outlined in the sampled individual's program plans are correctly implemented. In the absence of implementation, investigate further to determine if there was a justifiable reason for not implementing an intervention (e.g., the plan was revised, the specific situation demanded a different approach, the conditions for use of a particular technique were not present, etc.). When staff are unable to demonstrate how to correctly implement an intervention, or are unable to explain when and how the intervention is to be implemented, inadequate training is evident.

483.430(e)(4) Observe whether or not staff are competent and knowledgeable about the needs, programs and progress of each sampled individual with whom they are assigned to work. Staff should be able to demonstrate in practice the results of training for the individuals for whom they are responsible. See guidelines at §483.430(e)(3).

483.440(a)(1) "Continuous" is defined to mean the competent interaction of staff with individuals served at all times, whenever the need arises or opportunities present, in both formal and informal settings.

Verify that active treatment is identifiable during formal and informal interactions between staff and individuals served. The performance of the individual should reflect the success, if any, of interventions being applied or the need to alter the intervention procedures.

The ICF/MR ensures that each individual receives active treatment daily regardless of whether or not an outside resource(s) is used for programming (e.g., public school, day habilitation center, senior day services program, sheltered workshop, supported employment).

Those "active" interventions necessary to prevent or decelerate regression are considered to be part of the overall active treatment program. For example, if the application of a specific stimulation technique to the area of the mouth of an individual with severe physical and medical disabilities, decelerates the individual's rate of reliance on tube feedings, and helps the individual retain ability to take food by mouth, then this intervention is considered to be a component of active treatment for the individual.

Active treatment for elderly individuals may increasingly need to focus on interventions and activities which promote physical wellness and fitness, socialization and tasks that stress maintaining coordination skills and reducing the rate of loss of skills that accompanies the physical aspects of the aging process. Attending a senior center may be a justifiable part of an active treatment program for an elderly person.

Active treatment is the sum total of the major components of the active treatment process or loop which make up the requirements under this Condition of Participation (i.e., assessment, individual program planning, implementation, program documentation, program monitoring and change). It defines the primary nature of the services which must be provided by a facility (and received by its clients) in order to make it eligible under the law to be "certified" as an ICF/MR. Active treatment results in the positive outcomes identified by the Condition-level compliance principles. Surveyors must examine and evaluate all negative findings related to active treatment, and if determined to be significant, those findings should be cited at the salient tag numbers related to each of the components

of the active treatment process. When review of those deficiencies leads to the conclusion that active treatment is not being received, then this standard and the explicit statutory requirement for active treatment at §1905(d)(2) of the Social Security Act are not met. A determination of noncompliance with this requirement, therefore, must also result in a determination of noncompliance at the Condition of Participation level for Active Treatment Services and at §440.150(c), tag number W100.

Although the active treatment process must be identifiable in documentation, it must be observable in daily practice. Determine how the ICF/MR accomplishes (or fails to accomplish) an environment of competence that enables active treatment to occur.

483.440(a)(2) The regulations define the target population eligible for the ICF/MR benefit, by defining the services that are required for a facility to provide in order for it to qualify as an ICF/MR and receive Federal Financial Participation (FFP). At the front end, one of the "required services" is training in basic fundamental skills. The type of skills described in W242, by their very nature, target a population who have significant deficits in growth and development.

The presence of any group of individuals (court-ordered or not), could call into question the overall nature of the services provided by the ICF/MR. Individuals displaying some or all of the characteristics described in the Interpretive Guideline at §483.440(b)(1), do not "need active treatment services" or ICF/MR level of care, and are not appropriately placed. Agencies which provide residential services to persons with mental retardation do not qualify automatically for participation in Medicaid as ICFs/MR. Although the facility may be providing services to meet the needs of these types of individuals, the services provided by the facility do not meet the regulatory definition of "active treatment."

Furthermore, if the primary purpose of the facility is no longer to provide services to persons with mental retardation or related conditions who are in need of active treatment, then the facility does not meet the statutory requirement at §1905(d) of the Social Security Act and the regulatory definition of an ICF/MR, and therefore cannot be certified. A determination of noncompliance with this requirement, therefore, must result in a determination of noncompliance at the Condition of Participation level and at §440.150(c).

Conversely, if the overall facility meets the definition of an ICF/MR, the law does tolerate the presence of a few individuals for whom payment cannot be claimed. If an entity must serve both people who are generally independent and people who are in need of active treatment, then the entity may need to consider establishing a distinct part ICF/MR to serve those individuals who are in need of active treatment.

Negative findings about active treatment with regard to generally independent clients may be in conflict with level of care determinations made by State inspection of care (IOC) teams. Bring these negative active treatment findings to the attention of the IOC agency within the State for appropriate disposition of Medicaid ICF/MR certification. (See also W198, if the negative findings involve newly admitted individuals.)

There are some individuals who need the help of an ICF/MR to continue to function independently because they have learned to depend upon the programmatic structure it provides. The fact that they are not yet independent, even though they can be, makes it appropriate for them to receive active treatment services directed at achieving needed and possible independence.

483.440(b)(1) Individuals with the following characteristics do not necessarily require a continuous active treatment program in order to function or to achieve optimal independence. Review closely to what extent the ICF/MR serves individuals, who in the aggregate:

- Are independent without aggressive and consistent training;
- Are usually able to apply skills learned in training situations to other settings and environments;
- Are generally able to take care of most of their personal care needs, make known to others their basic needs and wants, and understand simple commands;
- Are capable of working at a competitive wage level without support, and to some extent, are able to engage appropriately in social interactions;
- Are engaged in productive work within the facility which is done at an acceptable level of independence (i.e., not done as part of a training program to teach the individual new skills);

- Are able usually, to conduct themselves appropriately when allowed to have time away from the facility's premises; and
- Do not require the range of professional services or interventions in order to make progress.

Based on the order of a court, the ICF/MR may be required to admit individuals who do not need active treatment. Although CMS has no jurisdiction to prevent the courts from ordering the placements of such individuals into institutions certified as ICFs/MR, the individuals, by definition, would be ineligible to be classified by Medicaid for the ICF/MR benefit. To the extent that the placement of these court-ordered individuals does not interfere with the ability of the ICF/MR to provide active treatment for its individuals, the facility's overall certification is not affected.

483.440(b)(2) No admission should be regarded as permanent. Readmission of an individual to the ICF/MR falls under the same requirements as initial admission.

In the absence of State regulations designating the person(s) authorized to approve admission (e.g., State or Regional Admissions Committees), the decision to admit an individual to the ICF/MR is based on the findings of an interdisciplinary team, including a QMRP.

Occasionally, emergency admissions of individuals may occur without benefit of a preliminary evaluation having been conducted prior to admission. For purposes of §483.440(b)(2) and consistent with §456.370(a), this requirement will be considered as "met" at such time that an evaluation is conducted which supports the need for an individual's placement in the ICF/MR. Refer to W210.

483.440(b)(3) The facility must decide, based on objective data, whether or not needs can be met. In some cases, the facility may be required to meet the "reasonable accommodation" requirement of the Americans with Disabilities Act. Failure to admit individuals merely because they have a particular medical condition may constitute a civil rights violation. All such instances should be reported to the Office of Civil Rights for investigation.

483.440(b)(4)(i) "Transfer" means the temporary movement of an individual between facilities, the temporary movement from the ICF/MR to a psychiatric or medical hospital for medical reasons, the permanent movement of an individual between living units of the same facility, or the permanent movement of an entire facility (including individuals served, staff and records) to a new location. "Discharge" means the permanent movement of an individual to another facility or setting which operates independently from the ICF/MR. Moving an individual for "good cause" means for any reason that is in the best interest of the individual.

483.440(b)(4)(ii) The family and the individual should be involved in any decision to move an individual, since this decision generally, should be part of a team process that includes the individual or guardian. If an individual has an advocate, the advocate should participate in the decision-making process.

483.440(b)(5)(ii) The discharge plan required by 42 CFR 456.380 and the post-discharge plan of care are the same. The regulations require only one discharge plan which meets the requirements.

483.440(c)(1) There is no "correct" number of individuals who comprise the interdisciplinary team. The regulation also does not specify the professional disciplines which make up the interdisciplinary team. Based upon outcomes, assess whether the expertise available to the team was appropriate to meet the needs of the individual.

The facility must make every effort to coordinate the IEP or program plan from an outside day program with the IPP process. This may result in a single IEP/IPP document, but there is no requirement for the IPP to be one document. The "collective" IPP must contain the information required under the regulations, and observation should confirm integration of the IPP across the various settings.

Negative answers to the following probes may indicate a lack of input from appropriate team members. Evaluate findings for systemic lack of input by a particular team member, lack of communication among team members, or lack of team effort and cooperation.

