Chapter HSS 105

PROVIDER CERTIFICATION

HSS 105.001 Statement of intent and general conditions. This chapter sets forth the terms and conditions under which persons may be certified and participate as providers in the medical assistance program. (The former Wis. Adm. Code chapter PW-MA 24 is repealed and recreated in this chapter and in chapter HSS 106 for purposes of certification, decertification, suspension and general conduct of providers).

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.01 Certification. A person may be certified as a provider of specified services for a reasonable period of time as specified by the department if:

(1) The person affirms in writing that, with respect to each service for which certification is sought, the person and each person employed by the person for the purpose of providing the service holds all licenses or similar entitlements, as specified in this rule and required by federal or state law, rule, or regulation for the provision of the service.

(2) The person affirms in writing that neither it, nor any person in whom it has a control interest, nor any person having a controlling interest in it has, during the preceding 5 years, been convicted of a crime related to, or been terminated from, federal or state assisted medical programs.

(3) The person furnishes to the department in writing the names and addresses of all vendors of drugs, medical supplies or transportation, or providers in which it has a control interest or ownership and all persons who have a controlling interest in it.

(4) The person has executed a provider agreement with the department.

(5) The following providers are required to be certified:

(a) *Institutional/group providers.* Institutional providers are provider groups or organizations which meet the conditions listed in this subsection. Institutional providers shall be:

1. Entities composed of more than one individual performing services; and

2. Licensed or approved by the appropriate state agency or certified for medicare participation, or both; and

3. Reimbursed according to a Medicare profile or other cost-based reimbursement mechanism. Examples of institutional providers are hospitals, nursing homes, home health agencies, 51.42 board-operated clinics.

(b) *Non-institutional providers.* Non-institutional providers are providers eligible for direct reimbursement, who are in single practice or providers who, although employed by a provider group, also have private patients for whom they submit claims to Medicaid.

(c) *Provider assistants.* Provider assistants are those providers (e.g. physical therapist assistant, physician's assistant, etc.) whose services

must be provided under the supervision of a certified or licensed professional provider. Such assistant providers, while required to be certified, are not eligible for direct reimbursement from Medicaid.

(6) Persons who do not need to be individually certified are: (a) Technicians or support staff for a provider, such as:

1. Dental hygienists

2. Medical record librarians or technicians

3. Hospital and nursing home administrators, clinic managers, and administrative and billing staff

4. Nursing aides, assistants and orderlies

5. Home health aides

6. Personal care workers

7. Dietitians

8. Laboratory technologists

9. X-ray technicians

10. Patient activities coordinators

11. Volunteers

12. All other persons whose cost of service is built into the charge submitted by the provider (housekeeping, maintenance staff, etc.); or

(b) Providers employed by or under contract to certified institutional providers, e.g., physicians, therapists, nurses and provider assistants when they are employes of a hospital, nursing home, home health agency or other certified institutional provider.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.02 Requirements for maintaining certification. Providers shall comply with the following requirements in order to maintain certification in the medical assistance program:

(1) Providers shall report to the department in writing any change in licensure, certification, corporate name or ownership by the time of the effective date of such changes. Such changes may require that the provider complete a new provider application and a new provider agreement. Changes in a provider's address require immediate notification of the department but do not require completion of a new provider application or a new provider agreement.

(2) In the event of a change of ownership, the provider agreement shall automatically terminate, except that provider shall continue to maintain records required by section HSS 105.02 (3), (4) and (5) unless an alternative method of providing for maintenance of such records has been established in writing and approved by the department.

(3) Providers shall prepare and maintain such records as are necessary fully to disclose the nature and extent of services provided by the provider under the program. Records to be maintained are those enumerated in section HSS 105.02 (4) and (5). All records shall be retained

by providers for a period of not less than 5 years from date of payment by the department for the services rendered, unless otherwise stated in this rule. In the event a provider's participation in the program is terminated for any reason, all Medicaid-related records shall remain subject to the conditions enumerated in section HSS 105.02 (2) and (3).

(4) All providers shall maintain the following records: (a) Contracts or agreements with persons or organizations for the furnishing of items or services, payment for which may be made in whole or in part, directly or indirectly, by the Medicaid program.

(b) Medicaid billings and records of services or supplies which are the subject of such billings, as are necessary fully to disclose the nature and extent of services or supplies.

(c) Any and all prescriptions necessary to disclose the nature and extent of services provided and billed under the program.

(5) These other records shall be maintained: (a) Hospitals, skilled nursing facilities (SNFs), intermediate care facilities (ICFs) and home health agencies (except that home health agencies are not required to maintain records listed at 11 and 14 below):

1. Annual budgets.

2. Patient census information.

a. All patients

b. Medical assistance recipients

3. Annual cost settlement reports for Medicare.

4. Reimbursement rate proposals (hospitals only).

5. Annual Medicaid cost reports (SNF and ICFs only).

6. Independent accountants' audit reports.

7. Records supporting historical costs of buildings and equipment.

8. Building and equipment depreciation records.

9. Cash receipt and receivable ledgers, and supporting receipts and billings.

10. Accounts payable, operating expense ledgers, and cash disbursement ledgers, with supporting purchase orders, invoices, or checks.

11. Records by department, of the use of support service departments such as dietary, laundry, plant and equipment, housekeeping.

12. Payroll records.

13. Inventory records.

14. Ledger identifying dates and amounts of all deposits to and withdrawals from medical assistance resident trust fund accounts, including documentation of the amount, date, and purpose of the withdrawal when withdrawal is made by anyone other than the resident. (When the resident chooses to retain control of the funds, such decision shall be documented in writing and retained in the resident's records. When

such decision is made and documented, the facility is relieved of responsibility to document expenditures under this subsection).

15. All policies and regulations as adopted by the provider's governing body.

(b) Pharmacy and other dispensary providers: 1. Prescriptions which support Medicaid billings.

2. Medicaid patient profiles.

3. Purchase invoices and receipts for such medical supplies and equipment billed to the medical assistance program.

(6) The provider agreement shall, unless terminated, remain in full force and effect for a maximum of one year from the date of execution. The date on which it was signed on behalf of the department by its authorized representative shall be considered the effective date. In the absence of a notice of termination by either party, the agreement shall automatically renew and be extended for periods of one year.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.05 Participation by non-certified persons under emergency conditions. If a Wisconsin or an out-of-state person who is not certified in the medical assistance program in this state provides emergency services to a Wisconsin recipient, that person shall not be reimbursed for those services from the Wisconsin MA program unless the person meets the conditions outlined in section HSS 105.05 (2).

(1) No other services provided by the person shall be reimbursed by the Wisconsin MA program unless:

(a) The person becomes certified in the Wisconsin MA program and meets all the requirements for coverage of services in the Wisconsin program; or

(b) The person participates again under emergency conditions and meets the conditions enumerated below.

(2) A non-certified person shall meet the following emergency conditions:

(a) Submit a provider data form and claim for reimbursement of emergency services to the department on forms prescribed by the department.

(b) Submit to the department a statement in writing on a form prescribed by the department explaining the nature of the emergency (including description of recipient's condition, cause of emergency, if known, diagnosis and extent of injuries); the services which were provided and when; and the reason that the recipient could not receive services from a participating certified provider.

(c) Shall be qualified to provide all services for which a claim is submitted.

(3) Based upon the signed statement and the claim for reimbursement, the department's professional consultants shall determine whether the services are reimbursable.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.06 Supervision of provider assistants. Unless otherwise specified under the appropriate section for each provider type, supervision means at least intermittent face-to-face contact between supervisor and assistant, and a regular review of the assistant's work by the supervisor.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.07 Certification of physicians. Physicians are required to be licensed to practice medicine and surgery pursuant to s. 448.05 and 448.07 Stats. and Wis. Adm. Code chapters Med 1, 2, 3, 4, 5, and 14.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.075 Certification of physician's assistants. Physician's assistants are required to be certified and registered pursuant to ss. 448.05 and 448.07 Stats. and Wis. Adm. Code chapter Med 8.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.077 Certification of inhalation therapists. Inhalation therapists are required to be registered with the American registry of inhalation therapy and shall provide service only under the immediate personal supervision of a physician.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.08 Certification of dentists. Dentists are required to be licensed pursuant to s. 447.05 Stats.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.09 Certification of general hospitals. Hospitals are required to be approved pursuant to s. 50.35, Stats. and to meet requirements of the rules and standards promulgated under Wis. Adm. Code chapter H 24 and to have a certificate of participation in Medicare or to be qualified to receive such certification, or to be accredited by the joint commission on the accreditation of hospitals (JCAH). Hospitals are required to have a utilization review plan that meets the requirements of section HSS 105.09 (2) through (12).

Note: (For purposes of program administration, the following rules, which are a codification of 42 CFR 405.1035 are adopted. For the sake of readability, some editing has been done. In the event of any conflict of meaning, the meaning of the original federal regulations shall hold).

(1) Hospitals participating in the Professional Standards Review Organization (PSRO) review program shall meet the requirements in the federal regulations for that program. Such hospitals need not meet the requirements of HSS 105.09 (2) through (12).

(2) The hospital shall have in effect a plan for utilization review which applies to the services furnished by the hospital to inpatients who are entitled to benefits under medical assistance. A hospital's utilization review plan shall provide at least for the timely review of the medical

necessity of admissions, extended duration stays, and professional services rendered, and shall have as its objectives both high quality patient care and effective and efficient utilization of available health facilities and services.

(3) Hospitals wishing to establish their eligibility to participate shall submit a written description of their utilization review plan and a certification that is currently in effect or that it will be in effect no later than the first day on which the hospital expects to become a participating provider of services.

(4) The review plan of a hospital shall have as its overall objective the maintenance of high quality patient care, and an increase in effective use of hospital services to be achieved through an educational approach involving study of patterns of care, and the encouragement of appropriate utilization. A review of the medical necessity of admissions and durations of stay shall take into account alternative use and availability of out-of-hospital facilities and services. The review of professional services furnished may include study of such conditions as overuse or underuse of services, logical substantiation of diagnoses, proper use of consultation, and whether required diagnostic workup and treatment are initiated and carried out promptly. Review of length of stay may consider not only medical necessity, but the effect that hospital staffing may have on duration of stay, whether assistance is available to the physician in arranging for discharge planning, and the availability of out-of-hospital facilities and services which will assure continuity of care.

(5) Costs incurred in connection with the implementation of the utilization review plan are includable in reasonable costs and are reimbursable to the hospital to the extent that such costs relate to medical assistance recipients.

(6) The operation of the utilization review plan is a responsibility of the medical staff. The plan in the hospital shall have the approval of the medical staff and of the governing body.

(7) The hospital shall have a currently applicable, written description of its utilization review plan. Such description shall include: (a) The organization and composition of the committee or committees which will be responsible for the utilization review function;

(b) Frequency of meetings;

(c) The type of records to be kept;

(d) The method to be used in selecting categories of admissions to be subjected to closer professional scrutiny, and methods for selecting and conducting medical care evaluation studies;

(e) The methods and criteria (including norms where available) used to assign initial extended stay review dates and used to assign or select subsequent dates for continued stay review;

(f) The relationship of the utilization review plan to claims administration by a third party;

(g) Arrangements for committee reports and their dissemination;

(h) Responsibilities of the hospital's administrative staff.

(8) Before or on the date assigned for extended stay review, the committee or group responsible for conducting utilization review shall make a finding about whether further stay in the hospital by the individual is medically necessary. Such review shall be based on the attending physician's reasons for and plan for continued stay, and other documentation the committee or group considers necessary. For purposes of such review, cases may be screened by a qualified nonphysician representative of the committee or group who uses appropriate criteria, provided that those cases in which further stay does not appear medically necessary according to such criteria are referred to a physician member of the committee or group for further review. If the individual's further stay is determined to be medically necessary, the duration of the further stay shall be certified for an appropriate period of time based on criteria established by the committee or group. Before the expiration of the new period, the case shall be reviewed again in like manner, with such reviews being repeated as long as the stay continues beyond the scheduled review dates and notice has not been given pursuant to section HSS 105.09 (9).

(9) If the committee or group, or its nonphysician representative, where a physician member concurs, has reason to believe that further stay is not medically necessary, the committee or group shall so notify the individual's attending physician and afford an opportunity to present views before it makes a final determination. If the final determination of the comittee or group is that further stay in the hospital is not medically necessary, written notice of such finding shall be given to the hospital, the attending physician, and the individual (or the next of kin, where appropriate) not later than 2 days after such determination is made. In no event shall such notification be given later than 2 working days after the end of the certified period.

(10) Records shall be kept of the activities of the committee, reports shall be regularly made by the committee to the executive committee of the medical staff, and relevant information and recommendations shall be reported through usual channels to the entire medical staff and the governing body of the hospital.

(a) The hospital administration shall study and act upon administrative recommendations made by the committee.

(b) A summary of the number and types of cases reviewed, and the findings, shall be made part of the records.

(c) Minutes of each committee meeting shall be maintained.

(d) Committee action in extended stay cases shall be recorded, with cases identified only by hospital case number.

(11) The committee(s) having responsibility for utilization review functions shall have the support and assistance of the hospital's administrative staff in assembling information, facilitating chart reviews, conducting studies, exploring ways to improve procedures, maintaining committee records, and promoting the most efficient use of available health services and facilities.

(a) With respect to each of these activities, an individual or department shall be designated as responsible for the particular service.

(b) In order to encourage the most efficient use of available health services and facilities, assistance to the physician in timely planning for post-hospital care shall be initiated as promptly as possible, either by hospital staff, or by arrangement with other agencies. For this purpose, the hospital shall make available to the attending physician current information on resources available for continued out-of-hospital care of patients and shall arrange for prompt transfer of appropriate medical and nursing information in order to assure continuity of care upon discharge of a patient.

(12) Medical care evaluation studies shall be performed to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care. Studies shall emphasize identification and analysis of patterns of patient care, and shall suggest possible changes for maintaining consistently high quality patient care and effective and efficient use of services. Each medical care evaluation study (whether medical or administrative in emphasis) shall identify and analyze factors related to the patient care rendered in the facility, and where indicated, results in recommendations for change beneficial to patients, staff, the facility, and the community. Studies on a sample or other basis shall include, but need not be limited to: admissions, durations of stay, ancillary services furnished (including drugs and biologicals), and professional services performed on the hospital premises. At least one study must be in progress at any given time, and at least one study shall be completed each year. The study shall be accomplished by considering and analyzing data obtained from any one or a combination of the following sources:

(a) Medical records or other appropriate hospital data;

(b) External organizations which compile statistics, design profiles, and produce other comparative data; and

(c) By cooperative endeavor with the Professional Standards Review Organization, fiscal intermediary, providers of services, or other appropriate agencies.

(d) The group or committee shall document the results of each medical care evaluation study and how such results have, where appropriate, been used to institute changes to improve the quality of care and promote more effective and efficient use of facilities and services.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.10 Certification of skilled nursing facilities. Skilled nursing facilities are required to be licensed pursuant to s. 50.03, Stats. and to meet the requirements of Wis. Adm. Code chapter H 32 and to meet the requirements for participation in Medicare.

Note: For purposes of program administration the following rules, which are a codification of 42 CFR 405.1101 through 42 CFR 405.1137, and 42 CFR Part 456, Subparts E and I, and 42 CFR Part 442, Subpart C are adopted. For the sake of readability, some editing has been done; also changes have been made to conform with state law and policy.

Note: The following skilled nursing facility rules will be placed into the next complete revision of Wis. Adm. Code chapter H 32, at which time these rules will be repealed.

(1) COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS. (a) *Licensure.* The facility shall be licensed pursuant to s. 50.02 (3) [50.03] Stats., except that a facility which formerly met fully such licensure requirements, but is currently determined not to meet fully all such requirements, may be recognized for a period specified by the department.

(b) *Licensure or registration of personnel.* Staff of the facility shall be licensed or registered in accordance with applicable laws.

(c) *Conformity with other federal, state, and local laws.* The facility shall be in conformity with all federal, state, and local laws relating to fire and safety, sanitation, communicable and reportable diseases, postmortem procedures, and other relevant health and safety requirements.

(2) GOVERNING BODY AND MANAGEMENT. The skilled nursing facility shall have an effective governing body, or designated persons so functioning, with full legal authority and responsibility for the operation of the facility. The governing body shall adopt and enforce rules and regulations concerning the health care and safety of patients, the protection of patients' personal and property rights, and the general operation of the facility.

(a) *Disclosure of ownership.* The facility shall supply full and complete information to the department on the identity of:

1. Each person who has any direct or indirect ownership interest of 10% [5%] or more in the facility or, each person who owns (in whole or in part) any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility, or any of the property or assets of the facility;

2. If the facility is organized as a corporation, each officer and director of the corporation; and

3. If the facility is organized as a partnership, each partner. The facility shall promptly report any changes affecting the current accuracy of the information required to be supplied.

(b) *Staffing patterns.* The facility shall furnish to the department information from payroll records setting forth the average numbers and types of personnel (in full-time equivalents) on each tour of duty during at least one week of each quarter. Such week shall be selected by the department.

(c) *Bylaws.* The governing body shall adopt effective patient care policies and administrative policies and bylaws governing the operation of the facility, in accordance with legal requirements. Policies and bylaws shall be in writing, dated, and made available to all members of the governing body which shall ensure the policies and bylaws are operational. The governing body shall review and revise policies and bylaws as necessary.

(d) *Independent medical evaluation (medical review).* The governing body shall adopt policies to ensure that the facility cooperates in an effective and regular program of independent medical evaluation and audit of the patients in the facility to the extent required by the programs in which the facility participates (including at least an annual

medical evaluation of each patient's need for skilled nursing facility care).

(e) *Administrator.* The governing body shall appoint a qualified administrator who shall be responsible for the overall management of the facility, for enforcing rules and regulations concerning the level of health care and safety of patients and the protection of their personal and property rights, and for planning, organizing, and directing those responsibilities delegated to the administrator by the governing body. Through meetings and periodic reports, the administrator shall maintain ongoing liaison among the governing body, medical and nursing staffs, and other professional and supervisory staff of the facility, and shall study and act upon recommendations made by the utilization review and other committees. In the absence of the administrator, an appropriate employe shall be authorized, in writing, to act on behalf of the administrator.

(f) *Institutional planning.* The skilled nursing facility, under the direction of the governing body shall prepare an overall plan and budget which provides for an annual operating budget and a capital expenditure plan.

1. Annual operating budget. The annual operating budget shall include all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that an item by item identification of the components of each type of anticipated income or expense is not required to be prepared).

2. Capital expenditure plan. a. The capital expenditure plan shall be in conformity with the requirements of ch. 150, Stats.

3. Preparation of plan and budget. The overall plan and budget shall be prepared under the direction of the governing body by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (or chief medical officer, or patient care policies advisory group as specified in section HSS 105.10 (3) (a) below).

4. Annual review of plan and budget. The overall plan and budget shall be reviewed and updated at least annually by the committee referred to in HSS 105.10 (2) (f) 3 under the direction of the governing body.

(g) *Personnel policies and procedures.* The governing body, through the administrator, shall implement and maintain written personnel policies and procedures that support sound patient care and personnel practices. Personnel records shall be current and available for each employe and shall contain sufficient information to support placement in the position to which assigned. Written policies for control of communicable disease shall be in effect to ensure that employes with symptoms or signs of communicable disease or infected skin lesions are not permitted to work, and that a safe and sanitary environment for patients and personnel exists, and that accidents to patients and personnel are reviewed to identify health and safety hazards. Employes shall be provided or shall otherwise obtain a periodic health examination to ensure freedom from communicable disease.

(h) *Staff development.* An ongoing educational program shall be planned and conducted for the development and improvement of skills of all the facility's personnel, including training related to problems and needs of the aged, ill, and disabled. Each employe shall receive appropriate orientation to the facility and its policies, and to the employe's position and duties. Inservice training shall include at least prevention and control of infections, fire prevention and safety, accident prevention, confidentiality of patient information, and preservation of patient dignity, including protection of privacy and personal and property rights. Records shall be maintained which indicate the content of, and attendance at, such staff development programs.

(i) *Use of outside resources.* If the facility does not employ a qualified professional person to furnish a specific service, it shall make arrangements to have such a service provided by an outside resource person or agency that will provide direct service to patients or act as a consultant to the facility. The responsibilities, functions, objectives, and the terms of agreement, including financial arrangements and charges, of each such outside resource shall be delineated in writing and signed by an authorized representative of the facility and the person or agency providing the service. Agreements pertaining to services shall specify that the facility assumes professional and administrative responsibility for the services rendered. The outside resource, when acting as a consultant, shall apprise the administrator of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the administrator for follow-up action and evaluation of performance.

(j) *Notification of changes in patient status.* The facility shall have appropriate written policies and procedures relating to notification of the patient's attending physician and other responsible persons in the event of an accident involving the patient, or other significant change in the patient's mental, physical, or emotional status, or patient charges, billings, and related administrative matters. Except in a medical emergency, a patient shall not be transferred or discharged, nor shall treatment be altered radically, without consultation with the patient, or, if the patient is incompetent, without prior notification of next of kin or sponsor.

(k) *Patient's rights.* The governing body shall establish written policies regarding the rights and responsibilities of patients and, through the administrator, be responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures shall be generally available. The staff of the facility shall be trained and involved in the implementation of these policies and procedures. The patient's rights policies and procedures shall comply with the requirements of s. 50.09, Stats. and Wis. Adm. Code H 32.055.

(l) *Patient care policies.* The skilled nursing facility shall have written patient care policies to govern the continuing skilled nursing care and related medical or other services provided.

1. The facility shall have policies, developed by the medical director or the organized medical staff, with the advice of (and with provision for review of such policies from time to time, but at least annually), by a group of professional personnel including one or more physicians and one or more registered nurses, to govern the skilled nursing care and

related medical or other services it provides. These policies shall be generally available and shall provide for the total medical and psychosocial needs of patients, including admission, transfer, and discharge planning; and the range of services available to patients, including frequency of physician visits by each category of patients admitted. These policies shall also include provisions to protect patients' personal and property rights. Medical records and minutes of staff and committee meetings shall reflect whether patient care is being rendered in accordance with the written patient care policies, and whether utilization review committee recommendations regarding the policies are reviewed and necessary steps taken to ensure compliance.

2. The medical director or a registered nurse shall be designated, in writing, to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated to a registered nurse, the medical director shall serve as the advisory physician from whom the nurse receives medical guidance.

(3) MEDICAL DIRECTION. The facility shall retain pursuant to a written agreement, a physician, licensed under state law to practice medicine or osteopathy, to serve as medical director on a part-time or full-time basis as is appropriate for the needs of the patients and the facility. If the facility has an organized medical staff, the medical director shall be designated by the medical staff with approval of the governing body. A medical director may be designated for a single facility or multiple facilities through arrangements with a group of physicians, a local medical society, a hospital medical staff, or through another similar arrangement. The medical director shall be responsible for the overall coordination of the medical care in the facility to ensure the adequacy and appropriateness of the medical services provided to patients and to maintain surveillance of the health status of employes.

(a) *Coordination of medical care.* Medical direction and coordination of medical care in the facility shall be provided by a medical director. The medical director shall be responsible for the development of written bylaws, rules, and regulations which shall be approved by the governing body and include delineation of the responsibilities of attending physicians. Coordination of medical care shall include liaison with attending physicians to ensure physicians' orders are written promptly upon admission of a patient, and periodic evaluation of the adequacy and appropriateness of health professional and supportive staff and services.

(b) *Responsibilities to the facility.* The medical director shall be responsible for surveillance of the health status of the facility's employes. Incidents and accidents that occur on the premises shall be reviewed by the medical director to identify hazards to health and safety. The administrator shall be given appropriate information to help ensure a safe and sanitary environment for patients and personnel. The medical director shall be responsible for the execution of patient care policies in accordance with section HSS 105.10 (2) (1).

(4) PHYSICIAN SERVICES. Patients in need of skilled nursing or rehabilitative care shall be admitted to the facility only upon the recommendation of, and shall remain under the care of, a physician. Each patient or patient sponsor should designate a personal physician if possible.

(a) *Medical findings and physicians' orders at time of admission.* There shall be made available to the facility, before or at the time of admission, information concerning the patient, including current medical findings, diagnoses, and orders from a physician for immediate care of the patient. Information about the rehabilitation potential of the patient and a summary of prior treatment shall be made available to the facility at the time of admission or within 48 hours thereafter.

(b) *Supervision of each patient by a physician.* Each patient shall be under the supervision of a physician who, based on a medical evaluation of the patient's immediate and long-term needs, shall prescribe a planned regimen of total patient care. Each attending physician shall make arrangements for the medical care of the physician's patients in the physician's absence. The medical evaluation of the patient shall be based on a physical examination done within 48 hours of admission unless such examination was performed within 5 days before admission. The patient shall be seen by the attending physician at least once every 30 days for the first 90 days following admission. The patient's total program of care (including medications and treatments) shall be reviewed during a visit by the attending physician at least once every 30 days for the first 90 days, and revised as necessary. A progress note shall be written and signed by the physician at the time of each visit. The physician shall sign all physician orders. After the 90th day following admission, an alternate schedule for physician visits may be adopted if the attending physician determines and so justifies in the patient's medical record that the patient's condition does not necessitate visits at 30 day intervals. This alternate schedule does not apply for patients who require specialized rehabilitative services. In that case, the review shall be in accordance with section HSS 105.10 (7) (b). At no time shall the alternate schedule exceed 60 days between visits. If the physician decides upon an alternate schedule of visits of more than 30 days for the patient:

1. The facility shall notify the department of the change in schedule, including justification; and

2. The utilization review committee or the medical review team shall promptly reevaluate the patient's need for monthly physician visits as well as the patient's continued need for skilled nursing facility services. If the utilization review committee or the medical review team does not concur in the schedule of visits at intervals of more than 30 days, the alternate schedule shall not be acceptable.

(c) *Availability of physicians for emergency patient care.* The facility shall have written procedures, available at each nurse's station, for procuring a physician to furnish necessary medical care in emergencies.

(5) NURSING SERVICES. The skilled nursing facility shall provide 24-hour service by licensed nurses, including the services of a registered nurse at least during the day tour of duty 7 days a week. There shall be an organized nursing service with a sufficient number of qualified nursing personnel to meet the total nursing needs of all patients in the facility.

(a) *Director of nursing services.* The director of nursing services shall be a qualified registered nurse employed full-time who has administrative authority, responsibility, and accountability for the functions, activities, and training of the nursing staff, and who shall serve only one

facility in this capacity. The director of nursing services' duties shall be clearly stated in writing. If the director of nursing services has other institutional responsibilities, a qualified registered nurse shall serve as an assistant so that there is the equivalent of a full-time director of nursing services on duty. The director of nursing services shall be responsible for the development and maintenance of nursing service objectives, standards of nursing practice, nursing policy and procedure manuals, written job descriptions for each level of nursing personnel, scheduling of daily rounds to see all patients, methods for coordinating nursing services with other patient services, for recommending the number and levels of nursing personnel to be employed, and nursing staff development.

(b) *Charge nurse.* A registered nurse, or a qualified licensed practical (vocational) nurse shall be designated as charge nurse by the director of nursing services for each tour of duty, and shall be responsible for supervision of the total nursing activities in the facility during each tour of duty. The director of nursing services shall not serve as charge nurse in a facility with an average daily total occupancy of 60 or more patients. The charge nurse shall delegate responsibility to nursing personnel for the direct nursing care of specific patients during each tour of duty on the basis of staff qualifications, size and physical layout of the facility, characteristics of the patient load, and the emotional, social, and nursing care needs of patients.

(c) *Twenty-four hour nursing service.* The facility shall provide 24-hour nursing services which are sufficient to meet total nursing needs and which are in accordance with the patient care policies. The policies shall be designed to ensure that each patient receives treatments, medications, and diet as prescribed, and rehabilitative nursing care as needed. Policies shall also ensure that patients receive proper care to prevent decubitus ulcers and deformities and are kept comfortable, clean, well-groomed, and protected from accident, injury, and infection. Patients shall be encouraged, assisted and trained in self-care and group activities. Nursing personnel, including at least one registered nurse on the day tour of duty 7 days a week, licensed practical nurses, nurses aides, orderlies, and ward clerks, shall be assigned duties consistent with their education and experience and based on the characteristics of the patient load. Weekly time schedules shall be maintained and shall indicate the number and classifications of nursing personnel, including relief personnel who worked on each unit for each tour of duty.

(d) *Patient care plan.* A written patient care plan for each patient shall be developed in coordination with other patient care services to be provided and maintained by the nursing service. This plan shall be consonant with the attending physician's plan of medical care, and shall be implemented upon admission. The plan shall indicate care to be given and goals to be accomplished and which professional service is responsible for each element of care. The patient care plan shall be reviewed, evaluated, and updated as necessary by all professional personnel involved in the care of a patient. The original copy of the care plan shall be maintained on the premises of the nursing home.

(e) *Rehabilitative nursing care.* Nursing personnel shall be trained in rehabilitative nursing, and the facility shall have an active program of rehabilitative nursing care which is an integral part of nursing service

and is directed toward assisting each patient to achieve and maintain an optimal level of self-care and independence. Rehabilitative nursing care services shall be performed daily for those patients who require such service, and shall be recorded.

(f) *Supervision of patient nutrition.* Nursing personnel shall be aware of the nutritional needs and food and fluid intake of patients and assist promptly where necessary in the feeding of patients. A procedure shall be established to inform the dietary service of physicians' diet orders and of patients' dietetic problems. Food and fluid intake of patients shall be observed, and deviations from normal shall be recorded and reported to the charge nurse and the physician.

(g) *Administration of drugs.* Drugs and biologicals shall be administered only by physicians, licensed nursing personnel, or by other personnel who have completed a state-approved training program in medication administration. Procedures shall be established by the pharmaceutical services committee to ensure that drugs to be administered are checked against physicians' orders, that the patient is identified before administration of a drug, and that each patient has an individual medication record and that the dose of drug administered to that patient is properly recorded therein by the person who administered the drug. Drugs and biologicals shall be administered as soon as possible after doses are prepared, and shall be administered by the same person who prepared the doses for administration, except under single unit dose package distribution system.

(h) *Conformance with physicians' drug orders.* 1. Drugs shall be administered in accordance with written orders of the attending physician. Drugs not specifically limited by physician's order as to time or number of doses shall be controlled by automatic shop orders or other methods in accordance with written policies. Physicians' verbal orders for drugs shall be given only to a licensed nurse, pharmacist, or physician and shall be immediately recorded and signed by the person receiving the order. (Verbal orders for drugs listed in ch. 161, Stats. and in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 shall be permitted only in the case of a bona fide emergency situation.) All orders shall be countersigned by the attending physician within 48 hours. The attending physician shall be notified of an automatic stop order prior to the last dose so that the physician may decide if the administration of the drug or biological is to be continued or altered.

(i) *Storage of drugs and biologicals.* Procedures for storing and disposing of drugs and biologicals shall be established by the pharmaceutical services committee. All drugs and biologicals shall be stored in locked compartments under proper temperature controls, and only authorized personnel shall have access to the keys. Separately locked, permanently affixed compartments shall be provided for storage of controlled drugs listed in ch. 161, Stats. and in Schedule II of the Comprehensive Drug Abuse Prevention & Control Act of 1970 and other drugs subject to abuse, except under single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. An emergency medication kit approved by the pharmaceutical services committee shall be kept readily available.

(6) DIETETIC SERVICES. The facility shall provide a hygienic dietetic service that meets the daily nutritional needs of patients, ensures that

special dietary needs are met, and provides palatable and attractive meals. A facility that has a contract with an outside food management company may be found to be in compliance with this condition provided the facility or company meets the standards listed herein.

(a) *Staffings.* Overall supervisory responsibility for the dietetic service shall be assigned to a full-time qualified dietetic service supervisor. If the dietetic service supervisor is not a qualified dietitian, the supervisor shall function with frequent, regularly scheduled consultation from a person so qualified. In addition, the facility shall employ sufficient supportive personnel to carry out the functions of the dietetic service. Food service personnel shall be on duty daily over a period of 12 or more hours. If consultant dietetic services are used, the consultant's visits shall be at appropriate times, and of sufficient duration and frequency to provide continuing liaison with medical and nursing staffs, advice to the administrator, patient counseling, guidance to the supervisor and staff of the dietetic service, approval of all menus, and participation in development or revision of dietetic policies and procedures and in planning and conducting inservice education programs.

(b) *Menus and nutritional adequacy.* Menus shall be planned and followed to meet nutritional needs of patients in accordance with physician orders and, to the extent medically possible, in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences.

(c) *Therapeutic diets.* Therapeutic diets shall be prescribed by the attending physician. Therapeutic menus shall be planned in writing, and prepared and served as ordered, with supervision or consultation from the dietitian and advice from the physician whenever necessary. A current therapeutic diet manual approved by the dietitian shall be readily available to attending physicians and nursing and dietetic service personnel.

(d) *Frequency of meals.* At least three meals or their equivalent shall be served daily, at regular hours, with not more than a 14-hour span between substantial evening meal and breakfast. If not prohibited by patient's diet or condition, bedtime nourishments shall be offered routinely to all patients.

(e) *Preparation and service of food.* Foods shall be prepared by methods that conserve nutritive value, flavor, and appearance, and shall be attractively served at the proper temperatures and in a form to meet individual needs. If a patient refuses food served, appropriate substitutes of similar nutritive value shall be offered.

(f) *Hygiene of staff.* Dietetic service personnel shall be free of communicable diseases and practice hygienic food-handling techniques. In the event food service employes are assigned duties outside the dietetic service, these duties shall not interfere with the sanitation, safety, or time required for dietetic work assignments.

(g) *Sanitary conditions.* Food shall be procured from sources approved or considered satisfactory by federal, state, or local authorities, and stored, prepared, distributed, and served under sanitary conditions. Waste shall be disposed of properly. Written reports of inspections by state and local health authorities shall be on file at the facility, with

notation made of action taken by the facility to comply with any recommendations.

(7) SPECIALIZED REHABILITATIVE SERVICES. In addition to rehabilitative nursing, the skilled nursing facility shall provide or arrange for under written agreement, specialized rehabilitative services by qualified personnel (i.e., physical therapy, speech pathology, audiology, and occupational therapy) as needed by patients to improve and maintain functioning. These services shall be provided upon the written order of the patient's attending physician. Safe and adequate space and equipment shall be available, commensurate with the services offered. If the facility does not offer such services directly, it shall not admit or retain patients in need of this care unless provision is made for such services under arrangement with qualified outside resources.

(a) *Organization and staffing.* Specialized rehabilitative services shall be provided, in accordance with accepted professional practices, by qualified therapists or by qualified assistants or other supportive personnel under the supervision of qualified therapists. Other rehabilitative services also may be provided, but shall be in a facility where all rehabilitative services are provided through an organized rehabilitative service under the supervision of a physician who determines the goals and limitations of these services and assigns duties appropriate to the training and experience of those providing such services. Written administrative and patient care policies and procedures shall be developed for rehabilitative services by appropriate therapists and representatives of the medical, administrative, and nursing staffs.

(b) *Plan of care.* Rehabilitative services shall be provided under a written plan of care, initiated by the attending physician and developed in consultation with appropriate therapist(s) and the nursing service. Therapy shall be provided only upon written orders of the attending physician. A report of the patient's progress shall be communicated to the attending physician within 2 weeks of the initiation of specialized rehabilitative services. The patient's progress shall thereafter be reviewed regularly, and the plan of rehabilitative care shall be re-evaluated as necessary, but at least every 30 days, by the physician and the therapist(s). The original copy of the plan of care shall be maintained on the premises of the nursing home.

