

APPENDIX A

19 CSR 30-84—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 - Division of Health Standards and Licensure



**Title 19—DEPARTMENT OF
HEALTH AND SENIOR SERVICES**
**Division 30—Division of Health Standards
and Licensure**
**Chapter 84—Training Program for
Nursing Assistants**
**19 CSR 30-84.010 Nurse Assistant Training
Program**

PURPOSE: The Omnibus Nursing Home Act mandates in section 198.082, RSMo that nursing assistants employed in skilled nursing and intermediate care facilities complete an approved training program. This rule gives information regarding the purpose of the training program, required objectives and curriculum content, designates what is the approved course curriculum and indicates the training locations and testing which are required for a program to be considered approved.

(1) Definitions.

(A) Basic course shall mean the seventy-five (75) hours of classroom training, the one hundred (100) hours of on-the-job supervised training and the final examination of the approved Nurse Assistant Training course.

(B) Certifying agency shall mean a long-term care (LTC) association or other entity approved by the division under subsection (11)(B) to issue certificates to nursing assistants.

(C) Challenge the final examination shall mean taking the final examination of the basic course without taking the entire basic course.

(D) Division shall mean the Missouri Division of Aging.

(E) Long-term care association shall mean the Missouri Health Care Association, the Missouri Association of Homes for the Aged, the League of Nursing Home Administrators or the Missouri Assisted Living Association.

(F) Nursing service shall mean an agency or organization, such as a Nursing Pool Agency or Hospice, which employs nurses and nursing assistants for temporary or intermittent placement in LTC facilities.

(G) Training agency shall mean the organization which sponsors the approved training program. An approved training agency is approved by the Division of Aging under section (7) of this rule.

(H) Program shall mean the Nurse Assistance Training Program as required by the Omnibus Nursing Home Act and section 198.082, RSMo 1994.

(2) The purpose of the Nurse Assistant Training Program shall be to prepare individuals for employment in a LTC facility. The program shall be designed to teach skills in resident care which will qualify students to perform uncomplicated nursing procedures and to assist licensed practical nurses or registered professional nurses in direct resident care.

(3) All aspects of the Nurse Assistant Training Program included in this rule (that is, qualified instructor, clinical supervisor, examiner, approved course curriculum, approved training agency, supervised on-the-job training, testing and student qualifications) shall be met in order for a program to be considered as approved.

(4) The program shall consist of a basic course consisting of a minimum of seventy-five (75) classroom hours of training on basic nursing skills, fire safety and disaster training, resident safety and rights, social and psychological problems of residents, and the methods of handling and caring for mentally confused residents such as those with Alzheimer's disease and related disorders; one hundred (100) hours of supervised on-the-job training (clinical practice); a final examination; and, following the basic course, continuing in-service training as provided for in 13 CSR 15-14.042(19) through (24).

(5) Curriculum content of the program shall include procedures and instructions on basic nursing skills in the following areas: basic hygiene techniques; bedmaking; personal care of residents; food service; charting; safety measures (including fire/safety and disaster preparedness, and infection control); basic preventative and restorative care and procedures; basic observation procedures, such as weighing and measuring; communication skills; methods of handling and caring for mentally confused residents; residents' rights; ethical and legal responsibilities; death and dying; and mental health and social needs.

(A) The course curriculum as outlined in the manual entitled *The Nurse Assistant in a Long-Term Care Facility*, produced by the Instructional Materials Laboratory, University of Missouri-Columbia, 1987, catalogue number 50-5061-S shall be considered an approved course curriculum. Other manuals and course material may be used to supplement the curriculum. Instructors shall use the companion instructor's guide, catalogue number 50-5061-I.



(B) An orientation module consisting of certain topics identified as such in the approved course curriculum shall be the first material covered in the course unless the course is taught in its entirety before nursing assistants have resident contact. All students must complete the nurse assistant orientation module prior to providing direct care to any resident. For those students already employed by an intermediate care or skilled nursing facility, the orientation module shall be taught at the beginning of the course and before the nursing assistant is allowed to provide direct care to residents independently.

1. The orientation module shall include, as a minimum, the following topics: handwashing, gloving and infection control; emergency procedures and Heimlich Maneuver; residents' rights; abuse and neglect reporting; safety (fire and accident); lifting; moving and ambulation; answering signal lights; bedpan, urinal, commode and toilet; preparing residents for and serving meals; feeding the helpless; bathing; dressing and grooming; mouth care; bedmaking (occupied and unoccupied); promoting residents' independence; communication and interpersonal skills.

2. Students shall complete the orientation module taught by a qualified instructor even though they may be employed in a facility that uses the approved course material for orientation as required by 13 CSR 15-14.042(20). The instructor, in that instance, may adjust the time required to cover the material or may integrate the material into the basic course content.

(C) The suggested time schedule included for each curriculum topic in the approved course cited in subsection (5)(A) may be adjusted by the instructor to meet the particular learning abilities of the students providing that the orientation module shall be taught in at least sixteen (16) hours for Medicare- or Medicaid-certified facilities. Licensed-only facilities shall provide at least twelve (12) hours of basic orientation approved by the division.

(D) The on-the-job supervised component of one hundred (100) hours shall start after the student has enrolled and started the course curriculum and shall precede the final examination.

(E) Continuing in-service education shall be offered in the intermediate care or skilled nursing facility (ICF/SNF) to nursing assistants on a regular basis following their successful completion of the basic course as required in 13 CSR 15-14.042(20) through (23).

(6) Student Enrollment and Qualifications.

(A) Any individual who is employable by an ICF/SNF to be involved in direct resident care shall be eligible to enroll in an approved training agency course if—

1. The individual is at least eighteen (18) years of age and employable. Employable shall mean that the individual is not listed on the Missouri Division of Aging Employee Disqualified List; who has not been found guilty of, pled guilty to, been convicted of, or *nolo contendere* to, a Class A or B felony under Chapters 565, 566 or 569, a Class D felony under section 568.020, RSMo 1994 or any violation of section 198.070.3, RSMo 1994, unless a good cause waiver has been granted by the division; and who meets requirements under 13 CSR 15-14.042(32); or

2. The individual is at least sixteen (16) years of age providing he or she is—

A. Currently enrolled in a secondary school health services occupation program or a cooperative work education program of an area vocational-technical school or comprehensive high school;

B. Placed for work experience in an ICF/SNF by that program; and

C. Under the direct supervision of the instructor or licensed nursing staff of the facility, or both, while completing the clinical portion of the course. A certified facility may not employ a student in the facility who is not certified within four (4) months of date of hire. A licensed-only facility may only employ a student in that facility for up to one (1) year from the date of hire prior to certification.

(B) All full or part-time employees of an ICF/SNF who are involved with direct resident care, and hired in that capacity after January 1, 1980, shall have completed the approved Nurse Assistant Training Program or shall enroll in and begin study in the approved training program within ninety (90) days of employment, except that the following persons shall be permitted to challenge the final examination:

1. Persons who were enrolled in a professional (RN) or practical (LPN) nursing education program for at least four (4) months or who are enrolled in this program and who have successfully completed the Fundamentals of Nursing Course, including clinical hours within the last five (5) years, may challenge the final examination of the course, as this training is deemed equivalent to the required classroom hours and on-the-job training;



2. Professional nursing or practical nursing licensure candidates who have failed state licensure examinations may challenge the final examination, as their training is deemed equivalent to the required classroom hours and on-the-job training;
3. Persons from other states who are approved to work as a nurse assistance in the other states may challenge the final examination, as their training is deemed equivalent to the required classroom hours and on-the-job training;
4. Students who have completed a nursing program outside the United States and who are awaiting the licensure examination in this country shall be required to apply to the division to take the challenge examination. In addition to a completed application, the student must also include: a copy of the out of country license or certificate; a copy of the school transcript translated to English; a copy of the out of country criminal background check translated to English. Students shall be required to complete the orientation module of the course as given in subsection (5)(B) of this rule and then may challenge the final examination, as their training is deemed equivalent to the other required classroom hours and on-the-job training;
5. Persons trained in acute care sections of hospitals as nursing assistants or persons trained as psychiatric aides shall complete the orientation module with special emphasis on the geriatric residents' needs, residents' rights and orientation to the facility and shall complete the one hundred (100) hours of on-the-job training in an LTC facility or LTC unit of a hospital and then they may challenge the final examination, as their training is deemed equivalent to the other required classroom hours and on-the-job training;
6. Persons trained in an LTC unit of a hospital and who have been employed in the LTC unit of the hospital for at least twelve (12) months and who submit a letter of recommendation from the administrator or director of nursing documenting their training may challenge the final examination after completing the units on residents' rights and care of the confused resident. Such training shall be deemed equivalent to the other required classroom hours and on-the-job training; and
7. Any other persons whose background, education and training in gerontology and health occupations includes the components of the approved training curriculum may be allowed to challenge the final examination after taking those portions of the course as determined to be

necessary based on evaluation of their credentials by the supervisor of health education of the Division of Aging.