483.440(c)(2) Meetings should be scheduled and conducted to facilitate the participation of all members of the team, but especially the individual, unless he or she is clearly unable or unwilling, the individual's parents (except in the case of a competent adult who does not desire them to do so) or the individual's guardian or legal representative. The ICF/MR is expected to pursue aggressively the attendance of all relevant participants at the team meeting, (e.g., a conference call with a consultant during deliberations meets this requirement). Question routine "unscheduled" absences by individuals, guardians and

particular disciplines or consultants, and determine the impact on effectiveness and responsiveness of the IPP to meet the individual's needs.

483.440(c)(3) "Accurate" assessments refer to assessment data that are current, relevant and valid, and that the skills, abilities, and training needs identified by the assessment correspond to the individual's actual status. Additionally, for assessment data to be accurate, the cultural background and experience of the individual must be reflected in the choice, administration and interpretation of the evaluation(s) used. A few examples of appropriate adaptations might be: specialized equipment, use of an interpreter, use of manual communication, tests designed to measure performance in the presence of visual disability, etc.

The contents of assessments or the particular assessment which must be used are not specified. A nursing assessment, for example, would not need to reference all domains, or a psychiatric or psychological evaluation would not necessarily have to be based on a particular "tool." Similarly, the results of the comprehensive assessment are not required to be written into a narrative report(s). Verify that the tests, evaluations, etc. that comprise the comprehensive functional assessment, yield data that are accurate, reflect the current status and needs of the individual, and can serve as a functional basis for an IPP to be developed.

483.440(c)(3) The active treatment assessment process should be sensitive to the behaviors of individuals throughout their life span. For example, infants and toddlers are expected to engage in more play-related, exploratory activities, adolescents are expected to engage in activities of increasingly greater responsibility in preparation for adulthood, adults are expected to support themselves or at least be engaged in training or education activities toward that end, and elderly citizens, are expected to choose whichever form of productive activity meets their needs and interests (employment, handiwork, pursuit of leisure, etc.) for as long as they are able.

483.440(c)(3)(i) In the presence of a diagnoses (medical or otherwise), evaluation data must be available to support the determination.

483.440(c)(3)(ii-iii) The comprehensive functional assessment (CFA) may be a report synthesizing the results of salient assessments or a series of reports. If individual reports are utilized, the complete diagnostic work-up or problem list identified by others is not required to be repeated unless it is relevant to the particular assessment. Findings are recorded in terms that facilitate clear communication across disciplines. Diagnoses or imprecise terms and phrases (including, but not limited to, "grade level," "age level," "developmental level," "good attending skills," and "poor motor ability") in the absence of specific terms, are not acceptable.

Assessment of the behavior assumed to be maladaptive should include analyses of the potential causes, such as lack of exposure to positive models and teaching strategies, lack of ability to communicate needs and desires, lack of success experiences, a history of punishing experiences, presence of a physiological condition, or other environmental or social conditions which may elicit or sustain the behavior.

Specific "developmental" strengths and needs describe what the individual "can" and cannot do.

483.440(c)(3)(iv) In the presence of significant developmental deficits, it is not acceptable for the comprehensive evaluation to identify that a particular professional therapy or treatment is not needed. To meet the requirement for "need for service," the assessment must identify the course of specific interventions recommended to meet the individual's needs in lieu of direct professional therapy or treatment.

483.440(c)(3)(v) The facility must assess in developmental areas, but not by professional disciplines unless the functional assessment shows a need for a full professional evaluation. Findings relative to the domains required under §483.440(c)(3)(v) include, but are not limited to:

483.440(c)(3)(v) 1. Physical development and health. Physical development includes the individual's developmental history, results of the physical examination conducted by a licensed physician, physician assistant, or nurse practitioner, health assessment data (including a medication and immunization history), which may be compiled by a nurse, and skills normally associated with the monitoring and supervision of one's own health status, and administration and or scheduling of one's own medical treatments. When indicated by physical examination results, consultations by specialists are provided

or obtained. The need for advance directives or do not resuscitate (DNR) orders may be assessed on a case-by-case basis, as part of this area by individuals qualified to do so.

483.440(c)(3)(v) 2. Nutritional status. Nutritional status includes determination of appropriateness of diet, adequacy of total food intake, and the skills associated with eating, (including chewing, sucking and swallowing disorders), food service practices, and monitoring and supervision of one's own nutritional status.

483.440(c)(3)(v) 3. Sensorimotor development. Sensory development includes the development of perceptual skills that are involved in observing the environment and making sense of it. Motor development includes those behaviors that primarily involve: muscular, neuromuscular, or physical skills and varying degrees of physical dexterity. Because sensory and motor development are intimately related, and because activities in these areas are functionally inseparable, attention to these two aspects of bodily activity is often combined in the concept of sensorimotor development. Assessment data identify the extent to which corrective, orthotic, prosthetic, or support devices would impact on functional status.

483.440(c)(3)(v) 4. Affective (Emotional) development. Affective or emotional development includes the development of behaviors that relate to one's interests, attitudes, values, and emotional expressions.

483.440(c)(3)(v) 5. Speech and language (communication) development. Communication development refers to the development of both verbal and nonverbal and receptive and expressive communication skills. Assessment data identify the appropriate intervention strategy to be applied, and which, if any, augmentative or assistive devices will improve communication and functional status.

483.440(c)(3)(v) 6. Auditory functioning. Auditory functioning refers to the extent to which a person can hear and to the maximum use of residual hearing if a hearing loss exists and whether or not the individual will benefit from the use of amplification, including a hearing aid or a program of amplification. An individual's treatment might need to include being desensitized to tolerate the use of a hearing aid or assistive listening device to prevent the device from being rejected or destroyed. Assessment may include teaching techniques for conducting the assessment or the use of electrophysiologic techniques.

483.440(c)(3)(v) 7. Cognitive development. Cognitive development refers to the development of those processes by which information received by the senses is stored, recovered, and used. It includes the development of the processes and abilities involved in memory, reasoning and problem solving.

483.440(c)(3)(v) 8. Social Development. Social development refers to the formation of those self-help, recreation and leisure, and interpersonal skills that enable an individual to establish and maintain appropriate roles and fulfilling relationships with others.

483.440(c)(3)(v) 9. Adaptive behaviors or independent living skills. Adaptive behavior refers to the effectiveness or degree with which individuals meet the standards of personal independence and social responsibility expected of their age and cultural group. Independent living skills include, but are not limited to, such things as meal preparation, doing laundry, bed-making, and budgeting. Assessment may be performed by anyone trained to do so. Standardized tests are not required. Standardized adaptive behavior scales which identify all or predominantly all "developmental needs" are not sufficient enough to meet this requirement, but can serve as a basis for screening.

483.440(c)(3)(v) 10. Vocational (prevocational) development, "as applicable." Vocational development refers to work interests, work skills, work attitudes, work-related behaviors, and present and future employment options. The determination of whether or not a vocational assessment is "applicable" is typically based on age (adolescents or adults more than likely require this type of assessment).

483.440(c)(4) The presence of a comprehensive list of behaviorally stated needs is acceptable for this portion of the requirement. "Comprehensive" means that objectives are stated for the needs identified in each domain included in the comprehensive functional assessment.

Objectives may address services to be provided, learning/treatment needs, adaptive equipment, etc., §§483.440(c)(4)(i)-(v) regulate requirements for current IPP training objectives (as opposed to staff, service, or long term objectives).

Validate that the needs identified by the team are appropriate for the individual based upon review of the comprehensive functional assessment data, observations, and interviews with the individual and staff.

483.440(c)(4) To organize objectives into a planned sequence the ICF/MR must consider the outcomes it projects for the individual in the long term. For example, if the long term objective is for the individual to travel independently in the community, the planned sequence may involve training the individual to recognize traffic signs, cross a street safely, and to obtain help when needed if lost or an emergency arises. Interview staff to discover the purpose to be achieved upon completion of the objective. For example, does staff know why an individual is taught to stack rings?

483.440(c)(4)(i) "Single" behavioral outcome means that for each discrete behavior that the team intends the individual to learn a separate objective is assigned. (For example, "Mary will bake a cake and clean the oven" are two separate behaviors and, therefore, should be stated in two separate objectives.) Performance of a series of separate behaviors could constitute a single behavioral outcome when appropriate for the individual. For example, completing a hygiene routine of face washing, tooth-brushing and hair-combing is one behavioral outcome when the individual is able to perform each of those skills, but needs to learn to complete the entire routine each morning.

483.440(c)(4)(ii) The "projected date of completion" for an IPP objective is not the same as a "review" date. For each objective assigned priority, the team should assign a projected date (month and year) by which it believes the individual will have learned the new skill, based on all of the assessment data. This date triggers the team to evaluate continuously whether or not the individual's progress or learning curve is sufficient to warrant a revision to the training program. There is no requirement to identify an implementation date for each objective in the plan.