(c) *Documentation of services.* The physician's orders, the plan of rehabilitative care, services rendered, evaluations or progress, and other pertinent information shall be recorded in the patient's medical record, and dated and signed by the physician ordering the service and the person who provided the service.

(d) *Qualifying to provide outpatient physical therapy services.* If the skilled nursing facility provides outpatient physical therapy services, it shall meet the applicable health and safety regulations pertaining to such services as are included in section HSS 105.34.

(8) PHARMACEUTICAL SERVICES. The skilled nursing facility shall provide appropriate methods and procedures for the dispensing and administering of drugs and biologicals. Whether drugs and biologicals are obtained from community or institutional pharmacists or stocked by the facility, the facility shall be responsible for providing such drugs and

biologicals for its patients, insofar as they are covered under the programs, and for ensuring that pharmaceutical services are provided in accordance with accepted professional principles and appropriate federal, state and local laws.

(a) *Supervision of services.* The pharmaceutical services shall be under the general supervision of a qualified pharmacist who is responsible to the administrative staff for developing, coordinating and supervising all pharmaceutical services. The pharmacist (if not a full-time employe) shall devote a sufficient number of hours, based upon the needs of the facility, during regularly scheduled visits to carry out these responsibilities. The pharmacist shall review the drug regimen of each patient at least monthly, and report any irregularities to the medical director and administrator. The pharmacist shall submit a written report at least quarterly to the pharmaceutical services committee on the status of the facility's pharmaceutical service and staff performance.

(b) *Control and accountability.* The pharmaceutical service shall have procedures for control and accountability of all drugs and biologicals throughout the facility. Only approved drugs and biologicals shall be used in the facility, and shall be dispensed in compliance with federal and state laws. Records of receipt and disposition of all controlled drugs shall be maintained in sufficient detail to enable an accurate reconciliation. The pharmacist shall determine that drug records are in order and that an account of all controlled drugs is maintained and reconciled.

(c) *Labeling of drugs and biologicals.* The labeling of drugs and biologicals shall be based on currently accepted professional principles, and shall include the appropriate accessory and cautionary instructions as well as the expiration date when applicable.

(d) *Pharmaceutical services committee.* A pharmaceutical services committee (or its equivalent) shall develop written policies and procedures for safe and effective drug therapy, distribution, control, and use of drugs. The committee shall include at least the pharmacist, the director of nursing services, the administrator, and one physician. The committee shall oversee pharmaceutical service in the facility, make recommendations for improvement, and monitor service to ensure its accuracy and adequacy. The committee shall meet at least quarterly and document its activities, findings, and recommendations.

(9) LABORATORY AND RADIOLOGIC SERVICES. The skilled nursing facility shall provide for promptly obtaining required laboratory, x-ray, and other diagnostic services.

(a) *Provision for services.* If the facility provides its own laboratory and x-ray services, these shall meet the applicable conditions established for certification of hospitals contained in Wis. Adm. Code sections H 24.09 and H 24.10 respectively. If the facility itself does not provide such services, arrangements shall be made for obtaining these services from a physician's office, a participating hospital or skilled nursing facility, or a portable x-ray supplier or independent laboratory approved to provide these services under the program. All such services shall be provided only on the orders of the attending physician, who shall be notified promptly of the findings. The facility shall assist the patient, if necessary, in arranging for transportation to and from the source of service. Signed and dated reports of clinical laboratory, x-ray,

and other diagnostic services shall be filed with the patient's medical record.

(b) *Blood and blood products.* Blood handling and storage facilities shall be safe, adequate, and properly supervised. If the facility provides for maintaining and transfusing blood and blood products, it shall meet the conditions established for certification of hospitals that are contained in Wis. Adm. Code, section H 24.09. If the facility does not provide its own facilities but does provide transfusion services alone, it shall meet at least the requirements of Wis. Adm. Code section H 24.09 (j), 1., 3., 4., 6., and 9.

(10) DENTAL SERVICES. The skilled nursing facility shall have satisfactory arrangements to assist patients to obtain routine and emergency dental care.

(a) *Advisory dentist.* An advisory dentist shall participate in the staff development program for nursing and other appropriate personnel and recommend oral hygiene policies and practices for the care of patients.

(b) *Arrangements for outside services.* The facility shall make arrangements for patients who do not have a private dentist. The facility shall assist the patient, if necessary, in arranging for transportation to and from the dentist's office.

(11) SOCIAL SERVICES. The facility shall have satisfactory arrangements for identifying the medically related social and emotional needs of the patient. The facility itself need not provide social services in order to participate in the program. If the facility does not provide social services, it shall have written procedures for referring patients in need of social services to appropriate social agencies. Social services offered by the facility shall be provided under a clearly defined plan, by qualified persons, to assist each patient to adjust to the social and emotional aspects of the patient's illness, treatment, and stay in the facility.

(a) *Social service functions.* The medically related social and emotional needs of the patient shall be identified and services shall be provided to meet them, either by qualified staff of the facility, or by referral to appropriate social service agencies. If financial assistance is indicated, arrangements shall be made promptly for referral to an appropriate agency. The patient and the patient's family or responsible person shall be fully informed of the patient's personal and property rights.

(b) *Staffing.* If the facility offers social services, a member of the staff of the facility shall be designated responsible for social services. If the designated person is not a qualified social worker, the facility shall have a written agreement with a qualified social worker or recognized social service agency for consultation and assistance on a regularly scheduled basis. The social service shall also have sufficient supportive personnel, easily accessible to patients and staff, and ensure privacy for interview.

(c) *Records and confidentiality of social data.* Records of pertinent social data about personal and family problems medically related to the patient's illness and care, and of action taken to meet the patient's needs, shall be maintained in the patient's medical record. If social services are provided by an outside resource, a record shall be maintained of each referral to such resource. Policies and procedures shall be established for ensuring the confidentiality of all patient's social information.

(12) PATIENT ACTIVITIES. The skilled nursing facility shall provide for an activities program appropriate to the needs and interests of each patient, to encourage self care, resumption of normal activities, and maintenance of an optimal level of psychosocial functioning.

(a) *Responsibility for patient activities.* A member of the facility's staff shall be designated responsible for the patient activities program. If the staff member is not a qualified patient activities coordinator, the staff member shall function with frequent, regularly scheduled consultation from a person so qualified.

(b) *Patient activities program.* Provision shall be made for an ongoing program of meaningful activities appropriate to the needs and interests of patients, designed to promote opportunities for engaging in normal pursuits, including religious activities of their choice, if any. Each patient's activities program shall be approved by the patient's attending physician as not in conflict with the treatment plan. The activities shall be designed to promote the physical, social, and mental well-being of the patients. The facility shall make available adequate space and a variety of supplies and equipment to satisfy the individual interests of patients.

(13) MEDICAL RECORDS. The facility shall maintain clinical (medical) records on all patients in accordance with accepted professional standards and practices. The medical record service shall have sufficient staff, facilities, and equipment to provide medical records that are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information. The original copy of the medical record shall be maintained on premises at the nursing home.

(a) *Staffing.* Overall supervisory responsibility for the medical record service shall be assigned to a full-time employe of the facility. The facility shall also employ sufficient supportive personnel competent to carry out the functions of the medical record service. If the medical record supervisor is not a qualified medical record practitioner, this person shall function with consultation from a person so qualified.

(b) *Protection of medical record information.* The facility shall safeguard medical record information against loss, destruction, or unauthorized use.

(c) *Content.* The medical record shall contain sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately. All medical records shall contain documented evidence of: assessment of the needs of the patient; establishment of an appropriate plan of treatment; care and services provided; authentication of hospital diagnosis (discharge summary, report from patient's attending physician, or transfer form); identification data and consent forms; medical and nursing history of the patient; report of physical examination(s); diagnostic and therapeutic orders; observations and progress notes; reports of treatments and clinical findings; and discharge summary including final diagnosis and prognosis.

(d) *Physician documentation.* Only physicians shall enter or authenticate in medical records opinions that require medical judgment (in accordance with medical staff bylaws, rules, and regulations, if applicable). All entries into the medical record shall be signed by the physician who makes the entry.

(e) *Completion of records and centralization of reports.* Current medical records and those of discharged patients shall be completed promptly. All clinical information pertaining to a patient's stay shall be centralized in the patient's medical record.

(f) *Retention and preservation.* Medical records shall be retained for 5 years from the date of discharge, or, in the case of a minor, 3 years after the patient becomes of age under state law.

(g) *Indexes.* Patients' medical records shall be indexed according to name of patient and final diagnoses to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(h) *Location and facilities.* The facility shall maintain adequate facilities and equipment, conveniently located, to provide efficient processing of medical records (reviewing, indexing, filing, and prompt retrieval).

(14) TRANSFER AGREEMENT. The skilled nursing facility shall have in effect a transfer agreement with one or more hospitals approved for Medicaid participation, under which inpatient hospital care or other hospital services are available promptly to the facility's patients when needed.

(a) *Transfer of patients.* A hospital and a skilled nursing facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the 2 institutions under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that:

1. Transfer of patients will be effected between the hospital and the skilled nursing facility ensuring timely admission, whenever such transfer is medically appropriate as determined by the attending physician; and

2. There shall be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for in other than either of the 2 institutions; and

3. Security and accountability for patients' personal effects are provided during transfer.

(b) A facility which does not have a patient transfer agreement in effect, but which is found by the department to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in HSS 105.10 (14) (a) 2. shall be considered to have such an agreement in effect if and for so long as the department finds that to do so is in the public interest and essential to ensuring skilled nursing facility services for eligible recipients in the community.

(c) In the case of transfer of a recipient from one facility to another, a copy of the plans of care and medical records shall be maintained in the facility from which the patient is transferred. The records of transferred patients shall be retained for 5 years from date of transfer.

(15) PHYSICAL ENVIRONMENT. The facility shall be constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public.

(a) *Life safety from fire.* The skilled nursing facility shall meet such provisions of the Life Safety Code of the National Fire Protection Association (21st Edition, 1967) as are applicable to nursing homes; except that, in consideration of a recommendation by the department, the department may waive, for such periods as deemed appropriate, specific provisons of such Code which, if rigidly applied, would result in unreasonable hardship upon a skilled nursing facility, but only if such waiver will not adversely affect the health and safety of the patients. Where waiver permits the participation of an existing facility of two or more stories which is not of at least 2-hour fire resistive construction, blind, nonambulatory, or physically handicapped patients shall not be housed above the street level floor unless the facility is of 1-hour protected noncombustible construction (as defined in National Fire Protection Association Standard No. 220), fully sprinklered 1-hour protected ordinary construction, or fully sprinklered 1-hour protected woodframe construction. Nonflammable medical gas systems, such as oxygen and nitrous oxide, installed in the facility shall comply with applicable provisions of National Fire Protection Association Standard No. 56B (Standard for the Use of Inhalation Therapy) 1968 and National Fire Protection Association Standard No. 56F (Nonflammable Medical Gas Systems) 1970.

(b) *Emergency power.* The facility shall provide an emergency source of electrical power necessary to protect the health and safety of patients in the event the normal electrical supply is interrupted. The emergency electrical power system shall supply power adequate at least for lighting in all means of egress; equipment to maintain fire detection, alarm, and extinguishing systems; and life support systems. Where life support systems are used, emergency electrical service shall be provided by an emergency generator located on the premises.

(c) *Facilities for physically handicapped.* The facility shall be accessible to, and functional for patients, personnel, and the public. All necessary accomodations shall be made to meet the needs of persons with semi-ambulatory disabilities, sight and hearing disabilities, disabilities of coordination, as well as other disabilities, in accordance with the American National Standards Institute (ANSI) Standard No. A117.1, American Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped. The department may waive in existing buildings, for such periods as deemed appropriate, specific provisions of ANSI Standard No. A117.1 which, if rigidly enforced, would result in unreasonable hardship upon the facility, but only if such waiver will not adversely affect the health and safety of patients.

(d) *Nursing unit.* Each nursing unit shall have at least the following basic service areas: nurses stations, storage and preparation area for drugs and biologicals, and utility and storage rooms adequate in size,

conveniently located, and well lighted to facilitate staff functioning. The nurses station shall be equipped to register patients' calls through a communication system from patient areas, including patient rooms and toilet and bathing facilities.

(e) *Patient rooms and toilet facilities.* Patient rooms shall be designed and equipped for adequate nursing care and the comfort and privacy of patients, and shall have no more than four beds, except in facilities primarily for the care of the mentally ill or retarded or both, where there shall be no more than 12 beds per room. Single patient rooms shall provide a minimum of 80 square feet per bed. The department may permit variations in individual cases where the facility demonstrates in writing that such variations are in accordance with the particular needs of the patients and will not adversely affect their health and safety. Each room shall be equipped with, or be conveniently located near adequate toilet and bathing facilities. Each room shall have direct access to a corridor and outside exposure, with the floor at or above grade level.

(f) *Facilities for special care.* Provisions shall be made for isolating patients as necessary in single rooms ventilated to the outside, with private toilet and handwashing facilities. Procedures in aseptic and isolation techniques shall be established in writing and followed by all personnel. Such areas shall be identified by appropriate precautionary signs.

(g) *Dining and patient activities rooms.* The facility shall provide one or more clean, orderly, and appropriately furnished rooms of adequate size designated for patient dining and other patient activities. These areas shall be well-lighted and well-ventilated. If a multipurpose room is used for dining and patient activities, there shall be sufficient space to accomodate all activities and prevent their interference with each other.

(h) *Kitchen and dietetic service areas.* The facility shall have kitchen and dietetic service areas adequate to meet food service needs. These areas shall be properly ventilated, and arranged and equipped for sanitary refrigeration, storage, preparation, and serving of food as well as for dish and utensil cleaning and refuse storage and removal.

(i) *Maintenance of equipment, building, and grounds.* The facility shall establish a written preventive maintenance program to ensure that equipment is operative and that the interior and exterior of the building are clean and orderly. All essential mechanical, electrical, and patient care equipment shall be maintained in safe operating condition.

(j) *Other environmental considerations.* The facility shall provide a functional, sanitary, and comfortable environment for patients, personnel, and the public. Provision shall be made for adequate and comfortable lighting levels in all areas, limitation of sounds at comfort levels, maintaining a comfortable room temperature, procedures to ensure water to all essential areas in the event of loss of normal water supply, and adequate ventilation through windows or mechanical means or a combination of both. Corridors shall be equipped with firmly secured handrails on each side.

(16) INFECTION CONTROL. The facility shall establish an infection control committee of representative professional staff with responsibility for overall infection control in the facility. All necessary housekeeping and maintenance services shall be provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Infection control committee.* The infection control committee shall be composed of members of the medical and nursing staffs, administration, and the dietetic, pharmacy, housekeeping, maintenance, and other services. The committee shall establish policies and procedures for investigating, controlling, and preventing infections in the facility, and shall monitor staff performance to ensure that the policies and procedures are executed.

(b) *Aseptic and isolation techniques.* Written effective procedures in aseptic and isolation techniques shall be followed by all personnel. Procedures shall be reviewed and revised annually for effectiveness and improvement.

(c) *Housekeeping.* The facility shall employ sufficient housekeeping personnel and provide all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employe shall be designated responsible for the services and for supervision and training of personnel. Nursing personnel shall not be assigned housekeeping duties. A facility that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the facility or outside resources meets the requirements of this standard.

(d) *Linen.* The facility shall have available at all times a quantity of linen essential for proper care and comfort of patients. Linens shall be handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Pest control.* The facility shall be maintained free from insects and rodents through operation of a pest control program.

(17) DISASTER PREPAREDNESS. The facility shall have a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from such disasters.

(a) *Disaster plan.* The facility shall have an acceptable written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan shall be developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and shall include procedures for prompt transfer of casualties and records, instructions regarding the location and use of alarm systems and signals and of firefighting equipment, information regarding methods of containing fire, procedures for notification of appropriate persons, and specifications of evacuation routes and procedures.

(b) *Staff training and drills.* All employes shall be trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program shall include orientation and ongoing training and drills for all personnel in all procedures so that each employe promptly and correctly carries out a specific role in case of a disaster. Drills shall be held at least 4 times a year on each shift.

(18) UTILIZATION REVIEW.

Note: Sub. (18) is a codification of 42 CFR Part 456 Subpart E.

(a) *UR plan required for skilled nursing facility services.* 1. The state plan must provide that each SNF furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the SNF furnishes.

2. Each written SNF UR plan must meet the requirements under HSS 105.10 (18) (a) through (s).

(b) *UR committee required.* The UR plan must:

1. Provide for a committee to perform UR required under this subpart;

2. Describe the organization, composition, and functions of this committee; and

3. Specify the frequency of meetings of the committee.

(c) *Organization and composition of UR committee; disqualification from UR committee membership.* 1. For the purpose of this subpart, "UR Committee" includes any group organized under subds. 2 and 3 of this section.

2. The UR committee must be composed of 2 or more physicians and assisted by other professional personnel and, in a SNF that cares primarily for mental patients, include at least one physician member who is knowledgeable in the diagnosis and treatment of mental diseases.

3. The UR committee must be constituted as: a. A committee of individuals with SNF staff privileges;

b. A group outside the SNF established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

c. A group capable of performing utilization review and established and organized in a manner approved by the department.

4. The UR committee may not include any individual who: a. Is directly responsible for the care of patients whose care is being reviewed;

b. Is employed by the SNF; or

c. Has a financial interest in any SNF.

(d) *Recipient information required for UR.* The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

1. Identification of the recipient.

2. The name of the recipient's physician.

3. Date of admission and dates of application for and authorization of medicaid benefits if application is made after admission.

4. The plan of care required under HSS 105.10 (5) (d).

5. Initial and subsequent continued stay review dates described under HSS 105.10 (18) (i) and (j).

6. Reasons and plan for continued stay if the attending physician believes continued stay is necessary.

7. Other supporting material that the committee believes appropriate to be included in the record.

(e) *Records and reports.* The UR plan must describe:

1. The types of records that are kept by the committee; and

2. The type and frequency of committee reports, and arrangements for their distribution to appropriate individuals.

(f) *Confidentiality.* The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

(g) *Continued stay review required.* The UR plan must provide for a review of each recipient's continued stay in the SNF to decide whether it is needed, in accordance with the requirements of HSS 105.10 (18) (h)-(n).

(h) *Evaluation criteria for continued stay.* The UR plan must provide that:

1. The committee develops written medical care criteria to assess the need for continued stay; and

2. The committee develops more extensive written criteria for cases that its experience shows are: a. Associated with high costs;

b. Associated with the frequent furnishing of excessive services; or

c. Attended by physicians whose patterns of care are frequently found to be questionable.

(i) *Initial continued stay review date.* The UR plan must provide that:

1. When a recipient is admitted to the SNF under admission review requirements of this subpart, the committee assigns a specified date by which the need for continued stay will be reviewed;

2. If an individual applies for medicaid while in the SNF, the committee assigns the initial continued stay review date within one working day after the SNF is notified of the application for medicaid;

3. The committee bases its assignment of the initial continued stay review date on the methods and criteria required to be described under HSS 105.10 (18) (k) 1.

4. The initial continued stay review date is either: a. Not later than 9 days after the date of the individual's admission or notice to the SNF of application for medicaid, if the date is established using specific periods for diagnostic categories or categories based on functional capabilities; or

b. Not later than 30 days after the date of the individual's admission or notice of application, if the date is established by another method; and

5. The committee ensures that the initial continued stay review date is recorded in the individual's record.

(j) *Subsquent continued stay review dates.* The UR plan must provide that:

1. The committee assigns subsequent continued stay review dates in accordance with HSS 105.10 (18) (i) and (k) 1.

2. The committee assigns subsequent continued stay review dates each time it decides under HSS 105.10 (18) (l) that the continued stay is needed, a. At least every 90 days if the dates are established using specific periods for diagnostic categories based on functional capabilities; or

b. At least every 30 days for the first 90 days and at least every 90 days thereafter if the dates are established by another method; and

3. The committee ensures that each continued stay review date that it assigns is recorded in the recipient's record.

(k) *Description of methods and criteria: continued stay review dates: length of stay modification.* The UR plan must describe:

1. The methods and criteria that the committee uses to assign initial and subsequent continued stay review dates under HSS 105.10 (18) (i) and (j); and

2. The methods used by the committee to modify an approved length of stay when the recipient's condition or treatment schedule changes.

(l) *Continued stay review process.* The UR plan must provide that:

1. Review of continued stay cases is conducted by: a. The UR committee;

b. A subgroup of the UR committee; or

c. A designee of the UR committee;

2. The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

3. For each continued stay of a recipient in the SNF, the committee, subgroup or designee reviews and evaluates the documentation described under HSS 105.10 (18) (d) against the criteria developed under HSS 105.10 (18) (h) and applies close professional scrutiny to cases described under HSS 105.10 (18) (h) 2.

4. If the committee, subgroup or designee finds that the recipient's continued stay in the SNF is needed, the committee assigns a new continued stay review in accordance with HSS 105.10 (18) (j).

5. If the committee, subgroup or designee finds that a continued stay does not meet the criteria, the committee or a subgroup that includes at

least one physician reviews the case to decide the need for continued stay;

6. If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

7. If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

8. If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. In an SNF that cares primarily for mental patients, one of these two physicians must be knowledgeable in the treatment of mental diseases. If they find that the recipient no longer needs SNF services their decision is final.

(m) *Notification of adverse decision.* The UR plan must provide that written notice of any adverse final decision on the need for continued stay under HSS 105.10 (18) (l) 6. through 8. is sent to:

1. The SNF administrator;

2. The attending physician;

3. The medicaid agency;

4. The recipient; and

5. If possible, the next of kin or sponsor.

(n) *Time limits for final decision and notification of adverse decision.* The UR plan must provide that:

1. The committee makes a final decision on a recipient's need for continued stay and gives notice under HSS 105.10 (18) (m) of an adverse decision within 3 working days after the assigned review date, except as required under paragraph (b) [2.] of the section.

2. If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under HSS 105.10 (18) (m) within 2 working days after the date of the final decision.

(o) *Purpose and general description—medical care evaluation studies.* 1. The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

2. Medical care evaluation studies: a. Emphasize identification and analyses of patterns of patient care; and

b. Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

(p) *UR plan requirement for medical care evaluation studies.* 1. The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under subdivision 2.a. of this section.

2. The UR plan must provide that the UR committee a. Determines the methods to be used in selecting and conducting medical care evaluation studies in the SNF;

b. Documents for each study its results; and how the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

c. Analyzes its findings for each study; and

d. Takes action as needed to: (i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient skilled nursing care procedures.

(q) *Content of medical care evaluation studies.* Each medical care evaluation study must:

1. Identify and analyze medical or administrative factors related to the SNF's patient care;

2. Include analysis of at least the following: a. Admissions,

b. Durations of stay.

c. Ancillary services furnished, including drugs and biologicals.

d. Professional services performed in the SNF; and

3. If indicated, contain recommendations for change beneficial to patients, staff, the SNF and the community.

(r) *Data sources for studies.* Data that the committee uses to perform studies must be obtained from one or more of the following sources:

1. Medical records or other appropriate data.

2. External organizations that compile statistics, design profiles, and produce other comparative data.

3. Cooperative endeavors with PSRO's; fiscal agents; other providers of services; or other appropriate agencies.

(s) *Number of studies required to be performed.* The SNF must, at least, have one study in progress at any time and complete one study each calendar year.

(t) *Discharge plan.* 1. The UR committee must review each recipient's discharge plan.

2. Each discharge plan must insure that the recipient has a planned program of post-discharge continuing care that takes the patient's needs into account.

(u) *Discharge planning procedures.* Each SNF must maintain discharge planning procedures that describe the following:

1. The staff member of the SNF or the health, social, or welfare agency responsible for discharge planning.

2. The authority of the member or agency, and the methods used in discharge planning, including the relationship with the SNF's staff.

3. The time allowed for determining each recipient's need for discharge planning. The period must not be longer than 7 days after the day of admission.

4. The period after which each recipient's discharge plan will be reevaluated.

5. The local resources available to the SNF, the recipient, and the attending physician to assist in developing and implementing discharge plans.

6. The provision for periodic review and reevaluation of the SNF's discharge planning program.

(v) *Information about discharged recipients.* 1. When a recipient is discharged, the SNF must provide information that will insure the optimal continuity of care, such as:

a. Current information relative to diagnosis;

a. Prior treatment;

c. Rehabilitation potential;

d. Physician advice concerning immediate care; and

e. Pertinent social information.

2. This information must be provided to those persons who are responsible for the recipient's post-discharge care.

[Note: Sub. (19) is a codification of 42 CFR Part 456 Subpart I.]

(19) INSPECTIONS OF CARE IN SKILLED NURSING AND INTERMEDIATE CARE FACILITIES AND INSTITITUTIONS FOR MENTAL DISEASES. (a) *Purpose.* This subpart prescribes requirements for periodic inspections of care and services in skilled nursing facilities (SNF's), intermediate care facilities (ICF's), and institutions for mental diseases (IMD's).

(b) *Inspection team.* 1. A team, as described in this section and HSS 105.10 (19) (c) must periodically inspect the care and services provided to recipients in each facility.

2. Each team conducting periodic inspections must have at least one member who is a physician or registered nurse and other appropriate health and social service personnel.

3. For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

4. For an ICF that primarily cares for mental patients, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

5. For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

6. For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

7. If there is no physician on the team, the medicaid agency must insure that a physician is available to provide consultation to the team.

8. If a team has one or more physicians, it must be supervised by a physician.

(c) *Financial interests and employment of team members.* 1. Except as provided in paragraph 2 of this section:

a. No member of a team that reviews care in a SNF may have a financial interest in or be employed by any SNF; and

b. No member of a team that reviews care in an ICF may have a financial interest in or be employed by an ICF.

2. A member of a team that reviews care in an IMD or an institution for the mentally retarded or persons with related conditions:

a. May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and

b. May not review care in an institution where the person is employed but may review care in any other facility or institution.

(d) *Physician team member inspecting care of recipients.* No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

(e) *Number and location of teams.* There must be a sufficient number of teams so located within the state that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

(f) *Frequency of inspections.* The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

(g) *Notification before inspection.* No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

(h) *Personal contact with and observation of recipients and review of records.* 1. For recipients under age 21 in psychiatric facilities and recipients in SNFs and ICFs, other than those described in paragraph 2 of this section, the team's inspection must include:

a. Personal contact with and observation of each recipient; and

b. Review of each recipient's medical record.

2. For recipients age 65 or older in IMDs, the team's inspection must include:

a. Review of each recipient's medical record; and

b. If the record does not contain complete reports of periodic assessment or if such reports are inadequate, personal contact with and observation of each recipient.

(i) *Determinations by team.* The team must determine in its inspection whether:

1. The services available in the facility are adequate to:

a. Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and

b. Promote the person's maximum physical, mental, and psychosocial functioning.

2. It is necessary and desirable for the recipient to remain in the facility;

3. It is feasible to meet the recipient's health needs and, in an ICF, the recipient's rehabilitative needs, through alternative institutional or noninstitutional services; and

4. Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in HSS 107.13 (1) (b).

(j) *Basis for determinations.* In making the determinations on adequacy of services and related matters under HSS 105.10 (19) (i) for each recipient, the team may consider such items as whether:

1. The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;

2. The attending physician reviews prescribed medications:

a. At least every 30 days in SNFs, psychiatric facilities, and mental hospitals; and

b. At least quarterly in ICFs;

3. Tests or observations of each recipient indicated by the medication regimen are made at appropriate times and properly recorded;

4. Physician, nurse and other professional progress notes are made as required and appear to be consistent with the observed condition of the recipient;

5. The recipient receives adequate services, based on such observations as:

a. Cleanliness;

b. Absence of bedsores;

c. Absence of signs of malnutrition or dehydration; and

d. Apparent maintenance of maximum physical, mental, and psychosocial function;

6. In an ICF, the recipient receives adequate rehabilitative services, as evidenced by:

a. A planned program of activities to prevent regression; and

b. Progress toward meeting objectives of the plan of care;

7. The recipient needs any service that is not furnished by the facility or through arrangements with others; and

8. The recipient needs continued placement in the facility or there is an appropriate plan to transfer the recipient to an alternate method of care.

(k) *Reports on inspections.* 1. The team must submit a report promptly to the agency on each inspection.

2. The report must contain the observations, conclusions, and recommendations of the team concerning:

a. The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and

b. Specific findings about individual recipients in the facility.

(l) *Copies of reports.* The agency must send a copy of each inspection report to:

1. The facility inspected;

2. The facility's utilization review committee;

3. The agency responsible for licensing, certification, or approval of the facility for purposes of medicare and medicaid; and

4. Other state agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD's, the appropriate state mental health authorities.

(m) *Action on reports.* The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

(n) *Inspections by utilization review committee.* A utilization review committee may conduct the periodic inspections required by this subpart if:

1. The committee is not based in the facility being reviewed; and

2. The composition of the committee meets the requirements of this subpart.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.105 Medicare bed requirement. (1) These rules, promulgated pursuant to ss. 49.45 (10) and 50.02 (2), Stats., define the obligation of skilled nursing facilities which are certified under the Medicaid program to make available beds which are certified under the Medicare program.

(2) Skilled nursing facilities in each district which have been certified to provide services and receive reimbursement under Medicaid, or which seek such certification, shall make beds available which have been certified under Medicare as follows:

(a) In each district, each large skilled nursing facility seeking recertification or initial certification under Medicaid shall be required to have the lesser of 30% of its beds, or such lower percentage as would be required to establish a ratio of 6 Medicare certified beds per 1,000 elderly population, but in no case fewer than 10 of its beds certified under Medicare.

(b) If the department determines annually that fewer than 6 Medicare certified beds per 1,000 elderly population in a district have been established as a result of section HSS 105.105 (2) (a), each skilled nursing facility in the district with at least 40 but fewer than 100 beds which seeks recertification or initial certification under Medicaid shall be required to have the lesser of 30% of its beds, or such lower percentage as would be required to establish a ratio of 6 Medicare certified beds/1,000 elderly population, but in no case fewer than 10 of its beds certified under Medicare.

(c) The date on which skilled nursing facilities must meet the requirements for certification of Medicare beds imposed by section HSS 105.105 (2) (a) or (b) and the requirements of s. 49.45 (6m) (g), Stats. shall, subject to Federal Title XVIII approval, be within 90 days of the date of issuance of an initial Medicaid provider agreement or the date of renewal of an existing Medicaid provider agreement.

(3) Any skilled nursing facility seeking recertification or initial certification under Medicaid shall be denied such certification until it meets the requirements imposed by this section.

(4) The department has the right to exempt skilled nursing facilities in an area provided the requirements of this rule are met by other skilled nursing facilities in the same area. Homes wishing to be exempted from the provisions of this rule may apply for such exemptions to the department. Exemption status will be based on assurance of an adequate supply and accessibility of Medicare certified beds.

(5) Homes with 50% or more of their residents classified as mentally retarded shall be exempt from this rule.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

Note: Section HSS 105.106 is a codification of 42 CFR Part 442, subpart C.

HSS 105.106 Certification of SNF's and ICF's. (1) CERTIFICATION WITH DEFICIENCIES: GENERAL PROVISIONS. If the department finds a facility deficient in meeting the standards specified in HSS 105.10, 11 or 12, the agency may certify the facility for medicaid purposes under the following conditions:

(a) The agency finds that the facility's deficiencies, individually or in combination, do not jeopardize the patient's health and safety, nor seriously limit the facility's capacity to give adequate care. The agency must maintain a written justification of these findings.

(b) The department finds acceptable the facility's written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the department documents that the facility:

1. Was unable to stay in compliance with the standard for reasons beyond its control, or despite intensive efforts to comply; and

2. Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the department documents that the facility:

1. Did achieve compliance with the standard at some time during the prior certification period;

2. Made a good faith effort, as judged by the department to stay in compliance; and

3. Again became out of compliance for reasons beyond its control.

(e) If an ICF or ICF/MR has a deficiency of the types specified in HSS 105.106 (3) or (4) that requires a plan or correction extending beyond 12 months, the department documents that the conditions of those sections are met.

(2) CERTIFICATION PERIOD: FACILITIES WITH DEFICIENCIES. (a) Facilities with deficiencies may be certified under HSS 105.106 (1) for the period specified in either paragraph (b) or (c) of this section. However, ICF's with deficiencies that may require more than 12 months to correct may be certified under HSS 105.106 (3) and (4).

(b) The department may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting the deficiencies. The certification period must not exceed 12 months, including the period allowed for corrections.

(c) The survey agency may certify a facility for up to 12 months with a condition that the certification will be automatically cancelled on a specified date within the certification period unless:

1. The department finds that all deficiencies have been satisfactorily corrected; or

2. The department finds that the facility has made substantial progress in correcting the deficiencies and has a new plan for correction that is acceptable.

(d) The automatic cancellation must be no later than 60 days after the last day specified in the plan for correction of deficiencies under HSS 105.106 (1).

(3) EXTENDED PERIOD FOR CORRECTING DEFICIENCIES: ICF'S OTHER THAN ICF'S/MR; ENVIRONMENT, SANITATION, AND LIFE SAFETY CODE DEFICIENCIES. (a) *Scope.* This section applies to ICF's other than ICF's/MR that are deficient in meeting requirements for:

1. Environment and sanitation in HSS 105.11 (24) through (30) 1; or

2. Life Safety Code in HSS 105.11 (21) through (23) 1.

(b) *Certification period.* The survey agency may certify an ICF other than an ICF/MR under HSS 105.106 (1) for up to 12 months even though the facility has deficiencies that may take up to 2 years after the first certification of the facility to correct, if the conditions in this section are met.

(c) *Written plan for correction.* The ICF must submit a written plan for correcting the deficiencies that:

1. Specifies the steps the facility will take to correct each deficiency;

2. Specifies a timetable for taking each of those steps and a date for completion of correction of each deficiency that is not later than 2 years after the date the facility is first certified; and

3. Is acceptable to the department.

(d) *Feasibility of plan.* The department must find that the facility can:

1. Potentially meet the requirements in which it is deficient by taking the steps specified in the plan for correction; and

2. Correct each deficiency by the date specified in the plan for correction; and

(e) *Progress in meeting correction plan.* Within each 6-month period after acceptance of the plan for correction, the department must find, and record in the survey record, that the facility has made substantial progress in meeting its plan for correction. These findings must be based on onsite surveys by qualified surveyors. The department must support these findings by placing signed contracts, work orders, or other documents in the survey record.

(f) *State fire safety and sanitation requirements.* The department must find that, during the period allowed for corrections, the facility meets state fire safety and sanitation codes and regulations.

(4) EXTENDED PERIOD FOR CORRECTING DEFICIENCIES: ICF'S/MR; LIFE SAFETY CODE AND LIVING/DINING/THERAPY AREA DEFICIENCIES. (a) *Scope.* This section applies to ICF's/MR that are deficient in meeting requirements for:

1. Life Safety Code [HSS 105.12 (106) through (108)];

2. Living units [HSS 105.12 (46) (a) 1., 2., 4., 5., (b), (c); (47) (d); (48) (a), (b); (49) (a) 2., (50) (a); (51) and (52)];

3. Dining rooms [HSS 105.12 (70) (a), (c)]; or

4. Therapy areas [HSS 105.12 (87) (e)].

(b) *Certification period.* The survey agency may certify an ICF/MR under HSS 105.106 (1) for up to 12 months even though the deficiencies listed in paragraph (a) of this section may take more than 12 months to correct, if the conditions in this section and HSS 105.106 (5) are met.