(C) Those persons designated in paragraphs (6)(B)1.-7., who want to challenge the final examination shall submit a request in writing to the division enclosing any applicable documentation. The division will respond, in writing, either approving or denying the request to challenge the final examination and, if approved, the letter from the division may be presented to an approved training agency to challenge the examination or complete the course or portions of the course as required and then challenge the examination.

(D) Those persons permitted to challenge the final examination shall have made arrangements to do so within sixty (60) days of employment as a nursing assistant and shall have successfully challenged the final examination prior to or within one hundred twenty (120) days of employment. Permission letters not utilized within the one hundred twenty (120)-day period shall be considered invalid and reapplication for permission to challenge shall be made to the division.

(E) Nursing assistants who are employed by a nursing service, or who are working on a private duty basis providing direct resident care shall have completed the approved basic course, shall have a current certificate from an approved certifying agency and shall be listed on the Division of Aging Certified Nurse Assistant Registry prior to functioning in an ICF/SNF.

(F) Allied health care personnel, such as emergency medical technicians, medical laboratory technicians, surgical technicians, central supply technicians and dental auxiliaries, shall not be considered qualified and shall not be allowed to challenge the final examination. Individuals, if employed by an ICF/SNF to provide direct patient care shall enroll in and successfully complete an approved program.

(G) If a student drops the course due to illness or incapacity, the student may reenroll in a course within six (6) months and make up the course material missed without retaking the entire course upon presenting proof of attendance and materials covered in the original class.

(H) A student shall complete the entire basic course (including passing the final examination) within one (1) year of employment as a nursing assistant in an SNF/ICF, except that a nursing assistant employed by a facility certified under



Title XVIII or Title XIX shall complete the course and be certified within four (4) months.

(I) A full or part-time employee of an ICF/SNF who is employed as a nursing assistant after January 1, 1989 who has not completed at least the classroom portion of the basic course shall not provide direct resident care until he or she has completed the sixteen (16)-hour orientation module and the twelve (12) hours of supervised practical orientation required in 13 CSR 15-14.042(20).

(J) All nursing assistants trained prior to January 1, 1989 who were not trained using the course curriculum referenced in subsection (5)(A) of this rule with at least seventy-five (75) hours of classroom instruction shall have attended a special four (4)-hour retraining program which used the manual entitled *Long-Term Care Nurse Assistant Update* produced by the Instructional Materials Laboratory, University of Missouri-Columbia, 1989, catalogue number 50-5062-I or 50-5062-S. Any nursing assistant who did not attend this retraining program by August 31, 1989 shall no longer be considered a trained nursing assistant and all previous credentials issued by any source shall be considered invalid. To be certified as required by the provisions of this rule, a person shall successfully complete the entire Nursing Assistant Training Program.

(7) Training Agencies.

(A) The following entities are eligible to apply to the division to be an approved training agency:

1. Area vocational technical schools and comprehensive high schools offering health service occupation programs which have a practice classroom and equipment used in delivering health care and a written agreement of cooperation with one (1) or more SNFs/ICFs or an LTC unit of a hospital in their vicinity for the one hundred (100)-hour on-the-job training component of the course;

2. Community junior colleges or private agencies approved by the Missouri Department of Elementary and Secondary Education or accredited by a nationally recognized accrediting agency or association on the list published by the secretary of the Department of Education, pursuant to the Higher Education Act (20 USC Sections 295-4(2)(D), 42 USC Section 298(b)(6)) and the Veterans' Readjustment Assistance Act (38 USC Section 1775(a)) which have a practice laboratory with one (1) or more bed units and equipment used in delivering

health care and have a written agreement of cooperation with one (1) or more SNFs/ICFs, or LTC units of a hospital in their vicinity for the on-the-job training component of the course; or

3. A licensed hospital, licensed SNF/ICF which has designated space sufficient to accommodate the classroom teaching portion of the course, and if the one hundred (100) hours of on-the-job training is not provided on-site, has a written agreement of cooperation with an LTC unit of a hospital or SNF/ICF to provide that portion.

(B) A school, agency, hospital or nursing facility which wants to be approved by the division to teach the Nursing Assistant Training Program shall file an application with the division giving the name(s) of the instructor(s) and clinical supervisor(s); and, if clinical training is not being done on-site, a copy of an agreement with a nursing facility for the clinical portion of the course.

(C) In order to be approved, the applicant shall have an area which will be designated during training sessions as a classroom with sufficient space to allow fifteen (15) students to be seated with room for note-taking, appropriate equipment as needed for teaching the course, approved instructors and clinical supervisors, and shall assure that the instructor and each student has a manual for the state-approved course. Any ICF/SNF which has received a Notice of Noncompliance related to administration and resident care from the division in the two (2)-year period prior to application for approval shall not be eligible for approval and if this Notice is issued after approval, approval shall be withdrawn by the division within ninety (90) days and the certifying agencies shall be notified of the withdrawal of approval. Students already enrolled in a class in this facility, however, may complete their course if a Notice is issued after a course has begun. However, a noncompliant facility where an extended or partially extended survey has been completed may apply in writing to the division requesting permission for approval to train and test nurse assistants for certification. The approval for each separate class may be granted to teach and test in the facility but not by the facility staff. If approval is granted for a waiver for a certified facility or exception for a licensed-only facility, the division shall require certain criteria to be met, depending on the issues such as time and distance to other training agencies in the area.

(D) The division shall make an on-site inspection of each approved training agency's



premises within two (2) years of approval to determine the adequacy of space; equipment and supplies; and, if clinical training is not done on-site, verify that there is a current copy of an agreement with a nursing facility for the clinical portion of the course.

(E) Upon receipt of a fully completed application form, the division shall notify the applicant in writing within ninety (90) days of approval or disapproval. If disapproved, the reasons why shall be given.

(F) Training agencies shall be approved for a two (2)-year period and shall submit a new application for approval thirty (30) days prior to the expiration of approval.

(8) Instructor/student ratio shall be a maximum of one to fifteen (1:15) and it is recommended that the ratio be one to ten (1:10) or less.

(9) Qualifications of Instructors, Clinical Supervisors and Examiners.

(A) Instructor.

1. An instructor shall be a registered professional nurse currently licensed in Missouri or shall have a temporary permit from the Missouri State Board of Nursing. The licensee shall not be subject of current disciplinary action, such as censure, probation, suspension or revocation.

2. An instructor shall have had, at a minimum, two (2) years of nursing experience and at least one (1) year of experience in the provision of LTC facility services in the last five (5) years. Other personnel from the health professions may assist the instructor; however, they must have at least one (1) year of experience in their field.

3. An applicant to be an instructor, shall submit credentials (resume) and a copy of his/her current license renewal card or temporary permit to the Division of Aging. A letter shall be provided by the division to the applicant indicating the status of the applicant's qualifications and, if not qualified, the reasons and what additional requirements are needed.

4. An applicant to be an instructor shall attend a seminar approved by the Division of Aging to learn the methodology of teaching the course but only after his/her credentials have been reviewed and approved by the Division of Aging. The Division of Aging shall issue a final letter of approval to be a qualified instructor after the person has satisfactorily completed the seminar. The seminar shall be conducted either by an LTC association or the Missouri Department of Elementary and Secondary Education using qualified teacher educators approved by the

Missouri Department of Elementary and Secondary Education and the Division of Aging.

5. Any registered nurse approved by the division or the Department of Elementary and Secondary Education as an instructor or examiner prior to January 1, 1990, except those involved in nurse assistant curriculum development with the division or who are employed by a certifying agency, shall attend a training seminar on teaching the nurse assistant course conducted by a LTC association or the Department of Elementary and Secondary Education by July 1, 1993 in order to maintain status as an approved instructor. Instructors approved prior to January 1, 1990 who are exempt from attending the training seminar shall write the Division of Aging submitting documentation of classes and students taught. The division will issue those instructors letters of approval so they will not have to attend the new training seminar. After July 1, 1993 all credentials issued prior to January 1, 1990 shall be void. Nurses who attend the approved seminar shall be issued new certificates and the division shall maintain a list of all approved instructors, including those issued letters of approval.

(B) Clinical Supervisor (On-the-Job Supervisor). The clinical supervisor shall be a currently licensed registered professional nurse or licensed practical nurse, whose license is not currently subject to disciplinary action such as censure, probation, suspension or revocation. The clinical supervisor shall be licensed in Missouri or shall have a temporary permit from the Missouri State Board of Nursing. The clinical supervisor shall be currently employed by the facility where the students are performing their duties or by the agency conducting the course and shall have attended a seminar approved by the Division of Aging to learn methodology of supervising the on-the-job training. Upon successful completion of the training seminar, the clinical supervisor shall be issued a certificate and the division shall maintain a list of approved clinical supervisors. The clinical supervisor shall be on the facility premises in which the students are performing their duties while the students are completing the on-the-job component of their training and shall directly assist the students in their training and observe their skills when checking their competencies. The clinical supervisor shall have at least one (1) year of experience in LTC if not currently employed by an LTC facility.

(C) Examiner.