483.440(c)(4)(iii) "Behavioral" terms include only those behaviors which are "individual" rather than "staff" oriented and those that any person would agree can be seen or heard. Determine if all staff who work with the individual can define the exact same outcome on which to measure the individual's performance. "Measurable indices of performance" are the quantifiable criteria to use in determining successful achievement of the objective. Criteria include various measurements of intensity and duration. For example, "M. will walk ten feet, with her tripod walker, for 5 consecutive days."

483.440(c)(4)(iv) To organize an objective in an appropriate progression, the ICF/MR must consider the person's current functional abilities and project what steps, methods and strategies are likely to be effective in achieving the objective. Baseline data are one means of establishing an appropriate starting point for an objective. Objectives must be adapted based upon the person's functional abilities. For example, if the objective is to learn to put on shoes independently and the person does not have the manual dexterity to tie shoe laces, then the objective could include the use of slip-on shoes or shoes with velcro closures in order to facilitate the person learning this skill.

483.440(c)(4)(v) After all the training objectives have been established as required by W227, the IPP identifies those objectives which the team considers to be most important, or which need to be implemented before others can be accomplished, and then assigns them priority. Some examples of assigning priority include, but are not limited to, rank ordering (most important to least important), assignment of "priority" or "non-priority," etc.

483.440(c)(5) The written training program refers only to those objectives to which the team has assigned priority status for formal implementation.

483.440(c)(5)(iii) This may or may not be the same person who implements the program. There is no requirement to identify who implements the program.

483.440(c)(5)(iv) The facility must determine the type of data necessary to judge an individual's progress on an objective, and describe that data collection method in the written training program. The facility determines what data to collect, but the system chosen must yield accurate measurement of the criteria stated in the individual's IPP objectives. For example, if the criteria in the individual's IPP objective specified some behavior to be measured by "accuracy," or "successes out of opportunities," then it would not be acceptable for the prescribed data collection method to record "level of prompt."

Methods of data collection on IPP training programs should be based on the total (including direct care) facility's staff analysis and observations of an individual's behavior. Examples of a few data

collection systems include, but are not limited to, level of prompt, successful trials completed out of opportunities given, frequency counts, frequency sampling, etc. The facility should collect data with enough frequency and enough content that it can measure appropriately the individual's performance toward the targeted IPP objective.

483.440(c)(6)(iii) The receipt of training targeted toward amelioration of these most basic skill deficit areas is a critical component of the active treatment program needed by individuals who are eligible for the ICF/MR benefit, and therefore, is a required ICF/MR service. Some ADL skills overlap with each other (e.g., personal hygiene, oral hygiene, grooming and bathing). It is acceptable for the interdisciplinary team to set priorities within these overlapping skills. It must be clear, however, that the facility has organized its services to emphasize training in these areas. This will be seen not only in the IPP, but also in the competent interaction of staff with individuals, in both formal and informal settings. This basic skill training defines the nature of ICF/MR services. To the extent that individuals demonstrate that they increasingly do not need the types of services described in this requirement, and increasingly correspond to the characteristics of clients described at W197 such that the "overall" nature of the facility services would not be required to provide the type of emphasis described at W242, question the appropriateness of the individual's placement in an ICF/MR and/or the certification of the facility as an ICF/MR (see W197 and W198).

"Training" as used in this regulation means:

Aggressive implementation of a systematic program of formal and informal techniques (competent interactions);

Continuously targeted toward the individual achieving the measurable behavioral level of skill competency specified in IPP objectives;

Conducted in all applicable settings; and

Conducted by all personnel involved with the client.

"Developmental incapability" is a decision to be made by the interdisciplinary team based on its assessment of the individual's developmental strengths and needs. For example, there is ample evidence that even individuals with the most severe physical and mental disabilities can be toilet trained. Recognition is given to the fact that some individuals, however, have insufficient sensory and neuromuscular control ever to be totally independent in toileting skills. For most of this group, there are intermediate steps which can be achieved, including toilet scheduling, in which the individual is able to be trained to a schedule of elimination with needed assistance from staff. The intent of the toileting part of this regulation is met if there is evidence that the individual has been provided an aggressive, well organized, and well executed toilet training program in the past and that the team determines the individual's "developmental incapability."

483.440(c)(6)(iv) Mechanical devices used to support an individual's proper body position or alignment may be essential to prevent contractures and deformities, but the staff should be sensitive to the fact that mechanical supports may restrict movement and the individual should not be in the supports all the time or as a substitute for programs or therapy which may reduce the dependency on the support. Some supports allow movement and provide opportunity for more increased functioning. Some examples of devices used as mechanical supports include splints, wedges, bolsters, lap trays, etc.

Wheelchairs are not generally used to position or align the body and would not alone constitute a mechanical support. However, adaptations to wheelchairs which do position or align the body would have to be specified according to this requirement. Adaptations to a wheelchair which facilitate correct body alignment by inhibiting reflexive, involuntary motor activity are also mechanical supports.

483.440(c)(6)(v) With the exception of those individuals who are acutely ill (such as those who are hospitalized or incapacitated by a short term illness), all individuals should be out of bed and outside their bedroom area as long as possible each day, and in proper body alignment at all times. This is a necessity in order to prevent regression, contractures, and deformities and to provide sensory stimulation.

Question patterns of bed rest "orders" or "scheduled" bed rest as a routine part of an individual's program. A nap period of an hour, for example, is not "bed rest." However, if the ICF/MR, as a general pattern of scheduling, expects an individual to be one - two hours in bed in the morning, one - two hours in bed in the afternoon, and an 8:00 p.m. bedtime in the evening, for example, then the practice becomes

"bed rest," and the intent of the regulation will more than likely not be met. Question seriously large amounts of time during which a resident is confined to bed.

483.440(c)(6)(vi) Due to the basic underlying importance "choice" plays in the quality of one's life, the ICF/MR should maximize daily activities for its individuals in such a way that varying degrees of decision-making can be practiced as skills are acquired. Examples of some activities leading toward responsibility for one's own self-management include, but are not limited to, choosing housing or roommates, choosing clothing to purchase or wear, choosing what to eat, making and keeping appointments, and choosing from an array of appropriate activities. Interview staff to determine how attitudes and activities of the team and consultants facilitate or impede individual choice.

Choices can be made by all individuals. The type of choices the person makes may vary from very simple to more complex, depending upon individual abilities. Look at choices in the context of the individuals served by the facility.

483.440(d)(1) For an individual newly admitted to the ICF/MR, the time period between admission and the 30 day interdisciplinary team meeting should be primarily for purposes of assisting the individual to become adjusted and acclimated to his or her new living environment and completing the functional assessment. During this time period the facility should also be providing those services and activities determined during the pre-admission assessment as essential to the individual's daily functioning. In order to be able to produce the comprehensive assessment, the facility must evaluate the individual's status in as many naturally occurring, functional environments as possible.

It must be clear that the active treatment program received by the individual is internally consistent and not simply a series of disconnected formal intervention applications within certain scheduled intervals.

The criteria of what constitutes a "sufficient number and frequency of interventions" are based on the individual's assessment and the progress the individual makes toward achieving IPP objectives.

Whether "structure" must be imposed by staff or whether the individual can direct his or her own activities for a period of time (without direct staff observation) is based on the individual's ability to engage in constructive, age-appropriate, adaptive behavior (without engaging in maladaptive behavior to self or others). Be certain that an individual's time in the home or living unit is maximized toward the further development and refinement (including self-initiation) of appropriate skills, including, but not limited to, leisure and recreation.

For the active treatment process to be effective, the overall pattern of interaction between staff and individuals must be accountable to the comprehensive functional assessment and the IPP process. During the overall observation of individuals, you should be able to track that: the individual's comprehensive assessment identified the specific developmental need or strength justifying the activity, technique or interaction; in the case of a "need," the team projected a measurable objective or target to address it; and the technique, interaction, or activity which is observed, produced the desired target, produced a close approximation of the target, or was modified based on the individual's response.

483.440(d)(2) The active treatment schedule directs the intensity of the daily work of the staff and the individuals in implementation of the IPP in both informal and formal training activities. To the extent possible, the schedule provides a range of options, rather than a fixed regimen. Individuals should have opportunities to choose activities and to engage in them as independently and freely as possible. Staff routines and schedules should be supportive of this goal and result in the presence of reasonable choices by individuals. Investigate any pattern of staff action or scheduling which results routinely in all or the majority of individuals engaging in the same activity or routine at the same time. For example, everyone is out of bed, awake and dressed before staff on the third shift go home, or everyone goes to bed before the third shift arrives.

The active treatment schedule is not required to be posted.