(c) *Written plan for correction.* Before certifying an ICF/MR under this section, the department must approve, in writing, the ICF/MR's written plan for correcting those deficiencies. The plan must:

1. State the extent to which the ICF/MR complies with the requirements it does not fully meet;

2. Specify the steps the ICF/MR will take to correct the deficiencies;

3. Specify a timetable for taking each of those steps and a date for completion of corrections;

4. For a public ICF/MR, be approved by the state or political subdivision that has jurisdiction over its operation (A public facility is defined as one that is the "responsibility of a governmental unit or over which a governmental unit exercises administrative control."); and

5. Meet the conditions of HSS 105.106 (5).

(d) *Progress in meeting correction plan.* Within each 6-month period after initial approval of the plan, the department must find, and record in the survey record, that the ICF/MR has made substantial progress in meeting the plan for correction. These findings must be based on onsite surveys by qualified surveyors. The survey agency must support these findings by placing signed contracts, work orders, or other documentation in the survey record.

(e) *State fire safety and sanitation requirements.* The department must find that, during the period allowed for corrections, the ICF/MR meets the state fire safety and sanitation codes and regulations.

(5) CORRECTION PLANS. (a) The ICF/MR's plan required by HSS 105.106 (4) must provide for completion of corrections by July 18, 1980, or, if authorized by the HEW secretary under paragraph (b) of this section, by July 18, 1982.

(b) If, at the time of the first survey of the ICF/MR after July 17, 1977, it is unable to develop a plan to complete corrections by July 18, 1980, the department may request the HEW secretary to authorize approval of a plan to complete them by July 18, 1982. The HEW secretary will authorize this approval for each deficiency if he determines that time beyond July 18, 1977, is needed:

1. As a practical matter to complete the corrections;

2. To prevent unreasonable hardship to the ICF/MR; and

3. To insure continued care for recipients served by the ICF/MR.

(c) If the plan provides for correction through structural change or renovation, it must:

1. Contain a timetable showing the corrective steps and their completion dates;

2. Specify the structural change or renovation; and

3. Document that sufficient financial resources are available to complete the change or renovation on schedule.

(d) If the plan provides for correction by phasing out part or all of the ICF/MR, it must:

1. Contain a timetable showing the buildings or units to be closed and describing the steps for phasing them out;

2. Describe the methods that insure the recipient's health and safety until the building or unit is closed; and

3. Provide that no new recipients will be admitted to the building or unit after the plan has been approved.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.11 Certification of intermediate care facilities. Intermediate care facilities are required to be licensed pursuant to s. 50.03, Stats., and to meet the following standards which are hereby adopted for purposes of program administration.

Note: The following rules are a codification of 42 CFR Part 442, Subparts E and F and 42 CFR Part 456 Subpart F. For the sake of readibility, some editing has been done; also, some changes have been made to conform with state law and policy. These rules will be incorporated into the next complete revision of Wis. Adm. Code chapter H 32, at which time these rules will be repealed.

(1) STATE LICENSING STANDARDS. (a) Except as provided in paragraph (b), an ICF must meet standards for a state license to provide, on a regular basis, health-related care and services to individuals who do not require hospital or SNF care, but whose mental or physical condition requires services above the level of room and board; and that can be provided only by an institution.

(b) An ICF that formerly met state licensing standards but does not currently meet them may continue to receive medicaid payments as a qualified provider during a period specified by the department if, during that period, the ICF takes the steps needed to again meet the standards.

(c) An ICF operated by a government agency must meet the licensing standards that apply to the same type of facility operated under any other ownership.

(d) An Indian Health Service ICF must meet state licensing standards although it need not obtain a license. In making this determination, the licensing authority may not take into account an absence of licensure of any staff member of the facility.

(2) STATE SAFETY AND SANITATION STANDARDS. An ICF must meet state safety and sanitation standards for nursing homes.

(3) FEDERAL DEFINITION AND STANDARDS. (a) An ICF other than an ICF/MR must meet the definition in chapter HSS 101 and the standards specified in this subsection and in HSS 105.115, except for provisions waived or accepted under plans of correction as specified in HSS 105 [105.106].

(b) An ICF/MR must meet the definition in HSS 101 and the standards specified in this subsection and in HSS 105.112 except for provisions waived or accepted under plans of correction as specified in HSS 105 [105.106].

(4) STANDARDS FOR HOSPITALS AND SNF'S PROVIDING ICF SERVICES. (a) If a hospital or SNF participating in medicare or medicaid is also a provider of ICF services other than ICF/MR services, it must meet the following ICF standards:

1. HSS 105.115 (4), resident services director.

2. HSS 105.115 (17), (a), (b), agreements with outside resources for institutional services.

3. HSS 105.115 (19), plan of care.

4. HSS 105.115 (20), resident financial records.

5. HSS 105.115 (24), (b), handrails.

6. HSS 105.115 (38) through (42), health services.

7. HSS 105.115 (43), rehabilitative services.

8. HSS 105.115 (44), social services.

9. HSS 105.115 (45), activities program.

10. HSS 105.115 (46), physician services.

(b) If a hospital or SNF participating in medicare or medicaid is also a provider of ICF/MR services, it must meet the standards in HSS 105.12.

Note: Sub. (5) is a codification of 42 CFR Part 456 Subpart F.

(5) UTILIZATION REVIEW REQUIREMENTS—ICF SERVICES. (a) *State plan UR requirements and options; UR plan required for intermediate care facility services.* The state plan must provide that:

1. UR is performed for each ICF that furnishes inpatient services under the plan;

2. Each ICF has on file a written UR plan that provides for review of each recipient's need for the services that the ICF furnishes the patient; and

3. Each written ICF UR plan meets requirements under HSS 105.11 (5) (a) through (o).

4. The state plan must specify the method used to perform UR, which may be:

a. Review conducted by the facility;

b. Direct review in the facility by individuals:

i. Employed by the medical assistance unit of the medicaid agency; or

ii. Under contract to the medicaid agency; or

c. Any other method.

(b) *Description of UR review function: how and when.* The UR plan must include a written description of:

1. How UR is performed in the ICF; and

2. When UR is performed.

(c) *Description of UR review function: who performs UR; disqualification from performing UR.* 1. The UR plan must include a written description of who performs UR in the ICF.

2. UR must be performed using a method specified under HSS 105.11 (5) (a) 4 by a group of professional personnel that includes:

a. At least one physician;

b. In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and

c. In an institution for the mentally retarded, at least one individual knowledgeable in the treatment of mental retardation.

3. The group performing UR may not include any individual who:

a. Is directly responsible for the care of the recipient whose care is being reviewed;

b. Is employed by the ICF; or

c. Has a financial interest in any ICF.

(d) *UR responsibilities of administrative staff.* The UR plan must describe:

1. The UR support responsibilities of the ICF's administrative staff; and

2. Procedures used by the staff for taking needed corrective action.

(e) *Recipient information required for UR.* The UR plan must provide that each recipient's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

1. Identification of the recipient.

2. The name of the recipient's physician.

3. The name of the qualified mental retardation professional (as defined under HSS 101.103) if applicable.

4. Date of admission, and dates of application for and authorization of medicaid benefits if application is made after admission.

5. The plan of care required under HSS 107.09 (3) (p);

6. Initial and subsequent continued stay review dates described under HSS 105.11 (5) (j) and (k).

7. Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.

8. Other supporting material that the UR group believes appropriate to be included in the record.

(f) *Records and reports.* The UR plan must describe:

1. The types of records that are kept by the group performing UR; and

2. The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

(g) *Confidentiality.* The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

(h) *Continued stay review required.* 1. The UR plan must provide for a review of each recipient's continued stay in the ICF at least every 6 months to decide whether it is needed.

2. The UR plan requirement for continued stay review may be met by:

a. Reviews that are performed in accordance with the requirements of HSS 105.11 (5) (i) through (n); or

b. Reviews that meet on-site inspection requirements under HSS 105.10 (19) if:

i. The composition of the independent professional review team under [105.10(19)] meets the requirements of HSS 105.11 (5) (c); and

ii. Reviews are conducted as frequently as required under HSS 105.10 (18) (i) and (j).

(i) *Evaluation criteria for continued stay.* The UR plan must provide that:

1. The group performing UR develops written criteria to assess the need for continued stay.

2. The group develops more extensive written criteria for cases that its experience shows are:

a. Associated with high costs;

b. Associated with frequent furnishing of excessive services; or

c. Attended by physicians whose patterns of care are frequently found to be questionable.

(j) *Initial continued stay review date.* The UR plan must provide that:

1. When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;

2. The group performing UR bases its assignment of the initial continued stay review date on the methods and criteria required to be described under HSS 105.11 (5) (l);

3. The initial continued stay review date is:

a. Not later than 6 months after admission; or

b. Earlier than 6 months after admission, if indicated at the time of admission; and

4. The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

(k) *Subsequent continued stay review dates.* The UR plan must provide that:

1. The group performing UR assigns subsequent continued stay review dates in accordance with HSS 105.11 (5) (l).

2. The group assigns a subsequent continued stay review date each time it decides under HSS 105.11 (5) (m) that the continued stay is needed:

a. At least every 6 months; or

b. More frequently than every 6 months if indicated at the time of continued stay review; and

3. The group insures that each continued stay review date it assigns is recorded in the recipient's record.

(l) *Description of methods and criteria; continued stay review dates.* The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under HSS 105.11 (5) (j) and (k).

(m) *Continued stay review process.* The UR plan must provide that

1. Review of continued stay cases is conducted by:

a. The group performing UR; or

b. A group designee of the UR group;

2. The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.

3. For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under HSS 105.11 (5) (e) against the criteria developed under HSS 105.11 (5) (i) and applies close professional scrutiny to cases described under HSS 105.11 (5) (i) 2;

4. If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with HSS 105.11 (5) (k);

5. If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

6. If the group or subgroup making the review under paragraph 5 of this section finds that a continued stay is not needed, it notifies the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives the physician or the professional 2 working days from the notification date to present the person's views before it makes a final decision on the need for the continued stay;

7. If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;

8. If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by:

a. The physician member(s) of the UR group, in cases involving a medical determination, and

9. If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

(n) *Notification of adverse decision.* The UR plan must provide that written notice of any adverse final decision on the need for continued stay under HSS 105.11 (5) (m) 7 through 9 is sent to:

1. The ICF administrator;

2. The attending physician;

3. The qualified mental retardation professional, if applicable;

4. The medicaid agency;

5. The recipient; and

6. If possible, the next of kin or sponsor.

(o) *Time limits for notification of adverse decision.* The UR plan must provide that the group gives notice under HSS 105.11 (5) (n) of an adverse decision not later than 2 days after the date of the final decision.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

Note: HSS 105.115 is a codification of 42 CFR Part 442, Subpart F. For the sake of readability, some editing has been done; also changes have been made to conform with state law and policy. This subpart prescribes standard for care, safety, and sanitation in intermediate care facilities. It applies to ICF's other than ICF's/MR.

HSS 105.115 Standards for ICF's other than facilities for the mentally retarded. (1) METHODS OF ADMINISTRATION. An ICF must have methods of administrative management that insure that it meets the requirements of HSS 105.115 (2) through (15).

(2) STAFFING. The ICF must have staff on duty 24 hours a day sufficient in number and qualifications to carry out the policies, responsibilities, and programs of the ICF.

(3) ADMINISTRATOR. (a) The ICF must have an administrator who is:

1. A nursing home administrator with a current state license; or

2. A hospital administrator, if the ICF is a hospital qualifying as an intermediate care facility.

(b) The administrator's responsibilities must include:

1. Managing the ICF; and

2. Implementing established policies and procedures.

(4) RESIDENT SERVICES DIRECTOR. (a) The ICF must designate the administrator or a professional staff member as resident services director.

(b) The duties of the resident services director must include coordinating and monitoring each resident's overall plan of care.

(5) WRITTEN POLICIES AND PROCEDURES; GENERAL REQUIREMENTS. The ICF must have written policies and procedures that:

(a) Govern all services provided by the ICF; and

(b) Are available to the staff, residents, members of the family and legal representatives of residents, and the public.

(6) WRITTEN POLICIES AND PROCEDURES: ADMISSION. The ICF must have written policies and procedures that insure that it admits as residents only those individuals whose needs can be met:

(a) By the ICF itself;

(b) By the ICF in cooperation with community resources; and

(c) By the ICF in cooperation with other providers of care affiliated with or under contract to the ICF.

(7) WRITTEN POLICIES AND PROCEDURES: TRANSFER AND DISCHARGE. The ICF must have written policies and procedures that insure that:

(a) It transfers a resident promptly to a hospital, skilled nursing facility, or other appropriate facility, when a change occurs in the resident's physical or mental condition that requires care or service that the ICF cannot adequately provide; and

(b) Except in an emergency, it:

1. Consults the resident, next of kin, the attending physician, and the responsible agency, if any, at least 5 days before a transfer or discharge; and

2. Uses casework services or other means to insure that adequate arrangements are made to meet the resident's needs through other resources.

(c) In the case of a transfer, a copy of the plans of care and medical records shall be maintained in the facility from which the patient is transferred. The records of transferred patients shall be retained for 5 years from date of transfer.

(8) WRITTEN POLICIES AND PROCEDURES: CHEMICAL AND PHYSICAL RESTRAINTS. The ICF must have written policies and procedures that:

(a) Define the uses of chemical and physical restraints;

(b) Identify the professional personnel who may, under s. 50.09 (1) (k), Stats., authorize use of these restraints in emergencies; and

(c) Describe the procedures for monitoring and controlling the use of these restraints.

(9) WRITTEN POLICIES AND PROCEDURES: RESIDENT COMPLAINTS AND RECOMMENDATIONS. The ICF must have written policies and procedures that:

(a) Describe the procedures the ICF uses to receive complaints and recommendations from its residents; and

(b) Insure that the ICF responds to these complaints and recommendations. All such policies and procedures shall comply with the requirements of s. 50.09 (6) Stats.

(10) WRITTEN POLICIES AND PROCEDURES: RESIDENT RECORDS. The ICF must have written policies and procedures governing access to, duplication of, and dissemination of information from the resident's record.

(11) WRITTEN POLICIES AND PROCEDURES: RESIDENT'S BILL OF RIGHTS. The facility shall comply with the requirements governing residents' rights enumerated in s. 50.09, Stats. and Wis. Adm. Code H 32.055. The facility shall have written policies and procedures governing residents' rights.

(12) WRITTEN POLICIES AND PROCEDURES: DELEGATION OF RIGHTS AND RESPONSIBILITIES. Pursuant to s. 50.09 (3), Stats., the ICF must have written policies and procedures that provide that all rights and responsibilities of a resident pass to the resident's guardian, next of kin, or sponsoring agency or agencies if the resident is adjudicated incompetent under chs. 51 or 880, Stats.

(13) EMERGENCIES. The ICF must:

(a) Have a written plan for staff and residents to follow in case of an emergency such as fire or an explosion and must rehearse the plan regularly; and

(b) Have written procedure for the staff to follow in case of an emergency involving a resident. These emergency procedures must include directions for:

1. Caring for the resident;

2. Notifying the attending physician and other individuals responsible for the resident; and

3. Arranging for transportation, hospitalization, or other appropriate services.

(14) STAFF TRAINING PROGRAM. The ICF must:

(a) Conduct an orientation program for all new employes that includes a review of all its policies;

(b) Plan and conduct an inservice staff development program for all personnel to assist them in developing and improving their skills; and

(c) Maintain a record of each orientation and staff development program it conducts. The record must include the content of the program and the names of the participants.

(15) HEALTH AND SAFETY LAWS. The ICF must meet all federal, state and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating:

(a) Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances;

(b) Construction, maintenance, and equipment for the ICF;

(c) Sanitation;

(d) Communicable and reportable diseases; and

(e) Post mortem procedures.

(16) TRANSFER AGREEMENTS. (a) Except as provided in paragraph (b) of this section, the ICF must have in effect a transfer agreement with one or more hospitals sufficiently close by to make feasible the prompt transfer of the resident and records to the hospital and to support a working arrangement between the ICF and the hospital for providing inpatient hospital services to residents when needed.

(b) If the department finds that the ICF tried in good faith to enter into an agreement but could not, the ICF will be considered to meet the requirements of paragraph (a) as long as the survey agency finds that it is in the public interest and essential to assuring ICF services for eligible individuals in the community.

(17) ARRANGEMENTS WITH OUTSIDE RESOURCES. (a) If the ICF does not employ a qualified professional to furnish a required institutional service, it must have in effect a written agreement with a qualified professional outside the ICF to furnish the required service.

(b) The agreement must:

1. Contain the responsibilities, functions, objectives, and other terms agreed to by the ICF and the qualified professional; and

2. Be signed by the administrator or his representative and by the qualified professional.

(c) The ICF must maintain effective arrangements with outside resources for promptly providing medical and remedial services required by a resident but not regularly provided within the ICF.

(18) RESIDENT RECORD SYSTEM. (a) The ICF must maintain an organized resident record system that contains a record for each resident. The original copy of the record shall be maintained on the premises of the nursing home.

(b) The ICF must make resident records available to staff directly involved with the resident and to appropriate representatives of the department.

(c) Each resident's record must contain:

1. Identification information;

2. Admission information, including the medical and social history of the resident;

3. The original copy of the overall plan of care as described in HSS 105.115 (19);

4. Copies of the initial and periodic examinations, evaluations, progress notes, all plans of care with subsequent changes, and discharge summaries;

5. Description of treatments and services provided and medications administered; and

6. All indications of illness or injury including the date, time, and action taken regarding each.

(d) The ICF must protect the resident records against destruction, loss, and unauthorized use.

(e) The ICF must keep a resident's record for at least 5 years after the date the resident is discharged.

(19) OVERALL PLAN OF CARE. The overall plan of care required by HSS 105.115 (18) must:

(a) Set the goals to be accomplished by the resident;

(b) Prescribe an integrated program of activities, therapies, and treatments designed to help each resident achieve treatment goals; and

(c) Indicate which professional service or individual is responsible for each service prescribed in the plan.

(20) RESIDENT FINANCIAL RECORDS. (a) The ICF must maintain a current, written financial record for each resident that includes written receipts for:

1. All personal possessions and funds received by or deposited with the ICF; and

2. All disbursements made to or for the resident.

(b) The financial record must be available to the resident and his family.

(21) FIRE PROTECTION. Except as provided in HSS 105.115 (22) and (23), the ICF must meet the provisions of the Life Safety Code of the National Fire Protection Association, 1967 edition, that apply to institutional occupancies.

(22) FIRE PROTECTION: EXCEPTION FOR SMALLER ICF'S. The department may apply the lodgings or rooming houses section of the residential occupancy requirements of the Life Safety Code of the National Fire Protection Association, 1967 edition, instead of the institutional occupancy provisions required by HSS 105.115 (21) to an ICF that has 15 beds or less if the ICF is primarily engaged in the treatment of alcoholism and drug abuse and a physician certifies that each resident is:

(a) Ambulatory;

(b) Engaged in an active program for rehabilitation designed to and reasonably expected to lead to independent living; and

(c) Capable of following directions and taking appropriate action for self-preservation under emergency conditions.

(23) FIRE PROTECTION: WAIVERS. (a) The department may waive specific provisions of the Life Safety Code required by HSS 105.115 (21), for as long as it considers appropriate, if:

1. The waiver would not adversely affect the health and safety of the residents;

2. Rigid application of specific provisions of the Code would result in unreasonable hardship for the ICF as determined under guidelines contained in the HCFA Long Term Care Manual; and

3. The waiver is granted in accordance with criteria contained in the Long Term Care Manual.

(b) If the department waives provisions of the Code for an existing building of two or more stories that is not built of at least 2-hour fire-resistive construction, the ICF may not house a blind, nonambulatory, or physically handicapped resident above the street-level floor unless it is built of:

1. One-hour protected, noncombustible construction as defined in National Fire Protection Association Standard No. 220;

2. Fully sprinklered, 1-hour protected, ordinary construction; or

3. Fully sprinklered, 1-hour protected, wood frame construction.

(24) RESIDENT LIVING AREAS. The ICF must:

(a) Design and equip the resident living areas for the comfort and privacy of each resident; and

(b) Have handrails that are firmly attached to the walls in all corridors used by residents.

(25) RESIDENTS' ROOMS. (a) Each resident room must:

1. Be equipped with or conveniently located near toilet and bathing facilities;

2. Be at or above grade level;

3. Contain a suitable bed for each resident and other appropriate furniture;

4. Have closet space that provides security and privacy for clothing and personal belongings;

5. Contain no more than four beds;

6. Measure at least 100 square feet for a single-resident room or 80 square feet for each resident for a multiresident room; and

7. Be equipped with a device for calling the staff member on duty.

(b) For an existing building, the department may waive the space and occupancy requirements of paragraphs (a) (5) and (6) of this section for as long as it is considered appropriate if it finds that:

1. The requirements would result in unreasonable hardship on the ICF if strictly enforced; and

2. The waiver serves the particular needs of the residents and does not adversely affect their health and safety.

(26) BATHROOM FACILITIES. The ICF must:

(a) Have toilet and bathing facilities that are located in or near residents' rooms and are appropriate in number, size, and design to meet the needs of the residents;

(b) Provide an adequate supply of hot water at all times for resident use; and

(c) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by residents.

(27) LINEN SUPPLIES. The ICF must have available at all time enough linen for the proper care and comfort of the residents and have clean linen on each bed.

(28) THERAPY AND ISOLATION AREAS. (a) The ICF's therapy area must be of sufficient size and appropriate design to:

1. Accommodate the necessary equipment;

2. Conduct an examination; and

3. Provide treatment.

(b) The ICF must make provision for isolating residents with infectious diseases.

(29) DINING, RECREATION, AND SOCIAL ROOMS. (a) The ICF must provide one or more areas, not used for corridor traffic, for dining, recreation, and social activities.

(b) A multipurpose room may be used if it is large enough to accommodate all of the activities without their interfering with each other.

(30) BUILDING ACCESSIBILITY AND USE. (a) The ICF must:

1. Be accessible to and usable by all residents, personnel, and the public, including individuals with disabilities; and

2. Meet the requirements of American National Standards Institute (ANSI) standard No. A117.1 (1961), American standard specifications for making buildings and facilities accessible to and usable by the physically handicapped.

(b) The department may waive, for as long as it considers appropriate, provisions of ANSI standard No. A117.1 (1961) if:

1. The construction plans for the ICF or a part of it were approved and stamped by the department before March 18, 1974;

2. The provisions would result in unreasonable hardship on the ICF if strictly enforced; and

3. The waiver does not adversely affect the health and safety of the residents.

(31) MEAL SERVICE. The ICF must:

(a) Serve at least 3 meals or their equivalent each day at regular times, not more than 14 hours between a substantial evening meal and breakfast;

(b) Procure, store, prepare, distribute, and serve all food under sanitary conditions; and

(c) Provide special eating equipment and utensils for residents who need them.

(32) MENU PLANNING AND SUPERVISION. (a) The ICF must have a staff member trained or experienced in food management or nutrition who is responsible for:

1. Planning menus that meet the nutritional needs of each resident, following the orders of the resident's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. (Recommended Dietary Allowances (8th ed., 1974) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and

2. Supervising the meal preparation and service to insure that the menu plan is followed.

(b) If the ICF has residents who require medically prescribed special diets, the ICF must:

1. Have the menus for those residents planned by a professionally qualified dietitian, or reviewed and approved by the attending physician; and

2. Supervise the preparation and serving of meals to insure that the resident accepts the special diet.

(c) The ICF must keep for 30 days a record of each menu as served.

(33) LICENSED PHARMACIST. The ICF must either:

(a) Employ a licensed pharmacist; or

(b) Have a formal arrangement with a licensed pharmacist to advise the ICF on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

(34) ORDERS FOR MEDICATIONS. (a) The resident's attending or staff physician must order all medications for the resident.

(b) The order may be either oral or written.

(c) If the order is oral:

1. The physician must give it only to a licensed nurse, pharmacist, or another physician; and

2. The individual receiving the order must record and sign it immediately and have the attending physician sign it in a manner consistent with good medical practice.

(35) METHODS TO CONTROL DOSAGE. The ICF must have written policies and procedures for controlling medication dosage, by automatic stop orders or other methods, when the physician does not include in the order a specific limit on the time and number of doses. These procedures must include notice to the attending physician that the medication is being stopped as of a certain date or after a certain number of doses.

(36) REVIEW OF MEDICATIONS. (a) A registered nurse must review medications monthly for each resident and notify the physician if changes are appropriate.

(b) The attending or staff physician must review the medications quarterly.

(37) ADMINISTERING MEDICATIONS. (a) Before administering any medication to a resident, a staff member must complete a state-approved training program in medication administration.

(b) The ICF may allow a resident to give to self a medication only if the attending physician gives permission.

(38) HEALTH SERVICES. (a) The ICF must provide for each resident health services that:

1. Meet the requirements of HSS 105.115 (39) through (42); and

2. Include treatment, medications, diet, and any other health service prescribed or planned for the resident.

(b) The ICF must provide these services 24 hours a day.

(39) SUPERVISION. (a) The ICF must have a registered nurse or a licensed practical or vocational nurse to supervise the ICF's health services full time, 7 days a week, on the day shift.

(b) The nurse must have a current license to practice in the state.

(c) If the ICF employs a licensed practical or vocational nurse to supervise health services, the ICF must have a formal contract with a registered nurse to consult with the licensed practical or vocational nurse at regular intervals, but not less than four hours each week.

(d) To be qualified to serve as a health services supervisor, a licensed practical or vocational nurse must be licensed pursuant to s. 441.10, Stats.

(40) 24-HOUR STAFFING. The ICF must have responsible staff members on duty and awake 24 hours a day to take prompt, appropriate action in case of injury, illness, fire, or other emergency.

(41) INDIVIDUAL HEALTH CARE PLAN. (a) Appropriate staff must develop and implement a written health care plan for each resident according to the instructions of the attending or staff physician.

(b) The plan must be reviewed and revised as needed but at least quarterly.

(42) NURSING CARE. The ICF must provide nursing care for each resident as needed, including restorative nursing care that enables each resident to achieve and maintain the highest possible degree of function, self-care, and independence.

(43) REHABILITATIVE SERVICES. (a) The ICF must provide rehabilitative services for each resident as needed.

(b) The ICF must either provide these services itself or arrange for them with qualified outside resources.

(c) The rehabilitative services must be designed to: 1. Maintain and improve the resident's ability to function independently;

2. Prevent, as much as possible, advancement of progressive disabilities; and

3. Restore maximum function.

(d) The rehabilitative service must be provided by: 1. Qualified therapists or qualified assistants, as defined in HSS 101, in accordance with accepted professional practices, or

2. Other supportive personnel under appropriate supervision.

(e) The rehabilitative services must be provided under a written plan of care that is: 1. Developed in consultation with the attending physician and, if necessary, an appropriate therapist; and

2. Based on the attending physician's orders and an assessment of the resident's needs.

(f) The resident's progress under the plan must be reviewed regularly and the plan must be changed as necessary.

(44) SOCIAL SERVICES. (a) The ICF must provide social services for each resident as needed.

(b) The ICF must either provide these services itself or arrange for them with qualified outside resources.

(c) The ICF must designate one staff member, qualified by training or experience, to be responsible for: 1. Arranging for social services; and

2. Integrating social services with other elements of the plan of care.

(d) These services must be provided under a written plan of care that is: 1. Placed in the resident's record; and

2. Evaluated periodically in conjunction with the resident's overall plan of care.

(45) ACTIVITIES PROGRAM. The ICF must: (a) Provide an activities program designed to encourage each resident to maintain normal activity and to return to self-care;

(b) Designate one staff member, qualified by training or experience in directing group activity, to be responsible for it;

(c) Have a plan for independent and group activities for each resident that is: 1. Developed according to the patient's needs and interests;

2. Incorporated in the overall plan of care;

3. Reviewed, with the patient's participation, at least quarterly; and

4. Changed as needed.

(d) Provide adequate recreation areas with sufficient equipment and materials to support the program.

(46) PHYSICIAN SERVICES. (a) The ICF must have policies and procedures to insure that the health care of each resident is under the continuing supervision of a physician.

(b) The physician must see the resident whenever necessary but at least every 60 days unless the physician decides that this frequency is unnecessary and records the reasons for that decision.

(47) OTHER REQUIREMENTS. The requirements in HSS 105.10 (19) and HSS 105.106 shall apply to ICFs where applicable.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.12 Requirements for certification of intermediate care facility services in an institution for the mentally retarded or persons with related conditions. Institutions for the mentally retarded or persons with related conditions are required to be licensed pursuant to s. 50.03, Stats., and to meet the standards in this section.

Note: The following rules are a codification of 42 CFR Part 442, Subpart G. For the sake of readability, some editing has been done; also, changes have been made to conform with state law and policy. These rules will be placed into the next compete revision of Wis. Adm. Code Chapter H-32, at which time these rules will be repealed.

(1) PHILOSOPHY, OBJECTIVES, AND GOALS. (a) The ICF/MR must have a written outline of the philosophy, objectives, and goals it is striving to achieve that includes, at least: 1. The ICF/MR's role in the state comprehensive program for the mentally retarded;

2. The ICF/MR's goals for its residents; and

3. The ICF/MR's concept of its relationship to the parents or legal guardians of its residents.

(b) The outline must be available for distribution to staff, consumer representatives, and the interested public.

(2) RESIDENT'S CIVIL RIGHTS. The ICF/MR must have written policies and procedures that insure the civil rights of all residents.

(3) RESIDENTS' BILL OF RIGHTS. The facility shall comply with the requirements governing residents' rights enumerated in s. 50.09, Stats. and Wis. Adm. Code H 32.055. The facility must have written policies and procedures that insure residents' rights are met.

(4) DELEGATION OF RIGHTS AND RESPONSIBILITIES. Pursuant to s. 50.09 (3), Stats., the ICF/MR must have written policies and procedures that provide that all rights and responsibilities of a resident pass to the resident's guardian, next of kin, or sponsoring agency or agencies if the resident is adjudicated incompetent under ch. 51 or 880, Stats.

(5) RESIDENT FINANCES. (a) The ICF/MR must have written policies and procedures that protect the financial interests of each resident.

(b) If large sums accrue to a resident, the policies and procedures must provide for appropriate protection of these funds and for counseling the resident concerning their use.

(c) Each resident must be allowed to possess and use money in normal ways or be learning to do so.

(d) The ICF/MR must maintain a current, written financial record for each resident that includes written receipts for: 1. All personal possessions and funds received by or deposited with the ICF/MR; and

2. All disbursements made to or for the resident.

(e) The financial record must be available to the resident and his family.

(6) POLICY AND PROCEDURE MANUALS. The ICF/MR must have manuals that: (a) Describe the policies and procedures in the major operating units of the ICF/MR;

(b) Are current, relevant, and available; and

(c) Are complied with by the units.

(7) MANAGEMENT AUDIT PLAN. The ICF/MR must have a plan for a continuing management audit to insure that the ICF/MR: (a) Complies with state laws and regulations; and

(b) Effectively implements its policies and procedures.

(8) GOVERNING BODY. (a) The ICF/MR must have a governing body that: 1. Exercises general direction over the affairs of the ICF/MR;

2. Establishes policies concerning the operation of the ICF/MR and the welfare of the individuals it serves;

3. Establishes qualifications for the chief executive officer in the following areas: education, experience; personal factors; skills; and

4. Appoints the chief executive officer.

(b) The governing body may consist of one individual or a group.

(9) CHIEF EXECUTIVE OFFICER. (a) The chief executive officer must: 1. Act for the governing body in the overall management of the ICF/MR; and

2. Arrange for one individual to be responsible for the administrative direction of the ICF/MR at all times.

(b) The chief executive officer must be an individual licensed in the state as a nursing home administrator or a qualified mental retardation professional except:

1. If the ICF/MR is licensed as a nursing home, the chief executive officer must be an individual licensed in the state as a nursing home administrator;

2. If the ICF/MR is a hospital qualifying as an institution for the mentally retarded or persons with related conditions, the chief executive officer must be a hospital administrator.

(c) Job titles for the chief executive officer may include any of the following: superintendent, director, and administrator.

(10) QUALIFIED MENTAL RETARDATION PROFESSIONAL. The ICF/MR must have a qualified mental retardation professional who is responsible for: (a) Supervising the delivery of each resident's individual plan of care;

(b) Supervising the delivery of training and habilitation services;

(c) Integrating the various aspects of the ICF/MR's program;

(d) Recording each resident's progress; and

(e) Initiating a periodic review of each individual plan of care for necessary changes.

(11) ORGANIZATION CHART. The ICF/MR must have an organization chart that shows: (a) The major operating programs of the ICF/MR;

(b) The staff divisions of the ICF/MR;

(c) The administrative personnel in charge of the programs and divisions, and

(d) The lines of authority, responsibility, and communication for administrative personnel.

(12) STAFF-RESIDENT COMMUNICATIONS. The ICF/MR must provide for effective staff and resident participation and communication in the following manners:

(a) The ICF/MR must establish appropriate standing committees such as human rights, research review, and infection.

(b) The committees must meet regularly and include direct-care staff whenever appropriate.

(c) Reports of staff meetings and standing and ad hoc committee meetings must include recommendations and their implementation, and be filed.

(13) COMMUNICATION WITH RESIDENTS AND PARENTS. (a) The ICF/MR must have an active program of communication with the residents and their families, that includes:

1. Keeping residents' families or legal guardians informed of resident activities that may be of interest to them or of significant changes in the resident's condition;

2. Answering communications from resident's relatives promptly and appropriately;

3. Allowing close relatives and guardians to visit at any reasonable hour, without prior notice, unless the resident's needs limit visits;

4. Allowing parents to visit any part of the ICF/MR that provides services to residents;

5. Encouraging frequent and informal visits home by the residents; and

6. Having rules that make it easy to arrange visits home.

(b) The ICF/MR must insure that individuals allowed to visit the ICF/MR under paragraph (a) (3) of this section do not infringe on the privacy and rights of the other residents.

(14) HEALTH AND SAFETY LAWS. The ICF/MR must meet all federal, state, and local laws, regulations and codes pertaining to health and safety, such as provisions regulating:

(a) Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances;

(b) Construction, maintenance, and equipment for the ICF/MR;

(c) Sanitation;

(d) Communicable and reportable diseases; and

(e) Post-mortem procedures.

(15) RESEARCH STATEMENT. If the ICF/MR conducts research, it must comply with the statement of assurance on research involving human subjects required by 45 CFR 46.104 through 46.108.

(16) AGREEMENTS WITH OUTSIDE RESOURCES. (a) If the ICF/MR does not employ a qualified professional to furnish a required institutional service, it must have in effect a written agreement with a qualified professional outside the ICF/MR to furnish the required service.

(b) The agreement must: 1. Contain the responsibilities, functions, objectives, and other terms agreed to by the ICF/MR and the qualified professional; and

2. Be signed by the administrator or a representative and by the qualified professional.

(17) ADMISSION CRITERIA AND EVALUATIONS. (a) Except as provided in paragraph (c) of this section, an ICF/MR may not admit an individual as a resident unless the person's needs can be met and an interdisciplinary professional team has determined that admission is the best available plan for that individual.

(b) The team must: 1. Conduct a comprehensive evaluation of the individual covering the physical, emotional, social, and cognitive factors; and

2. Before the individual's admission: a. Define the need for service without regard to the availability of those services; and

b. Review all available and applicable programs of care, treatment, and training and record its findings.

(c) If admission is not the best plan but the individual must be admitted nevertheless, the ICF/MR must: 1. Clearly acknowledge that the admission is inappropriate; and

2. Initiate plans to actively explore alternatives.

(18) AVAILABILITY OF RULES AND PROCEDURES. The facility must make available for distribution a summary of the laws, regulations, and procedures concerning admission, readmission, and release of a resident.

(19) NUMBER OF RESIDENTS. The ICF/MR must admit only that number of individuals that does not exceed:

a. Its rated capacity; and

b. Its ability to provide adequate programming.