1. The examiner shall be a registered professional nurse currently licensed in Missouri or shall have a temporary permit from the Missouri State Board of Nursing, and shall not be currently subject of disciplinary action such as censure, probation, suspension or revocation.

2. The examiner shall have taught a similar course or shall be qualified to teach a similar course; but shall not have been the instructor of the students being examined; and shall not be employed by the operator whose students are being examined. The examiner shall be specifically approved by the Division of Aging to administer final examinations of the state-approved nurse assistant training curriculum and shall have signed an agreement with the division to protect and keep secure the final examinations.

3. The examiner shall have attended an examiner's seminar given by the Division of Aging to learn the methodology and sign an agreement.

(D) Causes for Disqualification. A person shall not be allowed to be an instructor, clinical supervisor or examiner if it is found that he or she—

1. Knowingly acted or omitted any duty in a manner which would materially or adversely affect the health, safety, welfare or property of a resident;

2. Defrauded a training agency or student by taking payment and not completing a course, not administering the final examination as required, or not being on-site while students are being trained;

3. Failed to teach, examine or clinically supervise in accordance with 13 CSR 15-13.010, or taught students from the state test, changed answers on the state test, lost test booklets, or recorded false information on test materials or test booklets of the program; or

4. Failed to send documentation of a completed course to a certifying agency within thirty (30) days.

(E) Notification of Disqualification.

1. The division shall notify the individual that he or she is no longer eligible to be an instructor, clinical supervisor or examiner.

2. The division shall notify all approved training and certifying agencies if it has been determined that an individual is no longer considered an approved instructor, clinical supervisor or examiner and that person's name shall be removed from the lists maintained by the division of approved instructors, clinical supervisors or examiners.

3. To be reinstated as a state-approved instructor, clinical supervisor or examiner the individual shall submit a request in writing to the division director stating the reasons why reinstatement is warranted. The division director or the director's designee shall respond in writing to the request.

(10) Testing.

(A) In order to be eligible for testing, a student shall have either completed the state-approved training curriculum offered by an approved training agency or shall have a letter from the Division of Aging granting approval to challenge the final examination.

(B) A student shall pass a minimum of three (3) written or oral tests throughout the course with an eighty (80) score or better on each test in order to be eligible to take the final examination.

(C) The final examination shall be conducted by an approved examiner who may be assisted by the instructor using the following procedures:

1. The instructor will select an LTC resident to participate in the testing process and obtain approval for this activity from the resident;

2. The examiner shall verify the eligibility of the students by reviewing records to establish that the student has completed the approved training program or possesses an approval letter from the division granting approval to challenge the final examination. In the event that a qualified instructor for the nurse assistant LTC program did not sign records of a student who successfully completed the program, without justification or due to resignation from his/her position, the administrator of the approved training agency may validate the training by signature. Evidence of successful completion of the basic course (that is, test scores, class schedules and the like) shall be documented prior to a student taking the final examination;

3. The student shall successfully complete at least nine (9) procedures under the observation of the instructor or a facility licensed nurse and examiner.

A. The nine (9) procedures shall always include a type of bath, vital signs (temperature, pulse, respirations and blood pressure), transfer techniques, feeding techniques, dressing and grooming, skin care, active or passive, range of motion to upper and lower extremities (unless contraindicated by a physician's order) and handwashing and gloving from the standardized curriculum.

B. The remainder shall be selected according to the resident's care needs at the time of day that testing occurs.



C. The evaluation of the student shall include communication and interaction with the resident, provision of privacy, work habits, appearance, conduct and reporting and recording skills;

4. The student shall successfully answer forty (40) out of fifty (50) oral or written questions presented by the examiner based on the standardized curriculum and selected from a specific test pool of questions which are safeguarded by the Division of Aging;

5. Any person who fails the final examination, except those who have been permitted to challenge the examination, shall have the opportunity to retake the examination twice within ninety (90) days. The examiner shall notify the division and obtain different examinations to be administered each time. If it is failed a third time, the entire course or selected sections, as determined by the examiner, must be retaken before another examination can be given; and

6. Any person who is required by section 198.082, RSMo to enroll in the Nurse Assistant Program, but who has been permitted to challenge the final examination and who fails the examination, must immediately reenroll in and begin study in the next available course and shall complete the basic course within one (1) year of employment.

(11) Records and Certification.

(A) Records.

1. The examiner shall complete and sign the competency record sheet and the final examination score sheet which shall include scores and comments. The examiner shall advise the individual that successful completion of the evaluation will result in the addition of his/her name to the State Nursing Assistant Register.

2. After scoring, the examiner shall return all test materials, test booklets, answer sheets, and any appendices to the division. The examiner shall also provide the training agency with documentation of the student's test scores.

3. A copy of the student's final record sheets shall be provided to the student (except for the answer sheets). If the course is not completed, records and documentation regarding the portions completed shall be provided to the student, if requested, and to the training agency.

4. The training agency shall maintain the records of students trained. Records shall be maintained for at least two (2) years.

(B) Certification and Entry of Names on State Register.

1. The training agency shall submit within thirty (30) days, the student's final record sheets to any one of the long-term care associations or any other agency which is specifically approved by the division to issue nursing assistant certificates and provide names to the division for entry on the nurse assistant register.

2. Each student shall obtain a certificate from a state-approved association or agency validating successful completion of the training program.

3. The Division of Aging shall maintain a list of long-term care associations or other agencies approved to handle the issuance of certificates for the Nurse Assistant Training Program. In order for a long-term care association or agency to be approved by the Division of Aging, it shall enter into an agreement of cooperation with the Missouri Division of Aging which shall be renewable annually and shall effectively carry out the following responsibilities:

A. Issue certificates to individuals who have successfully completed the course;

B. Provide the Division of Aging with the names and other identifying data of those receiving certificates on at least a monthly basis; and

C. Maintain accurate and complete records for a period of at least two (2) years.

4. The certificate of any nurse assistant who has not performed nursing services for monetary compensation for at least one (1) day in a twenty-four (24)-consecutive month period shall be invalid and the person's name shall be removed from the Missouri nursing assistant register. This individual, however, may submit his/her credentials to the Division of Aging at any time and if unemployed for less than five (5) years, s/he may be authorized to challenge the final examination. If s/he passes the examination, the examiner shall submit the individual's records to a training agency so that s/he can be issued a new certificate and his/her name can be placed on the nurse assistant register again. If unemployed longer than five (5) years, the individual must successfully complete the entire course before s/he can be recertified and s/he is not eligible to challenge the final examination.

AUTHORITY: sections 198.079 and 198.082, RSMo 1994. This rule originally filed as 13 CSR 15-13.010. Original rule filed Aug. 13, 1982, effective Jan. 13, 1983. Amended: Filed March 10, 1983, effective June 11, 1983. Amended: Filed Sept. 12, 1984, effective Dec. 11, 1984. Amended: Filed Oct. 13, 1987, effective Jan. 29, 1988. Emergency amendment*



filed Dec. 16, 1988, effective Jan. 1, 1989, expired April 5, 1989. Amended: Filed Jan. 19, 1989, effective April 27, 1989. Amended: Filed June 16, 1992, effective Feb. 26, 1993. Amended: Filed May 26, 1998, effective Jan. 30, 1999. Moved to 19 CSR 30-84.010, effective Aug. 28, 2001.

*Original authority: 198.079, RSMo 1979 and 198.082, RSMo 1979, amended 1988.

19 CSR 30-84.020 Certified Medication Technician Training Program

PURPOSE: Individuals who administer medications in intermediate care and skilled nursing facilities are required by 13 CSR 15-14.042(49) to have successfully completed a medication administration training program approved by the Division of Aging. This rule sets forth the requirements for the approval of a medication technician training program designating the required course curriculum content, outlining the qualifications required of students and instructors, designating approved training facilities, outlining the testing and certification requirements, and establishing an update course.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.

(1) The purpose of the Certified Medication Technician Training Program shall be to prepare individuals for employment as certified medication technicians in intermediate care or skilled nursing facilities (ICF/SNF). The program shall be designed to teach skills in medication administration of nonparenteral medications which will qualify students to perform this procedure to assist licensed practical nurses or registered professional nurses in drug therapy.

(2) All aspects of the Certified Medication Technician Training Program included in this rule shall be met in order for a program to be approved. If the program is to be offered in an ICF/SNF, the administrator of that facility shall make the arrangements with the sponsoring educational agency to—

(A) Provide administration of the Test of Adult Basic Education (TABE) and review of the student's qualifications;

(B) Arrange for a certified instructor;

(C) Administer the final examination; and

(D) Certify the students through a state-approved certifying agency which is any one (1) of the long-term care associations or any other division approved agency authorized to issue certificates.

(3) The objective of the Certified Medication Technician Training Program shall be to ensure that the medication technician will be able to—

(A) Prepare, administer and chart medications by all routes except those given by the parenteral route;

(B) Observe, evaluate, report and record responses of residents to medications given;

(C) Identify responsibilities associated with control and storage of medications;

(D) Identify appropriate reference materials;

(E) Relate side effects, interactions and nursing implications of common medications;

(F) Identify lines of authority and areas of responsibility; and

(G) Identify what constitutes a medication error.