While the facility should have the individual's schedule from the day program, there is no requirement that this schedule and the residential schedule be merged into one document.

483.440(d)(3) The facility is responsible for ensuring that during staff time spent with individuals, the staff member is able to provide needed interventions or reinforce acquired skills in accordance with the

IPP. This is one of the ways the ICF/MR implements continuous active treatment. "All" staff includes direct care staff.

The activities of the ICF/MR are coordinated with other habilitative and training activities in which the individual may participate outside of the ICF/MR, and vice versa.

483.440(e)(1) Data collection is evidence of individual performance and should not be taken constantly as evidence for surveyors that "treatments" occurred. "Data" are defined to be performance information collected and reported in numerical or quantifiable form on training objectives assigned priority in the IPP.

Data are those performance measurements recorded at the time the treatment, procedure, intervention or interaction occurs with the individual. They should be located in a place accessible to staff who conduct training.

483.440(e)(2) See also §483.410(c) Client Records.

483.440(f)(1)(i) - (iv) The interval within which IPP reviews are conducted is determined by the facility. However, the facility's review system must be sufficiently responsive to ensure that the IPP is reviewed whenever the conditions specified in §§483.440(f)(1)(i-iv) occur. Information relevant to IPP changes should be recorded as changes occur.

483.440(f)(2) For the "annual" review to meet the requirement, it must be completed by at least the 365th day after the last review. The ICF/MR may be required to conduct reviews at more frequent intervals by other, more stringent regulations (e.g., 90 day reviews required by §456.380(6)(c), State regulation, etc.). The facility's failure to comply with these other, more stringent regulations would NOT be cited under this requirement. Refer cases of suspected non-compliance to the authority having jurisdiction for the regulations in question.

483.440(f)(2) The review of the CFA applies to all evaluations conducted for an individual, unless otherwise specified in the regulation (e.g., annual physical examination). It is not required that each assessment be completely redone each year. It is required that at least annually the assessment(s) be updated when changes occur so as to accurately reflect the individual's current status. Systematic behaviorally stated data become part of the comprehensive functional evaluation of the individual.

483.440(f)(2) Look for IPPs that are unchanged from one year to the next, for priority skills and behaviors that are deferred or ignored for one reason or the other, and for informal, vague, and programmatically worthless statements in the review (such as "John did better this year - he wasn't as upset most of the time like he used to be"). If the ICF/MR has not been providing the individual with a systematic, behaviorally-oriented active treatment program during the year, the review will be incapable of making systematic, behaviorally-oriented statements about progress and change. If you find problem behaviors which do not decrease significantly, relatively frequent usage of restraint or other intrusive restrictive procedures, a "plateauing" (e.g., reaches partial desired performance, but does not improve over time and staff does not reassess) of skills development, or any other signs of "sameness" year after year, questions should be raised about the extent to which the ICF/MR is providing active treatment, the adequacy of IPPs, staff training, etc., particularly, if many individuals' annual reviews reveal these characteristics.

483.440(f)(3) Depending on its size, complexity and available resources, the ICF/MR may establish one multi-purpose committee to serve it for all advisory functions, or it may establish separate single-purpose committees. The facility's human rights committee may be shared among other agencies or the ICF/MR may utilize a human rights committee established by another governing body, e.g., a county or a statewide group, as long as all pertinent regulatory requirements are met.

The regulation does not specify the professional credentials of the "qualified persons who have either experience or training in contemporary practices to change inappropriate client behavior." There is no requirement that any specific disciplines, such as nurse, physician or pharmacist be members of the committee.

The intent of including "persons with no ownership or controlling interest" on the committee is to assure that, in addition to having no financial interest in the facility, at least one member is an impartial outsider in that he/she would not have an "interest" represented by any other of the required members or the facility itself. Staff and consultants employed by the facility or at another facility under the same governing body cannot fulfill this role.

Although occasional absences from committee meetings are understandable, patterns of absence by the required membership of the committee is not acceptable. At least a quorum of committee members must review, approve and monitor the programs which involve risk to client rights and protections. Depending upon the size of the facility and the number of individuals who need intrusive or restrictive techniques as a part of active treatment programs, more than one specially constituted committee may be needed to effectively meet the intent of the regulation. The facility is responsible to organize itself in a manner which permits the timely review of proposed programs.

483.440(f)(3)(i) Each individual program developed to decrease inappropriate behavior and which involves potential risk to rights and protections must be reviewed and approved by the committee prior to the program's implementation. Some examples of programs requiring review include, but are not limited to, programs incorporating usage of restraints, aversive conditioning, any medication used to modify behavior, contingent denial of any right or "earning" of a right as part of a behavior shaping strategy, and behavioral consequences involving issues of client dignity. There is no requirement for the committee to function as a peer review for technical or clinical adequacy of plans submitted for approval. The purpose is to assure that each individual's rights are protected through use of a group of outside individuals who are not invested in the maintenance of facility practices. The committee reviews the context by which each program is recommended, and then evaluates whether the program's level of intrusiveness is warranted. The committee should consider factors such as whether less intrusive methods have been attempted and whether the severity of behavior outweighs the risks of the proposed program.

The committee need not reapprove a program when revisions are made, as long as those revisions are in accordance with the approved plan. For example, if the physician changes the dosage of a medication in accordance with the drug treatment component of the active treatment plan to which the legally authorized person has given consent and which has already been approved by the committee, then there is no need for the committee or the legally authorized person to reapprove the plan. (See also W263.) Generally, this would also apply if the medication was changed to another within the same therapeutic class or family. Reapproval would be needed, however, if the reason for the change was the individual's strong untoward response to the original medication. Due to the differences in side effects and potential adverse response between drugs of a different class, reapproval would also be required if the new medication was from a different therapeutic class or family of drugs.

483.440(f)(3)(ii) Informed consent consists of permission by the legally responsible party after having been informed of the specific issue, treatment or procedure; the individual's specific status with regard to the issue, treatment or procedure; the attendant risks and benefits; alternative forms of treatment; the right to refuse treatment and the consequences of that refusal. Informed consent implies that the person who is to give consent is competent to evaluate the decision requiring consent.

For children up to the age of 18 the parent (natural guardian) or legally appointed guardian must give consent for him or her. At the age of 18, however, children become adults and are assumed to be competent unless otherwise determined by a court.

For individuals who are minors or who are clearly incompetent, but have no appointed legal guardian, informed consent for use of restrictive programs, practices or procedures must be obtained from the legal guardian, parent or someone or some agency designated by the State, in accordance with State law, to act as the representative of the individual's interests. Become familiar with the statutes of the State in which the ICF/MR is located to determine who or what mechanism is designated to give informed consent in such circumstances. Verify whether or not consent was obtained in accordance with law. Additionally, under these circumstances, the facility is required to identify those individuals, and expected to advocate for them by demonstrating continuing efforts to obtain timely adjudication of the individual's legal status.

The committee must ensure that the informed and voluntary consent of the individual, parent of a minor, legal guardian, or the person or organization designated by the State is obtained prior to each of the following circumstances: the involvement of the individual in research activities, or implementation of programs or practices that could abridge or involve risks to individual protections or rights.

Informed consent should be specific, separate ("blanket" consents are not allowed), and in writing. In case of unplanned events requiring immediate action, verbal consent may be obtained, however, it should be authenticated in writing as soon as reasonably possible.

483.440(f)(3)(iii) The function of the committee is not limited to the review, approval and monitoring of restrictive behavior management practices. Examples of individual rights issues that might be reviewed by the committee, in addition to behavior management, include, but are not limited to, research proposals involving individuals, abuse, neglect and mistreatment of individuals, allegations dealing with theft of an individual's personal property or funds, damage to an individual's goods or denial of other individual rights, individual grievances, visitation procedures, guardianship/advocacy issues, rights training programs, confidentiality issues, advance directives/DNR orders, etc.

483.450(a)(1) "Conduct between staff and clients" refers to the language, actions, discipline, rules, order, and other types of interactions exchanged between staff and individuals or imposed upon individuals by staff during an individual's daily experiences and which affect the quality of an individual's life.

While the regulation requires the development of written policies and procedures, the primary survey emphasis should be placed on the latter aspect of the regulation, i.e., implementation of those policies and procedures. Observations of interactions between staff and individuals should confirm that, to the maximum extent possible, individuals are provided with opportunities for growth and self-determination.

Individual's dignity is respected by staff and their behavior is within the context of any rules of conduct which have been established.

483.450(a)(1)(iii) "Client conduct" refers to any behavior, choice, action, or activity in which an individual may choose to engage alone or with others. The policy or "house rules" include(s), for example: allowable individual conduct (e.g., swearing or cursing, freedom of choice in religion, consumption of alcohol, smoking, sexual relations), reasonable locations where this conduct may or may not occur, and parameters for decision-making when an individual's choice conflicts with the group's choice (e.g., consensus, voting, taking turns, negotiation of differences).