(20) REVIEW OF PREADMISSION EVALUATION. Within 1 month after admission, the interdisciplinary professional team must:

(a) Review and update the preadmission evaluation with the participation of direct care personnel;

(b) Develop, with the participation of direct care personnel, a prognosis that can be used for programming and placement;

(c) Record the results of the evaluation in the resident's record kept in the living unit; and

(d) Write an interpretation of the evaluation in terms of specific actions to be taken for: 1. The direct care personnel and the special services staff responsible for carrying out the resident's program; and

2. The resident's parents or legal guardian.

(21) ANNUAL REVIEW OF RESIDENT'S STATUS. (a) All relevant personnel of the ICF/MR, including personnel in the living unit, must jointly review the status of each resident at least once a year and produce program recommendations.

(b) This review must include consideration of the following: 1. The advisability of continued residence and alternative programs.

2. When the resident legally becomes an adult: a. The need for guardianship; and

b. How the resident may exercise civil and legal rights.

(22) RECORD AND REPORTS OF REVIEWS. The results of the reviews required by HSS 105.12 (20) and (21) must be:

(a) Recorded in the resident's record kept in the living unit;

(b) Made available to personnel involved in the direct care of the resident;

(c) Interpreted to the resident's parents or legal guardian who are involved in planning and decisionmaking; and

(d) Interpreted to the resident, when appropriate.

(23) RELEASE FROM THE ICF/MR. (a) The ICF/MR must establish procedures for counseling a parent or guardian who requests the release of a resident concerning the advantages and disadvantages of the release.

(b) Planning for release of a resident must include providing for appropriate services in the resident's new environment, including protective supervision and other followup services.

(c) When a resident is permanently released, the ICF/MR must prepare and place in the resident's record a summary of findings, progress, and plans.

(24) TRANSFER TO ANOTHER FACILITY. (a) Except as provided in paragraph (b) of this section, the ICF/MR must have in effect a transfer agreement with one or more hospitals sufficiently close by to make feasible the prompt transfer of the resident and records to the hospital and to support a working arrangement between the ICF/MR and the hospital for providing inpatient hospital services to residents when needed.

(b) If the department finds that the ICF/MR tried in good faith to enter into an agreement but could not, the ICF/MR will not [will be] be considered to meet the requirements of paragraph (a) as long as the department finds that it is in the public interest and essential to assuring ICF/MR services for eligible individuals in the community.

(c) When a resident is transferred to another facility, the ICF/MR making the transfer must: 1. Record the reason for the transfer and a summary of findings, progress, and plans;

2. Except in an emergency, inform the resident and parent or guardian in advance and obtain their written consent to transfer; and

3. Retain a copy of the resident's records, including plans of care and other pertinent medical records for 5 years from the date of transfer.

(25) EMERGENCIES OR DEATH OF A RESIDENT. (a) The ICF/MR must notify promptly the resident's next of kin or guardian of any unusual occurrence concerning the resident, including serious illness, accident, or death.

(b) If any autopsy is performed after a resident's death: 1. A qualified physician who has no conflict of interest or loyalty to the ICF/MR must perform the autopsy; and

2. The resident's family must be told of the autopsy findings if they so desire.

(26) WRITTEN POLICIES. The ICF/MR must:

(a) Have written personnel policies that are available to all employes;

(b) Make written job descriptions available for all positions; and

(c) Have written policies that prohibit employes with symptoms or signs of a communicable disease from working.

(27) LICENSURE AND PROFESSIONAL STANDARDS. The ICF/MR must:

(a) Require the same licensure, certification, or standards for positions in the facility as are required for comparable positions in community practice; and

(b) Take into account in its personnel activities the ethical standards of professional conduct developed by professional societies.

(28) SUSPENSION AND DISMISSAL. The ICF/MR must have an authorized procedure, consistent with due process, for suspending or dismissing an employe.

(29) STAFF TREATMENT OF RESIDENTS. (a) The ICF/MR must have written policies that prohibit mistreatment, neglect, or abuse of a resident by an employe of the ICF/MR.

(b) The ICF/MR must insure that all alleged violations of these policies are reported immediately.

(c) The ICF/MR must have evidence that: 1. All violations are investigated thoroughly;

2. The results of the investigation are reported to the chief executive or a designated representative within 24 hours of the report of the incident; and

3. If the alleged violation is verified, the chief executive officer imposes an appropriate penalty.

(30) SUFFICIENT STAFFING AND RESIDENT WORK. (a) The ICF/MR must have a staff of sufficient size that the ICF/MR does not depend on residents or volunteers for services.

(b) The ICF/MR must have a written policy to protect residents from exploitation if they engage in productive work.

(31) STAFF TRAINING PROGRAM. (a) The ICF/MR must have a staff training program, appropriate to the size and nature of the ICF/MR, that includes:

1. Orientation for each new employe to acquaint the employe with the philosophy, organization, program, practices, and goals of the ICF/MR;

2. Inservice training for any employe who has not achieved the desired level of competence;

3. Continuing inservice training for all employes to update and improve their skills; and

4. Supervisory and management training for each employe who is in, or a candidate for, a supervisor position.

(b) If appropriate to the size and nature of the ICF/MR it must have someone designated to be responsible for staff development and training.

(32) RESPONSIBILITIES OF LIVING UNIT STAFF. (a) The living unit staff must make care and development of the residents their primary responsibility. This includes training each resident in the activities of daily living and in the development of self-help and social skills.

(b) The ICF/MR must insure that the staff are not diverted from their primary responsibilities by excessive housekeeping or clerical duties or other activities not related to resident care.

(c) Members of the living unit staff from all shifts must participate in appropriate activities relating to the care and development of the resident including, at least, referral, planning, initiation, coordination, implementation, followthrough, monitoring, and evaluation.

(33) RESIDENT EVALUATION AND PROGRAM PLANS. The ICF/MR must have specific evaluation and program plans for each resident that are:

(a) Available to direct care staff in each living unit; and

(b) Reviewed by a member or members of an interdisciplinary professional team at least monthly with documentation of the review entered in the resident's record.

(34) RESIDENT ACTIVITIES. (a) The ICF/MR must develop an activity schedule for each resident that:

1. Does not allow periods of unscheduled activity to extend longer than 3 continuous hours;

2. Allows free time for individual or group activities using appropriate materials, as specified by the program team; and

3. Includes planned outdoor periods all year round.

(b) Each resident's activity schedule must be available to direct care staff and be carried out daily.

(c) The ICF/MR must insure that a multiple-handicapped or nonambulatory resident:

1. Spends a major portion of the waking day out of bed;

2. Spends a portion of the waking day out of the bedroom area;

3. Has planned daily activity and exercise periods; and

4. Moves around by various methods and devices whenever possible.

(35) PERSONAL POSSESSIONS. The ICF/MR must allow the residents to have personal possessions such as toys, books, pictures, games, radios, arts and crafts materials, religious articles, toiletries, jewelry, and letters.

(36) CONTROL AND DISCIPLINE OF RESIDENTS. (a) The ICF/MR must have written policies and procedures for the control and discipline of residents that are available in each living unit and to parents and guardians.

(b) If appropriate, residents must participate in formulating these policies and procedures.

(c) The ICF/MR may not allow: 1. Corporal punishment of a resident;

2. A resident to discipline another resident, unless it is done as part of an organized self-government program conducted in accordance with written policy; or

3. A resident to be placed alone in a locked room.

(37) PHYSICAL RESTRAINT OF RESIDENTS. (a) Pursuant to s. 50.09 (1) (k), Stats., the ICF/MR may allow the use of physical restraint on a resident in an emergency if absolutely necessary to protect the resident from injuring self or others or property. All other provisions of s. 50.09 (1) (k), Stats., regarding physical restraints shall be complied with. The facility's policies governing the use of physical restraints shall be in written form.

(b) Appropriate trained staff must check a resident placed in a physical restraint at least every 30 minutes and keep a record of these checks.

(c) A resident who is in a physical restraint must be given an opportunity for motion and exercise for a period of not less than 10 minutes during each 2 hours of restraint.

(38) MECHANICAL DEVICES USED FOR PHYSICAL RESTRAINT. (a) Mechanical devices used for physical restraint must be designed and used in a way that causes the resident no physical injury and the least possible physical discomfort.

(b) A totally enclosed crib or a barred enclosure is a physical restraint.

(c) Mechanical supports used to achieve proper body position and balance are not physical restraints. However, mechanical supports must be designed and applied:

1. Under the supervision of a qualified professional; and

2. In accordance with principles of good body alignment, concern for circulation, and allowance for change of position.

(39) CHEMICAL RESTRAINT OF RESIDENTS. The ICF/MR shall comply with the provisions of s. 50.09 (1) (k), Stats. regarding chemical restraints. In addition, the ICF/MR may not use chemical restraint:

(a) Excessively;

(b) As punishment;

(c) For the convenience of the staff;

(d) As a substitute for the activities or treatment; or

(e) In quantities that interfere with a resident's habilitation program.

(40) BEHAVIOR MODIFICATION PROGRAMS. (a) For purposes of this section: "Aversive stimuli" means things or events that the resident finds unpleasant or painful that are used to immediately discourage undesired behavior. "Time-out" means a procedure designed to improve a resident's behavior by removing positive reinforcement when the behavior is undesirable.

(b) Behavior modification programs involving the use of aversive stimuli or time-out devices must be: 1. Reviewed and approved by the ICF/MR's human rights committee or the qualified mental retardation professional;

2. Conducted only with the consent of the affected resident's parents or legal guardian; and

3. Described in written plans that are kept on file in the ICF/MR.

(c) A physical restraint used as a time-out device may be applied only during behavior modification exercises and only in the presence of the trainer.

(d) For time-out purposes, time-out devices and aversive stimuli may not be used for longer than one hour, and then only during the behavior modification program and only under the supervision of the trainer.

(41) RESIDENT CLOTHING. The ICF/MR must insure that each resident; (a) Has enough neat, clean, suitable, and seasonable clothing;

(b) Has the resident's own clothing marked with the resident's name when necessary;

(c) Is dressed daily in the resident's own clothes unless this is contraindicated in written medical orders;

(d) Is trained and encouraged, as appropriate, to: 1. Select daily clothing;

2. Dress self;

3. Change clothes to suit activities; and

(e) Has storage space for clothing that is accessible even if the resident is in a wheelchair.

(42) HEALTH, HYGIENE, GROOMING AND TOILET TRAINING. (a) Each resident must be trained to be as independent as possible in health, hygiene, and grooming practices, including bathing, brushing teeth, shampooing, combing and brushing hair, shaving, and caring for toenails and fingernails.

(b) Each resident who does not eliminate appropriately and independently must be in a regular, systematic toilet training program and a record must be kept of progress in the program.

(c) A resident who is incontinent must be bathed or cleaned immediately upon voiding or soiling, unless specifically contraindicated by the training program, and all soiled items must be changed.

(d) The ICF/MR must establish procedures for: 1. Weighing each resident monthly, unless the special needs of the resident require more frequent weighing;

2. Measuring the height of each resident every 3 months until the resident reaches the age of maximum growth;

3. Maintaining weight and height records for each resident; and

4. Insuring that each resident maintains a normal weight.

(e) At least every 3 days, a physician must review orders prescribing bed rest or prohibiting a resident from being outdoors.

(f) The ICF/MR must furnish, maintain in good repair, and encourage the use of dentures, eyeglasses, hearing aids, braces, and other aids prescribed for a resident by an appropriate specialist.

(43) GROUPING AND ORGANIZATION OF LIVING UNITS. (a) The ICF/MR may not house residents of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(b) The ICF/MR may not segregate residents on the basis of their physical handicaps. It must integrate residents who are mobile non-ambulatory, deaf, blind, epileptic, and so forth with others of comparable social and intellectual development.

(44) RESIDENT LIVING STAFF. (a) Each resident living unit must have suficient, appropriately qualified, and adequately trained personnel to conduct the resident living program as required by this subpart.

(b) The ICF/MR must have an individual, whose training and experience is appropriate to the program, who is administratively responsible for resident living personnel.

(c) Each resident living unit, regardless of organization or design, must have, as a minimum, overall staff-resident ratios (allowing for a 5-day work week plus holiday, vacation, and sick time) as follows unless program needs justify otherwise:

1. For units serving children under the age of 6 years, severely and profoundly retarded, severely physically handicapped, or residents who are aggresive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the overall ratio is 1 to 2.

2. For units serving moderately retarded residents requiring habit training, the overall ratio is 1 to 2.5.

3. For units serving residents in vocational training programs and adults who work in sheltered employment situations, the overall ratio is 1 to 5.

(45) RESIDENT LIVING AREAS. The ICF/MR must design and equip the resident living areas for the comfort and privacy of each resident.

(46) RESIDENT BEDROOMS: SPACE AND OCCUPANCY. (a) Bedrooms must:

1. Be at or above street grade level;

2. Be outside rooms;

3. Be equipped with or located near adequate toilet and bathing facilities;

4. Accommodate no more than 4 residents unless granted a variance under paragraph (b) of this section; and

5. Measure at least 60 square feet per resident in multiple resident bedrooms and at least 80 square feet in single resident bedrooms.

(b) The survey agency may grant a variance from the limit of 4 residents per room if it finds that:

1. A physician or psychologist who meets the definition of a qualified mental retardation professional in HSS 101 has justified in each affected

resident's plan of care that assignment to a bedroom of more than 4 residents is in accordance with the program needs of that resident; and

2. The variance does not adversely affect the health or safety of the residents.

(c) The variance may be granted only for the period of a specific certification.

(47) RESIDENT BEDROOMS: FURNITURE AND BEDDING. The ICF/MR must provide each resident with:

(a) A separate bed of proper size and height for the convenience of the resident;

(b) A clean, comfortable mattress;

(c) Bedding appropriate to the weather and climate; and

(d) Appropriate furniture, such as chest of drawers, a table or desk, and an individual closet with clothes racks and shelves accessible to the resident.

(48) STORAGE SPACE IN LIVING UNITS. The ICF/MR must provide:

(a) Space for equipment for daily out-of-bed activity for all residents who are not yet mobile, except those who have a short-term illness or those few residents for whom out-of-bed activity is a threat to life;

(b) Suitable storage space, accessible to the resident, for personal possessions, such as toys and prosthetic equipment; and

(c) Adequate clean linen and dirty linen storage areas for each living unit.

(49) RESIDENT BATHROOMS. (a) The ICF/MR must:

1. Have toilet and bathing facilities appropriate in number, size, and design to meet the needs of the residents;

2. Provide for individual privacy in toilets, bathtubs, and showers unless specifically contraindicated by program needs;

3. Equip bathrooms and bathroom appliances for use by the physically handicapped; and

4. Control the temperature of the hot water at all taps to which residents have access, by using thermostatically controlled mixing valves or other means, so that the water does not exceed 110° fahrenheit.

(b) The survey agency may grant a variance from the requirement in paragraph (a) 4. of this section if:

1. The hot water taps are in supervised areas; and

2. The purpose of the variance is to train residents in the use of hot water.

(c) The variance must be part of the survey record.

(50) HEATING AND VENTILATION IN LIVING UNITS. (a) Each habitable room in the ICF/MR must have:

1. At least one window; and

2. Direct outside ventilation by means of windows, louvers, air conditioning, or mechanical ventilation horizontally and vertically.

(b) The ICF/MR must: 1. Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

2. Use a heating apparatus that does not constitute a burn hazard to residents.

(51) FLOORS IN LIVING UNITS. The ICF/MR must have:

(a) Floors that have a resilient, nonabrasive, and slip-resistant surface; and

(b) Nonabrasive carpeting, if the living unit is carpeted and serves residents who crawl.

(52) EMERGENCY LIGHTING. If a living unit houses more than 15 residents, it must have emergency lighting with automatic switches for stairs and exits.

(53) NEEDED SERVICES. In addition to the resident living services detailed in subsections (32) through (52), the ICF/MR must provide professional and special programs and services to residents based upon their needs for these programs and services.

(54) QUALITY STANDARDS FOR OUTSIDE RESOURCES. (a) Programs and services provided by the ICF/MR or to the ICF/MR by outside agencies or individuals must meet the standards for quality of services required in this subpart.

(b) All contracts for these services must state that these standards will be met.

(55) PLANNING AND EVALUATION. Interdisciplinary teams consisting of individuals representative of the professions or service areas included in this subpart that are relevant in each particular case, must:

(a) Evaluate each resident's needs;

(b) Plan an individualized habilitation program to meet each resident's responses to his program and revise the program accordingly.

(c) Periodically review each resident's responses to the program and revise the program accordingly.

(56) DENTAL—DIAGNOSTIC SERVICES. (a) The ICF/MR must provide each resident with comprehensive diagnostic dental services that include a complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the resident's oral condition, not later than 1 month after a resident's admission to the ICF/MR unless the resident received the examination within 6 months before admission.

(b) The ICF/MR must review the results of the examination and enter them in the resident's record.

(57) DENTAL TREATMENT. The ICF/MR must provide each resident with comprehensive dental treatment that includes:

(a) Provision for emergency dental treatment on a 24-hour-a-day basis by a qualified dentist; and

(b) A system that assures that each resident is reexamined as needed but at least once a year.

(58) DENTAL EDUCATION AND TRAINING. The ICF/MR must provide education and training in the maintenance of oral health that includes:

(a) A dental hygiene program that informs resident's and all staff on nutrition and diet control measures and residents and living unit staff on proper oral hygiene methods; and

(b) Instruction of parents or guardians in the maintenance of proper oral hygiene in appropriate instances, for example when a resident leaves the ICF/MR.

(59) DENTAL RECORDS. The ICF/MR must:

(a) Keep a permanent dental record for each resident;

(b) Enter a summary dental progress report at stated intervals in each resident's record kept in the living unit;

(c) Provide a copy of the permanent dental record to any facility to which the resident is transferred.

(60) DENTAL—FORMAL ARRANGEMENTS. The ICF/MR must have a formal arrangement for providing each resident with the dental services required under this subpart.

(61) DENTAL STAFF. (a) The ICF/MR must have enough qualified dental personnel and support staff to carry out the dental services program.

(b) Each dentist and dental hygienist providing services to the facility must be licensed to practice in the state.

(62) TRAINING AND HABILITATION REQUIRED SERVICES. (a) The ICF/MR must provide training and habilitation services to all residents, regardless of age, degree of retardation, or accompanying disabilities or handicaps.

(b) Individual evaluations of residents must: 1. Be based upon the use of empirically reliable and valid instruments, whenever these instruments are available; and

2. Provide the basis for prescribing an appropriate program of training experiences for the resident.

(c) The ICF/MR must have written training and habilitation objectives for each resident that are: 1. Based upon complete and relevant diagnostic and prognostic data; and

2. Stated in specific behavioral terms that permit the progress of each resident to be assessed.

(d) The ICF/MR must provide evidence of services designed to meet the training and habilitation objectives for each resident.

(e) The training and habilitation staff must: 1. Maintain a functional training and habilitation record for each resident; and

2. Provide training and habilitation services to residents with hearing, vision, perceptual, or motor impairments.

(63) TRAINING AND HABILITATION STAFF. The ICF/MR must have enough qualified training and habilitation personnel and support staff, supervised by a qualified mental retardation professional, to carry out the training and habilitation program.

(64) FOOD AND NUTRITION REQUIRED SERVICES. The ICF/MR's food services must include:

(a) Menu planning;

(b) Initiating food orders or requisitions;

(c) Establishing specifications for food purchases and insuring that the specifications are met;

(d) Storing and handling food;

(e) Preparing and serving food;

(f) Maintaining sanitary standards in compliance with State and local regulations; and

(g) Orienting, training, and supervising food service personnel.

(65) DIET REQUIREMENTS. (a) The ICF/MR must provide each resident with a nourishing, well-balanced diet.

(b) Modified diets must be: 1. Prescribed by the resident's interdisciplinary team with a record of the prescription kept on file;

2. Planned, prepared, and served by individuals who have received adequate instruction; and

3. Periodically reviewed and adjusted as needed.

(c) The ICF/MR must furnish a nourishing, well-balanced diet, in accordance with the recommended daily allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, activity, and disability, unless otherwise required by medical needs. (Recommended Dietary Allowances (8th ed., 1974) is available from the Printing and Publication Office, National Academy of Sciences, Washington, D.C. 20418.)

(d) A resident may not be denied a nutritionally adequate diet as a form of punishment.

(66) MEAL SERVICE. (a) The ICF/MR must serve at least three meals daily, at regular times comparable to normal mealtimes in the community with:

1. Not more than 14 hours between a substantial evening meal and breakfast of the following day; and

2. Not less than 10 hours between breakfast and the evening meal of the same day.

(b) Food must be served: 1. In appropriate quantity;

2. At appropriate temperature;

3. In a form consistent with the developmental level of the resident; and

4. With appropriate utensils.

(c) Food served and uneaten must be discarded.

(67) MENUS. (a) Menus must:

1. Be written in advance;

2. Provide a variety of foods at each meal; and

3. Be different for the same days of each week and adjusted for seasonal changes.

(b) The ICF/MR must keep on file, for at least 30 days, records of menus as served and of food purchased.

(68) FOOD STORAGE. The ICF/MR must store:

(a) Dry or staple food items at least 12 inches above the floor, in a ventilated room not subject to sewage or waste water backflow or contamination by condensation, leakage, rodents or vermin; and

(b) Perishable foods at proper temperatures to conserve nutritive values.

(69) FOOD AND NUTRITION WORK AREAS. The ICF/MR must:

(a) Have effective procedures for cleaning all equipment and work areas; and

(b) Provide handwashing facilities, including hot and cold water, soap, and paper towels adjacent to work areas.

(70) DINING AREAS AND SERVICE. The ICF/MR must:

(a) Serve meals for all residents, including the mobile nonambulatory, in dining rooms, unless otherwise required for health reasons or by decision of the team responsible for the resident's program.

(b) Provide table service for all residents who can and will eat at a table, including residents in wheelchairs;

(c) Equip areas with table, chairs, eating utensils, and dishes designed to meet the developmental needs of each resident; and

(d) Supervise and staff dining rooms adequately to direct self-help dining procedures and to assure that each resident receives enough food.

(71) TRAINING OF RESIDENTS AND DIRECT-CARE STAFF. (a) The ICF/MR must provide residents with systematic training to develop appropriate eating skills, using special eating equipment and utensils if it serves the developmental process.

(b) Direct-care staff must be trained in and use proper feeding techniques.

(c) The ICF/MR must insure that residents eat in an upright position, unless medically contraindicated, and in a manner consistent with their developmental needs.

(72) FOOD AND NUTRITION STAFF. (a) The ICF/MR must have enough competent personnel to meet the food and nutrition needs of residents.

(b) A dietitian who directs food and nutrition services in ICF's/MR of 20 beds or more must meet the qualification requirements of HSS 101.03.

(c) The ICF/MR must designate a staff member who is trained or experienced in food management or nutrition to direct food and nutrition services in an ICF/MR with less than 20 beds.

(73) REQUIRED MEDICAL SERVICES. The ICF/MR must:

(a) Provide medical services through contact between physicians and residents and through contact between physicians and individuals working with the residents;

(b) Provide health services including treatment, medications, diet, and any other health service prescribed or planned for the resident, 24 hours a day;

(c) Have available electroencephalographic services as needed;

(d) Have enough space, facilities, and equipment to fulfill the medical needs of residents; and

(e) Provide evidence, such as utilization review committee records, that hospital and laboratory services are used in accordance with professional standards.

(74) MEDICAL GOALS AND EVALUATIONS. (a) Physicians must participate, when appropriate, in:

1. The continuing interdisciplinary evaluation of individual residents for the purposes of beginning, monitoring, and following up on individualized habilitation programs; and

2. The development for each resident of a detailed, written statement of: a. Case management goals for physical and mental health, education, and functional and social competence; and

b. A management plan detailing the various habilitation or rehabilitation services to achieve those goals, with clear designation of responsibility for implementation.

(b) The ICF/MR must review and update the statement of treatment goals and management plans as needed, but at least annually, to insure: 1. Continuing appropriateness of the goals:

2. Consistency of management methods with the goals; and

3. The achievement of progress toward the goals.

(75) ARRANGEMENTS WITH OUTSIDE MEDICAL RESOURCES. The ICF/MR must:

(a) Have a formal arrangement for providing each resident with medical care that includes care for medical emergencies on a 24-hour-a-day basis;

(b) Designate a physician, licensed to practice medicine in the state, to be responsible for maintaining the general health conditions and practices of the ICF/MR; and

(c) Maintain effective arrangements, for residents to receive prompt medical and remedial services that they require but that the ICF/MR does not regularly provide.

(76) PREVENTIVE HEALTH SERVICES. The ICF/MR must have preventive health services for residents that include:

(a) Means for the prompt detection and referral of health problems, through adequate medical surveillance, periodic inspection, and regular medical examinations;

(b) Annual physical examinations that include: 1. Examination of vision and hearing; and

2. Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed;

(c) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices and of the Committee on the Control of Infectious Diseases of the American Academy of Pediatrics;

(d) Tuberculosis control, appropriate to the ICF/MR's population, in accordance with the recommendations of the American College of Chest Physicians or the section on diseases of the chest of the American Academy of Pediatrics or both; and

(e) Reporting of communicable diseases and infections in accordance with law.

(77) REQUIRED NURSING SERVICES. The ICF/MR must provide residents with nursing services, in accordance with their needs, that include, as appropriate, the following: (a) Registered nurse participation in: 1. The preadmission evaluation study and plan;

2. The evaluation study, program design, and placement of the resident at the time of admission;

3. The periodic reevaluation of the type, extent, and quality of services and programming;

4. The development of the discharge plan; and

5. The referral to appropriate community resources.

(b) Training in habits of personal hygiene, family life, and sex education that includes but is not limited to family planning and venereal disease counseling.

(c) Control of communicable diseases and infections through: 1. Identification and assessment.

2. Reporting to medical authorities; and

3. Implementation of appropriate protective and preventive measures.

4. Development of a written nursing services plan for each resident as part of the total habilitation program.

5. Modification of the nursing plan, in terms of the resident's daily needs, at least annually for adults and more frequently for children, in accordance with developmental changes.

(78) NURSING—TRAINING. (a) A registered nurse must participate, as appropriate, in the planning and implementation of training of the ICF/MR's personnel.

(b) The ICF/MR must have direct-care personnel trained in: 1. Detecting signs of illness or dysfunction that warrant medical or nursing intervention;

2. Basic skills required to meet the health needs and problems of the residents; and

3. First aid for accident or illness.

(79) NURSING STAFF. (a) The ICF/MR must have available enough nursing staff, which may include currently licensed practical nurses and other supporting personnel, to carry out the various nursing services.

(b) The individual responsible for the delivery of nursing services must have knowledge and experience in the field of developmental disabilities.

(c) Nursing service personnel at all levels of experience and competence must be: 1. Assigned responsibilities in accordance with their qualifications;

2. Delegated authority commensurate with their responsibility; and

3. Provided appropriate professional nursing supervision.

(80) NURSING SUPERVISION OF HEALTH SERVICES. (a) The ICF/MR must have a registered nurse or licensed practical or vocational nurse to supervise the health services full time, 7 days a week, on the day shift.

(b) The nurse must have a current license to practice in the state.

(c) If the ICF/MR employs a licensed practical or vocational nurse to supervise health services, it must have a formal arrangement with a registered nurse to consult with the licensed practical or vocational nurse at regular intervals, but not less than 4 hours each week.

(d) To be qualified to serve as a health services supervisor, a licensed practical nurse must be licensed pursuant to s. 441.10, Stats.

(e) The ICF/MR must have responsible staff members on duty and awake 24 hours a day to take prompt, appropriate action in case of injury, illness, fire, or other emergency.

(f) An ICF/MR that has 15 beds or less, and only admits residents certified by a physician as not in need of professional nursing services, may meet the requirements of paragraphs (a) through (e) of this section by: 1. Contracting for the services of a public health nurse or other registered nurse to care for minor illnesses, injuries, or emergencies, and to consult on the health aspects of the individual plan of care; and

2. Having a responsible staff member on duty 24 hours a day who is immediately accessible to the residents to take reports of injuries, symptoms of illness, and emergencies.

(g) The health services supervisor is responsible for developing, supervising the implementation of, reviewing, and revising a written health care plan for each resident that is: 1. Developed and implemented according to the instructions of the attending or staff physician; and

2. Reviewed and revised as needed but not less often than quarterly.

(81) REQUIRED PHARMACY SERVICES. The ICF/MR must:

(a) Make formal arrangements for qualified pharmacy services, including provision for emergency service.

(b) Have a current pharmacy manual that:

1. Includes policies and procedures and defines the functions and responsibilities relating to pharmacy services; and

2. Is revised annually to keep abreast of current developments in services and mangement techniques; and

(c) Have a formulary system approved by a responsible physician and pharmacist and other appropriate staff. Copies of the ICF/MR's formulary system and of the American Hospital Formulary Service must be located and available in the facility.

(82) PHARMACIST. (a) Pharmacy services must be provided under the direction of a qualified licensed pharmacist.

(b) The pharmacist must: 1. When the resident is admitted, obtain, if possible, a history of prescription and nonprescription drugs used and enter this information in the resident's record;

2. Receive the original, or a direct copy, of the physician's drug treatment order;

3. Maintain for each resident an individual record of all prescription and nonprescription medications dispensed, including quantities and frequency of refills;

4. Participate, as appropriate, in the continuing interdisciplinary evaluation of individual residents for the purposes of beginning, monitoring, and following up on individualized habilitation programs; and

5. Establish quality specifications for drug purchases and insure that they are met.

(c) A pharmacist or registered nurse must regularly review the medication record of each resident for potential adverse reactions, allergies,

interactions, contraindications, rationality and laboratory test modifications and advise the physician of any recommended changes with reasons and with an alternate drug regimen.

(d) As appropriate to the ICF/MR, the responsible pharmacist, physician, nurse, and other professional staff must write policies and procedures that govern the safe adminstration and handling of all drugs. The following policies and procedures must be included: 1. There must be a written policy governing the self administration of drugs, whether prescribed or not.

2. The pharmacist or an individual under the pharmacist's supervision must compound, package, label, and dispense drugs including samples and investigational drugs. Proper controls and records must be kept of these processes.

3. Each drug must be identified up to the point of administration.

4. Whenever possible, the pharmacist must dispense drugs that require dosage measurements in a form ready to be administered to the resident.

(83) DRUGS AND MEDICATIONS. (a) A medication must be used by the resident for whom it is issued. Only appropriately trained staff may administer drugs.

(b) Any drug that is discontinued or outdated and any container with a worn, illegible, or missing label must be returned to the pharmacy for proper disposition.

(c) The ICF/MR must have: 1. An automatic stop order on all drugs;

2. A drug recall procedure that can be readily used;

3. A procedure for reporting adverse drug reactions to the Food and Drug Administration; and

4. An emergency kit available to each living unit and appropriate to the needs of its residents.

(d) Medication errors and drug reactions must be recorded and reported immediately to the practitioner who ordered the drug.

(84) DRUG STORAGE. The ICF/MR must:

(a) Store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security.

(b) Store poisons, drugs used externally, and drugs taken internally on separate shelves or in separate cabinets, at all locations;

(c) Keep medication that is stored in a refrigerator containing other items in a separate compartment with proper security;

(d) Keep all drugs under lock and key unless an authorized individual is in attendance;

(e) If there is a drug storeroom separate from the pharmacy, keep a perpetual inventory of receipts and issues of all drugs from that storeroom; and

(f) Meet the drug security requirements of federal and state laws that apply to storerooms, pharmacies, and living units.

(85) REQUIRED PHYSICAL AND OCCUPATIONAL THERAPY SERVICES. (a) The ICF/MR must provide physical and occupational therapy services through direct contact between therapists and residents and through contact between therapists and individuals involved with the residents.

(b) Physical and occupational therapy staff must provide treatment training programs that are designed to: 1. Preserve and improve abilities for independent function, such as range of motion, strength, tolerance, coordination, and activities of daily living; and

2. Prevent, insofar as possible, irreducible or progressive disabilities through means such as the use of orthotic and prosthetic appliances, assistive and adaptive devices, positioning, behavior adaptations, and sensory stimulation.

(c) The therapist must: 1. Work closely with the resident's primary physician and with other medical specialists;

2. Record regularly and evaluate periodically the treatment training progress; and

3. Use the treatment training progress as the basis for continuation or change in the resident's program.

(86) PT AND OT RECORDS AND EVALUATIONS. The ICF/MR must have evaluations results, treatment objectives, plans and procedure, and continuing observations of treatment progress.

(a) Recorded accurately, summarized, and communicated to all relevant parties;

(b) Used in evaluating progress; and

(c) Included in the resident's record kept in the living unit.

(87) PT AND OT STAFF AND FACILITIES. (a) The ICF/MR must have available enough qualified staff and support personnel to carry out the various physical and occupational therapy services in accordance with stated goals and objectives.

(b) Physical and occupational therapy personnel must be: 1. Assigned responsibilities in accordance with their qualifications;

2. Delegated authority commensurate with their responsibilities; and

3. Provided professional direction and consultation.

(c) Therapy assistants must work under the supervision of a qualified therapist.

(d) Physical and occupational therapists and therapy assistants must meet the qualification requirements of HSS 105.27 through 105.285, except that when occupational therapy assistants are working as habilitation staff or resident living staff (i.e. not directly providing occupational therapy) they do not need direct on-site supervision by an OTR.

(e) The ICF/MR must provide enough space and equipment and supplies for efficient and effective physical and occupational therapy services.

(88) REQUIRED PSYCHOLOGICAL SERVICES. The ICF/MR must:

(a) Provide psychological services through personal contact between psychologists and residents and through contact between psychologists and individuals involved with the residents; and

(b) Have available enough qualified staff and support personnel to furnish the following psychological services based on need: 1. Psychological services for residents, including evaluation, consultation, therapy, and program development.

2. Administration and supervision of psychological services.

3. Staff training.

(89) PSYCHOLOGIST. Psychologists must:

(a) Have at least a master's degree from an accredited program and experience or training in the field of mental retardation;

(b) Participate, when appropriate, in the continuing interdisciplinary evaluation of each individual resident, for the purposes of beginning, monitoring, and following up on the resident's individualized habilitation program;

(c) Report and disseminate evaluation results in a manner that: 1. Promptly provides information useful to staff working directly with the resident; and

2. Maintains accepted standards of confidentiality.

(d) Participate, when appropriate, in the development of written detailed, specific, and individualized habilitation program plans that: 1. Provide for periodic review, followup, and updating; and

2. Are designed to maximize each resident's development and acquisition of the following: Perceptual skills, sensorimotor skills, self-help skills, communication skills, social skills, self-direction, emotional stability, and effective use of time, including leisure time.

(90) REQUIRED RECREATION SERVICES. The ICF/MR must:

(a) Coordinate recreational services with other services and programs provided to each resident, in order to: 1. Make the fullest possible use of the ICF/MR's resources; and

2. Maximize benefits to the residents;

(b) Design and construct or modify recreation areas and facilities so that all residents, regardless of their disabilities, have access to them; and

(c) Provide recreation equipment and supplies in a quantity and variety that is sufficient to carry out the stated objectives of the activities program.

(91) RECREATION RECORDS. The ICF/MR's resident records must include:

(a) Periodic surveys of the resident's recreation interests; and

(b) The extent and level of the resident's participation in the recreation program.

(92) RECREATION STAFF. (a) The ICF/MR must have enough qualified staff and support personnel available to carry out the various receation services in accordance with stated goals and objectives.