(4) The course shall consist of at least sixty (60) classroom hours of instruction and a minimum of eight (8) hours of clinical practice under the direct supervision of an instructor or licensed registered nurse (RN) designated by the sponsoring educational agency, including a minimum of a two (2)-hour final practicum in a licensed ICF/SNF and a final written examination. The hours of a student's clinical practice required by an instructor may be greater, based on each student's mastery of course content as determined by the instructor.

(A) The approved course curriculum shall be the course developed by the Missouri Department of Elementary and Secondary Education and the Division of Aging as outlined in the manual entitled *Medication Technician* produced by the Instructional Materials Laboratory, University of Missouri-Columbia, revised 1994, catalogue number 50-6010-S.



Students shall each have a copy of this manual. The instructor shall use the companion *Instructor's Guide*, catalogue number 50-6010-I. These manuals and materials are incorporated in this rule by reference.

(B) The curriculum content shall include procedures and instructions in the following areas:

1. Basic review of body systems and drug effect on each;
2. Medical terminology;
3. Infection control;
4. Drug classifications;
5. Dosage, measurements and forms;
6. Storage and accountability;
7. Problems of observations in drug therapy;
8. Administration by oral, rectal, vaginal, otic, ophthalmic, nasal, skin, topical, transdermal patches, and oral metered dose inhaler; and
9. Special categories.

(C) A student shall not be allowed to independently administer medications until successfully completing the course. The final score sheet may be used as authorization to independently administer medications for up to ninety (90) days. After this period the student must have a certificate and be listed on the Missouri State Certified Medication Technician Registry.

(5) Student Qualifications.

(A) Any individual employable in an ICF/SNF who will be involved in direct resident care shall be eligible to enroll as a student in the course if the following criteria are also met:

1. High school diploma or General Education Development (GED) Certificate;
2. A minimum score of 8.9 on both Vocabulary and Comprehension tests and a minimum score of 7.0 on Mathematics Concepts and Application tests on the D level of the Test of Adult Basic Education (TABE). The tests shall be administered by the public educational sector;
3. Six (6) months of employment as a certified nurse assistant who is listed on the Missouri State Nurse Assistant Register and who has a letter of recommendation submitted to the training agency or school by the administrator or director of nursing of the facility, or, if now unemployed, by a previous employer; and
4. Nursing assistants who plan to enroll in the course may or may not be currently employed in a long-term care facility.

(B) The following individuals may qualify as certified medication technicians by successfully

challenging the course through a written and performance final examination:

1. Students enrolled in a professional nursing school or in a practical nursing program who have completed a medication administration course and who have a letter of endorsement from the school or program director;
2. Individuals who successfully completed a professional or practical nursing program but who failed the professional (RN) or practical (LPN) state licensure examination;
3. Individuals who provide evidence of successful completion of a state-approved certified medication technician course while working as aides at a facility operated by the Missouri Department of Mental Health providing that an individual successfully complete the orientation module of the approved Nurse Assistant Training Program and challenges the course by successfully completing the final examination of that program so that his or her name appears on the Missouri Certified Nurse Assistant Register. This shall be completed prior to challenging the Certified Medication Technician course;
4. Individuals who have successfully completed a state-approved medication technician course in another state, who are currently listed as Certified Medication Technicians in good standing in that state, and who submit a letter of recommendation to the division from an administrator or director of nursing of a facility in which he or she served as a medication technician; and
5. Individuals listed on the Certified Nurse Assistant (CNA) register. All individuals who qualify to challenge the final examination must first challenge the Certified Nurse Assistant final examination if not already listed on the registry as a CNA.

(C) Individuals who have successfully completed a professional or practical nursing program and who have not yet taken or received the results of the state licensure examination may request a letter from the division which entitles them to administer medication in a long-term care facility. However, if more than ninety (90) days have lapsed since graduation or since taking the Missouri State Board Examination with no results confirmed, the individual must ask for permission to challenge the final examination for certification as a medication technician. Challenge letters shall be valid for one hundred twenty (120) days.

(D) Those persons designated in subsections (5)(B) and (C) who want to challenge the final



examination or receive a letter of qualification, shall submit a request in writing to the division enclosing any applicable documentation. If approved to—

1. Challenge the examination, a letter so stating will be sent from the division and may be presented to a sponsoring educational agency so that arrangements can be made for testing; or
2. Qualify without taking the course or challenging the examination, a letter so stating will be sent by the division and shall be presented and used in lieu of a certificate.

(E) Individuals who must qualify by successfully completing the final examination or by special qualifying criteria shall not be allowed to administer medications until successfully completing the challenge process or receiving a letter of qualification from the division.

(6) Instructor Qualifications for Basic Course.

(A) An instructor shall be currently licensed to practice as a registered nurse in Missouri or shall have a temporary permit from the Missouri State Board of Nursing. The instructor shall not be the subject of current disciplinary action, such as censure, probation, suspension or revocation of license.

(B) The instructor shall meet state certification requirements as follows:

1. Hold a current full-time teaching certificate or a short-term instructor approval certificate from the Department of Elementary and Secondary Education, Division of Vocational and Adult Education;
2. Complete an instructor/examiner workshop to implement the program; and
3. Be responsible to a sponsoring educational agency, such as an area vocational-technical school, a comprehensive high school, a community college or an approved four (4)-year institution of higher learning.

(C) Instructor may be assisted by pharmacists as guest instructors in to the areas of drug distribution systems, regulations governing drugs, drug actions, adverse reactions and drug interactions.

(D) When the instructor is an employee of the ICF/SNF in which training is conducted, a qualified registered nurse approved by the sponsoring educational agency shall conduct the final examinations. The examiner may also be the instructor.

(E) A person shall not be approved to be an instructor or examiner if he or she has ever been found to have knowingly acted or omitted any duty in a manner which would materially and

adversely affect the health, safety, welfare or property of a resident.

(F) A person who has been approved to be an instructor or examiner shall have that status revoked if, after an investigation by the division, it is found that the person:

1. Knowingly acted or omitted any duty in a manner which materially and adversely affected the health, safety, welfare or property of a resident;
2. Defrauded a training agency or student by taking payment and not completing a course or following through with certification;
3. Did not administer the final examination as required, or was not on-site while students were being trained; or
4. Falsified information on the final score sheet or any other required documentation.

(G) When an individual is no longer qualified to be an instructor or examiner, the division shall notify:

1. The individual that he or she is no longer eligible to be an instructor or examiner; and
2. All approved training and certifying agencies if it has been determined that an individual is no longer considered an approved instructor or examiner and that the person's name shall be removed from the list of approved instructors and examiners maintained by the division.

(H) To be reinstated as an approved instructor or examiner the individual shall submit a request in writing to the division director stating the reasons why reinstatement is warranted. The division director or the director's designee shall respond in writing to the request.

(7) Training Agencies.

(A) The following entities are eligible to apply to the division to be an approved training agency: vocational-technical schools, comprehensive high schools, community college or approved four (4)-year institutions of higher learning.

(B) All classrooms shall contain sufficient space, equipment and teaching aids to meet the course objectives as determined by the sponsoring educational agency.

(C) A school desiring divisional approval to teach the Certified Medication Technician Course shall file an application with the division giving the names of the instructors, listing the equipment and classroom space that will be used and provide a copy of an agreement with the nursing facility conducting the clinical portion of the course.

(D) The ICF/SNF in which clinical practice and the final practicum examination are conducted shall allow students, instructors and examiners access to the medication room,



supervised access to residents and access to the medication recording area.

(E) There shall be a signed written agreement between the sponsoring educational agency and each cooperating ICF/SNF which specifies the rules, responsibilities and liabilities of each party.

(F) The sponsoring educational agency is responsible for sending the division a copy of the most current signed agreement with the cooperating ICF/SNF where clinicals will be conducted. The division shall review all signed agreements. On-site inspections of the training site or educational agency may be made by the division if problems occur or complaints are received. If requirements are not met the status as a training site may be revoked by the division.

(G) The classroom portion may be taught in an ICF/SNF if there is an approved educational agency as a sponsor.

(8) Basic Course Testing.

(A) Prior to the student's enrollment, the TABE shall be administered by qualified examiners from the public educational sector designated by the sponsoring educational agency. See paragraph (5)(A)2. of this rule.

(B) To be eligible for the final examination, students shall have achieved a score of at least eighty percent (80%) on each written examination in the course curriculum.

(C) The final examination shall consist of a written and practicum examination.

1. The written examination shall include fifty (50) multiple choice questions based on the course objectives. A score of at least eighty percent (80%) is required for passing.

2. The practicum examination shall include preparing and administering all nonparenteral routes and recording of medications administered to residents. It shall be conducted under the direct supervision of the instructor or examiner and the person responsible for medication administered in the ICF/SNF. Testing on medications not available in the ICF/SNF shall be done in a simulated classroom situation.

3. The final examination may be retaken one (1) time within ninety (90) days without repeating the course.

4. A challenge examination may be taken one (1) time. If failed the entire course shall be taken before retesting is allowed.