"House rules" on the other hand, may not authorize staff or other individuals served to use a "laundry list" of discipline techniques to control an individual's inappropriate behavior, without regard to individualized need. If it is determined that staff must use a technique or intervention, then its use must be incorporated into an individual program plan that meets all applicable requirements specified in §483.450(b)-(e). Refer to W123.

483.450(b)(1) Use of items, procedures, or systems which are potentially stigmatizing to the individual or otherwise would represent a substantial departure from the behavior of comparable peers without disabilities, to control or prevent inappropriate behavior, falls under this requirement as well. (For example, requiring an individual to live in a locked residence and not providing the individual with a key, using a high crib with bedrails for an adult who gets out of bed at night and wanders or upsets other individuals, requiring an individual who strips off his clothes at inappropriate times to wear a jumpsuit turned backwards, or other odd usages of fashion.)

483.450(b)(1)(iii) You should see clear evidence to justify the use of a more restrictive technique. This requirement does not take away the team's discretion to use technology which represents reasonable standards of good practice, but it does require that there be evidence that justifies any decision not to use a positive or less restrictive technique first. Based on extraordinary circumstances resulting in an emergency, a facility may need to use a more restrictive method of intervention to protect the individual and others from harm than is consistent with the hierarchy it has established. This regulation does not prohibit a facility from using good judgment in this situation.

The surveyor should assess the use of emergency restrictive interventions to assure that the facility could not have reasonably anticipated the behavior, and verify that the team has reviewed the individual program plan for its adequate attention to the problem precipitating the emergency measure.

The facility is not required to justify discontinuing the use of a more restrictive technique before initiating a less restrictive technique, since the intent of the regulation is to use the most positive, least intrusive technique possible.

483.450(b)(5) Ongoing authorization for "programs" or "programmatic usages" of restrictive techniques, in the absence of evidence to justify such usage, constitutes a "standing" or "as needed program" to control inappropriate behavior, and are therefore not permitted.

483.450(c)(1) The use of time-out rooms is effective only if the individual does not like to be removed from an activity or from people. Look for patterns of frequent, lengthy time-out usage which often indicates that the environment is not reinforcing to the individual (i.e., the activities in and of themselves are not engaging, and/or the scheduled activities are potentially engaging yet the schedule is not implemented). If the individual who is in a time-out room engages in self-abuse, becomes incontinent or shows other signs of illness, staff should immediately discontinue the procedure and intervene.

Verify whether or not anyone standing or lying in any position, in any part of the time-out room can be seen.

Key locks, latch locks, and doors that open inward without an inside doorknob are not devices or mechanisms which require constant physical pressure from a staff member to keep a door shut, and, therefore, are not permitted by the regulations.

Pressure sensitive mechanisms must allow staff to enter the room at the moment the need arises.

483.450(c)(3) A door that opens inward can potentially be held closed, either intentionally or inadvertently, by the individual in the room, thereby denying staff immediate access to the room.

483.450(d)(1)(ii) "Emergency measure" is defined as use of the least restrictive procedures and for the briefest time necessary to control severely aggressive or destructive behaviors that place the individual or others in imminent danger when those behaviors reasonably could not have been anticipated, and only as they are necessary within the context of positive behavioral programming. Examine closely how frequently "emergency measures" are employed. Repeated applications of such measures within short intervals of time, without subsequent incorporation into a written active treatment program, as required by §483.440(c), raises serious questions about the individual's receipt of active treatment and the individual's right to be free from unnecessary restraint.

483.450(d)(2) The facility determines who may authorize use of emergency restraints.

483.450(d)(2)(i) The specific 12-hour authorization and re-authorization to use or extend usage of physical restraints does not apply to restraints used as an integral part of the individual program plan or to those that qualify as a health-related protection, as defined in the regulation.

483.450(d)(2)(ii) This refers to the reporting and retrospective authorization of the emergency measure when no prior use authorization could be obtained due to the seriousness and immediacy of the event.

483.450(d)(4) The frequency of monitoring will vary according to the type and design of the device and the psychological and physical well-being of the individual. For example, an individual in four-point restraints might require constant monitoring while someone in soft mittens may require less frequent monitoring. It is also true that for some individuals, constant visual supervision would serve to reinforce the inappropriate behavior and thereby reduce the clinical effectiveness of using the restraint. However, in no case may the 30 minute time limit be extended.

"As quickly as possible" means as soon as the individual is calm or no longer a danger to self or others.

483.450(D)(6) "Motion and exercise" includes an opportunity for liquid intake and toileting, if needed by the individual.

483.450(d)(6) In the presence of a restraint being worn during sleeping hours, surveyors must determine whether it is truly the nature of the individual's behavior which warrants this significant level of intrusion, or whether it in fact is a substitute for lower staffing during night time hours. The "motion and exercise" requirement applies to all restraints which restrict the range of motion of a limb or joint. Therefore, for example, if a helmet is applied to protect a head wound during sleeping hours, and the individual's range of motion in the neck has not been affected, then this requirement does not apply.

This requirement also does not apply to cases of medical restraints that are specifically ordered for the immobilization of bones and joints during the physical healing process involved with fractures, sprains, etc. (e.g., a broken bone immobilized by a cast or splint). However, if a physical restraint was applied to an extremity to prevent an individual from removing post-operative sutures, the restraint would be required to be released every two hours for a period of not less than 10 minutes.

Even though usage of mechanical supports, defined at §483.440(c)(6)(vi), may confine the movement of an individual, W306 does not apply to such usage.

483.450(e)(1) Section 483.450(e)(1) applies to all medications, including medications prescribed to control inappropriate behavior.

Overmedication occurs for many reasons. For medications prescribed to control maladaptive behavior, the most common reasons are: the individual's maladaptive behavior may not be responsive to drugs (e.g., if an individual has a non-drug-responsive form of self injury, then use of psychotropics may simply lead up to maximum drug doses without suppressing the behavior), drug therapy may be exacerbating the behavior (e.g., if a drug-induced side effect is mistaken for agitation, then the physician may mistakenly believe that the individual is undermedicated and increase the dose), presence of polypharmacy within the same drug class may result in a drug dose that would exceed the maximum daily limit for any one drug, the individual may be receiving too frequent injections which may result in significant drug accumulation over time, and the use of daily medication plus PRN or stat (one time) doses may result in greater than the recommended daily doses being prescribed (especially since intramuscular administration may be up to four times as potent). Overmedication may also occur as a result of the interaction between drugs, whether these drugs were prescribed for control of inappropriate behavior, or for a physical or medical condition.

Administration of PRN or stat doses for periods greater than a few weeks may indicate that the individual's daily dose is sub-therapeutic, the problem will not respond to the prescribed drug or the drug is exacerbating the problem. In such instances, the surveyor should verify whether or not the drug regimen has been reassessed.

483.450(e)(2) For drugs to be an effective therapeutic tool, they must be prescribed only to the extent that they are necessary for normal medical management of the individual.

In an emergency, a physician may authorize the use of a drug to control an inappropriate behavior. However, orders for continued emergency drug usage cannot continue until the team gives approval and the drug's usage has been included in the plan. Psychotropic drug therapy may not be used outside of an active treatment program targeted to eliminate the specific behaviors which are thought to be drug responsive.

Although only a physician can prescribe medication, the decision to use medication for control of behavior must be based on input from other team members. W329 and W330 address the physician's participation in the person's individual program plan as part of the interdisciplinary team. The interdisciplinary team involvement in this decision-making process is inextricably linked to an obligation to develop and implement effective non-drug interventions that address the targeted behavior. This obligation requires constant monitoring of the non-drug interventions to determine its efficacy, and to determine whether the judicious use of drug therapy may at times be appropriate.

Individuals who receive psychoactive drugs for behaviors associated with a diagnosed mental disorder, require an active treatment program designed to reduce, ameliorate, compensate or eliminate the psychiatric symptoms. The psychiatric diagnosis must be based on a comprehensive psychiatric evaluation in which the evidence supports the conclusion of a psychiatric diagnosis as required by W212. The focus of active treatment, in this instance, would be on the mental health of the individual.

Drugs from categories other than the principle drug classes that have behavior controlling properties (e.g., antipsychotic, antianxiety, and antidepressants) are sometimes used to control inappropriate behavior. Examples include the use of propranolol (Inderal), which is classified as an antihypertensive and antianginal drug, for self-injurious behavior, and carbamazepine (Tegretol), which is an anticonvulsant, for aggression. The regulation was written to encompass any drug when its use is for purposes of controlling inappropriate behavior. This requirement does not apply to drugs, such as propranolol, when they are used to treat medical conditions. However, if their use (e.g. dose, duration, etc.) indicates that they are being used to control inappropriate behavior, the interdisciplinary team must be involved in the decision to use them, and they must be incorporated into the active treatment program plan.