(b) Staff conducting the recreation program must have: 1. A bachelor's degree in recreation, or in a specialty area, such as art, music, or physical education;

2. An associate degree in recreation and 1 year of experience in recreation;

3. A high school diploma, or an equivalency certificate and: a. Two years of experience in recreation; or

b. One year of experience in recreation plus completion of comprehensive inservice training in recreation; or

4. Demonstrated proficiency and experience in conducting activities in one or more recreational program areas.

(93) REQUIRED SOCIAL SERVICES. The ICF/MR must provide, as part of an interdisciplinary set of services, social services to each resident directed toward:

(a) Maximizing the social functioning of each resident;

(b) Enhancing the coping capacity of each resident's family;

(c) Asserting and safeguarding the human and civil rights of the retarded and their families; and

(d) Fostering the human dignity and personal worth of each resident.

(94) SOCIAL WORKERS. (a) During the evaluation process to determine whether or not admission to the ICF/MR is necessary, social workers must help the resident and family: 1. Consider alternative services, based on the retarded individual's status and important family and community factors; and

2. Make a responsible choice as to whether and when residential placement is indicated.

(b) Social workers must participate, when appropriate, in the continuing interdisciplinary evaluation of individual residents for the purposes of beginning, monitoring, and following up on individualized habilitation programs.

(c) During the retarded individual's admission to, and residence in the facility, social workers must, as appropriate, provide liaison between the patient, the ICF/MR, the family, and the community, in order to: 1. Help the staff:

a. Individualize and understand the needs of the resident and family in relation to each other;

b. Understand social factors in the resident's day-to-day behavior, including staff-resident relationships; and

c. Prepare the resident for changes in the living situation;

2. Help the family develop constructive and personally meaningful ways to support the resident's experience in the ICF/MR through: a. Counseling concerning the problems of changes in family structure and functioning; and

b. Referral to specific services, as appropriate; and

3. Help the family participate in planning for the resident's return to home or other community placement.

(d) After the resident leaves the ICF/MR, social workers must provide systematic followup to assure referral to appropriate community agencies.

(e) The ICF/MR must have available enough qualified staff and support personnel to carry out the various social services activities.

(f) Social workers providing service to the ICF/MR must meet the qualification requirements of HSS 101.103.

(g) Social work assistants or aides employed by the ICF/MR must be supervised by a social worker.

(95) REQUIRED SPEECH PATHOLOGY AND AUDIOLOGY SERVICES. (a) The ICF/MR must provide speech pathology and audiology services through direct contact between speech pathologists and audiologists and residents, and working with other personnel, including but not limited to teachers and direct-care staff.

(b) Speech pathology and audiology services available to the ICF/MR must include: 1. Screening and evaluation of residents with respect to speech and hearing functions;

2. Comprehensive audiological assessment of residents, as indicated by screening results, that include tests of puretone air and bone conduction, speech audiometry, and other procedure, as necessary, and the assessment of the use of visual cues;

3. Assessment of the use of amplification;

4. Provision for procurement, maintenance, and replacement of hearing aids, as specified by a qualified audiologist;

5. Comprehensive speech and language evaluation of residents, as indicated by screening results, including appraisal of articulation, voice, rhythm, and language;

6. Participation in the continuing interdisciplinary evaluation of individual residents for purposes of beginning, monitoring, and following up on individualized habilitation programs;

7. Treatment services as an extension of the evaluation process, that include: a. Direct counseling with residents;

b. Consultation with appropriate staff for speech improvement and speech education activities; and

c. Work with appropriate staff to develop specialized programs for developing each resident's communication skills in comprehension, including speech, reading, auditory training, and hearing aid utilization, and skills in expression, including improvement in articulation, voice, rhythm, and language; and

8. Participation in inservice training programs for direct-care and other staff.

(96) SPEECH PATHOLOGY AND AUDIOLOGY EVALUATIONS AND ASSESSMENTS. (a) Speech pathologists and audiologists must accurately and systematically report evaluation and assessment results in order to:

1. Provide information, when appropriate, that is useful to other staff working directly with the resident; and

2. Include evaluative and summary reports in the resident's record kept in the living unit.

(b) Continuing observations of treatment progress must be: 1. Recorded accurately, summarized, and communicated; and

2. Used in evaluating progress.

(97) SPEECH PATHOLOGY AND AUDIOLOGY STAFF AND FACILITIES. (a) The ICF/MR must have available enough qualified staff and support personnel to carry out the various speech pathology and audiology services, in accordance with stated goals and objectives.

(b) Staff who assume independent responsibilities for clinical services must meet the qualification requirements for their provider type.

(c) The ICF/MR must provide adequate, direct, and continuing supervision to personnel, volunteers, or support personnel used in providing clinical services.

(d) The ICF/MR must have enough space, equipment, and supplies to provide efficient and effective speech pathology and audiology services.

(98) MAINTENANCE OF RESIDENT RECORDS. (a) The ICF/MR must maintain a record for each resident that is adequate for: 1. Planning and continuous evaluation of the resident's habilitation program;

2. Furnishing documentary evidence of each resident's progress and response to his habilitation program; and

3. Protecting the legal rights of the residents, the ICF/MR, and the staff.

(b) Any individual who makes an entry in a resident's record must make it legibly, date it, and sign it.

(c) The ICF/MR must provide a legend to explain any symbol or abbreviation used in a resident's record.

(d) The original copy of the resident's records shall be maintained on the premises of the nursing home.

(99) ADMISSION RECORDS. At the time a resident is admitted, the ICF/MR must enter in the individual's record the following information:

(a) Name, date of admission, birth date and place, citizenship status, marital status, and social security number.

(b) Father's name and birthplace, mother's maiden name and birthplace, and parents' marital status.

(c) Name and address of parents, legal guardian, and next of kin if needed.

(d) Sex, race, height, weight, color of hair, color of eyes, identifying marks, and recent photograph.

(e) Reason for admission or referral problem.

(f) Type and legal status of admission.

(g) Legal competency status.

(h) Language spoken or understood.

(i) Sources of support, including social security, veterans' benefits, and insurance.

(j) Religious affiliation, if any.

(k) Reports of the preadmission evaluations.

(l) Reports of previous histories and evaluations, if any.

(100) RECORD ENTRIES DURING RESIDENCE. (a) Within 1 month after the admission of each resident, the ICF/MR must enter in the resident's record:

1. A report of the review and updating of the preadmission evaluation;

2. A prognosis that can be used for programming and placement; and

3. A comprehensive evaluation and individual program plan, designed by an interdisciplinary team.

(b) The ICF/MR must enter the following information in a resident's record during residence: 1. Reports of accidents, seizures, illnesses, and treatments for these conditions.

2. Records of immunizations.

3. Records of all periods that restraints were used, with justification and authorization for each.

4. Reports of regular, at least annual, review and evaluation of the program, developmental progress, and status of each resident.

5. Enough observations of the resident's response to his program to enable evaluation of its effectiveness.

6. Records of significant behavior incidents.

7. Records of family visits and contracts.

8. Records of attendance and absences.

9. Correspondence pertaining to the resident.

10. Periodic updates of the information recorded at the time of admission.

11. Appropriate authorizations and consents.

(c) The ICF/MR must enter a discharge summary in the resident's record at the time of discharge.

(101) CONFIDENTIALITY. (a) The ICF/MR must keep confidential all information contained in a resident's records, including information contained in an automated data bank.

(b) The record is the property of the ICF/MR which must protect it from loss, damage, tampering, or use by unauthorized individuals.

(c) The ICF/MR must have written policies governing access to, duplication of, and release of information from the record.

(d) The ICF/MR must obtain written consent of the resident, if competent, or a guardian before it releases information to individuals not otherwise authorized to receive it.

(102) CENTRAL RECORD SERVICE. The ICF/MR must:

(a) Maintain an organized central record service for the collection and release of resident information;

(b) Make records readily accessible to authorized personnel if a centralized system is used;

(c) Have appropriate records available in the resident living units;

(d) Have a master alphabetical index of all residents admitted to the ICF/MR; and

(e) Retain records for 5 years from date of discharge or transfer of resident to another facility.

(103) STAFF AND FACILITIES. The ICF/MR must have:

(a) Enough qualified staff and support personnel to accurately process, check, index, file, and retrieve records and record data promptly; and

(b) Adequate space, equipment, and supplies to provide efficient and effective record services.

(104) EMERGENCY PLAN AND PROCEDURES. (a) The ICF/MR must have a written staff organization plan and detailed written procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing residents.

(b) The ICF/MR must: 1. Clearly communicate and periodically review the plan and procedures with the staff; and

2. Post the plan and procedures at suitable locations throughout the facility.

(105) EVACUATION DRILLS. (a) The ICF/MR must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to:

1. Insure that all personnel on all shifts are trained to perform assigned tasks;

2. Insure that all personnel on all shifts are familiar with the use of the ICF/MR's firefighting equipment; and

3. Evaluate the effectiveness of emergency and disaster plans and procedures.

(b) The ICF/MR must: 1. Actually evacuate residents to safe areas during at least one evacuation drill each year, on each shift;

2. Make special provisions for the evacuation of the physically handicapped, such as fire chutes and mattressloops with poles;

3. Write and file a report and evaluation of each evacuation drill; and

4. Investigate all accidents and take corrective action to prevent similar accidents in the future.

(106) FIRE PROTECTION. Except as provided in HSS 105.12 (107) and (108), the ICF/MR must meet the provisions of the Life Safety Code of the National Fire Protection Association, 1967 edition, that apply to institutional occupancies.

(107) FIRE PROTECTION EXCEPTIONS FOR SMALLER ICF/MR. The department may apply the lodgings or rooming houses section of the residential occupancy requirements of the Life Safety Code of the National Fire Protection Association, 1967 edition, instead of the institutional occupancy provisions required by subsection (106), to an ICF/MR that has 15 beds or less if a physician or psychologist who meets the definition of qualified mental retardation professional in section HSS 101.03 certifies that each resident is:

(a) Ambulatory;

(b) Receiving active treatment; and

(c) Capable of following directions and taking appropriate action for self-preservation under emergency conditions.

(108) FIRE PROTECTION WAIVERS. (a) The department may waive specific provisons of the Life Safety Code required by HSS 105.12 (106), for as long as it considers appropriate, if:

1. The waiver would not adversely affect the health and safety of the residents;

2. Rigid application of specific provisions would result in unreasonable hardship for the ICF/MR as determined under guidelines contained in the HCFA long-term care manual; and

3. The waiver is granted in accordance with criteria contained in the long-term care manual.

(b) If the department waives provisions of the Code for an existing building of 2 or more stories that is not built of at least 2-hour fire-resistive construction, the ICF/MR may not house a blind, nonambulatory, or physically handicapped resident above the street-level floor unless it is built of:

1. One-hour protected, noncombustible construction as defined in National Fire Protection Association Standard No. 220;

2. Full-sprinklered, 1-hour protected, ordinary construction;

3. Full-sprinklered, 1-hour protected, wood frame construction.

(109) PAINT. The ICF/MR must:

(a) Use lead-free paint inside the facility; and

(b) Remove or cover old paint or plaster containing lead so that it is not accessible to residents.

(110) BUILDING ACCESSIBILITY AND USE. (a) The ICF/MR must:

1. Be accessible to and usable by all residents, personnel, and the public, including individuals with disabilities; and

2. Meet the requirements of American National Standards Institute (ANSI) Standard No. A117.1 (1961) American Standard Specifications for Making Buildings and Facilities Accessible to and Usable by the Physically Handicapped.

(b) The State survey agency may waive, for as long as it considers appropriate, specific provisions of ANSI Standard No. A117.1 (1961) if:
1. The construction plans for the ICF/MR or a part of it were approved and stamped by the department before March 18, 1974;

2. The provisions would result in unreasonable hardship on the ICF/MR if strictly enforced; and

3. The waiver does not adversely affect the health and safety of the residents.

(111) SANITATION RECORDS AND REPORTS. The ICF/MR must keep:

(a) Records that document compliance with sanitation, health, and environmental safety codes of the state or local authorities having primary jurisdiction over the ICF/MR; and

(b) Written reports of inspections by state or local health authorities, and records of action taken on their recommendations.

(112) SUPPORT SERVICES. (a) The ICF/MR must provide adequate, modern administrative support to efficiently meet the needs of residents and facilitate attainment of the ICF/MR's goals and objectives.

(b) The ICF/MR must: 1. Document its purchasing process;

2. Adequately operate its inventory control system and stockroom;

3. Have appropriate storage facilities for all supplies and surplus equipment; and

4. Have enough trained and experienced personnel to do purchase, supply, and property control functions.

(113) COMMUNICATION SYSTEM. (a) The ICF/MR must have an adequate communication system, including telephone service, that insures:

1. Prompt contact of onduty personnel; and

2. Prompt notification of responsible personnel in an emergency.

(114) ENGINEERING AND MAINTENANCE. The ICF/MR must have:

(a) An appropriate, written preventive maintenance program; and

(b) Enough trained and experienced personnel for engineering and maintenance functions.

(115) LAUNDRY SERVICES. The ICF/MR must manage its laundry services so that it meets daily clothing and linen needs without delay.

(116) OTHER REQUIREMENTS. The requirements found in HSS 105.10 (19) and HSS 105.106 shall apply to ICF/MRs where applicable.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.13 Certification of tuberculosis public health dispensaries. Dispensaries defined in s. 149.06, Stats. shall meet the requirements of Wis. Adm. Code section H 46.07, and be operated by or under the direction of a licensed physician.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.15 Certification of pharmacies. Pharmacies shall meet the requirements for registration and practice enumerated in ss. 450.02, and 450.04, Stats., and shall meet the requirements in Wis. Adm. Code chapters Phar 1 to 6.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

Note: The following rules are a codification of 42 CFR 405.1201 through 42 CFR 405.1230. For the sake of readability, some editing has been done. In the event of any conflict of meaning, the meaning of the federal regulations shall hold.

HSS 105.16 Requirements for certification of home health agencies. Home health agencies are required to meet the conditions of participation enumerated in this section.

(1) COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS. An agency shall be eligible for certification by the department if it meets the standards in this section. In addition, a proprietary organization which is not exempt from federal income taxation under section 501 of the Internal Revenue Code of 1954 shall be licensed as a home health agency pursuant to s. 141.15, Stats.

(2) ORGANIZATION, SERVICES, ADMINISTRATION. Organization, services provided, administrative control, and lines of authority for the delegation of responsibility down to the patient care level shall be clearly set forth in writing and shall be readily identifiable. Administrative and supervisory functions shall not be delegated to another agency or organization. All services not provided directly shall be monitored and controlled by the primary agency, including services provided through subunits of

the parent agency. If an agency has subunits, appropriate administrative records shall be maintained for each subunit.

(a) *Services provided.* 1. Part-time or intermittent skilled nursing services and at least one other therapeutic service (physical, speech, or occupational therapy), or home health aide or personal care services, shall be made available on a visiting basis, in a place of residence used as a patient's home. A public or nonprofit home health agency shall provide at least one of the qualifying services directly through agency employees but may provide the second qualifying service and additional services under arrangements with another agency or organization, except for personal care services which shall be provided directly by the agency, whenever the service is offered. A proprietary home health agency shall provide all services directly, through agency employes.

2. In those areas where personal care services are not available, the department may, at its discretion, certify a county social service or human service agency to provide personal care services, stipulated by contract.

3. If a social service agency is certified to provide personal care services at the effective date of this rule, it may be certified for a period of no longer than 2 years, unless it can otherwise meet the requirements of this rule for home health agencies. If it can, at or before the end of the 2 years, meet the requirements of a home health agency, it may be certified as a home health agency and may be discontinued as an approved social service agency.

(b) *Governing body.* A governing body (or designated persons so functioning) shall assume full legal authority and responsibility for the operation of the agency. The governing body shall appoint a qualified administrator, arrange for professional advice, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the agency. The name and address of each officer, director, and owner shall be disclosed. If the agency is a corporation, all ownership interests of 10% [5%] or more (direct and indirect) shall also be disclosed.

(c) *Administrator.* The administrator, who may also be the supervising physician or registered nurse shall organize and direct the agency's ongoing functions; maintain ongoing liaison among the governing body, the group of professional personnel, and the staff; employ qualified personnel and ensure adequate staff education and evaluations; ensure the accuracy of public information materials and activities; and implement an effective budgeting and accounting system. A qualified person shall be authorized in writing to act in this capacity in the absence of the administrator.

(d) *Supervising physician or registered nurse.* The skilled nursing and other therapeutic services provided shall be under the supervision and direction of a physician or a registered nurse (who preferably has at least 1 year of nursing experience and is a public health nurse). This person or similarly qualified alternate, shall be available at all times during operating hours and shall participate in all activities relevant to the professional services provided, including the developing of qualifications and assignments of personnel.

(e) *Personnel policies.* Personnel practices and patient care shall be supported by appropriate, written personnel policies. Personnel records shall include job descriptions, qualifications, licensure, performance evaluations, and health examinations, and shall be kept current.

(f) *Personnel under hourly or per visit contracts.*

1. If personnel under hourly or per visit contracts are utilized by the agency,there shall be a written contract between such personnel and the agency clearly designating:

a. That patients are accepted for care only by the primary home health agency,

b. The services to be provided,

c. The necessity to conform to all applicable agency policies including personnel qualifications,

d. The responsibility for participating in developing plans of treatment,

e. The manner in which services shall be controlled, coordinated, and evaluated by the primary agency.

f. The procedures for submitting clinical and progress notes, scheduling of visits, periodic patient evaluation, and

g. The procedures for determining charges and reimbursement, including the provision that only the home health agency shall bill the program and be reimbursed.

(g) *Coordination of patient services.* All personnel providing services shall maintain liaison with each other to assure that their efforts effectively complement one another and support the objectives outlined in the plan of treatment as explained in section HSS 105.16(4). The clinical record or minutes of case conferences shall establish that effective interchange, reporting, and coordinated patient evaluation does occur. A written summary report for each patient shall be sent to the attending physician at least every 60 days.

(h) *Services under arrangements.* Services provided under arrangements shall be subject to a written contract conforming with the requirements specified in paragraph (f) of this section, and with the requirements of section 1861(w) of the Social Security Act (42 USC 1395x(w)).

(i) *Institutional planning.* The home health agency, under the direction of the governing body, shall prepare an overall plan and budget which provides for an annual operating budget and a capital expenditure plan.

1. *Annual operating budget.* There shall be an annual operating budget which includes all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items (except that it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense).

2. *Capital expenditure plan.* The capital expenditure plan shall be in compliance with ch. 150, Stats. Records relating to the capital expenditure plan shall comply with the requirements of section HSS 105.02 (2) and (3).

3. *Preparation of plan and budget.* The overall plan and budget shall be prepared under the direction of the governing body of the home health agency, by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the home health agency.

4. *Annual review of plan and budget.* The overall plan and budget shall be reviewed and updated at least annually under the direction of the governing body of the home health agency, by the committee referred to in section HSS 105.16(2) (i) 3.

(3) GROUP OF PROFESSIONAL PERSONNEL. (a) A group of professional personnel, which shall include at least one physician and one registered nurse (preferably a public health nurse), with appropriate representation from other professional disciplines, shall establish and annually review the agency's policies governing scope of services offered, admission and discharge policies, medical supervision and plans of treatment, emergency care, clinical records, personnel qualifications, and program evaluation. At least one member of the group shall be neither an owner nor an employe of the agency.

(b) *Advisory and evaluation function.* The group of professional personnel meets frequently to advise the agency on professional issues, to participate in the evaluation of the agency's program to assist the agency in maintaining liaison with other health care providers in the community, and to assist the agency in its community information program. Its meetings shall be documented by minutes, which shall be dated.

(4) ACCEPTANCE OF PATIENTS, PLAN OF TREATMENT, MEDICAL SUPERVISION. Patients shall be accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, and social needs can be met adequately by the agency in the patient's place of residence. If personal care services are considered necessary, an evaluation through the use of a functional assessment scale, provided by the department pursuant to HSS 105.16(8) (c) 1., shall first be made. Exception: Personal care services provided to disabled individuals who have been determined to be permanently disabled by the bureau of social security disability insurance (BSSDI) shall be exempt from this evaluation through the functional assessment scale. However all other plans of treatment and medical supervision requirements shall apply. Care shall follow a written plan of treatment approved and periodically reviewed by a physician, and care shall continue under the supervision of a physician.

(a) *Plan of treatment.* The plan of treatment developed in consultation with the agency staff shall cover all pertinent diagnoses, including mental state, types of services and equipment required, frequency of visits, prognosis, rehabilitation potential, functional limitations, activities permitted, nutritional requirements, medications and treatment, any safety measures to protect against injury, instructions for timely discharge or referral, and any other appropriate items. If a physician refers a patient under a plan of treatment which cannot be completed until

after an evaluation visit, the physician shall be consulted to approve additions or modifications to the original plan. Orders for therapy services shall include the specific procedures and modalities to be used and the amount, frequency, and duration. The therapist and other agency personnel shall participate in developing the plan of treatment.

(b) *Periodic review of plan of treatment.* The total plan of treatment shall be reviewed by the attending physician and home health agency personnel as often as the severity of the patient's condition requires, but at least every 60 days. Agency professional staff shall promptly alert the physician to any changes that suggest a need to alter the plan of treatment.

(c) *Conformance with physician's orders.* Drugs and treatments shall be administered by agency staff only as ordered by the physician. The nurse or therapist immediately shall record and sign oral orders and obtain the physician's countersignature. Agency staff shall check all medicines a patient may be taking to identify possible ineffective drug therapy or adverse reactions, significant side effects, drug allergies, and contraindicated medication. Any problems shall be reported promptly to the physician.

(d) When a recipient is receiving either home health aide or personal care services, the agency shall develop an agreement with the county social service agency in the recipient's county of residence. The agreement shall include a plan of coordination with the county social service agency for exchange of information about services provided to recipients in their home (including but not limited to information on providing of home health aid, personal care, and supportive home care to recipients), in order to minimize the duplication of services.

(5) SKILLED NURSING SERVICE. The home health agency shall provide skilled nursing service by or under the supervision of a registered nurse and in accordance with the plan of treatment.

(a) *Duties of the registered nurse.* The registered nurse shall make the initial evaluation visit, shall regularly reevaluate the patient's nursing needs, shall initiate the plan of treatment and necessary revisions, shall provide those services requiring substantial specialized nursing skill, shall initiate appropriate preventive and rehabilitative nursing procedures, shall prepare clinical and progress notes, shall coordinate services, shall inform the physician and other personnel of changes in the patient's condition and needs, shall counsel the patient and family in meeting nursing and related needs, shall participate in inservice programs, and shall supervise and teach other nursing personnel.

(b) *Duties of the licensed practical nurse.* The licensed practical nurse shall provide services in accordance with agency policies, shall prepare clinical and progress notes, shall assist the physician or registered nurse in performing specialized procedures, shall prepare equipment and materials for treatments observing aseptic technique as required, and shall assist the patient in learning appropriate self-care techniques.

(6) THERAPY SERVICES. Any therapy services offered by the home health agency directly or under arrangement shall be given by a qualified therapist or by a qualified assistant under the supervision of a qualified therapist in accordance with the plan of treatment. The qualified therapist shall assist the physician in evaluating level of function, shall help develop the plan of treatment (revising as necessary), shall prepare clinical and progress notes, shall advise and consult with the family and other agency personnel, and shall participate in inservice programs.

(a) *Supervision of physical therapist assistant and occupational therapy assistant.* Services provided by a qualified physical therapist assistant or qualified occupational therapy assistant may be furnished under the supervision of a qualified physical or occupational therapist. A physical therapist assistant or occupational therapy assistant shall perform services planned, delegated, and supervised by the therapist, shall assist in preparing clinical notes and progress reports, and shall participate in educating the patient and family, and in inservice programs.

(b) *Supervision of speech therapy services.* Speech therapy services shall be provided only by or under supervision of a qualified speech pathologist or audiologist.

(7) HOME HEALTH AIDE SERVICES. Home health aides shall be selected on the basis of such factors as a sympathetic attitude toward the care of the sick, ability to read, write, and carry out directions, and maturity and ability to deal effectively with the demands of the job. Aides shall be carefully trained in methods of assisting patients to achieve maximum self-reliance, principles of nutrition and meal preparation, the aging process and emotional problems of illness, procedures for maintaining a clean, healthful, and pleasant environment, changes in patient's condition that should be reported, work of the agency and the health team, ethics, confidentiality, and recordkeeping. They shall be closely supervised to assure their competence in providing care.

(a) *Assignment and duties of the home health aide.* The home health aide shall be assigned to a particular patient by a registered nurse. Written instructions for patient care shall be prepared by a registered nurse or therapist as appropriate. Duties include the performance of simple procedures as an extension of therapy services, personal care, ambulation and exercise, household services essential to health care at home, assistance with medications that are ordinarily self-administered, reporting changes in the patient's conditions and needs, and completing appropriate records.

(b) *Supervision.* The registered nurse, or appropriate professional staff member, if other services are provided, shall make a supervisory visit to the patient's residence at least once every 30 days, either when the aide is present to observe and assist, or when the aide is absent, to assess relationships and determine whether goals are being met.

(8) PERSONAL CARE SERVICES. Personal care workers shall be employed by the home health agency, unless personal care services are provided pursuant to HSS 105.16 (2) (a) 2. or 105.16 (2) (a) 3.

(a) *Training.* Each personal care worker shall be trained in the provision of personal care services. Training shall consist of a minimum of 40

classroom hours, 25 of which shall cover personal and restorative care subjects. The 40 classroom hours shall include the subjects listed in the "Curriculum Guidelines for Training Homemakers in the Provision of Personal Care Services" which may be obtained from the Division of Community Services. Training shall emphasize techniques and aspects of caring for the target populations.

(b) *Supervision by registered nurse.* Each personal care worker shall be supervised by a registered nurse oriented to or experienced in providing nursing care in the home.

(c) *Requests for services.* Requests for personal care services may be made by the recipient, the recipient's physician, social service agency personnel or other individuals or organizations acting on behalf of the recipient.

1. Except as specified in HSS 105.16 (4), before involvement in a personal care program, the recipient shall undergo an evaluation through the use of the functional assessment scale provided by the department, to determine the medical necessity for personal care and the person's ability to benefit from it.

2. If it is determined that the level of care needed is personal care, a physician's prescription or orders shall be obtained by the registered nurse, and a plan of care shall be developed by the registered nurse, in consultation with the physician.

(d) *Other requirements of the agency.* In addition to requirements stated elsewhere in this section, the home health agency shall:

1. Provide the personal care worker with the basic materials and equipment to deliver personal care services;

2. Maintain time sheets documenting, by funding source, the types and duration of services provided by the personal care worker;

4. The home health agency shall maintain a health care record for each recipient receiving personal care services through the agency. The record shall be kept up to date, and shall include all health services provided by the agency. The record shall include:

a. Nursing assessment, medical plan of care, nursing plan of care, personal care worker's assignment, recording of all assignments whether completed or not and general remarks.

b. The record shall be signed by both the personal care worker and the supervising registered nurse.

c. The personal care worker shall record each visit with the recipient on the health care record, including observations made, activities carried out and not carried out.

d. The personal care worker shall report promptly to the registered nurse supervisor any significant changes in the condition of the recipient.

e. A copy of the written agreement with the health agency or registered nurse providing supervision shall be on file at the agency.

5. The agency shall cooperate with other health and social service agencies in the area and with interested community referral groups in an attempt to avoid duplication of services and to provide the best possible coordination of personal care services to area recipients.

6. Requirements of the registered nurse supervisor. The registered nurse providing the health care supervision shall:

a. Review with appropriate personnel the evaluation based upon the rating scale designated pursuant to HSS 105.16 (9) [(8)] (c) 1., before any personal care services are provided.

b. Secure from the physician the necessary written orders;

c. Develop a plan of care in consultation with the physician, prepare the assignment in writing, interpret this assignment to the personal care worker, if necessary, and maintain a copy of the physician's plan of care with the home health agency's health record;

d. Develop an apppropriate time and services reporting mechanism for the personal care worker and instruct the personal care worker in the use of reporting mechanism;

e. Identify in the plan of care the frequency and anticipated duration of personal care services;

f. Give written instructions, or if necessary a demonstration to the personal care worker, of the services to be performed;

g. Teach or arrange for the teaching of personal care services to family members, if available and appropriate;

h. Confer with the home health agency staff, the personal care worker, the physician, and other involved professionals in regard to the recipient's progress;

i. Judge the competency of the personal care worker to perform the personal care services; and

j. Review the plan of care and perform an evaluation of the patient's condition not less frequently than every 60 days. The evaluation includes at least one visit to the home and a review of the personal care worker's daily written record, and discussion with the physician of any need for changes in type or level of care or discontinuance of care. If a change is necessary, appropriate referrals shall be made.

7. Requirements of the personal care worker. The personal care worker who shall not be a responsible relative as legally defined under s. 52.01 (1) (a), Stats., or a child of the client receiving services, shall:

a. Perform tasks assigned by the registered nurse for which appropriate training has been received;

b. Report in writing to the supervising registered nurse on each assignment;

c. Report promptly to the registered nurse any changes in the recipient's condition; and

d. Confer with the registered nurse regarding the recipient's progress.

8. Records. The following records shall be made available by the agency to the approved survey team and other authorized department personnel:

a. Written personnel policies;

b. Written job descriptions for all positions which are part of the personal care services program;

c. Written plan indicating total process for referral through delivery of services and follow-up;

d. Written statement defining scope of personal care services (The statement shall include: target population, service needs of target population, service priorities and hours the services are available.);

e. Record of each personal care worker's 40 hours of training in personal care;

f. Personal care worker's daily time sheets;

g. Health care record;

h. Medical assistance billings;

i. Cost reports; and

j. Contracts with agencies.

(9) CLINICAL RECORDS. A clinical record containing pertinent past and current findings in accordance with accepted professional standards shall be maintained for every patient receiving home health services. In addition to the plan of treatment, the record shall contain appropriate identifying information; name of physician; drug, dietary, treatment, and activity orders; signed and dated clinical and progress notes (clinical notes shall be written the day service is rendered and shall be incorporated no less often than weekly); copies of summary reports sent to the physician; and a discharge summary.

(10) EVALUATION. The home health agency shall have written policies requiring an overall evaluation of the agency's total program at least once a year by the group of professional personnel (or a committee of this group), home health agency staff, and consumers, or by professional people outside the agency working in conjunction with consumers. The evaluation program shall be appropriate, adequate, effective, and efficient. Results of the evaluations shall be reported to and acted upon by those responsible for the operation of the agency and shall be maintained separately in administrative records.

(a) *Policy and administrative review.* As part of the evaluation process the policies and administrative practices of the agency shall be reviewed to determine the extent to which they promote appropriate, adequate, effective, and efficient patient care. Mechanisms shall be established in writing for the collection of pertinent data to assist in evaluation. The data to be considered may include but are not limited to: number of patients recieving each service offered, number of patient visits, reasons for discharge, breakdown by diagnosis, sources of referral, number of patients not accepted and reasons, and total staff days for each service offered.

(b) *Clinical record review.* At least quarterly, appropriate health professionals, representing at least the scope of the program, shall review a sample of both active and closed clinical records to assure that established policies are followed in providing services (direct services as well as services under arrangement). There shall be continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of treatment and appropriateness of continuation of care.

(11) QUALIFYING TO PROVIDE OUTPATIENT PHYSICAL THERAPY OR SPEECH PATHOLOGY SERVICES. As a provider of services, a home health agency may qualify to provide outpatient physical therapy or speech pathology services if the agency meets the statutory requirements of section 1861 (o) of the Social Security Act and complies with other health and safety requirements prescribed by the secretary of DHEW for home health agencies. The agency shall also comply with applicable health and safety requirements of HSS 105.34 (3), (4), (5), (7), (9), and (11) pertaining to provision of outpatient physical therapy or speech pathology services.

(12) Home health agencies shall provide or make available part time or intermittent nursing services, home health aide services and medical supplies, equipment and appliances suitable for use in the home.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.19 Certification of licensed practical nurses. Licensed practical nurses are required to be licensed pursuant to s. 441.10, Stats.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.20 Certification of registered nurses. (1) Registered nurses are required to be registered pursuant to s. 441.06, Stats.

(2) NURSE PRACTITIONERS. (a) Until the effective date of any permanent administrative rule promulgated by the state department of regulation and licensing which certifies and specifies standards and procedures of practice for nurse practitioners, nurse practitioners shall be eligible to participate only when employed by a rural health clinic.

(b) A nurse practitioner shall be registered and shall meet one of the following requirements:

1. Certification as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates; or

2. Satisfactory completion of a formal one-year academic program which prepares registered nurses to perform an expanded role in the delivery of primary care, which includes at least four months of classroom instruction and a component of supervised clinical practice, and which awards a degree, diploma, or a certificate to persons who successfully complete the program; or

3. Successful completion of a formal education program intended to prepare registered nurses to perform an expanded role in the delivery of primary care but which does not meet the requirements of (a) 2. above, and performance of an expanded role in the delivery of primary care for

a total of 12 months during the 18-month period immediately preceeding July 1, 1978, the effective date of federal regulations governing Medicaid certification of rural health clinics.

(c) A nurse practitioner certified as a Medicaid provider shall develop and maintain with a licensed physician a written protocol of services provided and procedures to follow. Such joint protocol shall include but not be limited to, explicit agreements on the expanded primary care services which can be provided by the nurse practitioner. The protocol also shall include arrangements for: communication of directions, consultation with the physician, assistance with medical emergencies, patient referrals, and other agreed-to provisions. In rural health clinics, the written policies incorporated as section HSS 105.35 (10) (b) of this rule shall be considered sufficient evidence of a joint written protocol.

(d) All written protocols shall be reviewed and approved by the interdisciplinary professional team enumerated in section HSS 105.35 (10) (b) 4.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

Note: The following rules are a codification of 42 CFR 405.1037 and 1038. For the sake of readability, some editing has been done. In the event of any conflict of meaning the meaning of the original federal regulations shall hold.

HSS 105.21 Certification of psychiatric hospitals. Psychiatric hospitals shall be eligible for certification if they are approved pursuant to s. 50.35 Stats. as meeting the rules and standards promulgated under Wis. Adm. Code chapter H 24 and if they have a certification of participation in Medicare or a certificate or accreditation from the Joint Commission on Accreditation of Hospitals (or if they meet requirements equivalent to those for certification or accreditation). Psychiatric hospitals are required to have a utilization review plan that meets the requirements of section HSS 105.09 of this rule. Hospitals participating in the PSRO review program shall meet the requirements of that program instead of those enumerated in section HSS 105.09.

(1) Only a distinct part of an *institution which is primarily engaged in furnishing psychiatric care* shall meet the definition of a psychiatric hospital. A distinct part of a general hospital which primarily or exclusively treats psychiatric cases, shall be considered a general hospital because it is *part of a general hospital.* Therefore, *none of the restrictions* which apply to payments for inpatient hospital services in psychiatric hospitals apply. A psychiatric facility which is part of a general hospital or a large medical center or complex will be included within the certification of the overall institution unless the psychiatric facility operates as a separate functioning entity, that is, is located in a separate building, wing, or part of a building, has its own administration, and maintains separate fiscal records. Any institution which is primarily for the care and treatment of mental diseases cannot qualify as a "hospital" unless it meets the special requirements of a psychiatric hospital as enumerated in this section.

(2) SPECIAL MEDICAL RECORD REQUIREMENTS FOR PSYCHIATRIC HOSPITALS. Medical records maintained by a psychiatric hospital shall stress the psychiatric components of the record, including history of finding and treatment rendered for the psychiatric condition(s) for which the

patient is hospitalized. Medical records shall meet the following standards:

(a) Identification data shall include the patient's legal status.

(b) A provisional or admitting diagnosis shall be made on every patient at the time of admission and shall include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

(c) The complaint of others regarding the patient shall be included as well as the patient's comments.