(D) The instructor and examiner shall complete the final records and the record sheet shall include competencies and scores and other identifying information.

(9) Records and Certification.

(A) Records.

1. For at least two (2) years, the sponsoring educational agency shall maintain records of individuals who have completed the Certified Medication Technician Training Program and shall submit to one (1) of the state-approved certifying agencies the student's name, student's Social Security number, class beginning date and completion date, a challenge or full course and other identifying information from the final score sheet.

2. A copy of the final record shall be provided to the certified medication technician.

3. A transcript may be released with written permission from the student in accordance with the provisions of the Privacy Act—P.L. 90-247.

(B) Certification.

1. The sponsoring educational agency shall maintain the records of individuals who have been enrolled in the Certified Medication Technician Program and shall submit to a state approved certifying agency the names and address of all individuals who successfully complete the program. Upon receipt of the successful completion of course material and final examination, the state-approved certifying agency shall issue a certificate of completion to the student through the sponsoring educational agency (school). Any final examination documentation over ninety (90) days old shall be invalid.

2. On a monthly basis, the certifying agency shall provide the division with names and other identifying information of those receiving certificates.

3. The division shall maintain a list of certifying agencies approved to handle the issuance of certificates for the Certified Medication Technician Training Program. In order for a certifying agency to be approved by the division, it shall enter into an annually renewable agreement of cooperation with the division.

(10) Certified Medication Technician Update Course.

(A) All medication technicians with certificates from state-approved certifying agencies who have not taken the new sixty-eight (68)-hour course using the 1994 edition, curriculum catalog number 50-6010-S shall successfully complete the Certified Medication Technician Update Course (number 50-6015-S) to remain qualified certified medication technicians. Any individual taking the update course shall be certified as a nurse assistant with



his or her name listed on the Missouri State Nurse Assistant Registry. Any previously qualified student who does not attend the update course prior to June 30, 2000, must take the complete sixty-eight (68)-hour course.

(B) The certifying agency must receive the score sheet and accompanying documentation within ninety (90) days after the Certified Medication Technician Update Course final examination is administered. Score sheets and documents shall become invalid if not properly submitted within ninety (90) days after the final examination is given.

(C) The following may request permission from the division to take the Certified Medication Technician Training Update Course:

1. Individuals trained by the then existing Missouri Division of Health Institutional Advisory Nurses prior to 1978;
2. Individuals certified through the vocational educational system using the Department of Health-approved curriculum;
3. Individuals who have completed a long-term care medication technician course in another state which has been approved by the appropriate state agency and who have a letter from the division giving permission to work as certified medication technicians;
4. All medication technicians with valid certificates from the Department of Elementary and Secondary Education; and
5. All medication technicians with valid certificates from state-approved certifying agencies who have not taken the new sixty-eight (68)-hour course using the 1994 revised curriculum catalog number 50-6010-S.

(D) Prior to a sponsoring educational agency accepting a Certified Medication Technician Update Course student, the sponsoring educational agency, the student's employing facility or the student him/herself shall send the division the following information: current legal name and any prior name(s); address; a copy of the student's Social Security card; a copy of the student's current certified medication technician certificate or qualifying information and a copy of the student's current certified nurse assistant certificate. This information will be used for student validation and placement in an update course. No student may be admitted to the update course without first presenting a letter from the division allowing him or her to take the update course. The division will complete the processing of all update course requests within twelve (12) working days of receipt of the appropriate and complete information.

(E) The update course shall consist of at least seven (7) hours of classroom instruction, to include demonstrations on apical pulse, ophthalmic medication, transdermal patch, oral metered dose, and inhaler medications. The update course also includes information on body systems and infection control. In order to be approved, the certified medication technician training agency, school, or ICF/SNF, under the auspices of the approved training agency shall have an area that will be designated during training sessions as a classroom with sufficient space to allow at least twenty (20) students to be seated with room for note-taking and appropriate equipment as needed for teaching the update course. Each student and instructor shall have an update course manual.

(F) The final examination shall consist of at least fifty (50) multiple choice questions taken from one (1) of the two (2) tests found in the 50-6015-I manual for instructors and examiners. Test time may be no longer than one (1) hour. A score of eighty percent (80%) is required for passing. If not successfully passed, a second test from the same manual may be administered one (1) time within the next ninety (90) days. Any individual who fails the examination on the first attempt, may no longer administer medication. If the examination is failed the second time, the full sixty-eight (68)-hour course must be taken or retaken.

(G) The instructor or examiner shall complete the final Score Sheet for Certified Medication Technician Update Course Examination and shall include competencies, scores and signatures which shall be sent to a certifying agency for recertification as stated in section (10) of this rule. The letter of permission to take the update course must also be sent to the certifying agency.

(H) The instructor or examiner of the Certified Medication Technician Update Course shall be an approved instructor as designated in section (6) of this rule.

(I) The sponsoring educational agency shall maintain, for at least two (2) years, the records of individuals who have taken the update course. The sponsoring educational agency shall provide a certifying agency approved by the division with documentation showing successful completion and testing of the update course and the Score Sheet for Certified Medication Technician Update Course. Any final examination score sheet not received within (90) days by the certifying agency after the final examination is given shall be invalid. The certifying agency shall provide a certificate to



the student which documents successful completion of the state-approved Certified Medication Technician Update Course.

(J) The division shall maintain a list of long-term care associations or other agencies that issue certificates to individuals who have successfully completed the course. On at least a monthly basis, the long-term care associations or certifying agencies shall provide the division with the names and other identifying data of those individuals receiving update course certificates. The long-term care associations or certifying agencies shall maintain these update course records for at least two (2) years.

(K) The division shall maintain a Certified Medication Technician Register listing names and other relevant and identifying information.

AUTHORITY: section 198.079, RSMo 1994. This rule originally filed as 13 CSR 15-13.020. Original rule filed Aug. 13, 1982, effective Jan. 13, 1983. Amended: Filed Oct. 13, 1987, effective Jan. 29, 1988. Amended: Filed July 13, 1998, effective Feb. 28, 1999. Moved to 19 CSR 30-84.020, effective Aug. 28, 2001.*

**Original authority: 198.079, RSMo 1979.*

19 CSR 30-84.030 Level I Medication Aide

PURPOSE: Individuals who administer medications in residential care facilities I and II are required by 13 CSR 15-15.042(49) to be either a physician, a licensed nurse, a certified medication technician or a level I medication aide. This rule sets forth the requirements for approval of a Level I Medication Aide Training Program designating the required course curriculum content, outlining the qualifications required of students and instructors, designating approved training facilities and outlining the testing and certification requirements.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) The Level I Medication Aide Training Program shall be administered by the

Department of Health and Senior Services (the department) in order to prepare individuals for employment as level I medication aides in residential care facilities (RCFs) and assisted living facilities (ALFs). The program shall be designed to teach skills in medication administration of nonparenteral medications in order to qualify students to perform this procedure only in RCFs and ALFs in Missouri.

(2) All aspects of the level I Medication Aide Training Program included in this rule shall be met in order for a program to be considered approved.

(3) The objective of the level I Medication Aide Training Program shall be to ensure that the medication aide will be able to—define the role of a level I medication aide; prepare, administer and chart medications by nonparenteral routes; observe, report and record unusual responses to medications; identify responsibilities associated with control and storage of medications; and utilize appropriate drug reference materials.

(4) The course shall be an independent self-study course with a minimum of sixteen (16) hours of integrated formal instruction and practice sessions supervised by an approved instructor which shall include a final written and practicum examination.

(5) The curriculum content shall include procedures and instructions in the following areas: basic human needs and relationships; drug classifications and their implications; assessing drug reactions; techniques of drug administration; medication storage and control; drug reference resources; and infection control.

(6) The course developed by the Missouri Department of Elementary and Secondary Education and the Department of Health and Senior Services as outlined in the manual entitled *Level I Medication Aide* (50-6064-S and 50-6064-I) 1993 edition, produced by the Instructional Materials Laboratory, University of Missouri-Columbia, incorporated by reference in this rule and available through the Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570, shall be considered the approved course curriculum. This rule does not incorporate any subsequent amendments or additions to the materials incorporated by reference. Students and instructors each shall have a copy of this manual.



(7) A student shall not administer medications without the instructor present until s/he successfully completes the course and obtains a certificate.

(8) Student Qualifications.

(A) Any individual employable by an RCF or ALF to be involved in direct resident care shall be eligible to enroll as a student in the course. Employable shall mean an individual who is at least eighteen (18) years of age; not listed on the department's Employee Disqualification List (EDL) and has not been convicted of, or entered a plea of guilty or *nolo contendere* to a crime in this state or any other state, which if committed in Missouri would be a class A or B felony violation of Chapters 565, 566, and 569, RSMo, any violation of section 568.020, RSMo or any violation of section 198.070.3, RSMo, unless a good cause waiver has been granted by the department pursuant to the provisions of 19 CSR 30-82.060.