In order for an individual to receive dental or medical treatment, the physician may need to prescribe a sedative as part of the normal medical management for that individual. This situation, occurring rarely,

would not require an active treatment program targeted toward elimination of the behavior. The decision to use sedation for medical appointments must be made on an individual basis, and with input from the interdisciplinary team. When the individual is regularly exhibiting behaviors that are interfering with the ability to receive routine medical and dental treatment, then use of the sedative is required to be incorporated into a specific active treatment program.

483.450(e)(4)(i) Unless the physician regularly evaluates the individual and meets with those who work most closely with the individual to review treatment progress, it will be difficult to assess whether the individual responded positively to the treatment.

Since each drug has a specific profile of side effects, potential reactions should be looked for by direct examination and questioning. It is important that everyone who works with the individual be aware of the conclusion drawn from these drug reviews.

In addition to monitoring at regular intervals, the individual should be assessed at the time the medication is changed, as well. Individuals receiving long term antipsychotic drug therapy should be examined regularly for motor restlessness, such as Parkinsonian symptoms or tardive dyskinesia.

483.450(e)(4)(ii) Planned drug withdrawals must be carefully instituted. For example, usage of antipsychotic drug therapy may not only cause tardive dyskinesia but may mask the clinical manifestations of tardive dyskinesia during treatment. This requirement applies only to drugs prescribed to modify behavior; therefore, if Thorazine is prescribed to decrease aggressive behavior, the annual drug withdrawal requirement applies. However, if Phenobarbital is prescribed to prevent seizures, or Insulin is prescribed to control diabetes, then this requirement does not apply.

In determining whether there is clinical contraindication to the annual drug withdrawal, the physician and interdisciplinary team should consider the individual's clinical history, diagnostic/behavioral status, previous reduction/discontinuation attempts, and current regimen effectiveness. The individual's current clinical status or the nature of a psychiatric illness may indicate that gradual withdrawal of the drug is unwise at this time. It is not acceptable, however, to preclude a gradual drug withdrawal for a person, including a person with a psychiatric impairment, merely because of the possibility that his or her behavior may be exacerbated. Data which shows a direct relationship between past attempts at withdrawal, and an increase in the targeted behavior or symptoms should be available to support the decision not to attempt a gradual withdrawal. This data should reflect the programmatic interventions utilized to respond to the behavior prior to determining that gradual withdrawal is contraindicated. The team should periodically re-evaluate the decision not to attempt a gradual withdrawal based on the individual's progress or other changes in clinical status.

483.460(a)(2) The use of a medical care plan is intended only for those who are so ill or so at medical risk that 24-hour licensed nursing care is essential. A medical care plan need not be developed unless the individual requires licensed nursing care around the clock. Thus, individuals with chronic, but stable health problems such as controlled epilepsy, diabetes, etc. do not require a medical care plan.

It is not required that an individual have a health deficit and/or a medical care plan in order to receive ICF/MR services. The regulation is sufficiently flexible that the entire range of individuals, from those in good physical health to those who are very medically fragile, may be served.

A medical care plan may be temporary, in that it may be established to address acute health problems and then discontinued when those problems are resolved.

483.460(a)(3) Medical services are provided as necessary to maintain an optimum level of health for each individual and to prevent disability. Medical services include evaluation, diagnosis and treatment, as needed, by individuals.

Medical services, including sources for laboratory, radiology, and other medical and remedial services available to the individual must be provided if not provided in-house. There must be a written agreement that specifies the responsibilities of the facility and outside provider. (See §483.410(a).)

483.460(a)(3)(i) This standard is intended to be an annual screening so that individuals who need further indepth examination can be identified. If hearing screens are conducted annually by speech-language pathologists or audiologists the physical exam does not need to repeat this information.

Information relevant to knowing if the individual can see or hear, and how well, is tantamount for designing an appropriate active treatment strategy responsive to need.

If an individual's vision or hearing can only be assessed through examinations conducted by specialists (e.g., comprehensive ophthalmological examinations and evoked response audiometry (ERA)), these tests need not be conducted yearly, but rather upon specialist's recommendations. In such situations determine if yearly, the team evaluates the individual's vision and hearing response behaviors for change, and makes referrals, if necessary.

483.460(a)(3)(ii) These immunization guides can be obtained from the American Academy of Pediatrics, Elk Grove, IL, telephone: (708) 228-5005, or from the Centers for Disease Control, Division of Immunization Center for Preventive Services, telephone: (404) 639-8215.

483.460(a)(3)(iii) This does not preclude screening tests available to the general public such as tests for urine sugar.

483.460(a)(3)(iv) These recommendations can be obtained from the American Academy of Pediatrics, Elk Grove Village, IL, telephone: (708) 228-5005, or the American College of Chest Physicians, Northbrook, IL, telephone: (708) 498-1400.

The American College of Chest Physicians and the American Academy of Pediatrics endorse the recommendations of the Center for Disease Control and Prevention, Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities, (most recent edition). The facility should have in place a system appropriate to its population for the identification, reporting, investigation, and control of TB in order to prevent its transmission within the facility. This system should include policies and procedures for screening new employees, new clients, and other people who interact on a consistent basis with individuals residing in the facility; for reporting positive TB test results to the appropriate State authorities; for the investigative procedures that would be put in place should an individual or staff person test positive for TB; and for the evaluation of the effectiveness of the entire system. There should be arrangements with outside service providers, when needed, to ensure that any individual who tests positive for TB will receive appropriate medical treatment. Also, the system should address the issue of any staff member who tests positive for TB. The Occupational Health and Safety Administration (OSHA) requirements regarding exposure control plans and activities may also apply.

483.460(b)(1) During the admission process, which extends from the time the individual is admitted to the time the initial IPP is completed, a physician is required to ensure that an assessment of the individual's medical status is thoroughly considered and addressed by the team as it develops the IPP. The physician's input may be by means of written reports, evaluations, and recommendations.

42 CFR 456.380 requires that a physician must establish a written plan of care for each applicant or recipient before admission to an ICF. This is done in conjunction with the interdisciplinary team. (See §483.440(c).) The written plan of care required by §456.380 and the IPP required by §483.440(c) may be the same document, which can fulfill both requirements.

483.460(b)(2) The need for physician participation is determined by the medical needs of the individual. How the participation (whether through written report, telephone consultation, attendance at the meeting, etc.) is to be accomplished is left to the discretion of the facility.

483.460(c)(1) Unless the individual is on a medical care plan, this participation may be through a written report.

483.460(c)(2) See also W416.

483.460(c)(3)(i) A direct physical examination means a visual review of the body as well as examination of body systems that might be necessary. This includes observing for any clues (including visual, tactile, nonverbal gestures, grimaces, etc.) to detect if there is a potential for needed follow-up and monitoring. A paper review of the individual's medical record and health statistics is not a direct physical examination.

If an individual is on a medical care plan, it is not necessary to perform the quarterly direct nursing physical examination.

483.460(c)(3)(ii) The term "licensed nurse" for purposes of this requirement means a registered nurse, a licensed practical nurse or a licensed vocational nurse. A facility is allowed to use a physician, in place of a licensed nurse, although this is certainly not required.

483.460(c)(3)(iii) "On a quarterly basis" means that the examination must be performed within the month in which the end of the quarter falls. If during the course of a year, there were three examinations

conducted by a licensed nurse and one annual examination performed by a physician, each of which is performed within the month in which the end of the quarter or year falls, the intent of this requirement is met.

483.460(c)(3)(iv) The record includes the date of the exam.

483.460(c)(3)(v) Some physical findings discovered by the nurse while conducting the physical exam will not necessarily result in referral to the physician. This practice is acceptable if the nurse is acting within the scope of the Nurse Practice Act of the State in which he or she is licensed.

483.460(c)(4) This includes nursing care for individuals without a medical care plan.

483.460(c)(5)(i) Facility staff need to know what the limits of their responsibilities are with medically involved individuals, and how to teach individuals on a continuing basis how to take care of minor accidents until further care can be provided.

483.460(d)(2) In evaluating whether or not there is sufficient licensed nursing staff, evaluate the need for licensed nursing care represented by the health characteristics of the individuals served (as described in physical exam results, IPPs, and medical care plans) in relation to the competency and qualifications represented by the staff who provide care (through the onsite survey). Make a judgment about the sufficiency of nursing staff to care for this particular population.

483.460(f)(1) A "month" is defined as the interval between the date of admission and close of business of the corresponding day in the following month.

483.460(f)(2) The requirement applies to all individuals (including those without teeth), and more frequently as dictated by the individual's needs.