(d) The psychiatric evaluation, including a medical history, shall contain a record of mental status and shall note the onset of illness, the circumstances leading to admission, attitudes, behavior, estimate of intellectual functioning, memory functioning, orientation, and an inventory of the patient's assets in descriptive, not interpretative, fashion.

(e) A complete neurological examination shall be recorded at the time of the admission physical examination, when indicated.

(f) The social service records, including reports of interviews with patients, family members and others, shall provide an assessment of home plans, family attitudes, and community resource contacts as well as a social history.

(g) Reports of consultations, psychological evaluations, report of electroencephalograms, dental records and reports of special studies shall be included in the record.

(h) The individual comprehensive treatment plan shall be recorded, based on an inventory of the patient's strengths and disabilities, and shall include a substantiated diagnosis in the terminology of the American Psychiatric Association's Diagnostic and Statistical Manual. The plan also shall include short-term and long-range goals, and the specific treatment modalities utilized as well as the responsibilities of each member of the treatment team. The plan shall provide adequate justification and documentation for the diagnoses and for the treatment and rehabilitation activities carried out.

(i) The treatment received by the patient shall be documented in such a manner and with such frequency as to assure that all active therapeutic efforts such as individual and group psyhcotherapy, drug therapy, milieu therapy, occupational therapy, recreational therapy, industrial or work therapy, nursing care and other therapeutic interventions are included.

(j) Progress notes shall be recorded by the physician, nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. Frequency of such notes shall be determined by the condition of the patient but should be recorded at least weekly for the first 2 months and at least once a month thereafter, and should contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

(k) The discharge summary shall include a recapitulation of the patient's hospitalization and recommendations from appropriate services

concerning follow-up as well as a brief summary of the patient's condition on discharge.

(l) The psychiatric diagnoses contained in the final diagnoses shall be written in the terminology of the American Psychiatric Association's Diagnostic and Statistical Manual.

(3) SPECIAL STAFF REQUIREMENTS FOR PSYCHIATRIC HOSPITALS. (a) Inpatient psychiatric facilities (psychiatric hospitals, distinct parts of psychiatric hospitals or inpatient components of community mental health centers) shall be staffed with the number of qualified professional, technical and supporting personnel and consultants required to carry out an intensive and comprehensive treatment program. Such program shall include evaluation of individual needs, establishment of treatment and rehabilitation goals, and implementation, directly or by arrangement, of a broad ranged therapeutic programs including at least professional psychiatric, medical, surgical, nursing, social work, psychological and activity therapies as required to carry out an individual treatment plan for each patient.

1. Qualified professional, technical, and consultant personnel shall be available to evaluate each patient at the time of admission, including diagnosis of any intercurrent disease. Services necessary for such evaluation include laboratory, radiological and other diagnostic tests, obtaining psychosocial data, carrying out psychiatric and psychological evaluations, and completing a physical examination, including a complete neurological examination when indicated, shortly after admission.

2. The number of qualified professional personnel, including consultants and technical and supporting personnel, shall be adequate to assure representation of the disciplines necessary to establish short-term and long-range goals; and to plan, carry out, and periodically revise a written individualized treatment program. Such treatment plan shall be based on scientific interpretation of:

a. Degree of physical disability and indicated remedial or restorative measures, including nutrition, nursing, physical medicine, and pharmacological therapeutic interventions;

b. Degree of psychological impairment and appropriate measures to be taken to relieve treatable distress and to compensate for nonreversible impairments where found;

c. Capacity for social interaction and appropriate nursing measures and milieu therapy to be undertaken, including group living experiences, occupational and recreational therapy, and other prescribed rehabilitative activities to maintain or increase the individual's capacity to manage activities of daily living;

d. Environmental and physical limitations required to safeguard the individual's health and safety, with a plan to compensate for these deficiencies and required to develop the individual's potential for return home, or to a foster home, an extended care facility, a community mental health center, or to another alternative type of facility.

(b) *Director of inpatient psychiatric services.* Inpatient psychiatric services shall be under the supervision of a clinical director, service chief or equivalent who is qualified to provide the leadership required for an

intensive treatment program. The number and qualifications of physicians shall be adequate to provide essential psychiatric services.

1. The clinical director, service chief or equivalent shall be certified by the American Board of Psychiatry and Neurology, or shall meet the training and experience requirements for examination by the board ("board eligible"). In the event the psychiatrist in charge of the clinical program is board eligible, there shall be evidence of consultation given to the clinical program on a continuing basis from a psychiatrist certified by the American Board of Psychiatry and Neurology.

2. The medical staff shall be qualified legally, professionally and ethically for the positions to which they are appointed.

3. The number of physicians shall be commensurate with the size and scope of the treatment program.

4. Residency training shall be under the direction of a properly qualified psychiatrist.

(c) *Availability of physicians and other personnel.* Physicians and other appropriate professional personnel shall be available at all times to provide necessary medical and surgical diagnostic and treatment services including specialized services. If such services are not available within the institution, qualified consultants or attending physicians shall be immediately available, or a satisfactory arrangement shall be established for transferring patients to a certified general hospital.

(d) *Nursing services.* Nursing services shall be under the direct supervision of a registered professional nurse who is qualified by education and experience for the position. The number of registered professional nurses, licensed practical nurses, and other nursing personnel shall be adequate to formulate and carry out the nursing components of the individual treatment plan for each patient.

1. The registered professional nurse supervising the nursing services shall have a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing, or shall be qualified (by education, experience in the care of the mentally ill, and demonstrated competence to participate in interdisciplinary formulation of individual treatment plans) to give skilled nursing care and therapy, and to direct, supervise and train others who assist in implementing and carrying out the nursing components of each patient's treatment plan.

2. The staffing pattern shall insure the availability of a registered professional nurse 24 hours each day: for direct care, for supervising care performed by other nursing personnel, and for assigning nursing care activities not requiring the services of a professional nurse to other nursing service personnel. Such assignment shall be according to the patient's needs and according to the preparation and competence of the nursing staff available.

3. The number of registered professional nurses, including nurse consultants, shall be adequate to formulate in writing a nursing care plan for each patient and shall be adequate to assure that each nursing care plan is carried out.

4. Registered professional nurses and other nursing personnel shall be prepared by continuing inservice and staff development programs for active participation in interdisciplinary meetings affecting the planning or implementation of nursing care plans for patients. Such programs shall include preparation for participation in diagnostic conferences, treatment planning sessions, and meetings held to consider alternative facilities and community resources.

(e) *Psychological services.* Psychological services shall be under the supervision of a qualified psychologist. The psychology staff, including consultants, shall be adequate in numbers and qualifications to plan and carry out assigned responsibilities.

1. The psychology department or service shall be under a psychologist with a doctoral degree in psychology from an American Psychological Association-approved program in clinical psychology or its adjudged equivalent. Where a psychologist who does not hold the doctoral degree directs the program, the psychologist shall have attained recognition of competency through the American board of Examiners for Professional Psychology, through state licensing, or through endorsement by the state psychological association.

2. Psychologists, consultants and supporting personnel shall be adequate in number and qualifications: to assist in essential diagnostic formulations; and to participate in program development and evaluation of program effectiveness, training and research activities, therapeutic interventions such as milieu, individual or group therapy, and interdisciplinary conferences and meetings held to establish diagnoses, goals, and treatment programs.

(f) *Social work services and staff.* Social work services shall be under the supervision of a qualified social worker. The social work staff shall be adequate in numbers and qualifications to fulfill specific needs of individual patients and their families; to develop community resources and to consult with other staff and community agencies.

1. The director of the social work department or service shall have a master's degree from an accredited school of social work and meet the experience requirements for certification by the Academy of Certified Social Workers.

2. Social work staff, including other social workers, consultants and other assistants or case aides, shall be qualified and numerically adequate to conduct prehospitalization studies; to provide psychosocial data for diagnosis and treatment planning; to provide direct therapeutic services to patients, patient groups or families; to develop community resources, including family or foster care programs; to conduct appropriate social work research and training activities; and to participate in interdisciplinary conferences and meetings concerning diagnostic formulation and treatment planning, including identification and utilization of other facilities and alternative forms of care and treatment.

(g) *Qualified therapists and others.* Qualified therapists, consultants, volunteers, assistants or aides shall be sufficient in number to provide comprehensive therapeutic activities, including at least occupational, recreational and physical therapy, as needed, to assure that

appropriate treatment is rendered for each patient, and to establish and maintain a therapeutic milieu.

1. Occupational therapy services shall be under the supervision of an occupational therapist meeting the requirements of HSS 105.28. In the absence of a full-time, qualified occupational therapist, an occupational therapy assistant meeting the requirements of HSS 105.285 may function as the director of the activities program, with consultation from a fully qualified occupational therapist.

2. When physical therapy services are offered, the services shall be given by or under the supervision of a physical therapist who meets the requirements of HSS 105.27. In the absence of a full-time, qualified physical therapist, physical therapy services shall be available by arrangement with a certified general hospital or by either consultation or part-time services furnished by a fully qualified physical therapist.

3. Recreational or activity therapy services shall be available under the direct supervision of a member of the staff who has demonstrated competence in therapeutic recreation programs.

4. Other occupational therapy, recreational therapy, activity therapy and physical therapy assistants or aides shall be directly responsible to qualified supervisors and shall be provided special on-the-job training to fulfill assigned functions.

5. The total number of rehabilitation personnel, including consultants, shall be sufficient to permit adequate representation and participation in interdisciplinary conferences and meetings affecting the planning and implementation of activity and rehabilitation programs, including diagnostic conferences; and to maintain all daily scheduled and prescribed activities including maintenance of appropriate progress records for individual patients.

6. Voluntary service workers shall be under the direction of a paid professional supervisor of volunteers, shall be provided appropriate orientation and training, and shall be available daily in sufficient numbers to be of assistance to patients and their families in support of therapeutic activities.

(4) INSPECTIONS OF CARE. The pertinent sections of HSS 105.10 (19) which relate to inspections of care in psychiatric facilities shall apply.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

Note: Chapter PW-MA 25 is repealed and partially recreated in HSS 105.22 for purposes of certification.

HSS 105.22 Requirements for certification of psychotherapy providers. (1) Psychotherapy providers are required to be either:

(a) A licensed physician who has completed a residency in psychiatry;

(b) A licensed psychologist who is listed or eligible to be listed in the National Register of Health Services Providers in Psychology; or

(c) An outpatient facility operated by a "board" as defined in chapter one of this rule which is certified under PW-MH 60.65 (and 60.72 if applicable) Wis. Adm. Code and s. 632.89 (1) (a), Stats.; or

(d) An outpatient facility operated by a provider hospital which is certified under PW-MH 60.65 (and 60.72 if applicable) Wis. Adm. Code and s. 632.89 (1) (a), Stats. or which is accredited by JCAH, Accreditation Program for Psychiatric Facilities; or

(e) At the discretion of the department, an outpatient facility under contract to a "board" as defined in chapter one of this rule which is certified under PW-MH 60.65 (and 60.72 if applicable), Wis. Adm. Code and s. 632.89 (1) (a), Stats and which has made substantial effort to comply with the requirements for accreditation by JCAH, Accreditation Program for Psychiatric Facilities; or

(f) Clinics certified under rules promulgated by the department to govern s. 632.89, Stats.

(2) STAFFING REQUIREMENTS FOR OUTPATIENT FACILITIES. (a) To provide psychotherapy reimbursable under the medical assistance program, personnel employed by an outpatient facility as defined in HSS 105.22 (1) (c), (d), (e), or (f) shall be required to meet provider certification standards specified in this subsection and shall be under the supervision of a licensed physician or licensed phychologist who meets the requirements of HSS 105.22 (1) (a) or (b). Persons employed by board operated or hospital outpatient psychotherapy facilities shall not be required to be individually certified as providers and may provide psychotherapy services upon the department's issuance of certification to the facility by which they are employed. In this case, the facility shall provide a list naming personnel employed by the facility who shall be performing psychotherapy services for which reimbursement shall be claimed under the medical assistance program. Such listing shall certify the credentials possessed by the named persons which would qualify them for certification under the standards specified in this subsection. A facility, once certified, shall be under a continuing obligation to promptly advise the department in writing of the procurement or termination of employes who shall be, or have been, providing psychotherapy services under the medical assistance program. Persons eligible in this subsection shall be:

1. A person with a masters degree in social work from a graduate school of social work accredited by the Council on Social Work Education, with course work emphasis in case work or clinical social work and who is listed in or eligible to be listed in either the NASW Register of Clinical Social Workers or the National Registry of Health Care Providers in Clinical Social Work; or

2. A person with a masters degree in psychiatric mental health nursing from a graduate school of nursing accredited by the National League for Nursing;

3. A person with any of the following masters degrees and course work emphasis in clinical psychology: counseling and guidance, counseling psychology, clinical psychology, psychology or school psychology, if the person also is listed or eligible to be listed in their National Registry or has met the equivalent of the requirements for registration in the National Registry of Health Care Providers in Clinical Social Work or in the NASW Register of Clinical Social Work; or

4. A licensed psychologist or licensed physician.

5. Providers defined by subparagraphs 1 through 3 shall also have 3,000 hours of supervised experience in clinical practice. Supervised during the 3,000 hour period means a minimum of one hour per week of face-to-face supervision by another person meeting the minimum qualifications to be a provider.

(3) REIMBURSEMENT FOR OUTPATIENT PSYCHOTHERAPY SERVICES. Outpatient psychotherapy services shall be reimbursed according to medicare profiles or other mechanisms established by the department for the applicable provider and shall be as follows:

(a) For the services of any provider working in a certified outpatient facility, reimbursement shall be to the facility;

(b) For the services of any provider in private practice who is licensed and certified according to section HSS 105.22(1) (a) or (b), reimbursement shall be to that provider.

(4) REIMBURSEMENT FOR INPATIENT PSYCHOTHERAPY SERVICES. Reimbursement shall be made to providers defined in HSS 105.22(1) (a) and (b) who provide psychotherapy services to a recipient while the recipient is an inpatient in a general, acute care hospital or in a psychiatric facility. Psychotherapy services provided to such inpatients shall be reimbursed according to medicare profiles or other mechanisms established by the department for the applicable provider and shall be as follows:

(a) For the services of a provider who is a licensed physician defined in HSS 105.22(1) (a) or a licensed psychologist defined in HSS 105.22(1) (b) employed by or under contract to an outpatient facility, reimbursement shall be to the facility;

(b) For the services of any provider who is a licensed physician defined in HSS 105.22(1) (a) or a licensed psychologist defined in HSS 105.22(1) (b) in private practice, reimbursement shall be to the physician or psychologist.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.23 Certification of alcohol and other drug abuse treatment providers. (1) Outpatient alcohol and other drug abuse treatment providers are required to be:

(a) An outpatient facility operated by a "board" as defined in chapter one of this rule which is certified under PW-MH 61.03 Wis. Adm. Code and s. 632. 89(1) (a), Stats.; or

(b) An outpatient facility operated by a hospital which is certified under PW-MH 61.03 Wis. Adm. Code and s. 632.89(1) (a), Stats. and which is accredited by JCAH; or

(c) At the discretion of the department, an outpatient facility under contract to a "board" as defined in chapter one of this rule which is certified under PW-MH 61.03 Wis. Adm. Code and s. 632.89(1) (a), Stats. and has made substantial effort to comply with the requirements for accreditation by JCAH.

(d) Providers defined in HSS 105.22(1) (a) and (b) are eligible for reimbursement for AODA services if provider has a written agreement

with a facility defined in HSS 105.23 (1) (a), (b) or (c) and the recipient being treated is enrolled in an AODA program at such facility.

(2) STAFFING REQUIREMENTS FOR AODA OUTPATIENT FACILITIES. (a) To provide AODA services reimbursable under the medical assistance program, personnel employed by an outpatient facility defined in HSS 105.23 (1) (a), (b) and (c) shall meet the requirements in section HSS 105.22 (2) (a) 1, 2, 3; or

(b) Shall be an alcohol and drug abuse counselor certified by the Wisconsin Alcoholism and Drug Abuse Counselor Certification Board, Inc. AODA counselors shall work under the supervision of a provider who is a licensed physician or licensed psychologist, employed by the same facility.

(c) The facility shall provide a list naming personnel employed by the facility performing AODA services for which reimbursement shall be claimed under the medical assistance program. Such listing shall certify the credentials possessed by the named persons which would qualify them for certification under the standards specified in section HSS 105.23 (2) (a) and (b). A facility, once certified, shall be under a continuing obligation to promptly advise the department in writing of the procurement or termination of employes who shall be, or have been, providing [AODA] services under the medical assistance program.

(3) REIMBURSEMENT FOR AODA SERVICES. Reimbursements for outpatient alcohol and other drug abuse treatment services shall be according to medicare profiles or other mechanisms established by the department for the applicable providers as follows:

(a) For the services of any provider employed by or under contract to a certified AODA facility, reimbursement will be made to the facility;

(b) For the services of any provider who is a physician or licensed psychologist defined in HSS 105.23 (1) (d) in private practice, reimbursement shall be to the physician or psychologist.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.245 Day treatment or day hospital services. (1) Day treatment or day hospital service providers are required to be either:

(a) A medical program operated by a "board" as defined in chapter one of this rule which is certified under PW-MH 60.67 (and 60.73 or 61.03 if applicable) Wis. Adm. Code and s. 632.89 (1) (a), Stats.; or

(b) A medical program under contract to a "board" as defined in chapter one of this rule which is certified under PW-MH 60.67 (and 60.73 or 61.03 if applicable), Wis. Adm. Code and s. 632.89 (1) (a), Stats. Hospital programs shall be accredited by JCAH, Accreditation Program for Psychiatric Facilities.

(2) PROGRAM PERSONNEL AND STAFFING. (a) A registered nurse and a registered occupational therapist shall be on duty to participate in program planning, program implementation and daily program coordination.

(b) The day treatment program shall be planned for and directed by designated members of the interdisciplinary team including but not limited to a social worker, a phychologist, an occupational therapist and a registered nurse (or other appropriate health care professional, e.g. physician, physician's assistant).

(c) A written patient evaluation involving an assessment of the patient's progress by each member of the multidisciplinary team shall be made once at least every 60 days.

(d) For the purposes of daily program performance, coordination, guidance and evaluation, there shall be:

1. One qualified professional staff (e.g. OTR, MSW, RN, licensed psychologist, MS psychologist) per group; or

2. One certified occupational therapist assistant and one other paraprofessional per group; and

3. Other appropriate staff, including volunteer staff.

(3) BILLING AND REIMBURSEMENT FOR DAY TREATMENT OR DAY HOSPITAL SERVICES.

(a) Reimbursement for medical day treatment or day hospital services shall be at 90% of the rate established and approved by the department less any third party recoupments. For programs defined by HSS 105.245(1)(b), the authorizing board shall be responsible for the remainder of the reimbursement.

(b) Billing submitted for medical day treatment or day hospital services shall, with the exception of state-operated facilities, verify that the service has been approved by the board.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.25 Certification of podiatrists. Podiatrists are required to be licensed pursuant to s. 448.04 (1) (d), Stats., and registered pursuant to s. 448.07, Stats. and Wis. Adm. Code chapter Med 30.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.26 Certification of chiropractors. Chiropractors are required to be licensed pursuant to s. 446.02, Stats.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.27 Certification of physical therapists. Physical therapists are required to be licensed pursuant to ss. 448.07 and 448.05, Stats. and Wis. Adm. Code chapter Med 7.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.275 Certification of physical therapist assistants. Physical therapist assistants are required to be graduated from a 2-year college-level program approved by the American Physical Therapy Association, and to provide their services under the direct, immediate on-premises supervision of a physical therapist certified pursuant to section HSS 105.27 of this rule. Physical therapist assistants are not eligible to bill or to be reimbursed directly for their services.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.28 Certification of occupational therapists. Occupational therapists are required to be certified by the American Occupational Therapy Association as occupational therapists, registered; or to be graduated from a program in occupational therapy accredited by the Council on Medical Education of the American Medical Association and the American Occupational Therapy Association and to have completed the required supplemental field work experience, and to have made application to the American Occupational Therapy Association for the certification examination for occupational therapist, registered.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.285 Certification of occupational therapy assistants. Occupational therapy assistants are required to be certified by the American Occupational Therapy Association as certified occupational therapy assistants, and shall provide services under the direct, immediate on-premises supervision of an occupational therapist certified pursuant to section HSS 105.28. Occupational therapy assistants are not eligible to bill directly or to be reimbursed directly for their services.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.29 Certification of speech and hearing clinics. Speech and hearing clinics are required to be accredited by the American Speech and Hearing Association (ASHA) pursuant to the guidelines of "Accreditation of Professional Services Programs in Speech Pathology and Audiology" published by ASHA.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.30 Certification of speech pathologists. (1) Speech pathologists are required to possess a Certificate of Clinical Competence from the American Speech and Hearing Association or to have completed the equivalent educational requirements and work experience necessary for such a certificate, or shall have completed the academic program and be in the process of accumulating the supervised work experience required to qualify for such a certificate.

(2) Speech pathologists having a bachelor's degree with a major emphasis in speech pathology from an accredited college or university are eligible to participate in the program if supervised by a speech pathologist certified pursuant to section HSS 105.30 (1). Such speech pathologists are not eligible to bill or to be reimbursed directly for their services.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.31 Certification of audiologists. Audiologists are required to possess a Certificate of Clinical Competence from the American Speech and Hearing Association (ASHA) or to have completed the equivalent educational requirements and work experience necessary for such a certificate, or shall have completed the academic program and be in the process of accumulating the work experience required to qualify for such a certificate.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.32 Certification of optometrists. Optometrists are required to be licensed and registered pursuant to s. 449.04, and 449.06, Stats.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.33 Certification of opticians. Opticians are eligible to participate in the program.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.34 Certification of clinics, rehabilitation agencies and public health agencies providing outpatient physical therapy or speech pathology services, or both. Clinics, rehabilitation agencies and public health agencies providing outpatient physical therapy or speech pathology are required to be certified to participate in Medicare.

Note: For purposes of program administration, the following rules, which are a codification of 42 CFR 405.1702 through 1726, are adopted. For the sake of readability, some editing has been done; also, changes have been made to conform with state law and policy.

(1) COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS. All organization staff shall be licensed or registered pursuant to applicable Wisconsin law.

(2) ADMINISTRATIVE MANAGEMENT. (a) *Governing body.* There shall be a governing body (or designated person(s) so functioning) which shall assume full legal responsibility for the overall conduct of the clinic or agency and for compliance with applicable laws and regulations. The name of the owner(s) of the organization, (or if the organization is a corporation, the names of the corporate officers) shall be disclosed to the department.

(b) *Administrator.* the governing body shall appoint a full time administrator to direct the internal operation of the clinic or agency in accordance with established written policies. The administrator's responsibilities for procurement and direction of personnel shall be clearly defined. Such persons shall have a bachelor's degree and:

1. Experience or specialized training in the administration of health institutions or agencies; or

2. Qualifications and experience in one of the professional health disciplines.

(c) *Personnel policies.* Personnel policies and records shall be documented in writing and kept current. Personnel records include job descriptions, qualifications, licensure, performance evaluations, and health examinations.

(d) *Patient care policies.* Patient care policies shall be established by a group of one or more physicians associated with the organization and one or more physical therapists (if physical therapy services are provided) and one or more speech pathologists (if speech pathology services are provided). Patient care policies shall be documented in writing. Policies shall cover scope of services offered, admission and discharge policies, physicians' services, patient care plans and methods of implementation, care of patients in an emergency, clinical records, administrative records, use and maintenance of plant and equipment and program evaluation. Policies shall be reviewed annually.

(3) PHYSICIAN'S DIRECTION AND PLAN OF CARE. (a) The organization shall have available a physician to furnish medical care in case of emergencies. Each recipient shall be under the general medical direction of a physician, who shall provide appropriate medical information concerning the recipient's condition. The physician is responsible for general medical direction of services. Outpatient physical therapy or speech pathology services shall be provided only upon order by such physician.

(b) The following items shall be made available to the organization before or at the time of initiation of treatment: patient's significant past history; current medical findings; diagnosis (es); physician's orders; rehabilitation goals, if determined; contraindication, if any; the extent to which the patient is aware of diagnosis (es); prognosis and where appropriate, summary of treatment provided and results achieved during previous periods of physical therapy or speech pathology services or institutionalization.

(c) A written plan of care shall be established by the physician and amended as necessary for each recipient. Plan of care shall include goals of treatment and type, amount, frequency and duration of therapy. Plan of care shall be reviewed at least every 30 days by the physician.

(d) The patient in need of therapy shall be seen by the physician at least once every 30 days. The organization is responsible for contacting the physician if the patient has not been seen by the physician within a 30-day period. There shall be evidence in the clinical record that the physician has seen the recipient.

(e) A recipient's attending physician or another responsible physician shall be promptly notified of any changes in the recipient's condition. If changes are required, they shall be approved by the physician and noted in the clinical record.

(f) One or more physicians shall be available on call to provide emergency medical care. A list of names and phone numbers of these physicians on call shall be posted. There shall be established procedures to be followed in case of an emergency.

(4) PHYSICAL THERAPY SERVICES. (a) If the clinic or agency provides physical therapy servies, the organization shall provide physical therapy staff qualified to perform a full range of services, including evaluations, tests, exercises and other customary treatments and equipment necessary to provide services. If services are provided off the premises by a qualified physical therapist assistant, supervision shall comply with the provisions of s. 448.03 Stats.

(b) The agency or clinic shall have the facilities and equipment necessary to carry out its physical therapy program.

(c) Physical therapy services shall be provided by or under the supervision of a physical therapist. A physical therapist shall be on the premises or readily available during operating hours.

(d) Supportive personnel shall be instructed in patient care techniques by a physical therapist.

(5) SPEECH PATHOLOGY SERVICES. (a) If the clinic or agency provides speech pathology services, the speech pathology program shall include effective diagnostic and treatment services.

(b) The clinic or agency shall have the facilities and equipment necessary to carry out its speech pathology program.

(c) Speech pathology services shall be provided or supervised by a speech pathologist, who shall be present whenever speech pathology services are provided.

(6) REHABILITATION PROGRAM. In addition to either physical therapy services or speech pathology services, or both, the organization shall provide a rehabilitation program that includes social or vocational adjustment. Qualified staff shall be available for the rehabilitation progam.

(a) A qualified vocational specialist may provide vocational adjustment services. Either a psychologist or social worker may provide vocational or social adjustment services.

(b) If a rehabilitation agency does not provide social or rehabilitation services through salaried employes, it may provide such services by means of a written contract with others. Such contract shall:

1. Require development of an appropriate regimen of services by physician and professional staff;

2. Specify the geographical areas in which the services are to be provided;

3. Require the services are provided by appropriate qualified personnel;

4. Require that personnel under contract participate in patient care conferences;

5. Require that treatment records and notes be prepared and promptly incorporated into clinic or agency records;

6. Specify the effective dates and manner of termination or renewal of the contract;

7. Specify that the organization retains responsibility for and control and supervision of services.

(7) ARRANGEMENT FOR PHYSICAL THERAPY OR SPEECH PATHOLOGY SERVICES PROVIDED BY OTHER THAN SALARIED ORGANIZATION STAFF. (a) If a clinic or agency provides outpatient physical therapy or speech pathology services, or both, under an arrangement with others, such services shall be provided according to the terms of a written contract. Such contract shall stipulate that the organization retains professional and administrative responsibility for, and control and supervision of services, and shall:

1. Require that services be provided in accordance with a written plan of care as enumerated in section HSS 105.34 (3);

2. Specify the geographical areas in which services will be provided;

3. Provide that contracted services and personnel meet the same applicable requirements that would apply if the clinic or agency were directly providing the services;

4. Require that personnel under contract participate in patient care conferences;

5. Require that treatment records and notes be prepared and promptly incorporated into clinic or agency records;

6. Provide that only the contractor clinic or agency shall submit claims for services to the program, and that recipients shall not be billed for services covered by the program;

7. Specify the effective dates of the contract and the manner of termination or renewal;

8. Except as stated in section HSS 105.34 (7) (a) 9, require that services be provided in the recipient's home, on the premises of the contractor organization or on the premises of a hospital or skilled nursing facility participating in the program;

9. If the contractor is a public health agency, allow services to be provided on the premises of the supplier of services if the following conditions are met:

a. The public health agency is not able to provide the required physical therapy or speech pathology services on its premises;

b. The required services are not provided on an outpatient basis in another accessible participating provider;

c. Only those services not available on the premises of the public health agency are provided on the premises of the supplier;

d. The public health agency notifies the department of the name of each supplier with whom it contracts for services; and

e. All records of patients of the public health agency who have been treated on the premises of the supplier are reviewed at least every 2 weeks by an appropriate health professional employed by the public health agency.

(8) CLINICAL RECORDS. Complete, accurate, accessible and organized clinical records shall be maintained on all patients.

(a) Written procedures shall be established to protect the confidentiality of clinical records. The patient's written consent is required for release of information not authorized by law.

(b) Clinical records shall contain sufficient information to clearly identify each patient, to justify all diagnoses and treatment, and to accurately document results.

(c) Clinical records shall be completed promptly, with all physicians' entries signed by the physician making the entry.

(d) Clinical records shall be retained for not less than 5 years.

(e) Clinical records shall be indexed at least according to patient name.

(f) The organization shall maintain adequate, conveniently located equipment and facilities to ensure efficient processing of clinical records.

(9) PHYSICAL ENVIRONMENT. (a) The clinic or agency shall comply with all applicable state and local building, fire and safety codes.

(b) The building shall have permanently attached automatic fire-extinguishing systems of adequate capacity in all areas considered to have special fire hazards. Fire extinguishers shall be conveniently located on each floor and fire regulations shall be prominently posted throughout the building.

(c) Doorways, passageways and stairwells negotiated by patients shall be:

1. Of adequate width to allow for easy movement of all patients.

2. Free from obstruction at all times; and

3. In the case of stairs, equipped with firmly attached handrails on at least one side.

(d) Lights shall be placed at exits and in corridors used by patients and shall be supported by an emergency power source.

(e) There shall be a functional fire alarm system with local alarm capability, and an emergency power source where applicable.

(f) At least 2 persons shall be on duty on the premises of the organization whenever a patient is being treated.

(g) No occupancies or activities which are undesirable or injurious to the health and safety of patients shall be located in the building.

(h) There shall be a written preventive-maintenance program to ensure that:

1. Equipment is operative and properly calibrated; and

2. The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel and the general public.

(i) Provision shall be made for adequate and comfortable lighting levels in all areas; a comfortable room temperature; and adequate ventilation through windows, mechanical means, or both.

(j) Toilet rooms, toilet stalls and lavatories shall be accessible and constructed to allow use by nonambulatory and semi-ambulatory persons.

(k) There shall be adequate space for services provided and for administrative functions.

(10) INFECTION CONTROL. (a) There shall be an infection control committee which establishes policies and procedures for investigating, controlling and preventing infections, and monitors execution of the policies and procedures.

(b) Written effective procedures in aseptic techniques shall be followed by all personnel. Procedures shall be reviewed and revised annually for effectiveness and improvement.

(c) The agency or clinic shall employ sufficient housekeeping personnel and provide all necessary equipment to maintain a safe, clean and orderly interior. A full-time employe shall be responsible for housekeeping services and for supervision and training of housekeeping personnel. An organization that has a contract with an outside housekeeping service shall be considered to meet the requirements of this paragraph if the outside service meets the requirements of this paragraph.

(d) *Pest control.* A pest control program shall be in operation to maintain the organization free from insects and rodents.

(11) DISASTER PREPAREDNESS. (a) *Disaster plan.* The organization shall have in operation a written plan with procedures to be followed in the event of fire, explosion or other disaster. Qualified fire, safety and other appropriate experts shall assist in the development and maintenance of the plan, which shall include:

1. Procedures for prompt transfer of casualties and records,

2. Instructions regarding the location and use of alarm systems and signals and firefighting equipment,

3. Information regarding methods of containing fire,

4. Procedures for notification of appropriate persons, and

5. Descriptions of evacuation routes and procedures.

(b) *Staff training and drills.* All employes shall be trained as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program shall include orientation and ongoing training and drills for all personnel in all procedures so that each employe promptly and correctly carries out an assigned role in case of a disaster.

(12) PROGRAM EVALUATION. (a) *Clinical record review.* A sample of active and closed clinical records shall be reviewed quarterly by appropriate health professionals to assure that established policies are followed in providing services.

(b) *Annual statistical evaluation.* An evaluation shall be conducted annually of statistical data such as the number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis, sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.35 Certification of rural health clinics. (1) PURPOSE. It is the intention of the Rural Health Clinic Services Act of 1977 (P.L. 95-210) to increase the availability of medical care and services to residents of areas that have a shortage of health manpower. The department, with the encouragement of the U.S. department of health, education and welfare, intends to implement the legislative intent, that is, the unique circumstances of these clinics shall be taken into account, and the clinics

shall be subject to regulations which are more flexible and less complex than requirements applicable to hospitals and other large institutions.

Note: The following rules are a codification of 42 CRF Part 481. For the sake of readability, some editing has been done; also, changes have been made to conform with state law and policy.

(2) CERTIFICATION OF CLINICS. A clinic is required to be certified under Medicare in order to be eligible for participation under Medicaid. Certification by Medicare shall be considered as meeting the standards for certification under Medicaid.

(a) The clinic shall be licensed pursuant to all other local and state laws and regulations.

(b) The staff of the clinic shall be licensed, certified, or registered in accordance with appropriate state laws.

(c) *Program evaluation.* 1. The clinic shall carry out or arrange for an annual evaluation of its total program.

2. The evaluation shall include review of:

a. the utilization of clinic services, including at least the number of patients served and the volume of services;

b. A representative sample of both active and closed clinical records; and

c. The clinic's health care policies.

3. The purpose of the evaluation is to determine whether:

a. The utilization of services was appropriate;

b. The established policies were followed; and

c. The changes are needed.

4. The clinic staff shall consider the findings of the evaluation and take corrective action if necessary.

(3) LOCATION. A clinic must be located in a rural area meeting the conditions of a medically underserved area or a critical health manpower shortage area. It may be either a permanent or a mobile unit.

(4) CRITERIA FOR DETERMINING A SHORTAGE AREA. (a) The criteria for determination of shortage of personal health services (under section 1302 (7) of the Public Health Services Act) are:

1. The ratio of primary care physicians practicing within the area to the resident population;

2. The infant mortality rate;

3. The percent of the population 65 years of age or older; and

4. The percent of the population with a family income below the poverty level. (See 42 CFR 110.203 (g) and 41 FR 45718, October 15, 1976).

(b) The criteria for determination of shortage of primary medical care manpower (under section 332 (a) (1) (A) of the Public Health Services Act) are:

1. The area served is a rational area for the delivery of primary medical care services;

2. The ratio of primary care physicians practicing within the area to the resident population; and

3. The primary medical care manpower in contiguous areas is overutilized, excessively distant, or inaccessible to the population in this area. (See 42 CFR Part 5; 42 FR 1586, January 10, 1978).

(5) PHYSICAL PLANT AND ENVIRONMENT. (a) *Construction.* The clinic shall be constructed, arranged, and maintained to insure access to and safety of patients, and shall provide adequate space for the provision of direct services.

(b) *Maintenance.* The clinic shall have a preventive maintenance program to ensure that:

1. All essential mechanical, electrical and patient-care equipment is maintained in safe operating condition;

2. Drugs and biologicals are appropriately stored; and

3. The premises are clean and orderly.

(c) *Emergency procedures.* The clinic shall assure the safety of patients in case of non-medical emergencies, by:

1. Training staff in handling emergencies;

2. Placing exit signs in appropriate locations; and

3. Taking other appropriate measures that are consistent with the particular conditions of the area in which the clinic is located.