(B) The following individuals may qualify as level I medication aides by successfully challenging the final examination: Individuals either enrolled in or who have been enrolled in a professional nursing school or in a practical nursing program who have completed the medication administration or pharmacology course and who have letters of endorsement from the directors of their respective programs.

(9) Those persons wanting to challenge the final examination shall submit a request in writing to the department's Section of Long Term Care director enclosing applicable documentation. If approved to challenge the examination, a letter so stating will be sent from the division to present to an approved instructor so that arrangements can be made for testing.

(10) Instructor Qualifications.

(A) An instructor shall be currently licensed to practice as either a registered nurse or practical nurse in Missouri or shall hold a current temporary permit from the Missouri State Board of Nursing. The licensee shall not be subject to current disciplinary action such as censure, probation, suspension or revocation. If the individual is a licensed practical nurse, the following additional requirements shall be met:

1. Shall be a graduate of an accredited program which has pharmacology in the curriculum.
2. This additional requirement shall not be waived.

(B) In order to be qualified as an instructor, the individual shall have had one (1) year's experience working in a long-term care (LTC) facility licensed by the department or the Department of Mental Health within the past five (5) years; or shall be currently employed in an LTC facility licensed by the department or the Department of Mental Health and shall have been employed by that facility for at least six (6) months; or shall be an instructor in a Health Occupations Education program; and shall have attended a "Train the Trainer" workshop to implement the Level I Medication Aide Program conducted by a Missouri registered nurse presenter approved by the department.

(C) Upon completion of the workshop and receipt of all credentials validating qualifications, the presenter shall issue a certificate indicating that an instructor is approved to teach the level I medication aide course and shall submit the names of the approved instructors to the approved LTC association.

(D) A person who has been approved as an instructor shall have that status revoked if, after an investigation by the division, it is found that the instructor:

1. Accepted money from a student and did not follow through with the class or upon successful completion of the class did not follow through with certification;
2. Falsified information on the final score sheet or any other required documentation; or
3. Administered the final examination incorrectly and not in accordance with section (12) of this rule.

(E) Once an instructor's status is revoked only the director of the division or his/her designee may reinstate the individual after the individual requests reinstatement documenting new circumstances. If the instructor's status is revoked or reinstated, the division shall immediately notify all certifying agencies of the action.

(11) Sponsoring Agencies.

(A) The following entities are eligible to apply to the department to be an approved training agency: an area vocational-technical school, a comprehensive high school, a community college, an approved four (4) year institution of higher learning or an RCF or ALF licensed by the department or an LTC association.

(B) The sponsoring agency is responsible for obtaining an approved instructor, determining the number of manuals needed for a given



program, ordering the manuals for the students and presenting a class schedule for approval by an approved LTC association. The required information will include: the name of the approved instructor; the instructor's Social Security number, current address and telephone number; the number of students enrolled; the name, address, telephone number, Social Security number and age of each student; the name and address of the facility that employs the student, if applicable; the date and location of each class to be held; and the date and location of the final examination. The LTC association which approved the course shall be notified in advance if there are any changes in dates or locations.

(C) Classrooms used for training shall contain sufficient space, equipment and teaching aids to meet the course objectives as determined by an approved LTC association.

(D) If the instructor is not directly employed by the agency, there shall be a signed written agreement between the sponsoring agency and the instructor which shall specify the role, responsibilities and liabilities of each party.

(12) Testing.

(A) The final examination shall consist of a written and a practicum examination administered by the instructor.

1. The written examination shall include twenty-five (25) questions based on the course objectives.

2. The practicum examination shall be done in an LTC facility which shall include the preparation and administration by nonparenteral routes and recording of medications administered to residents under the direct supervision of the instructor and the person responsible for medication administration in the long-term care facility. Testing on medications not available in the LTC facility shall be done in a simulated classroom situation.

(B) A score of eighty percent (80%) is required for passing the final written examination and one hundred percent (100%) accuracy in the performance of the steps of procedure in the practicum examination.

(C) The final examination, if not successfully passed, may be retaken within ninety (90) days one (1) time without repeating the course, however, those challenging the final examination must complete the course if the examination is not passed in the challenge process.

(D) The instructor shall complete final records and shall submit these and all test booklets to the sponsoring agency.

(13) Records and Certification.

(A) Records.

1. The sponsoring agency shall maintain records of all individuals who have been enrolled in the Level I Medication Aide Program and shall submit to the LTC association which approved the course all test booklets, a copy of the score sheets and a complete class roster.

2. A copy of the final record shall be provided to any individual enrolled in the course.

3. A final record may be released only with written permission from the student in accordance with the provisions of the Privacy Act (PL 90-247).

(B) Certification.

1. The LTC association which approved the course shall award a Level I medication aide certificate to any individual successfully completing the course upon receiving the required final records and test booklets from the sponsoring agency.

2. The LTC association which approved the course shall submit to the department the names of all individuals receiving certificates.

(14) The department shall maintain a list of LTC associations approved to handle the Level I Medication Aide Training Program. In order for an LTC association to be approved by the department the association shall enter into an agreement of cooperation with the department which shall be renewable annually and shall effectively carry out the following responsibilities:

(A) Maintain a roster of approved instructors;

(B) Approve sponsoring agencies, class schedules and classroom space;

(C) Distribute final examinations, review test booklets, score sheets and class rosters;

(D) Award certificates to individuals who successfully complete the course, provide the department with the names of those receiving certificates; and

(E) Maintain records.

(15) Maintaining Certification.

(A) If the department, upon completion of an investigation, finds that the Level I medication aide has stolen or diverted drugs from a resident or facility or has had his/her name added to the employee disqualification list, the division shall delete such person's name from the department's



Level I medication aide listing. Such deletion shall render the medication aide's certificate invalid.

AUTHORITY: sections 198.076, RSMo 2000 and 198.005 and 198.073, RSMo Supp. 2006. This rule originally filed as 13 CSR 15-13.030. Original rule filed May 14, 1985, effective Sept. 1, 1985. Amended: Filed Oct. 16, 1985, effective Jan. 12, 1986. Amended: Filed May 26, 1998, effective Jan. 30, 1999. Moved to 19 CSR 30-84.030, effective Aug. 28, 2001. Amended: Filed Aug. 23, 2006, effective April 30, 2007.*

**Original authority: 198.005, RSMo 2006; 198.073, RSMo 1974, amended 1984, 1992, 1999, 2006; and 198.076, RSMo 1979, amended 1984.*

19 CSR 30-84.040 Insulin Administration Training Program

PURPOSE: This rule sets forth the requirements for approval of an insulin administration training program, designates the required course curriculum content, outlines the qualifications required of students and instructors and outlines the testing and records requirements.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

(1) The Insulin Administration Training Program shall be administered by the Department of Health and Senior Services (the department) in order to prepare medication technicians in a skilled nursing facility (SNF) or intermediate care facility (ICF), or medication aides in a residential care facility (RCF) or an assisted living facility (ALF) to administer insulin. The program shall be designed to present information on diabetes as it relates to symptoms and implications of proper or improper treatment, and to teach skills in insulin administration in order to qualify students to perform this

procedure in long-term care (LTC) facilities in Missouri. All aspects of the Insulin Administration Training course included in this rule shall be met in order for the program to be approved.

(2) The course shall consist of at least four (4) hours of classroom instruction by an approved instructor and shall include a final written and practicum examination. The practicum examination shall not be conducted in a simulated situation.

(3) The curriculum content shall include procedures and instruction in the following areas: diabetes and its treatment and complications, types of insulin, technique of insulin administration and methods of monitoring blood sugar levels.

(4) The manual entitled *Insulin Administration* (50-6080-S and 50-6080-I), 2001 edition, produced by the Instructional Materials Laboratory, University of Missouri-Columbia, which is incorporated by reference in this rule, and available through the Department of Health and Senior Services, PO Box 570, Jefferson City, MO 65102-0570, shall be considered the approved course curriculum. This rule does not incorporate any subsequent amendments or additions to the materials incorporated by reference. Students and instructors shall each have a copy of the manual.

(5) A student shall not administer insulin without the instructor present until s/he has successfully completed the course.

(6) Student Qualifications.

(A) Any level I medication aide working in an RCF or ALF, who is recommended in writing for training by an administrator/manager or nurse with whom s/he has worked shall be eligible to enroll as a student in this course.

(B) Any certified medication technician who is recommended in writing for training by the administrator or director of nursing with whom s/he has worked shall be eligible to enroll as a student in this course. The letter of recommendation shall be given to the training agency or instructor at enrollment.

(7) Instructor Qualifications. Only a registered nurse who is an approved instructor for the Level I Medication Aide Program, instructor/examiner for the Certified Nurse Assistant Program or instructor for the Certified Medication

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Technician Program shall be considered qualified to teach the Insulin Administration Course.

(8) Testing.

(A) The final examination shall consist of a written and practicum examination administered by an approved instructor or examiner.

1. The written examination shall include ten (10) questions extracted from the list in the instructor's manual.

2. The practicum examination shall include the preparation, administration and recording of administration of insulin to a resident(s) under the direct supervision of the instructor/examiner.