483.460(g) Comprehensive dental treatment might include, but is not limited to:

1. Periodic examination and diagnosis, including radiographs, when indicated and detection of all manifestations of systemic disease;
2. Elimination of infection or life hazardous oral conditions, oral cancer, or cellulitis;
3. Treatment of injuries;
4. Restoration of decayed or fractured teeth;
5. Retention or recovery of space between teeth in children, when indicated;
6. Replacement of missing permanent teeth, when indicated; and
7. Appropriate pain control procedures for optimal care of the patient.

483.460(h)(1) A "dental summary" means a brief written report of each visit to the dentist and includes any care instructions to be followed-up by facility staff as a result of treatment.

483.460(i) Emphasis is placed on the provision of the service, and not on its method of delivery. Whether the facility utilizes the unit dose, individual prescription or a combination of these systems, or whether the facility has its own pharmacy or provides the service through arrangement with a community pharmacy, the emphasis is on the accuracy of the drug distribution system and the effectiveness of the drug therapy.

483.460(j)(1) The pharmacist should review on a more frequent basis the drug regimen of individuals whose response indicates problems with drug therapy. Refer to the "Indicators for Surveyor Assessment of the Performance of Drug Regimen Reviews" as stated in Appendix N to the State Operations Manual (Pharmaceutical Service Requirements in Long Term Care Facilities) to evaluate the drug regimen review done by the pharmacist.

483.460(j)(2) The physician and interdisciplinary team must consider the report of the pharmacist and determine whether to accept or reject the recommendations in the report. The pharmacist is not required to repeatedly report the same minor irregularities which have already been considered by the physician and the interdisciplinary team, but were rejected based upon the individual's specific condition.

483.460(j)(4) Each dose of medication, whether self-administered or not, shall be properly recorded in the individual's record. The intent of this requirement is to maintain a record of drugs administered.

483.460(j)(5) This regulation does not exclude the pharmacist from the evaluation process, but the pharmacist can best determine how to expend his/her efforts most productively in service to individuals at the facility.

483.460(k)(2) A medication "error" is a discrepancy between what the physician has ordered, and what you observe during the drug pass observation. The regulation does not allow for any medication errors.

"Self administered" means administration of medications by the individual, independent of a staff person obtaining, selecting, and preparing the medications for the individual. This includes all usage forms (oral, injections and suppositories).

The individual should be trained until he/she can perform this function without error.

483.460(k)(3) "Unlicensed personnel" of the facility does not refer to the situation of individuals administering their own medication. Unlicensed personnel administer only those forms of medication which State law permits.

483.460(k)(6) Do not expect individuals served to be more knowledgeable than members of the general public in order to self-administer medication. There is no requirement for the individual to be able to state both the generic and brand names of the medication being taken, nor is it expected that the individual be able to list all potential side effects of the medication. The test of competency to self-administer is whether the individual can take the correct medication, in the correct dosage, at the correct time.

483.460(k)(7) When individuals go out of a facility for home visits, or to attend workshops or school, drugs they are taking must be packaged and labeled in accordance with State law by a responsible person approved to administer medications. Be aware whether or not there are applicable State laws which may allow packaging by someone other than the pharmacist.

The test of adequacy of packaging and labeling is whether or not other persons administering medications are able to identify the individual's medication, method of administration, contraindications, if appropriate, and administration schedule.

483.460(l)(2) "Authorized persons" must be restricted to those who administer the drugs and nursing supervisors (if any). No other personnel should have access to these keys.

483.460(l)(2) Drugs that are self-administered do not have to be double locked. The purpose for the double locking is to limit access to scheduled drugs. Since the individual is generally the only one who has access to his/her drug supply (with perhaps the exception of a facility's Director of Nursing Services, who may have access to all of the facility's drug supplies), there is no need to further limit access.

483.460(l)(3) The facility may also use the medication administration record for purposes of documenting receipt and disposition of controlled drugs. By recording the amount received, a record of the receipt and disposition, can be realized.

483.460(l)(4) Reconciliation of receipt and disposition of controlled drugs need not be done on each shift. If periodic (e.g., weekly or monthly) reconciliations indicate losses, more frequent reconciliation (daily or by shift) may need to be performed to identify and stop losses.

483.460(m)(3) If a physician discontinues a drug for a particular individual, that particular drug supply should be removed from its usual storage area. This precludes that drug from being administered to the individual in error.

483.460(n) A "laboratory service or test" is defined as any examination or analysis of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.

483.460(n)(2) A facility performing any laboratory service or test must have applied to CMS, and received either a certificate of waiver or a certificate of registration. An application for a certificate of waiver may be made if the facility performs only those tests on the waiver list. Those tests are:

- Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:
  - Bilirubin;
  - Glucose;
  - Hemoglobin;
  - Ketone;
  - Leukocytes;
  - Nitrite;
  - pH;
  - Protein;
  - Specific gravity; and
  - Urobilinogen.
- Fecal Occult blood;

- Ovulation tests - visual color comparison tests for human luteinizing hormone;
- Urine pregnancy tests - visual color comparison tests;
- Erythrocyte sedimentation rate (non-automated);
- Hemoglobin - copper sulfate (non-automated);
- Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;
- Spun microhematocrit; and
- Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

If the facility performs tests, other than those on the waiver list, a certificate of registration is required. These certificates are required regardless of the frequency with which the laboratory services or tests are conducted. When no tests are performed, a certificate is not needed. Facilities only collecting specimens and not performing testing do not need a certificate.

A not-for-profit or a State or local government organization may have one certificate covering all the facilities it operates (i.e., all the separately certified residences which fall under its governing body), if no more than a total of 15 types of waivered or moderately complex laboratory tests are used.

483.470(a)(1) Individuals should live in the least restrictive grouping in keeping with their level of functioning. Prime consideration in the grouping of individuals is made according to social and intellectual development, friendship patterns, and commonality of interests.

The use of "grossly different ages" is intended to ensure, for example, that very young children are not inappropriately housed together with much older individuals. Extreme differences may in some instances actually impede appropriate training and may pose a threat to the safety of younger, more vulnerable individuals.

483.470(a)(2) The surveyor should determine if the individuals' skill level, rather than the individuals' physical, sensory or medical disability, justifies the housing pattern.

483.470(b)(l)(v) An "initially certified" facility includes any facility or portion thereof that is certified for participation in Medicaid after a period of non-participation (e.g., if its certification has been terminated or voluntarily withdrawn).

Each of the three criteria specified below must exist in order for a facility to qualify as undergoing "major renovations or conversions":

- Individuals must vacate the building during the period of renovation or construction;
- No Medicaid billing takes place during the period of renovation or construction; and
- A resurvey of the building is required before individuals may return to live in the building.

Facilities with buildings which were undergoing major renovations and were not reoccupied prior to October 3, 1988, are expected to meet the floor to ceiling wall requirements. This also applies to those facilities with buildings that had plans for renovation approved prior to October 3. There is no provision in the regulation for granting waivers of this requirement.

In a facility certified prior to October 3, 1988, if the conditions which define "major renovation or conversion" are avoided during installation of walls to divide "open bay sleeping areas," it is allowable for the walls not to extend from floor to ceiling.

483.470(b)(2) The intent of the regulation is to prohibit the housing of individuals in basements that are entirely below grade. Individuals may be housed on the lower level of housing (e.g., a bi-level house), provided the window height requirements are met.

483.470(b)(3) The only acceptable reason for individuals to be housed in bedrooms serving more than four people is because the individual is in very fragile health and needs extensive life support services, such as posturing for clearing the airways, or monitoring for uncontrolled seizures. If more than four people are housed together in the same room, the number should remain small, and each individual placed in the grouping must have a high level of medical monitoring need.

Most extensive life support services, by their very nature are able to be provided by licensed personnel alone, or only under the direct visual supervision of licensed personnel. The presence of a medical care plan is not required because all such life threatening possibilities are difficult to predict. However, the greatest majority of individuals who might qualify for this variance will be on a medical care plan.

See §2140 for the documentation required for a medical variance.

483.470(b)(4)(iii) A single bedspread may be used year round, if it is appropriate for all seasons.

483.470(b)(4)(iv) "Furniture" is to be distinguished from "furnishings" (such as plants, pictures, etc.), which though encouraged as being an appropriate and desirable aspect of a normalized living environment, cannot serve as a substitute for appropriate individual furniture that can be used by the individual alone.

The facility is permitted either to provide the individual with an individualized closet or with a designated area in a shared closet. The use of central clothing bins in a facility clothing room, in the absence of required individual closet space in the bedroom, is not an acceptable practice.

483.470(c)(2) For a storage space to be determined as "suitable," it must assure the safekeeping of the individual's possessions among other things being stored.