(6) ORGANIZATIONAL STRUCTURE. (a) *Basic requirements.*

1. The clinic shall be under the medical direction of a physician, and shall have a health care staff that meets the requirements of HSS 105.37 (7).

2. The organization's policies and its lines of authority and responsiblilities shall be clearly set forth in writing.

(b) *Disclosure.* The clinic shall disclose the names and addresses of:

1. Its owners, in accordance with Section 1124 of the Social Security Act (42 USC 132 A-3);

2. The person principally responsible for directing the operation of the clinic; and

3. The person responsible for medical direction.

(7) STAFFING AND STAFF RESPONSIBILITIES. (a) *Staffing.* 1. The clinic shall have a health care staff that includes one or more physicians and one or more physician's assistants or nurse practitioners.

2. The physician's assistant shall be certified pursuant to section HSS 105.075.

3. Nurse practitioners shall be certified pursuant to section HSS 105.20, and any regulations promulgated in accordance with ch. 441, Stats.

4. The physician member of the staff may be the owner of the clinic, or may be working under agreement with the clinic to carry out the responsibilities required under this section.

5. The nurse practitioner member of the staff may be the owner of the clinic or an employe of the clinic.

6. The staff may also include ancillary personnel who are supervised by the professional staff.

7. The staff shall be sufficient to provide services essential to the operation of the clinic.

(8) PHYSICIAN RESPONSIBILITIES. The physician shall:

(a) Provide medical direction for the clinic's health care activities, and shall provide consultation for and medical supervision of, the health care staff.

(b) In conjunction with the physician's assistant or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the clinic's written policies and the services provided to medical assistance patients.

(c) Periodically review the clinic's patient records, provide medical orders, and provide medical care services to the patients of the clinic.

(d) Be present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances), to provide the medical direction, medical care services, consultation and supervision described in this subsection, and be available through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances shall be documented in the records of the clinic.

(9) PHYSICIAN'S ASSISTANT AND NURSE PRACTITIONER. (a) The physician's assistant and the nurse practitioner members of the clinic's staff shall:

1. Participate in the development, execution and periodic review of the written policies governing services;

2. Participate with a physician in a periodic review of the patients' health records.

3. Be available to furnish patient care services at least 60% of the time the clinic operates.

(b) The physician's assistant or nurse practitioner shall perform the following functions, to the extent they are not being performed by a physician:

1. Provide services in accordance with the clinic's policies;

2. Arrange for, or refer patients to needed services that cannot be provided at the clinic; and

3. Assure that adequate patient health records are maintained and transferred as required when patients are referred.

(10) PROVISION OF SERVICES. (a) *Basic requirements.* 1. The clinic shall be primarily engaged in providing outpatient health services and shall meet all other conditions of this subsection.

(b) *Patient care policies.* 1. The clinic's health care services shall be furnished in accordance with appropriate written policies consistent with applicable state law.

2. The policies shall be developed with the advice of a group of professional personnel that includes one or more physicians and one or more physician's assistants or nurse practitioners. At least one member shall not be a member of the clinic staff.

3. The policies shall include: a. A description of the services the clinic furnishes directly and of those furnished through agreement or arrangement.

b. Guidelines for: the medical management of health problems including the conditions requiring medical consultation or patient referral; for the maintenance of health care records; and for procedures for the periodic review and evaluation of the services furnished by the clinic.

c. Rules for the storage, handling, and administration of drugs and biologicals.

4. Before certification of the rural health clinic, the written policies shall be reviewed and approved by a state inter-disciplinary professional team, including representatives from the medical profession (physician or physician assistant), the nursing profession (nurse or nurse practitioner), the pharmacy profession, the department, and at least 2 public members, one of whom shall be from a rural underserved population and the other of whom shall be from an urban underserved population.

5. These policies shall be reviewed at least annually by the group of professional personnel required under section HSS 105.35 (10) (b) 2, reviewed as necessary by the clinic, and reviewed and evaluated annually as part of the certification process by the state interdisciplinary team specified in section HSS 105.35 10 (b) 4.

(c) *Direct services.* 1. *General.* The clinic staff shall furnish those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at the entry point into the health care delivery system. These include medical history, physical examination, assessment of health status, and treatment for a variety of medical conditions.

2. *Laboratory.* The clinic shall provide basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

a. Chemical examinations of urine by stick or tablet methods or both (including urine ketones);

b. Microscopic examinations of urine sediment;

c. Hemoglobin or hematocrit;

d. Blood sugar;

e. Gram stain;

f. Examination of stool specimens for occult blood;

g. Pregnancy tests;

h. Primary culturing for transmittal to a certified laboratory; and

i. Test for pinworm.

3. *Emergency.* The clinic shall provide medical emergency procedures as a first response to common life-threatening injury and acute illness, and shall have available the drugs and biologicals commonly used in life-saving procedures, such as analgesics, anesthetics (local), antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids.

(d) *Services provided through agreement or arrangements.* 1. The clinic shall have agreements or arrangements with one or more certified providers or suppliers to furnish other services to its patients, including:

a. Inpatient hospital care;

b. Physician services; and

c. Additional and specialized diagnostic and laboratory services that are not available at the clinic.

2. If the agreements are not in writing, there shall be evidence that patients referred by the clinic are being accepted and treated.

(11) PATIENT HEALTH RECORDS. (a) *Record system.* 1. The clinic shall maintain a clinical record system in accordance with written policies and procedures.

2. A designated member of the professional staff shall be responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

3. For each patient receiving health care services, the clinic shall maintain a record that includes, as applicable:

a. Identification and social data, evidence of consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition and instructions to the patient;

b. Reports of physical examinations, diagnostic and laboratory test results, and consultative findings;

c. All physician's orders, reports of treatments and medications and other pertinent information necessary to monitor the patient's progress;

d. Signatures of the physician or other health care professional.

(b) *Protection of record information.* 1. The clinic shall maintain the confidentiality of record information and shall provide safeguards against loss, destruction or unauthorized use.

2. Written policies and procedures shall govern the use and removal of records from the clinic, and the conditions for release of information.

(c) *Retention of records.* Records shall be retained for at least 6 years from date of last entry.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.36 Certification of family planning clinics (agencies). Family planning clinics (agencies) are required to meet the following conditions:

(1) CERTIFICATION. In order to qualify for medicaid reimbursement, family planning clinics must certify to the department that:

(a) All conditions for eligibility including income, assets and relative responsibility, as enumerated in HSS 103, have been verified;

(b) A medical assistance card has been shown before services were provided; and

(c) Services were prescribed by a physician.

(d) No sterilization procedures are available to persons who are incompetent, institutionalized or under the age of 21.

(2) PRINCIPLES OF OPERATION. (a) Family planning services shall be made available:

1. Upon referral from any source upon the patient's own application;

2. Without regard to race, nationality, religion, family size, marital status, maternity, paternity, handicap or age, in conformity with the spirit and intent of the Civil Rights Act of 1964 and the Rehabilitation Act of 1973;

3. With respect for the dignity of the individual; and

4. With efficient administration procedures for registration and delivery of services, avoiding prolonged waiting and multiple visits for registration. Patients shall be seen on an appointment basis whenever possible.

(b) Acceptance of family planning service shall be voluntary, and individuals shall not be subjected to coercion either to receive services or to employ or not to employ any particular methods of family planning. Acceptance or nonacceptance of family planning services shall not be a prerequisite to eligibility for or receipt of any other service funded by local, state, or federal tax revenue.

(c) A variety of medically approved methods of family planning, including the natural family planning method, shall be available to persons to whom family planning services are offered and provided.

(d) The clinic shall not provide abortion as a method of family planning.

(e) Diagnostic and treatment services for infertility shall be provided for in the family planning clinic. If such services are not available, the clinic shall make referrals to an appropriate, certified provider of such services.

(f) Efforts shall be made to obtain third party payments when available for services provided.

(g) All personal information obtained shall be treated as privileged communications, shall be held confidential, and shall be divulged only upon the recipient's written consent except when necessary to provide services to the individual or to seek reimbursement for such services. The agency director shall insure that all participating agencies preserve the confidentiality of patient records. Information may be disclosed in summary, statistical, or other form which does not identify specific recipients.

(3) ADMINISTRATION. (a) *Governing body.* The family planning clinic shall have a governing body which is responsible for the conduct of the staff and the operation of the clinic.

(b) *Chief clinic officer.* A designated person shall be responsible for the day-to-day operation of the clinic.

(c) Written policies and procedures shall be developed which govern the utilization of staff, services to patients, and the general operation of the clinic.

(d) Job descriptions for volunteer and paid staff shall be prepared to assist staff members in the performance of their duties.

(e) Each clinic shall have a record system that includes the following components:

1. Patient records; a. With pertinent medical and social history.

b. With all patient contacts and outcomes.

c. With accumulated data on supplies, staffing, appointments, and other administrative functions.

d. For purposes of following up on patients for medical services or referrals to other community resources.

e. For purposes of program evaluation.

2. Fiscal records accounting for cash flow;

3. Organizational records to document staff time, governing body meetings, adminstrative decisions, fund raising, etc.

(f) Each clinic shall engage in a continuing effort of evaluating, reporting, planning, and implementing changes in program operation.

(g) A system of appointments and referrals which is flexible enough to meet community needs shall be developed by each clinic.

(h) Provision shall be made for a medical back-up for patients who experience family planning related problems at a time when the clinic staff is unavailable.

(4) STAFFING. (a) Clinic staff, either paid or volunteer, shall perform the following functions:

1. Outreach workers or community health personnel shall have primary responsibility to contact appropriate individuals, initiate family planning counseling, and assist in receiving, successfully using, and continuing medical services.

2. Secretary or receptionist shall be responsible for greeting patients at the clinic, arranging for services, and performing a variety of necessary clerical duties.

3. Interviewer or counselor shall be responsible for taking social histories, providing family planning information to patients, and counseling patients regarding their family planning and related problems.

4. Nurse or clinic aide shall be responsible for assisting the physician in providing medical services to the patient.

5. Physician shall be responsible for provision of, or supervision over, all medical and related services provided to patients.

6. Clinic coordinator shall be responsible for overseeing the operation of the clinic.

(b) *Training.* 1. Training programs shall be available periodically to train new personnel.

2. For existing staff, time shall be allotted for staff conferences, and inservice training in new techniques and procedures.

(c) For volunteers, time shall be allocated for staff to coordinate, train, and supervise volunteers to be an effective, integral part of the clinic.

(d) *Paraprofessionals.* Paraprofessional personnel may be hired and trained.

(5) PATIENT AND COMMUNITY OUTREACH. Each clinic shall have an active outreach effort aimed at:

(a) Recruiting and retaining patients in the family planning clinic, through:

1. A system of identifying the primary target populations;

2. A method of contacting the target population;

3. Procedures for family planning counseling and motivating appropriate persons to avail themselves of family planning medical services;

4. Assisting individuals in receiving family planning medical services;

5. Activities designed to follow-up potential and actual family planning patients as indicated.

6. A record system sufficient to support the above functions (1 through 5).

(b) Meeting all human needs through appropriate and effective referral to other community resources;

(c) Increasing community awareness and acceptance of the family planning clinic through:

1. The use of mass media;

2. Presentations to community organizations and agencies;

3. Public information campaigns utilizing all channels of communication;

4. Development of formal referral arrangements with community resources;

5. Involvement of appropriate community residents in the operation of the family planning clinic.

(6) PATIENT EDUCATION AND COUNSELING. At the time the patient is to receive family planning medical services, the following components of social services shall be provided:

(a) An intake interview designed to obtain pertinent information regarding the patient, to explain the conditions under which services are provided, and to create the opportunity for a discussion of the patient's problems;

(b) A group or individual information session which includes:

1. Reproductive anatomy and physiology;

2. Methods of contraception, including how they work, side effects and effectiveness;

3. An explanation of applicable medical procedures;

4. An opportunity for patients to ask questions and discuss their concerns;

5. An optional discussion of such topics as breast and cervical cancer, venereal disease, human sexuality or vaginopathies.

(c) An exit interview which is designed to:

1. Clarify any areas of concern or questions regarding medical services;

2. Elicit from the patient a complete understanding regarding the use of family planning methods;

3. Effectively inform the patient what procedures are to be followed if problems are experienced;

4. Inform the patient about the clinic's follow-up procedures and possible referral to other community resources;

5. Arrange for the next visit to the clinic.

(7) MEDICAL SERVICES. All medical and related services shall be provided by or under the supervision and responsibility of a physician.

(a) The following medical services shall be made available:

1. Complete medical and obstetrical history;

2. Physical examination;

3. Laboratory evaluation;

4. Prescription of the family planning method of patient's choice unless medically contraindicated;

5. Instructions on the use of the chosen method, provision of supplies, and schedule for revisits;

6. Infertility screening and diagnosis;

7. Inpatient service referral when necessitated by complications of contraceptive services provided by the clinic.

(b) Equipment and supplies in the clinic shall be commensurate with the services offered. Sufficient first aid equipment shall be available for use when needed.

(c) Treatment for minor vaginal infections and venereal disease may be made available either by clinic staff or through referral.

(8) FACILITIES. The family planning clinic shall be designed to provide comfort and dignity for the patients and to facilitate the work of the staff. A clinic facility shall be adequate for the quantity of services provided, and shall include:

(a) A comfortable waiting room with an area for patient reception, record processing, and children's play;

(b) Private interviewing counseling areas;

(c) A group conference room for staff meetings and patient education;

(d) A work room or laboratory area with sufficient equipment and nearby storage space, none of which is accessible to the patient;

(e) A sufficient number of private and well-equipped examining rooms with proximal dressing areas which ensure the dignity of the patient;

(f) Adequate toilet facilities, preferably near the dressing room;

(g) Arrangements for routine and restorative facility maintenance.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.37 Certification of early and periodic screening, diagnosis and treatment (EPSDT) agencies. (1) EPSDT OUTREACH AND FOLLOW-UP SERVICES. (a) In order to facilitate the delivery of Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services to individuals under the age of 21 who are eligible for medical assistance, outreach and follow-up providers shall be certified to provide the following services:

1. Identification of the target population within the provider's service area. The department and its agent shall assist providers in identifying the target population and in initially notifying the population of the availability of services.

2. Initial and periodic notification of eligible recipients, or their parents or guardians, of available program benefits;

3. Assistance to recipients in obtaining the screening, diagnosis, and treatment benefits available;

4. Necessary follow-up of initial contact to arrange for appointments, transportation, and other needed services to enable recipients to participate in the EPSDT program.

(b) Such providers shall enter into a provider contract with the department to provide both outreach and follow-up services, and shall meet the requirements of this rule.

(c) *Experience and orientation requirements.* Providers of outreach and follow-up services shall have demonstrated involvement with the EPSDT population as indicated by at least one year's active participation in one or more of the following programs:

1. Women and Infant Care;

2. Headstart;

3. Community Action;

4. Children and Youth;

5. Family Planning Clinics;

6. Food Stamp Outreach;

7. Other Title V or Title V-related programs which demonstrate experience applicable to the provision of EPSDT outreach and follow-up activities;

8. Local Public Health Agencies;

9. City and County Social Service Agencies;

10. Neighborhood Health Centers;

11. Private Clinics, HMO's, Hospital Outpatient Clinics, and Rural Health Clinics; or

12. Other providers actively performing EPSDT services as of July 1, 1979.

(d) *Procedural and personnel requirements.* Providers of outreach and follow-up services shall meet the following conditions:

1. Services shall be concentrated upon the target population compiled and identified by the department.

2. Providers shall employ or contract with skilled medical workers, outreach personnel, and other agency personnel to provide required services.

a. Skilled medical worker may include a physician, dentist, nurse, medical social worker, psychiatric social worker, medical administrator, hospital or public health administrator, nursing home administrator, or other specialized medical care personnel or professional health practitioner.

b. At least one skilled medical worker shall provide direct supervision of outreach personnel.

c. Other agency personnel shall include, but not be limited to field workers, secretarial and clerical workers. Other agency personnel shall

be trained in their respective duties and shall complete a basic orientation, according to standards and criteria provided by the department. Duties of other agency personnel shall be in direct association with or in support of functions necessary for carrying out the duties of the medical professional.

3. Providers shall submit a detailed plan of operation including but not limited to a description of:

a. The physical plant and personnel which shall be adequate to serve the target population identified as that provider's caseload.

b. Ways to provide outreach services for clients, including those whose primary language is not English and those for whom written materials would be inappropriate.

c. Transportation arrangements to facilitate the use of screening, diagnosis and treatment services.

d. Cooperative written agreements with providers of screening, diagnosis, and treatment services.

e. Arrangements for transfer of necessary information to the appropriate agency and for notification of the department if the client moves to another location.

4. The services of outreach and follow-up where appropriate shall be delivered to each eligible client not more than once in any 12 month period, except where stipulated otherwise by the department's periodicity schedule.

5. a. Outreach and follow-up agencies shall inform eligible families and offer to provide or arrange for the provision of EPSDT services:

i. Through written material and face-to-face contact within 60 days of the time from which the client first becomes eligible for medical assistance or becomes eligible after a period of ineligibility;

ii. Through written material for families who have not requested EPSDT services within one year of the date from which they were last notified; and

iii. Through written material for families who have requested EPSDT services and for those children are eligible for a periodic screen based upon the periodicity schedule developed by the department.

b. If a family first notified makes no response requesting services, the outreach agency shall make at least one attempt to follow-up and obtain a response. Such attempt, to be made within 60 days of the date of initial notification, may be by mail, by face-to-face contact, or by telephone.

c. Both written and face to face means of notification shall specifically describe EPSDT services in clear, non-technical language and shall include at least the following information:

i. The nature and value of preventive health services;

ii. That screening services should be received periodically; that the family can request information specifying which screening services will be provided upon request; at what ages after an initial screening; and in

the case of families notified according to the periodicity schedule, that it is time for a periodic screening for the family's children and that the family should tell the state whether it wants such periodic screening services;

iii. The elements of the screening package available under the program;

iv. That treatment services covered under the program will be provided for problems discovered through screening, including treatment for vision, hearing and dental problems;

v. How EPSDT services can be obtained, including an offer to schedule appointments, if requested, for EPSDT services, and to provide, if requested, necessary transportation as required;

vi. Where the family may obtain such services;

vii. That the family is entitled to EPSDT services covered under the program at no cost;

viii. That the department will assure that the family receives EPSDT services on a timely basis;

ix. That the family should tell the department whether it does or does not request EPSDT services and department assistance with scheduling and transportation;

x. This information shall be in accordance with the methods required by the department.

d. Written and face-to-face notification shall be adjusted to the language requirements of families who are blind, or illiterate, cannot read English, or are not conversant in English.

6. The outreach agency shall provide or arrange to provide EPSDT services for eligible recipients requesting services, as follows:

a. All requested initial and periodic screening services shall be completed within 120 days of the request for initial services;

b. All necessary follow-up treatment services covered shall be initiated within 120 days of the request for services;

c. Requested assistance with transportation shall be provided pursuant to this rule;

d. Initiation of treatment services for the EPSDT program shall occur with the first encounter between the eligible individual and the health care provider(s) to begin treatment and, as appropriate, diagnosis.

7. *Exceptions to requirements for timely service delivery.* The requirements under HSS 105.37 (1) (d)6 do not apply when it can be shown that the following condition(s) exist:

a. In the case of necessary treatment services not initiated within the 120 day period, the eligible individual(s) declined the treatment service indicated to be necessary by screening.

b. The family requested EPSDT services but did not request assistance with scheduling appointments; the appointment(s) necessary to

complete screening services or to initiate necessary treatment services were not scheduled or not kept; and the outreach provider made at least one attempt (after determining that such appointment(s) were not scheduled or kept) within 150 days of the request for EPSDT services to offer scheduling and transportation assistance for the necessary appointments;

c. Assistance requested with the scheduling of EPSDT appointments was provided, but the eligible individual failed to keep the appointment, and the outreach provider made at least one attempt (after determining that the appointment was not kept) within 150 days of the family's request for EPSDT to offer scheduling and transportation assistance for each of the appointments that were missed. In cases where the eligible individual misses 2 appointments scheduled by the outreach provider for the same service, no further assistance from the provider is required for that recorded request.

(e) *Records and documentation.* Providers of outreach and follow-up services shall fulfill all of the following documentation requirements:

1. The written materials used by outreach agencies to notify families and the materials used or available to persons notifying families through face-to-face contact shall be available as part of the agency's records.

2. All necessary information shall be completed upon the case management form stipulated by the department. Such documentation shall include but need not be limited to the following items:

a. For each family, the date(s) of initial and annual or periodic notification through face-to-face contact or through written material;

b. For each family notified which has not requested EPSDT services, whether such family has specifically declined the services;

c. For each applicable family, the date of the attempt to obtain a response to notification;

d. For each eligible individual for whom initial and periodic, as applicable, EPSDT services are requested:

i. The date of the request(s) for EPSDT services, whether for initial or periodic services;

ii. That scheduling or transportation assistance was requested or declined (whether in response to notification to the follow-up attempt after such notification or to the follow-up attempt after missed appointments) and that such assistance was provided, if requested, or that no response has been made to the outreach providers offer(s) of such assistance;

iii. Where an appointment scheduled with the outreach provider's assistance is missed, that an attempt was made to offer scheduling and transportation assistance for a second appointment, and the date of such attempt;

iv. Where the outreach provider's assistance with scheduling has not been requested, and where it is determined that the screening services have not been completed or necessary follow-up treatment services not

initiated within 120 days of request for EPSDT services, that the attempt was made to offer scheduling and transportation services and the date of such attempt;

v. The date of initiation of treatment service(s) covered under the program and provided as a result of positive screening (or, as appropriate, diagnostic) findings, or the date that such services were declined.

3. A provider may be decertified or suspended from the EPSDT program for:

a. Failure to file complete and accurate outreach claims for 90% of its designated caseload responsibility for two successive quarters; or

b. Non-compliance with other requirements in this rule.

(2) EPSDT SCREENING SERVICES. (a) The following providers shall be eligible to be certified to provide EPSDT screenings:

1. Physicians;

2. Outpatient hospital facilities;

3. Health maintenance organizations;

4. Visiting nurse associations;

5. Clinics operated under physician's supervision;

6. Local public health agencies;

7. Home health agencies;

8. Rural health clinics;

9. Indian health agencies; or

10. Neighborhood health centers.

b. *Procedures and personnel requirements.* 1. Screening providers shall provide or arrange to provide and record the entire screening package, appropriate to the client's age and health needs, and shall explain the results to the recipient's parent or guardian or to the recipient, if appropriate.

2. EPSDT screening services shall be delivered under the supervision of skilled medical personnel, defined as physicians, nurse practitioners, public health nurses, or registered nurses. Individual procedures may be completed by trained paraprofessional medical staff who are supervised by skilled medical personnel, provided that:

a. Successful completion of the training and orientation package developed by the department has been accomplished by the para-professional personnel; and

b. Such personnel receive continuing inservice education and training on a yearly basis as specified by the department.

3. All conditions uncovered which warrant further care as defined by department-approved referral levels and good medical practice, shall be diagnosed or treated or both by the provider, if appropriate, or referred to other appropriate providers. Such a referral may either be a direct

referral (i.e. to the appropriate health care provider) recorded through the outreach provider, or a referral recommendation submitted through the outreach agency responsible for the patient's case management and advocacy.

(c) *Records and documentation.* 1. Certified providers of EPSDT screening services shall:

a. Complete the department's EPSDT screening claim form; and

b. Maintain a file on each client receiving EPSDT screening services.

2. The screening provider shall release information on the results of screening to the outreach agency responsible for the client's case management, when authorized to do so.

(3) DIAGNOSIS AND TREATMENT SERVICES. (a) *Certification requirements.* Providers of diagnosis and treatment services for EPSDT are required to be certified according to the appropriate provisions of this rule.

(b) Providers of such services shall be subject to all other appropriate conditions of participation pertaining to their provider type under this rule.

(c) *Other limitiations.* Diagnosis and treatment services provided for EPSDT patients shall be covered in the same scope and with the same limitations as when those services are provided to the general medical assistance population.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.38 Certification of ambulance providers. (1) Ambulance providers are required to be licensed pursuant to s. 146.50, Stats., and shall meet the following requirements:

(a) The federal specifications contained in document KKK-A-1822, entitled "Federal Specification Ambulance, Emergency Medical Care Vehicle," issued by the U.S. General Services Administration, Federal Supply service;

(b) Definitions stated in s. 340.01 (3) (i), Stats.

(2) Equipment for patient care shall meet the requirements of the American College of Surgeons' equipment list.

(3) Emergency medical services systems development in the state division of health, department of health and social services, shall maintain copies of the documents referred to in sections HSS 105.38 (1) (a) and (2).

(4) Emergency vehicles may provide non-emergency services.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.39 Certification of specialized medical transportation services. Specialized medical transportation services shall meet the requirements of this section and shall sign an affidavit with the department stipulating that they are in compliance with the requirements of this section.

(1) VEHICLES. (a) There shall be insurance of not less than $100,000 personal liability per person and not less than $300,000 personal liability per occurrence on all vehicles used in transporting recipients.

(b) Vehicle inspections shall be performed not less frequently than every 7 days, by an assigned driver, to ensure:

1. The proper functioning of all headlights, emergency flasher lights, turn signal lights, tail lights, brake lights, clearance lights, windshield wipers, brakes, front suspension and steering mechanisms, shock absorbers, heater/defroster systems, doors and ramps, moveable windows and passengers and driver restraint systems;

2. That all tires are properly inflated according to vehicle or tire manufacturers' recommendations and that all tires possess a minimum of ⅛ inch of tread at the point of greatest wear; and

3. That windshields and mirrors are free from cracks or breaks.

(c) The driver inspecting the vehicle shall document all vehicle inspections in writing, noting any deficiencies.

1. All deficiencies shall be corrected before any recipient is transported in the vehicle. Corrections shall be documented by the driver.

2. Documentation shall be retained for not less than 12 months, except as authorized by the department.

(d) Windows, windshield and mirrors shall be maintained in a clean condition with no obstruction to vision.

(e) No smoking shall be permitted in the vehicle.

(f) Police, sheriff's department and ambulance emergency telephone numbers shall be posted on the dash of the vehicle in an easily readable manner. If the vehicle is not equipped with a working two-way radio, sufficient money in suitable denominations shall be carried to enable not less than three local telephone calls to be made from a pay telephone.

(2) VEHICLE EQUIPMENT. (a) The vehicle shall be equipped at all times with the following items: jack and lug wrench, flashlight in working condition, first aid kit containing 2 rolls of sterile gauze, sterile gauze compression bandages equal in number to the passenger-carrying capacity of the vehicle, 1 roll of adhesive tape and 1 tourniquet and a fire extinguisher. The fire extinguisher shall be periodically serviced as recommended by the local fire department.

(b) Passenger restraint devices, including restraint devices for wheelchair-bound recipients, if such recipients are carried, shall be provided and used.

1. Wheelchair restraints shall secure both the passenger and the wheelchair.

(c) Provision shall be made for secure storage of removable equipment and passenger property in order to prevent projectile injuries to passengers and driver in the event of an accident.

(3) DRIVERS. (a) Each driver shall possess a valid Wisconsin chauffeur's license which shall be unrestricted, except that vision restrictions may be waived if driver's vision is corrected to an acuity of 20/30 or better by the use of eyeglasses. In this event, the driver shall wear corrective eyeglasses while transporting recipients.

(c) All drivers shall hold a current card issued as proof of successful completion of the American Red Cross (or equivalent) basic course in first aid.

(d) Within 30 days of the date of employment or the date the specialized transportation service is certified as a provider, all drivers shall receive specific instruction on care and handling of epileptics in seizure. Drivers who certify in writing that they have had prior training in the care and handling of seizure victims shall be considered to meet this requirement.

(4) COMPANY POLICY. Company policy and procedure shall include:

(a) Compliance with all applicable state, county and city laws and regulations governing the conduct of company business.

(b) Establishment and implementation of scheduling policies that assure timely pick-up and delivery of passengers going to and returning from medical appointments.

(c) Documentation that transportation services for which medical assistance program reimbursement is sought are:

1. For medical purposes only.

2. Ordered by the attending provider of medical service.

3. Provided only to persons who require such transportation since they lack other means of transport, and who are also physically or mentally incapable of the use of public transportation.

(d) Maintenance of records of services for 5 years, unless otherwise authorized by the department.

(e) Making available for inspection, upon request of the department, records documenting both medical providers' orders for services and the actual provision of services.

(5) AFFIDAVIT. The provider shall submit to the department a notarized affidavit attesting that the provider meets the requirements listed in section HSS 105.39. The affidavit shall be on a form developed by and available from the department, and shall contain the following:

(a) A statement of the requirements listed in section HSS 105.39;

(b) The date the form is completed by the provider;

(c) The provider's business name, address, telephone number and type of ownership;

(d) The name and signature of a person authorized to act on behalf of the provider; and

(e) Notarizing information.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.40 Certification of dealers of medical supplies and equipment, oxygen supplies or prosthetic and orthotic devices. (1) Any individual, corporation, business or organization owning or selling medical equipment, medical supplies, oxygen supplies or prosthetic and orthotic devices is eligible to participate in the program, except as noted in (2) below.

(2) Orthotists and prosthetists who develop and fit appliances for recipients shall be certified by the American Board for Certification in Orthotics and Prosthetics (A.B.C.). Such certification shall be a result of successful participation in an A.B.C. examination in prosthetics, orthotics, or both, and shall be for one of the following classes:

(a) Certified Prosthetist (C.P.);

(b) Certified Orthotist (C.O.); or

(c) Certified Prosthetist and Orthotist (C.P.O.)

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.41 Certification of hearing aid dealers. Hearing aid dealers are required to be licensed pursuant to s. 459.05, Stats.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.42 Certification of physician office laboratories. (1) Physician office laboratories, except as noted in (2) below, are required to be licensed pursuant to s. 143.15, Stats. and shall meet the requirements in Wis. Adm. Code H 38.

(2) *Exception.* Physician office laboratories which serve no more than 2 physicians, podiatrists, chiropractors, or dentists and which do not accept specimens on referral from outside providers, shall not be required to be licensed or to meet the H 38 standards. These laboratories, however, shall submit an affidavit to the department specifying that they do not accept outside specimens.

(3) Physician office laboratories which accept referrals of 100 or more specimens a year in a specialty shall have (in addition to licensure under s. 143.15, Stats.) a certification of participation in the Medicare program or shall be qualified to participate in Medicare.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.43 Certification of independent clinical laboratories. Laboratories and clinical laboratories as defined in Wis. Adm. Code section H 38.02 (1), are required to be licensed pursuant to s. 143.15, Stats., and to have a certificate of participation in Medicare (or be qualified for such certificate).

Note: The following rules, which are a codification of 42 CFR 405.1310 through 1317, are hereby adopted. For the sake of readability, some editing has been done; also, changes have been made to conform with state law and policy.

(1) LABORATORY DIRECTOR. The clinical laboratory shall be under the direction of a qualified person.

(a) *Administration.* The laboratory shall have a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests.

1. The director shall serve the laboratory either full time, or on a regular part-time basis. If the director serves on a regular part-time basis, the director shall not individually serve as director of more than 3 laboratories (hospital or independent) with one exception. If the director does serve as director of more than 3 laboratories, the director shall provide for an associate in section HSS 105.43 (1) (b), to serve as assistant director in each laboratory. Such assistant director shall not serve more than 3 laboratories.

2. Commensurate with the laboratory workload, the director shall spend an adequate amount of time in the laboratory to direct and supervise the technical performance of the staff and shall be readily available for personal or telephone consultation.

3. The director shall be responsible for the proper performance of all tests made in the laboratory.

4. The director shall be responsible for the employment of qualified laboratory personnel and for their inservice training.

5. If the director is to be continuously absent for more than one month, arrangements shall be made for a qualified substitute director.

(b) *Laboratory director—qualifications.* The laboratory director shall be one of the following:

1. A physician certified in anatomical or clinical pathology or both by the American Board of Pathology or the American Osteopathic Board of Pathology or possessing qualifications which are equivalent to those required for each certification (board eligible);

2. A physician who either is:

a. Certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or

b. Certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or

c. Certified by the American Society of Cytology to practice cytopathology or possesses qualifications which are equivalent to those required for such certification, or

d. Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in an approved clinical laboratory;

3. For the specialty of oral pathology only, a dentist who is certified by the American Board of Oral Pathology or who possesses qualifications which are equivalent to those required for certification (board eligible);

4. A person holding an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject who is either certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to the department in one of the laboratory specialties. Such director may also be a person who subsequent to graduation, has had 4 years of full-time general clinical laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in an approved clinical laboratory.

5. With respect to individuals first qualifying prior to July 1, 1971, a person responsible for the direction of a clinical laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, who meets one of the following requirements:

a. Was a physician and subsequent to graduation has had at least 4 years of pertinent full-time clinical laboratory experience;

b. Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and, after graduation, has had at least 4 years of pertinent full-time clinical laboratory experience;

c. Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation has had at least 6 years of pertinent full-time clinical laboratory experience; or

d. Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970.

(2) CLINICAL LABORATORY SUPERVISION. The clinical laboratory shall be supervised by qualified personnel.

(a) *Supervision.* The laboratory shall have one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reports of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures. A laboratory director who qualified under HSS 105.43 (1) (b) 1., 2., 4. or 5. is also qualified as a general supervisor; therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

1. *Required supervisors.* There shall be a general supervisor and a technical supervisor. A general supervisor shall meet the requirements of HSS 105.43 (2) (b) and shall be on the laboratory premises during all hours in which tests are being performed. With respect to the specialty of diagnostic cytology, cytotechnologists shall not examine slide preparations unless a supervisor who qualifies pursuant to the provisions of HSS 105.43 (2) (b) 4 or HSS 105.43 (3) (b) 9 is on the premises at all times. A technical supervisor who meets the pertinent requirements of

HSS 105.43 (3) (b) shall spend an adequate amount of time in the laboratory to supervise the technical performance of the staff in the specialty and shall be readily available for personal or telephone consultation. A general supervisor may also be a technical supervisor in those specialties in which the requirements of HSS 105.43 (3) (b) are met.

2. *Supervision of emergency procedures.* When emergencies arise outside regularly scheduled hours of duty, an individual who qualifies as a general supervisor is not required to be on the premises if the technologist performing tests is qualified to perform such tests, and the supervisor responsible for the results of the work reviews it during the next duty period, and a record is maintained to reflect the actual review.

(b) *General supervisor qualification.* The laboratory supervisor shall be a person who either:

1. Is a physician, or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical or biological sciences and, after graduation, has had at least 2 years of experience in one of the laboratory specialties in an approved clinical laboratory; or

2. Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences and after graduation, has had at least 4 years of pertinent full-time laboratory experience, of which not less than 2 years have been spent working in the designated laboratory specialty in an approved clinical laboratory; or

3. Is qualified as a clinical laboratory technologist pursuant to the provisions of HSS 105.43 (4) (b) 1, 2, 3, 4, or 6 and, after qualifying as a clinical laboratory technologist, has had at least 6 years of pertinent full-time laboratory experience, of which not less than 2 years have been spent working in the designated laboratory specialty in an approved clinical laboratory; or

4. With respect to the specialty of diagnostic cytology, qualified as a supervisory cytotechologist by virtue of meeting the provisions of HSS 105.34 (4) (c) and has had 4 years of full-time experience as a cytotechnologist in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding 10 years; or

5. With respect to individuals qualifying before July 1, 1971, has had at least 15 years of pertinent full-time clinical laboratory experience before January 1, 1968. This required experience may be met by the substitution of education for experience.

(3) TESTS PERFORMED. The clinical laboratory shall perform only those laboratory tests and procedures that are within the specialties or sub-specialties in which the laboratory director or supervisors are qualified.