(B) A score of eighty percent (80%) is required for passing the final written examination and one hundred percent (100%) accuracy in the performance of the steps of procedure in the practicum examination.

(C) The final examination, if not successfully passed, may be retaken one (1) time within thirty (30) days without repeating the course.

(9) Records.

(A) The instructor shall complete the final record of the insulin administration course and shall distribute copies in the following manner:

1. A copy shall be provided to each individual who successfully completes the course;

2. A copy shall be kept in the instructor's file; and

3. The original shall be sent to a certifying agency.

(B) Each student shall obtain a certificate from a state-approved certifying agency validating successful completion of the training program.

(C) Records shall be retained by instructors for at least two (2) years.

(D) The department shall maintain a list of approved certifying agencies to handle issuance of certificates for the Insulin Administration Program. In order for an agency to be approved by the department to be a certifying agency, it shall enter into an agreement of cooperation with the department which shall be renewable annually and the agency shall effectively carry out the following responsibilities:

1. Review all documents submitted by the instructor to assure that the instructor is qualified in accordance with section (7);

2. Assure that all program requirements have been met as set forth in these rules or as stipulated in the agreement with the department;

3. Issue certificates to individuals who successfully complete the course;

4. Provide the department with the names of those receiving certificates on at least a monthly basis; and

5. Maintain accurate and complete records for a period of at least two (2) years.

AUTHORITY: sections 198.009 and 198.076, RSMo 2000 and 198.005 and 198.073, RSMo Supp. 2006. This rule originally filed 13 CSR 15-13.040. Original rule filed Oct. 15, 1990, effective March 14, 1991. Amended: Filed May 26, 1998, effective Nov. 30, 1998. Moved to 19 CSR 30-84.040, effective Aug. 28, 2001. Amended: Filed Aug. 23, 2006, effective April 30, 2007.*

**Original authority: 198.005, RSMo 2006; 198.009, RSMo 1979, amended 1993, 1995; 198.073, RSMo 1979, amended 1984, 1992, 1999, 2006 and 198.076, RSMo 1979, amended 1984.*

APPENDIX B

Excerpts from Federal Regulations (OBRA) for Skilled Nursing
Facilities (SNFs) and Nursing Facilities (NFs)
Effective Date; March, 2005

§483.10 Resident Rights

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident.

F155 – §483.10(b) (4)

The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph (8) of this section.

Interpretive Guidelines §483.10(b)(4)

“Treatment” is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms.

If a resident’s refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. A resident’s refusal of treatment does not absolve a facility from providing a resident with care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well-being in the context of making that refusal.

F157 – §483.10(b)(11) – Notification of changes.

- (i) A facility must immediately inform the resident; consult with the resident’s physician; and if known, notify the resident’s legal representative or an interested family member when there is--
 - (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
 - (B) A significant change in the resident’s physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
 - (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
 - (D) A decision to transfer or discharge the resident from the facility as specified in §483.12(a).

Interpretive Guidelines §483.10(b)(11)

For purposes of §483.10(b)(11)(i)(B), life-threatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II pressure sore, onset, or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment “significantly” means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before).

In the case of a competent individual, the facility must still contact the resident’s physician and notify interested family members, if known. That is, a family that wishes

to be informed would designate a member to receive calls. Even when a resident is mentally competent, such a designated family member should be notified of significant changes in the resident's health status because the resident may not be able to notify them personally, especially in the case of sudden illness or accident.

The requirements at §483.10(b)(1) require the facility to inform the resident of his/her rights upon admission and during the resident's stay. This includes the resident's right to privacy (§483.10(e), F164). If, after being informed of the right to privacy, a resident specifies that he/she wishes to exercise this right and not notify family members in the event of a significant change as specified at this requirement, the facility should respect this request, which would obviate the need to notify the resident's interested family member or legal representative, if known. If a resident specifies that he/she does not wish to exercise the right to privacy, then the facility is required to comply with the notice of change requirements.

In the case of a resident who is incapable of making decisions, the representative would make any decisions that have to be made, but the resident should still be told what is happening to him or her.

In the case of the death of a resident, the resident's physician is to be notified immediately in accordance with State law.

F164 – §483.10(e) Privacy and Confidentiality

The resident has the right to personal privacy and confidentiality of his or her personal and clinical records.

- (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident;
- (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility;
- (3) The resident's right to refuse release of personal and clinical records does not apply when--
 - (i) The resident is transferred to another health care institution; or
 - (ii) Record release is required by law

Interpretive Guidelines – §483.10(e) "Right to privacy"

Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.

Personal and clinical records include all types of records the facility might keep on a resident, whether they are medical, social, fund accounts, automated or other.

F176 – §483.10(n) Self-Administration of Drugs

An individual resident may self-administer drugs if the interdisciplinary team, as defined by §483.20(d)(2)(ii), has determined that this practice is safe.

Interpretive Guidelines §483.10(n)

If a resident requests to self-administer drugs, it is the responsibility of the interdisciplinary team to determine that it is safe for the resident to self-administer drugs before the resident may exercise that right. The interdisciplinary team must also determine who will be responsible (the resident or the nursing staff) for storage and documentation of the administration of drugs, as well as the location of the drug administration (e.g., resident’s room, nurses’ station, or activities room). Appropriate notation of these determinations should be placed in the resident’s care plan.

The decision that a resident has the ability to self-administer medication(s) is subject to periodic re-evaluation based on change in the resident’s status. The facility may require that drugs be administered by the nurse or medication aide, if allowed by State law, until the care planning team has the opportunity to obtain information necessary to make an assessment of the resident’s ability to safely self-administer medications. If the resident chooses to self-administer drugs, this decision should be made at least by the time the care plan is completed within seven days after completion of the comprehensive assessment.

F222 – Use Tag F222 for deficiencies concerning chemical restraints.

§483.13(a) - Restraints

The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.

Intent §483.13(a)

The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints.

Interpretive Guidelines §483.13(a) – Definitions of Terms

“Chemical Restraints” is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms.

“Discipline” is defined as any action taken by the facility for the purpose of punishing or penalizing residents.

“Convenience” is defined as any action taken by the facility to control a resident’s behavior or manage a resident’s behavior with a lesser amount of effort by the facility and not in the resident’s best interest.

“Medical Symptom” is defined as an indication or characteristic of a physical or psychological condition.

Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident’s unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The resident’s right to participate in care planning and the right to refuse treatment are addressed at §§483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse restraints.

F271 – §483.20(a) Admission Orders

At the time each resident is admitted, the facility must have physician orders for the resident’s immediate care.

Intent §483.20(a)

To ensure the resident receives necessary care and services.

Interpretive Guidelines §483.20(a)

“Physician orders for immediate care” are those written orders facility staff need to provide essential care to the resident, consistent with the resident’s mental and physical status upon admission. These orders should, at a minimum, include dietary, drugs (if necessary) and routine care to maintain or improve the resident’s functional abilities until staff can conduct a comprehensive assessment and develop an interdisciplinary care plan.

F272 – §483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized reproducible assessment of each resident’s functional capacity.

Intent §483.20

To provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident’s status. The facility is expected to use resident observation and communication as the primary source of information when completing the RAI. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident’s physician, family members, or outside consultants and review of the resident’s record.

§483.20(b) Comprehensive Assessments

§483.20(b)(1) Resident Assessment Instrument

A facility must make a comprehensive assessment of a resident's needs, using the RAI specified by the State.

§483.20(b) Intent

To ensure that the RAI is used in conducting comprehensive assessments as part of an ongoing process through which the facility identifies the resident's functional capacity and health status.

§483.20(b) Guidelines

The information required in §483.20(b)(i-xvi) is incorporated into the MDS, which forms the core of each State's approved RAI. Additional assessment information is also gathered using triggered RAPs.

Each facility must use its State-specified RAI (which includes both the MDS and utilization guidelines which include the RAPs) to assess newly admitted residents, conduct an annual reassessment and assess those residents who experience a significant change in status. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or RAPs. The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident. Furthermore:

(xiv) Medications

"Medications" (xiv) corresponds to MDS v. 2.0, section O, and section U, if completed.

"Medications" refers to all prescription and over-the-counter medications taken by the resident, including dosage, frequency of administration, and recognition of significant side effects that would be most likely to occur in the resident. This information need not appear in the assessment. However, it must be in the resident's clinical record and included in the care plan.

F281 – §483.20(k)(3)

The services provided or arranged by the facility must -

- (i) Meet professional standards of quality.

Intent §483.20(k)(3)(i)

The intent of this regulation is to assure that services being provided meet professional standards of quality (in accordance with the definition provided below) and are provided by appropriate qualified persons (e.g., licensed, certified).

Interpretive Guidelines §483.20(k)(3)(i)

"Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards

regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include:

- Current manuals or textbooks on nursing, social work, physical therapy, etc.
- Standards published by professional organizations such as the American Dietetic Association, American Medical Association, American Medical Directors Association, American Nurses Association, National Association of Activity Professionals, National Association of Social Work, etc.
- Clinical practice guidelines published by the Agency of Health Care Policy and Research.
- Current professional journal articles.