Use of the term "accessible" does not require unrestricted access in situations where this is precluded by an active treatment program designed to eliminate inappropriate behavior, or in which the individual's interdisciplinary team determines that unrestricted access would endanger the individual or others. The surveyor should determine whether or not there is a pattern of restricted access not because of the behavior of the individual, but because of the behavior of others with whom the individual lives. This could also raise the question of inappropriate grouping of individuals due to different functioning abilities.

483.470(d)(1) "Bathing facilities appropriate in . . . design" must include provisions for a mirror and sink/tooth-brushing area.

483.470(d)(2) Gang showers and open toilets are inappropriate to the quality of life, privacy, and personal dignity of the individuals served in the facility.

Individual privacy does not preclude the assistance provided by facility staff, when necessitated by the individual's condition.

483.470(d)(3) Individuals must be under the direct supervision of staff while being trained to operate hot water temperature controls.

483.470(e)(1)(i) Since a door serves primarily to provide egress rather than to perform the ventilation and aesthetic functions of an outside window, it may not be used for room ventilation in place of a window.

483.470(e)(2)(i) A "normal comfort range" in most instances is defined as not going below a temperature of 68 degrees Fahrenheit or exceeding a temperature of 81 degrees Fahrenheit for facilities in most geographic areas of the country (primarily at the Northernmost latitudes) where that temperature is exceeded only during rare, brief episodes of unseasonably hot weather.

483.470(f)(1) "Slip-resistant" is to be distinguished from "slip-free." There is a presumption made that floors will ordinarily be dry, and when wet, appropriate precautions will be taken.

483.470(g)(2) The term "furnish" means that the facility is responsible for obtaining or purchasing these items and is responsible for making any necessary arrangements to enable the individual actually to receive them. However, if an item is available free of charge the facility would satisfy the requirement simply by making the necessary arrangements for the individual to receive them. Individuals' personal funds should not be used for these items since this is a covered service under the ICF/MR benefit.

The term "maintain in good repair" means that the facility is responsible for ensuring that these items are kept in good working order.

483.470(g)(3) A bedroom hamper can be an acceptable dirty linen storage "area" if kept odor free, consistent with the infection control requirements at §483.470(l).

483.470(i)(2)(i) All facilities, regardless of their size require actual evacuation. "Actually evacuate," as used in this standard, applies to all individuals. The drills are conducted not only to rehearse the individuals and staff for fire (see §483.470(i)(2)(v)), but for other disasters such as hurricanes, tornadoes, floods, etc. Such disasters would require the entire occupancy to be evacuated, and, therefore, the actual evacuation must be practiced, as required.

483.470(i)(3) Since live-in staff and their relief personnel are generally the same staff who work with the individuals on a round-the-clock basis, they must conduct a minimum of 4 drills a year, each of which must occur at different times within the day (24-hour period) (i.e., morning, afternoon, and night (sleep

time)), and generally when individuals are at different locations within the house. If the facility has large numbers of relief personnel, more drills may be needed to meet the intent of this requirement.

483.470(j) These standards are covered by the Life Safety Code (LSC) survey. The facility must meet the appropriate chapter of the Life Safety Code, 1985 edition.

483.470(l)(1) An "active program" includes such observable practices as: the direct care staff routinely washing their hands or changing gloves after working with an individual who has an infectious disease or working with each individual during mealtimes; the use of aseptic technique, when appropriate; an ongoing program of communicable disease control and investigation of infections; and an active training program that ensures the individuals served receive adequate prevention of transmission information and skills, according to needs.

Procedures must be followed to prevent cross-contamination, including hand washing or changing gloves at mealtimes, after providing personal care to more than one individual, or when performing other tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for hand washing must exist and be available to staff. Toothbrushes and other personal hygiene items must be stored and used in such a manner to prevent cross-contamination.

Both the OSHA and the CDC have specific requirements regarding human immunodeficiency virus (HIV), TB, and hepatitis precautions. These requirements should be incorporated into the facility's practices when relevant to the individuals residing in the facility. Concerns about OSHA violations should be referred to OSHA.

483.470(l)(3) This regulation does not require the recording or tracking of specific groups of symptoms, if a record of incidents and corrective actions related to infections is maintained. This regulation does not address the form or location of this record or direct that it be separate from the documentation required by CFR 483.410(c)(1).

483.470(l)(4) The facility should use the Recommendations for Prevention of Communicable Disease Transmission in Health Care Settings (such as preventing HIV) issued by the Centers for Disease Control, Atlanta, Georgia 30333, as well as OSHA guidelines in these areas.

A facility participating in the Medicaid program may not discriminate against individuals who are HIV-infected so long as these individuals do not (on a case-by-case basis) pose a substantial health and safety risk to others, or pose a performance problem, and are "otherwise qualified."

483.480(a)(1) "Modified and specially-prescribed" diets are defined as diets that are altered in any way to enable the individual to eat (for example, food that is chopped, pureed, etc.) or diets that are intended to correct or prevent a nutritional deficiency or health problem.

483.480(a)(5) Since the main purpose of food is to support and maintain the health of an individual, it is important that the use of food as a behavior reinforcing device (primary reinforcement) not be abused. Foods are selected to provide essential nutrients. When these foods are routinely removed and denied during the meals, without comparable replacements, the individual is at risk of consuming a diet that is not adequate to meet nutritional needs, and in violation of §483.420(d)(1)(ii), which does not allow food contributing to a nutritionally adequate diet to be used as "punishment." Likewise, the addition of high caloric reinforcers must be coordinated into the total daily diet intake.

483.480(a)(6) For suggested guidelines write to:

1. U.S. Department of Agriculture
   Human Nutrition Information Services
   Washington, D.C. 20250
2. The National Dairy Council
   Rosemont, Illinois 60028-42334

483.480(b)(l)(i) A "substantial evening meal" is defined as offering of three or more menu items at one time, one of which includes a high-quality protein such as meat, fish, eggs, or cheese. The meal represents no less than 20 percent of the day's total nutritional requirements.

483.480(b)(1)(i) A "nourishing snack" is an offering of items, single or in combination, from the daily food guide.

483.480(b)(2)(iii) The term "form," as used in this requirement, refers to food consistency (i.e., pureed, chopped, ground, etc.).

483.480(b)(3) This standard does not apply to food served in family-style dishes, unless the length of time the food is on the table or other considerations (such as individuals fingering or drooling in the food) compromise the safety and nutritive value for reuse of the food.

483.480(d)(1) For purposes of this standard, "dining areas" mean discrete eating areas located outside of bedrooms, established, furnished, and equipped for the purpose of eating meals. For purposes of this standard, provision of meals in dining areas outside of the home (such as restaurants, food vendors, etc.) may also be included.

To the maximum extent possible, individuals should be afforded the opportunity to eat routine meals (like breakfast and dinner) in dining areas that approximate those afforded to their peers without disabilities (e.g., dining areas that are a part of the living unit, rather than eating all meals in buildings exclusively established for eating purposes).

483.480(d)(2) The intent of this regulation is to afford individuals the opportunity to participate in the social experience of dining with their companions. Observe whether or not facility staff model and reinforce appropriate communication and social behavior between dining companions seated at the same table.

483.480(d)(3) Single service eating devices must be discarded after each use.

Determine if the following types of adaptive devices are made available when needed:

- Double suction cups or other devices to anchor dishes on a table or tray for individuals with major coordination problems;
- Rocking one-handed knife-fork or knife-spoon for an individual with the use of only one hand;
- Built up or extended handles or silverware for those with problems of grasp or range of motion;
- Plate guards or plates with raised rims to provide a surface against which the individual with a physical disability can push food onto a fork or a spoon;
- Flexible drinking straws;
- Spoon bent to a 90 degree angle at the bowl or a swivel spoon to assist an individual without normal wrist motions.
- Any other adaptive device deemed by the team as needed by the individual to eat more independently.

483.480(d)(4) To the maximum extent possible, staff should model appropriate mealtime behavior and conversation by sitting at the table with individuals, and, when possible, eating meals with individuals.

Mastery of the social skills involved in eating in a variety of dining areas and settings is another step to the individual's independence beyond the health aspects of nutrition and the basic skills involved in eating independently. Achieving independence will further help the individual to live in less restrictive environments. Determine to what extent individuals are exposed to out-of-the-home dining environments available to the general public (e.g., restaurants, fast-food establishments, picnics, parties, cafeterias, etc.).

Depending on the needs of the individuals and the available space it may be more effective for meals to be conducted in two different seatings or groupings.

483.480(d)(5) This applies to all individuals, including those fed by nasogastric tube or gastrostomy tube. The IPP should identify the most appropriate position for the individual to be positioned during mealtime, in relation to the placement of the food contents.

[**ARC 0906C**, IAB 8/7/13, effective 11/6/13]