(a) *Proficiency testing.* All clinical laboratories shall successfully participate in a proficiency testing program described in Wis. Adm. Code section H 38.14 covering all tests in clinical laboratory and anatomical pathology specialties and subspecialties the laboratory makes available and is approved to perform.

(b) *Competency.* The laboratory shall perform only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified.

1. If the laboratory director or supervisor is a physician certified in both a. anatomical and b. clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification (board eligible), the laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties.

2. If the requirements of HSS 105.43 (3) (b) 1 are not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, virology, mycology, and parasitology, the director or a supervisor shall hold an earned doctoral or master's degree in microbiology from an accredited institution, or shall have at least 4 years of experience in clinical microbiology gained after graduation.

3. If the requirements of HSS 105.43 (3) (b) 1 are not met and the laboratory performs tests in the specialty of serology, the director or a supervisor shall hold an earned doctoral or master's degree in biology, chemistry, immunology or microbiology from an accredited institution or shall be a physician who has had at least 4 years of experience in serology gained after graduation.

4. If the requirements of HSS 105.43 (3) (b) 1 are not met and the laboratory performs tests in the specialty of hematology, including gross and microscopic examination of the blood, the director or a supevisor shall hold a master's degree or a bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution, and, shall have had at least 4 years of experience in hematology gained after graduation.

5. a. If the requirements of HSS 105.43 (3) (b) 1 are not met and the laboratory performs tests in the specialty of immunohematology, the director or a supevisor shall be a physician with at least 2 years of experience in immunohematology gained after graduation; or

b. If such laboratory performs tests within the subspecialties of ABO grouping and Rh typing, antibody detection, identification, and titering only, the director or a supervisor shall hold a master's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and shall have had at least 4 years of experience in immunohematology gained after graduation.

6. If the requirements of HSS 105.43 (3) (b) 1 are not met and the laboratory performs tests in the specialty of clinical chemistry, the director or a supervisor shall hold an earned doctoral or master's degree in chemistry from an accredited institution or shall be a physician who has had at lest 4 years of experience in clinical chemistry gained after graduation.

7. If the requirements of HSS 105.43 (3) (b) 1 are not met and the laboratory performs tests in the specialty of radiobioassay, the director or a supervisor shall hold an earned doctoral, master's or bachelor's degree in chemistry, physics, biology, or medical technology from an accredited institution or shall be a physician who has had least 4 years of experience in radiobioassay gained after graduation.

8. If the laboratory performs tests in the specialty of tissue pathology, the director or a supervisor shall meet the requirements of HSS 105.43 (3) (b) 1. If the laboratory performs tests limited to skin pathology, the director or a supervisor shall be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or shall possess qualifications which are equivalent to those required for certification (board eligible).

9. If the requirements of HSS 105.43 (3) (b) 1.a. are not met and the laboratory performs tests in the specialty of diagnostic cytology, the director or a supervisor shall be either: a physician certified by the American Society of Cytology to practice cytopathology, or a physician who possesses qualifications which are equivalent to those required for certification (under this provision the laboratory is qualified to perform such tests only on that anatomic site for which the director or supervisor is certified); or an individual who, pursuant to a request to establish qualifications filed before January 1, 1971, has demonstrated competency by all of the following means:

a. Through at least 7 years of experience accumulated in a position of diagnostic responsibility in the field of clinical cytology, or through 5 years of full-time training in diagnostic clinical cytology with suitable endorsement by a physician who has been supervisor in such activity; and

b. By the publishing of treatises, texts, or other publications on the subject of diagnostic cytology which are generally acknowledged and recognized by the medical profession as authoritative in the field; and

c. By appointment to and service in pertinent teaching and research positions in recognized schools of medicine; and

d. By acceptance into or award of membership and office in professional societies in this field; and

e. By receipt of other professional honors for excellence in the use of procedures in exfoliative cytology for the diagnosis of a pathological condition (under this provision the laboratory shall be qualified to perform such tests only on that anatomic site with respect to which such competency is so established). The department, with appropriate professional advice, shall make all determinations with respect to the requirements set forth in HSS 105.43 (3) (b) 9.a. through e. An individual who qualifies under the above subparagraphs shall be deemed to also meet the requirements of HSS 105.43 (1) (b) 2.c.

10. If the requirements of HSS 105.43 (3) (b) 1.a. are not met and the laboratory performs tests in oral pathology, the director or supervisor shall be a dentist who is certified in oral pathology by the American Board of Oral Pathology or who possesses qualifications which are equivalent to those required for certification (board eligible).

11. An exception to the requirements in HSS 105.43 (3) (b) 2., 3., 4., 5b., 6., and 7. is made with respect to an individual who qualified as a director under HSS 105.43 (1) (b) 5.c. A laboratory directed by such an individual may perform tests in:

a. Microbiology: If the director has a bachelor's degree in a biological science and at least 6 years of experience in microbiology gained after graduation;

b. Hematology: If the director has a bachelor's degree in biology, immunology or microbiology from an accredited institution and has had at least 6 years of clinical laboratory experience of which at least 4 years are in hematology, gained after graduation;

c. Serology: If the director has a bachelor's degree in biology, immunology, chemistry or microbiology and at least 6 years of experience in serology gained after graduation;

d. Radiobioassay: If the director has a bachelor's degree in a chemical, physical, or biological science and has had at least 6 years of laboratory experience, at least one year of which is in radiobioassay, all of which are gained after graduation;

e. Blood grouping and Rh typing, antibody detection, identification, and titering: If the director has a bachelor's degree in biology, immunology or microbiology from an accredited institution and at least 6 years of clinical laboratory experience of which at least 4 years are in immunohematology, all of which are gained after graduation;

f. Clinical chemistry: If the director has a bachelor's degree in a chemical science or its equivalent and at least 6 years of experience in clinical chemistry gained after graduation;

g. Any of the above specialties: If the director has a bachelor's degree in medical technology and at least the designated years of specialized experience gained after graduation.

12. A laboratory whose director qualifies under HSS105 (1) (b) 5.d. may perform tests in the laboratory specialties in which director achieved a satisfactory grade in the examination conducted or sponsored by the Public Health Service. A director who achieved a satisfactory grade in chemistry or blood grouping and Rh typing is deemed to meet the requirements of section HSS 105.43 (3) (b) 5. or 7.

13. Notwithstanding paragraph HSS 105.43 (3) (b) 1., if the laboratory performs tests in the specialty of histocompatibility testing, the director or supervisor shall hold an earned doctoral degree in a biological science or shall be a physician, with 4 years of experience in immunology, 2 of which have been in histocompatibility testing, and all of which are gained after graduation.

(4) CLINICAL LABORATORY—TECHNICAL PERSONNEL. The clinical laboratory shall have a sufficient number of properly qualified technical personnel for the volume and diversity of tests performed.

(a) *Technologist duties.* The laboratory shall employ a sufficient number of clinical laboratory technologists or cytotechnologists or both to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment.

1. The clinical laboratory technologists shall perform tests requiring the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisors, only in those specialties or

subspecialties in which the laboratory technologists are qualified by education, training, and experience.

2. Specialties in which the clinical laboratory technologist is not qualified by education, training, or experience shall be performed only under the direct supervision of the laboratory supervisor or qualified technologist.

3. Clinical laboratory technologists shall be in sufficient number to adequately supervise the work of technicians and trainees.

4. An individual qualified as a cytotechnologist solely under HSS 105.43 (4) (c) shall supervise technicians and trainees only in the specialty of cytology.

(b) *Technologist qualifications.* Each clinical laboratory technologist shall:

1. Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements of entrance into a school of medical technology accredited by an accrediting agency approved by the department, and have successfully completed a course of training of at least 12 months in such a school; or

2. Have earned a bachelor's degree in medical technology from an accredited college or university; or

3. Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, have at least one year of pertinent full-time laboratory experience or training in the specialty or subspecialty in which the individual performs tests; or

4. Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses:

a. *For those whose training was completed before September 15, 1963.* At least 24 semester hours shall have been in chemistry and biology courses. At least 6 such semester hours shall have been in inorganic chemistry and at least 3 semester hours shall have been in other chemistry courses. At least 12 such semester hours shall have been in biology courses pertinent to the medical sciences.

b. *For those whose training was completed after September 14, 1963.* At least 16 semester hours shall have been in chemistry courses which included at least 6 semester hours in inorganic chemistry and which are acceptable toward a major in chemistry. At least 16 semester hours shall have been in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences. At least 3 semester hours shall have been in mathematics.

5. Have experience or training covering several fields of medical laboratory work of at least one year and of such quality as to provide the individual with education and training in medical technology equivalent to that described in HSS 105.43 (4) (b) 1. and 2.; or

6. With respect to individuals qualifying before July 1, 1971, the technologist:

a. Shall have performed the duties of a clinical laboratory technologist at any time between July 1, 1961, and January 1, 1968; and

b. Shall have had at least 10 years of pertinent clinical laboratory experience before January 1, 1968. This required experience may be met by the substitution of education for experience.

7. Have achieved a satisfactory grade in a proficiency examination approved by the department. However, after December 31, 1977, initial qualification as a technologist shall be in accordance with HSS 105.43 (4) (b) 1., 2., 3., 4., or 5.

(c) *Cytotechnologists qualifications.* Each laboratory cytotechnologist shall:

1. Have successfully completed 2 years in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by the deparment, or

2. Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by the department and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed such formal 6-month training, or

3. Before January 1, 1969, have graduated from high school, completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology, and completed 2 years of full-time supervised experience in cytotechnology, or

4. Have achieved a satisfactory grade in a proficiency examination approved by the department. However, after December 31, 1977, initial certificaton as a cytotechnologist must be in accordance with HSS 105.43 (4) (c) 1. or 2.

(d) *Technician duties.* Clinical laboratory technicians shall be employed in sufficient number to meet the workload demands of the laboratory and shall function only under direct supervision of a clinical laboratory technologist.

1. Each technician shall perform only those clinical laboratory procedures which require a degree of skill commensurate with education, training, and technical abilities and which involve limited exercise of independent judgement.

2. No clinical laboratory technician shall perform procedures in the absence of a qualified clinical laboratory technologist, supervisor, or director.

3. A technician trainee shall perform only repetitive procedures which require a minimal exercise of independent judgment, and the technician shall perform such procedures only under the personal and direct supervision of a qualified supervisor or technologist.

(e) *Technician qualifications.* Each clinical laboratory technician shall meet one of the following requirements:

1. Completion of 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution, or an associate degree from an accredited institution based on a course of study including those subjects.

2. High school graduation or equivalent and completion of at least one year in a technician training program in a school accredited by an accrediting agency approved by the department.

3. High school graduation or equivalent and 2 years of pertinent full-time laboratory experience as a technician trainee in an approved clinical laboratory.

4. High school graduation or equivalent and successful completion of an official military medical laboratory procedures course of at least 50 weeks' duration and holding of the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

5. With respect to a technician not meeting the training and experience requirements defined in HSS 105.43 (4) (d) [e] 1.,2.,3. or 4.,

a. The technician shall have performed the duties of a clinical laboratory technician any time between July 1, 1961, and January 1, 1968, and

b. The technician shall have had at least 5 years of pertinent clinical laboratory experience before January 1, 1968. (This required experience may be met by substitution of education for experience).

6. Achievement of a satisfactory grade in a proficiency examination approved by the department. However after December 31, 1977, initial certification as a technician must be in accordance with HSS 105.43 (4) (e) 1., 2., 3., or 4.

(f) *Personnel policies.* There shall be written personnel policies, practices, and procedures that adequately support sound laboratory practice.

1. Current employe records shall be maintained and shall include a resume of each employe's training, experience, duties, and date(s) of employment.

2. Files shall contain evidence of adequate health supervision of employes, such as results of pre-employment physical examinations, including chest X-rays, immunization records, and records of all illnesses and accidents occurring on duty.

3. Work assignments shall be consistent with qualifications.

(5) CLINICAL LABORATORY MANAGEMENT. The clinical laboratory shall maintain records and facilities which are adequate and appropriate for the services offered.

(a) *Laboratory procedure manual.* A compilation shall be kept of all automated and manual methods for tests which are performed in or offered by the laboratory. Each procedure shall be reviewed and dated by the technical supervisor at least annually. For those tests which are normally performed on automated test equipment, provision shall be made and documented for performing such tests by alternate methods, or for

storing the test specimens, in the event this equipment becomes inoperable.

(b) *Laboratory management.* Space and facilities shall be adequate to properly perform the services which are performed in or offered by the laboratory.

1. Workbench space shall be ample, well-lighted, and convenient to sink, water, gas, and suction and electrical outlets as necessary.

2. Work areas shall be arranged so as to minimize problems in transportation and communications.

3. The laboratory shall be properly ventilated.

4. Volatile chemicals and inflammable solvents shall be properly stored in areas unlikely to ignite them or restricted from open flame or heat.

5. Temperature and humidity shall be controlled within limits required for proper performance of tests and operation of instruments affected by these variations.

6. Voltage levels at electrical sources to which automated equipment is connected shall be monitored and recorded.

7. Adequate fire precautions and occupational safety and health laws shall be known, posted, and observed, insuring that there is freedom from unnecessary physical, chemical, and biological hazards.

(c) *Collection of specimens.* No persons other than a licensed physician, or other authorized by law, shall manipulate a patient for the collection of specimens except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction or upon the written request of a licensed physician.

(d) *Sterilization.* Syringes, needles, lancets, or other blood-letting devices capable of transmitting infection from one person to another shall not be reused unless they are properly sterilized before each use and wrapped in a manner which will insure that they remain sterile until used. Appropriate sterilization and disinfection techniques shall be used, as required, for tests performed on potentially contaminated material, and for the protection of laboratory personnel. Disposable syringes, needles, pipettes, Petri dishes, and other disposable items shall be appropriately discarded immediately after use. Each sterilizing cycle shall contain a device which indicates proper sterilization, or an adequate recording thermometer shall be used and records kept of temperature readings. Proper operation of the autoclave shall be checked monthly with viable spores or appropriate indicators.

(e) *Examination and reports.* The laboratory shall examine specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the findings of laboratory examinations and shall report only to those authorized by law to receive such results.

1. If the patient is sent to the laboratory, a written request for the desired laboratory procedures shall be obtained from a person authorized by law to use findings of laboratory examination.

2. If only a specimen is sent, it shall be accompanied by a written request.

3. If the laboratory receives reference specimens from another laboratory, the laboratory shall report back to the laboratory submitting the specimens.

(f) *Specimen records.* The laboratory shall maintain a record indicating the daily accession of specimens, each of which is numbered or otherwise appropriately identified. The records shall contain the following information:

1. The laboratory number or other identification of the specimen.

2. The name and other identification of the person from which the specimen was taken.

3. The name of the licensed physician or other authorized person or clinical laboratory which submitted the specimen.

4. The date the specimen was collected by the physician or other authorized person.

5. The date the specimen was received in the laboratory.

6. The condition of unsatisfactory specimens when received (e.g. broken, leaked, hemolyzed or turbid, etc.)

7. The type of test performed.

8. The date that test was performed.

9. The results of the laboratory test or cross-reference to results and the date of reporting.

10. The name and address of the laboratory to which forwarded if the procedure is not performed at this laboratory.

(g) *Laboratory report and record.* The laboratory report shall be sent promptly to the licensed physician or other authorized person who requested the test, and a suitable record of each test result shall be preserved by the laboratory for a period of five years.

1. The laboratory director shall be responsible for the laboratory report.

2. Duplicate copies or a suitable record of laboratoy reports shall be filed in a manner which permits identification and accessiblility.

3. Tissue pathology reports shall utilize acceptable terminology of a recognized system of disease nomenclature.

4. The results of laboratory tests or procedures or transcripts thereof shall not be sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

5. Pertinent "normal" ranges as determined by the laboratory performing the tests shall be available to the physician requesting such tests.

6. A list of analytical methods employed by the laboratory and a basis for the listed "normal" range shall be maintained in the laboratory. The list shall be made available upon request to any physician ordering an examination.

7. If the laboratory refers specimens to another laboratory, the laboratory receiving the specimens shall meet the applicable conditions of this rule. Each physician ordering an examination shall be notified that the specimen was referred to another laboratory. Such notice shall show the name and address or other identification of the laboratory to which the specimen is referred. If the physician so requests, the referring laboratory may authorize the testing laboratory to report directly to the physician or other authorized person who requested the test, in which event the testing laboratory shall send a duplicate of the report to the referring laboratory.

(6) QUALITY CONTROL. (a) Quality controls imposed and practiced by the laboratory shall provide for and assure:

1. Preventive maintenance, periodic inspection, and testing for proper operation of equipment and instruments as may be appropriate; validation of methods; evaluation of reagents and volumetric equipment; surveillance of results; and remedial action to be taken in response to detected defects.

2. Adequacy of facilities, equipment, instruments, and methods for performance of the procedure, or categories of procedures for which a certification is approved; proper lighting for accuracy and precision; convenient location of essential utilities; monitoring of temperature-controlled spaces and equipment, including water baths, incubators, sterilizers, and refrigerators, to assure proper performance; evaluation of analytical measuring devices, such as photometers and radioactivity counting equipment, with respect to all critical operating characteristics.

3. Labeling of all reagents and solutions to indicate identity, and when significant, titer, strength or concentration, recommended storage requirements, preparation or expiration date, and other pertinent information. Materials of substandard reactivity and deteriorated materials shall not be used.

4. The availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category (e.g. clinical chemistry, hematology, and pathology), of current laboratory manuals or other complete written descriptions and instructions relating to the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews; reagents, control and calibration procedures, and pertinent literature references. Textbooks shall be used as supplements to such written descriptions but shall not be used in lieu thereof.

5. Written approval by the director or supervisor of all changes in laboratory procedures.

6. Maintenance and availability to laboratory personnel and to the department of records reflecting dates and, where appropriate, the nature of inspection, validation, remedial action, monitoring, evaluation, and changes and dates of changes in laboratory procedures.

7. Solicitation designed to provide for collection, preservation, and transportation of specimens sufficiently stable to provide accurate and precise results suitable for clinical interpretation.

(b) *Quality control system methodologies.* Provision shall be made for an acceptable quality control program covering all types of analysis performed by the laboratory for verification and assessment of accuracy, measurement of precision, and detection of error.

1. *Microbiology.* Chemical and biological solutions, reagents, and antisera shall be tested and inspected each day of use for reactivity and deterioration.

a. *Bacteriology and mycology.* Staining materials shall be tested for intended reactivity by concurrent application to smears of micro-organisms with predictable staining characteristics. Each batch of medium shall be tested before or concurrently with use with selected organisms to confirm required growth characteristics, selectivity, enrichment, and biochemical response.

b. *Parasitology.* A reference collection of slides, photographs, or gross specimens of identified parasites shall be available and used in the laboratory for appropriate comparison with diagnostic specimens. A calibrated ocular micrometer shall be used for determining the size of ova and parasites, if size is a critical factor.

c. *Virology.* Systems for the isolation of viruses and reagents for the identification of viruses shall be available to cover the entire range of viruses which are etiologically related to clinical diseases for which services are offered. Records shall be maintained which reflect the systems used and the reactions observed. In tests for the identification of viruses, controls shall be employed which will identify erroneous results. If serodiagnostic tests for virus diseases are performed, requirements for quality control as specified for serology shall apply.

2. *Serology.* Serologic tests on unknown specimens shall be run concurrently with a positive control serum of known titer or contols of graded reactivity plus a negative control in order to detect variations in reactivity levels. Controls for all test components (antigens, complement, erythrocyte indicator systems, etc.) shall be employed to insure reactivity and uniform dosage. Test results shall not be reported unless the predetermined reactivity pattern of the controls is obtained.

a. Each new lot of reagent shall be tested concurrently with one of known acceptable reactivity before the new reagent is placed in routine use.

b. Equipment, glassware, reagents, controls, and techniques for tests for syphilis shall conform to those recommended in the "Manual of Tests for Syphilis 1969," U.S. Public Health Service Publication No. 411, January 1969.

3. *Clinical chemistry.* Each instrument or other device shall be recalibrated or rechecked at least once on each day of use. Records which document the routine precision of each method, automated or manual, and its recalibration schedule shall be maintained and be available to laboratory personnel and the department. At least one standard and one reference sample (control) shall be included with each run of unknown

specimens where such standards and reference samples are available. Control limits for standards and reference samples shall be recorded and displayed and shall include the course of action to be [followed when] the results are outside the acceptable limits.

a. Screening or qualitative chemical urinalysis shall be checked daily by use of suitable reference samples.

4. *Immuno-hematology.* ABO grouping shall be performed by testing unknown red cells with anti-A and anti-B grouping serums licensed by the Federal Food and Drug Administration, or possessing equivalent potency, using the technique for which the serum is specifically designed to be effective. For confirmation of ABO grouping, the unknown serum shall be tested with known A1 and B red cells.

a. The Rho (D) type shall be determined by testing unknown red cells with anti-RHo (anti-D) typing serum licensed by the federal food and drug administration, or possessing an equivalent potency, using the technique for which the serum is specifically designed to be effective. Anti-Rho' (CD), anti-RHo" (DE), and anti-RHo rh'rh" (CDE) serums licensed by the federal food and drug administration, or possessing an equivalent potency may be used for typing donor blood. All Rho negative donor and patient cells shall be tested for the Rho variant (Du). A control system of patient's cells suspended in the patient's own serum or in albumin shall be employed when the test is performed in a protein medium.

b. The potency and reliability of reagents (antisera known test cells, and antiglobulin-Coombs serum) which are used to ABO grouping, RH typing, antibody detection and compatability determinations must be tested for reactivity on each day of use and when a new lot of reagents is first used.

5. *Hematology.* Instruments and other devices used in hematological examination of specimens shall be recalibrated or retested or reinspected, as may be appropriate, each day of use. Each procedure for which standards and controls are available shall be rechecked each day of use with standards or controls covering the entire range of expected values. Tests such as the one-stage prothrombin time test shall be run in duplicate unless the laboratory can demonstrate that low frequency of random error or high precision makes such testing unnecessary. Reference materials, such as hemoglobin pools, and stabilized cells, shall be tested at least once each day of use to insure accuracy of results. Standard deviation, coefficient of variation, or other statistical estimates of precision shall be determined by random replicate testing of specimens. The accuracy and precision of blood cell counts and hematocrit and hemoglobin measurements shall be tested each day of use.

6. *Exfoliative cytology; histopathology; oral pathology.* a. *Exfoliative cytology.* The laboratory director or supervisor qualified in cytology or cytotechnologist shall rescreen for proper staining and correct interpretation at least a 10% random sample of gynecological smears interpreted to be one of the benign categories by personnel not possessing director or supervisor qualifications. All gynecological smears interpreted to be in the "suspicious" or positive categories by screeners shall be confirmed by the laboratory director or qualified supervisor, and the report shall be signed by a physician qualified in pathology or cytology.

All non-gynecological cytological preparations, positive and negative, shall be reviewed by a director or supervisor qualified in cytology. Non-manual methods shall provide quality control similar to that provided in other non-manual laboratory procedures. All smears shall be retained for not less than 2 years from date of examination.

b. *Histopathology and oral pathology.* All special stains shall be controlled for intended reactivity by use of positive slides. Stained slides shall be retained for not less than 2 years from date of examination and blocks shall be retained for not less than one year from such date. Remnants of tissue specimens shall be retained in a fixative solution until those portions submitted for microscopy have been examined and a diagnosis made by a pathologist.

7. *Radiobioassay.* The counting equipment shall be checked for stability at least once on each day of use, with radioactive standards or reference sources. Reference samples with known activity and within expected levels of normal samples shall be processed in replicate quarterly. For each method, records which document the routine precision and the recalibration schedule shall be maintained and available to the staff and to the department.

8. *Histocompatibility testing.* In addition to the standards for quality control in immunohematology and serology which are applicable to the histocompatibility testing laboratory, the histocompatibility testing laboratory shall utilize the following control systems and validation methods for the performance of tests in the following:

a. For renal allotransplantation, crossmatching of potential recipients and donors before transplantation shall be performed with one or more techniques using the most reactive and most recent sera.

b. Also for renal allotransplantation, HLA serologic typing of both donor and recipient which includes at least those antigens detectable with serum capable of defining the same antigens as those definable by the National Institutes of Health serum tray(s).

c. Additionally for renal allotransplantation, characterization for antibody against histocompatibility antigens in serum from potential recipients of organ or tissue grafts.

d. For transfusions and bone marrow transplants, the tests in HSS 105.43 (6) (b) 8.a. and b. are required.

e. For disease association studies, HSS 105.43 (6) (b) 8.b. applies.

f. Mixed lymphocyte cultures or other recognized methods to detect cellular-defined antigens shall be performed in accordance with prescribed methods.

g. Procedures shall be established regarding freezing of lymphocytes and to provide for a comprehensive panel of fresh or frozen lymphocytes.

h. The reactivity of cell panels used for antibody detection shall be tested at least twice a month with appropriate known antisera.

i. The laboratory shall at least once each month have each person performing tests be given a previously tested specimen as an unknown to

verify such person's ability to reproduce tests results. The results of such testing shall be recorded.

j. The laboratory shall participate in at least one national or regional cell exchange program, if available, or develop an exchange with another laboratory in order to validate interlaboratory reproducibility.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.44 Certification of radiology providers. An x-ray facility is required to be owned and directed by a physician or group of physicians and shall be registered pursuant to s. 140.54, Stats. and shall have a certificate of participation in Medicare (or shall be qualified for such certificate).

(Note: The following rules are a codification of 42 CFR 405.1411 through 405.1416. For the sake of readability, some editing has been done.)

(1) REGISTRATION. Providers of portable x-ray services shall be registered pursuant to s. 140.54, Stats. and shall be approved as meeting the standards in Wis. Adm. Code, chapter H 57.

(2) SUPERVISION BY A QUALIFIED PHYSICIAN. Portable x-ray services shall be provided under the supervision of a qualified physician.

(a) *Physician supervision.* The performance of the roentgenologic procedures shall be supervised by a physician who meets the requirements of HSS 105.44 (2) (b). In addition, either

1. The supervising physician shall own the equipment and the equipment is operated only by the physician's employes; or

2. The supervising physician shall certify annually that the physician periodically checks the procedural manuals and observes the operators' performance, that the physician has verified that equipment and personnel meet applicable registration requirements and that safe operating procedures are used.

(b) *Qualifications of the physician supervisor.* The supervising physician shall be either:

1. Certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or in possession of qualifications which are equivalent to those required for such certification, or

2. Certified or meets the requirements for certification in a medical specialty in which the physician has become qualified by experience and training in the use of x-rays for diagnostic purposes, or

3. Specialized in radiology and recognized by the medical community as a specialist in radiology.

(3) QUALIFICATIONS AND ORIENTATION OF TECHNICAL PERSONNEL AND EMPLOYE RECORDS. Portable x-ray services shall be provided by qualified technologists.

(a) *Qualifications of technologists.* All operators of the portable x-ray equipment shall meet one of the following requirements:

1. Successful completion of a program of formal training in x-ray technology of not less than 24 months' duration in a school approved by the

Council on Education of the American Medical Association or by the American Osteopathic Association, or a bachelor's or associate degree in radiologic technology from an accredited college or university; or

2. For those whose training was complete before July 1, 1966 but on or after July 1, 1960: Successful completion of 24 full months of training or experience under the direct supervision of a physician who is certified in radiology by the American College of Radiology or possession of qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable x-ray equipment operation experience in the 5 years before January 1, 1968.

3. For those whose training was completed before July 1, 1960: Successful completion of 24 full months of training or experience or both, of which at least 12 full months were under the direct supervision of a physician who is certified in radiology by the American College of Radiology or who possesses qualifications which are equivalent to those required for such certification, and at least 12 full months of pertinent portable x-ray equipment operation experience in the five years before January 1, 1968.

(b) *Personnel orientation.* The provider of portable x-ray services shall have an orientation program for personnel, based on a procedural manual. Such manual shall be available to all members of the staff, shall incorporate relevant portions of professionally recognized documents, and shall include instruction in all of the following:

1. Precautions to be followed to protect the patient from unnecessary exposure to radiation;

2. Precautions to be followed to protect an individual supporting the patient during x-ray procedures from unnecessary exposure to radiation;

3. Precautions to be followed to protect other individuals in the surrounding environment from exposure to radiation;

4. Precautions to be followed to protect the operator of portable x-ray equipment from unnecessary exposure to radiation;

5. Considerations in determining the area which will receive the primary beam;

6. Determination of the time interval at which to check personnel radiation monitors;

7. Use of the personnel radiation monitor in providing an additional check on safety of equipment;

8. Proper use and maintenance of equipment;

9. Proper maintenance of records;

10. Technical problems which may arise and methods of solution;

11. Protection against electrical hazards;

12. Hazards of excessive exposure to radiation.

(c) *Employe records.* Current employe records shall be maintained and shall also include a resume of each employe's training and experience. Records also shall contain evidence of adequate health supervision of employes, including records of all illness and accidents occurring on duty as well as results of a pre-employment and periodic physical examination.

(4) REFERRAL FOR SERVICE AND PRESERVATION OF RECORDS. All portable x-ray services performed for recipients shall be ordered by a physician, and records of examinations performed shall be properly preserved.

(a) *Referral by a physician.* The supplier's records shall show that:

1. The x-ray test was ordered by a licensed physician, and

2. Such physician's written, signed order specifies the reason an x-ray test is required, the area of the body to be exposed, the number of radiographs to be obtained, and the views needed; it also includes a statement concerning the condition of the patient which indicates why portable x-ray services are necessary.

(b) *Records of examinations performed.* The supplier shall make for each patient a record of the date of the x-ray examination, the name of the recipient, a description of the procedures ordered and performed, the referring physician, the operator (s) of the portable x-ray equipment who performed the examination, the physician to whom the radiograph was sent, and the date it was sent.

(c) *Preservation of records.* Records specified in HSS 105.44 (4) (b) shall be maintained for a period of at least 5 years.

(5) SAFETY STANDARDS. X-ray examinations shall be conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) *Tube housing and devices to restrict the useful beam.* The tube housing shall be of diagnostic type. Diaphragms, cones or adjustable collimators capable of restricting the useful beam to the area of clinical interest shall be used and shall provide the same degree of protection as is required of the housing.

(b) *Total filtration.* 1. The aluminum equivalent of the total filtration in the primary beam shall not be less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

Operating kVp	Total filtration (inherent plus added)
Below 50 kVP	0.5 millimeters aluminum.
50-70 kVp	1.5 millimeters aluminum.
Above 70 kVp	2.5 millimeters aluminum.

2. If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

Operating kVp	Half-value layer
50kVp	0.6 millimeters aluminum.
70kVp	1.6 millimeters aluminum.
90kVp	2.6 millimeters aluminum.
100kVp	2.8 millimeters aluminum.
110kVp	3.0 millimeters aluminum.
120kVp	3.3 millimeters aluminum.

(c) *Termination of exposure.* A device shall be provided to terminate the exposure after a pre-set time or exposure.

(d) *Control panel.* The control panel shall provide a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of x-rays whenever the x-ray tube is energized. The control panel shall include appropriate indicators (labelled control settings or meters) which show the physical factors (such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

(e) *Exposure control switch.* The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.

(f) *Protection against electrical hazards.* Only shockproof equipment shall be used. All electrical equipment shall be grounded.

(g) *Mechanical supporting or restraining devices.* Mechancial supporting or restraining devices shall be provided so that such devices can be used when a patient must be held in position for radiography.

(h) *Protective gloves and aprons.* Protective gloves and aprons shall be provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.

(i) *Restriction of the useful beam.* Diaphragms, cones, or adjustable collimators shall be used to restrict the useful beam to the area of clinical interest.

(j) *Personnel monitoring.* A device which can be worn to monitor radiation exposure (e.g., a film badge) shall be provided to each individual who operates portable x-ray equipment. The device shall be evaluated for radiation exposure to the operator at least monthly, and appropriate records shall be maintained by the supplier of portable x-ray services of radiation exposure measured by such a device for each individual.

(k) *Personnel and public protection.* No individual occupationally exposed to radiation shall be permitted to hold patients during exposures except during emergencies, nor shall any other individual regularly be used for this service. Care shall be taken to assure that pregnant women do not assist in portable x-ray examinations.

(6) INSPECTION OF EQUIPMENT. Inspections of all x-ray equipment and shielding shall be made by qualified individuals at intervals not greater than every 24 months. The supplier shall maintain records of current inspections which include the extent to which equipment and shielding are in compliance with the safety standards outlined in HSS 105.44 (5).

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.45 Certification of dialysis facilities. Dialysis facilities are required to meet the requirements enumerated in Wis. Adm. Code sections H 52.05 and 52.06, and shall have a certificate of participation in Medicare.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.46 Certification of blood banks. Blood banks are required to be licensed or registered with the U.S. food and drug administration and shall be approved pursuant to s. 143.15, Stats., and Wis. Adm. Code section H 38.05.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.47 Certification of health care project grant centers, health maintenance organizations and prepaid health plans. Health care project grant centers, health maintenance organizations and prepaid health plans shall enter into a written contract with the department for providing services to enrolled recipients.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.

HSS 105.48 Certification of out-of-state providers. (1) BORDER STATUS PROVIDERS. Providers enumerated in section HSS 105.48 (1) (a), (b), (c), whose normal practice includes providing service to Wisconsin recipients may be certified as Wisconsin border status providers if they meet the requirements for certification outlined in this rule. Certified border status providers shall be subject to the same regulations and contractual agreements as Wisconsin providers.

(a) Providers other than nursing homes and hospitals located in the following communities shall be eligible for certification as Wisconsin providers:

IOWA	ILLINOIS	MINNESOTA	MICHIGAN
Dubuque	Antioch	Duluth	Bessemer
Guttenberg	Durland	Hastings	Crystal Falls
Lansing	E. Dubuque	Kingsdale	Iron Mountain
McGregor	Freeport	LaCrescent	Iron River
	Galena	Lake City	Ironwood
	Harvard	Markville	Kingsford
	Hebron	Minneapolis	Marenisco
	Richmond	Red Wing	Menominee
	Rockford	Rochester	Norway
	S. Beloit	Rush City	Wakefield
	Stockton	St. Paul	Watersmeet
	Warren	Stillwater	
	Woodstock	Taylor Falls	
		Wabasha	
		Winona	
		Wrenshall	

(b) Hospitals in Ironwood, Michigan, Iron Mountain, Michigan, Winona, Minnesota, and Red Wing, Minnesota are eligible for certification as Wisconsin border status providers of inpatient and outpatient services. Hospitals in other communities listed in section HSS 105.48 (1) (a) are eligible for border status certification only as hospital outpatient services providers.

(c) Out-of-state diagnostic laboratories, regardless of location, are eligible for certification as Wisconsin border status providers.

(d) Other out-of-state providers may apply to the department for border status, except that out-of-state nursing homes are never eligible for border status. Such requests for border status shall be considered by the department on a case-by-case basis.

(2) LIMITATION ON CERTIFICATION OF OUT-OF-STATE PROVIDERS. (a) Providers certified in another state whose services are not covered in Wisconsin (e.g., music therapists, art therapists, etc.) shall be denied border status certification in the Wisconsin program.

(b) Providers denied certification in another state shall be denied certification in Wisconsin.

(c) Providers denied certification in another state because their services are not a Medicaid covered benefit in that state, may be eligible for Wisconsin border status certification if their services are covered benefits in Wisconsin. For example, Michigan Medicaid does not cover private duty nursing but Wisconsin Medicaid does. A private duty nurse in Bessemer, Michigan may wish to become a certified Wisconsin border status provider, and may be eligible if the nurse meets the Wisconsin program requirements for certification.

History: Cr. Register, December, 1979, No. 288, eff. 2-1-80.