F329 – §483.25(I) Unnecessary Drugs

1. General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:

- (i) In excessive dose (including duplicate therapy); or
- (ii) For excessive duration; or
- (iii) Without adequate monitoring; or
- (iv) Without adequate indications for its use; or
- (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
- (vi) Any combinations of the reasons above.

It is important to note that these regulations and interpretive guidelines are not meant to cast a negative light on the use of psychopharmacological drugs in long term care facilities. The use of psychopharmacological drugs can be therapeutic and enabling for residents suffering from mental illnesses such as schizophrenia or depression. The goal of these regulations and guidelines is to stimulate appropriate differential diagnosis of "behavioral symptoms" so the underlying **cause** of the symptoms is recognized and treated appropriately. This treatment may include the use of environmental and/or behavioral therapy, as well as, psychopharmacological drugs. The goal of these regulations is also to **prevent** the use of psychopharmacological drugs when the "behavioral symptom" is caused by conditions such as:

An excellent differential diagnostic process for behavioral symptoms is described in the RAP on Behavior Problems (soon to be known as behavioral symptoms). Also, a number of very practical manuals are now available that teach nursing personnel how to assess and provide individualized care for behavioral symptoms, which leads to the avoidance of physical restraints, and unnecessary drugs. These manuals include, but are not limited to, the following list:

1. "Managing Behavior Problems in Nursing Home Residents"
Department of Preventive Medicine
Vanderbilt University School of Medicine
2. "Retrain, Don't Restrain"
American Association of Homes and Services for the Aging, or
The American Health Care Association

3. “Innovations in Restraint Reduction”
American Health Care Association
4. “Avoiding Physical Restraint Use: New Standards in Care,”
National Citizens’ Coalition for Nursing Home Reform
5. “Avoiding Drugs Used as Chemical Restraints: New Standards in Care”
National Citizens’ Coalition for Nursing Home Reform

Interpretive Guidelines **§483.25(l)(1)**

A. Long-Acting Benzodiazepine Drugs

The following long-acting benzodiazepine drugs should not be used in residents unless an attempt with a shorter-acting drug (i.e., those listed under B. Benzodiazepine or Other Anxiolytic/Sedative Drugs, and under C. Drugs Used for Sleep Induction) has failed.

After an attempt with a shorter-acting benzodiazepine drug has failed, a long-acting benzodiazepine drug should not be used unless:

- Evidence exists that other possible reasons for the resident’s distress have been considered and ruled out. (see §483.25(l)(1)(iv);)
- Its use results in maintenance or improvement in the resident’s functional status (to evaluate functional status, (see §483.25(a) through (k)) and MDS 2.0 sections B through P). (see §483.25(l)(1)(iv));
- Daily use is less than four continuous months unless an attempt at a **gradual** dose reduction is unsuccessful (see §483.25(l)(1)(ii)); and
- Its use is less than, or equal to, the following listed total **daily** doses unless higher doses (as evidenced by the resident’s response and/or the resident’s clinical record) are necessary for the maintenance, or improvement in the resident’s functional status. (see §483.25(l)(1)(i).)

Long-Acting Benzodiazepines - Not Maximum Doses

Generic	Brand	Daily Oral Dosage
Flurazepam	(Dalmane)	15mg
Chlordiazepoxide	(Librium)	20mg
Clorazepate	(Tranxene)	15mg
Diazepam	(Valium)	5mg
Clonazepam	(Klonopin)	1.5mg
Quazepam	(Doral)	7.5mg
Halazepam	(Paxipam)	40mg

NOTES: When diazepam is used for neuromuscular syndromes (e.g., cerebral palsy, tardive dyskinesia or seizure disorders), this guideline does not apply.
When long-acting benzodiazepine drugs are being used to withdraw residents from short-acting benzodiazepine drugs, this guideline does not apply.

When clonazepam is used in bi-polar disorders, management of tardive dyskinesia, nocturnal myoclonus or seizure disorders, this guideline does not apply.

The daily doses listed under long-acting Benzodiazepines are doses (usually administered in divided doses) for “geriatric” or “elderly” residents. The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it was necessary for the maintenance or improvement in the resident’s functional status.

“**Duplicate drug therapy**” is any drug therapy that duplicates a particular drug **effect** on the resident. For example, any two or more drugs, whether from the same drug category or not, which have a sedative effect. Duplicate drug therapy should prompt the facility to evaluate the resident for accumulation of the adverse effects.

For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated.

B. Benzodiazepine or other Anxiolytic/Sedative Drugs

Use of listed Anxiolytic/Sedative drugs for purposes other than sleep induction should only occur when:

1. Evidence exists that other possible reasons for the resident’s distress have been considered and ruled out. (see §483.25(l)(1)(iv));
2. Use results in a maintenance or improvement in the resident’s functional status, (to evaluate functional status, (see §483.25(a) through (k)) and MDS 2.0 sections B through P). (see §483.25(l)(1)(iv));
3. Daily use (at any dose) is less than four continuous months unless an attempt at a gradual dose reduction is unsuccessful. (see §483.25(l)(1)(ii));
4. Use is for one of the following indications as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) or subsequent editions. (see §483.25(l)(1)(iv):)
 - a. Generalized anxiety disorder;
 - b. Organic mental syndromes (now called “delirium, dementia, and amnesic and other cognitive disorders” by DSM-IV) with associated agitated behaviors, which are quantitatively and objectively documented (see note number one) which are persistent and not due to preventable reasons and which constitute sources of distress or dysfunction to the resident or represent a danger to the resident or others;
 - c. Panic disorder;
 - d. Symptomatic anxiety that occurs in residents with another diagnosed psychiatric disorder (e.g., depression, adjustment disorder); and
5. Use is equal to or less than the following listed total **daily** doses, unless higher doses (as evidenced by the resident response and/or the resident’s clinical record) are necessary for the improvement or maintenance in the resident’s functional status. (see §483.25(l)(1)(i), F342.)

Short-Acting Benzodiazepines - Not Maximum Doses

Generic	Brand	Dose By Mouth
Generic	Brand	Daily Oral Dosage
Lorazepam	(Ativan)	2 mg
Oxazepam	(Serax)	30mg
Alprazolam	(Xanax)	0.75mg
Estazolam	(ProSom)	0.5mg

Other Anxiolytic And Sedative Drugs

Generic	Brand	Dose By Mouth
Diphenhydramine	(Benadryl)	50mg
Hydroxyzine	(Atarax, Vistaril)	50mg
Chloral Hydrate	(Many Brands)	750mg

NOTES

1. This documentation is often referred to as “behavioral monitoring charts” and is necessary to assist in: (a) assessing whether the resident’s behavioral symptom is in need of some form of intervention, (b) determining whether the behavioral symptom is transitory or permanent, (c) relating the behavioral symptom to other events in the resident’s life in order to learn about potential causes (e.g., death in the family, not adhering to the resident’s customary daily routine), (d) ruling out environmental causes such as excessive heat, noise, overcrowding, etc., (e) ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be know as behavioral symptoms).
2. The daily doses listed under Short-Acting Benzodiazepines are doses (usually administered in divided doses) for “geriatric” or “elderly” residents. The facility is encouraged to initiate therapy with lower doses and, when necessary, only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident’s functional status.
3. For drugs in this category, a gradual dose reduction should be attempted at least twice within one year before one can conclude that a gradual dose reduction is clinically contraindicated.
4. Diphenhydramine, hydroxyzine and chloral hydrate are not necessarily drugs of choice for treatment of anxiety disorders. They are only listed here in the event of their potential use.

C. Drugs for Sleep Induction - Drugs used for sleep induction should only be used if:

- Evidence exists that other possible reasons for insomnia (e.g., depression, pain, noise, light, caffeine) have been ruled out. (see §483.25(l)(1)(iv));
- The use of a drug to induce sleep results in the maintenance or improvement of the resident’s functional status (to evaluate functional status, see §483.25(a) through (k) and MDS 2.0 sections B through P). (see §483.25(l)(1)(iv);)
- Daily use of the drug is less than ten continuous days unless an attempt at a gradual dose reduction is unsuccessful. (see §483.25(l)(1)(ii);) and
- The dose of the drug is equal or less than the following listed doses unless higher doses (as evidenced by the resident response and/or the resident’s clinical record) are necessary for maintenance or improvement in the resident's functional status. (see §483.25(l)(1)(i).)

Hypnotic Drugs - Not Maximum Doses

Generic	Brand	Dose By Mouth
Temazepam	(Restoril)	7.5mg
Triazolam	(Halcion)	0.125mg
Lorazepam	(Ativan)	1mg
Oxazepam	(Serax)	15mg
Alprazolam	(Xanax)	0.25mg
Estazolam	(ProSom)	0.5mg
Diphenhydramine	(Benadryl)	25mg
Hydroxyzine	(Atarax, Vistaril)	50mg
Chloral Hydrate	(Many Brands)	500mg
Zolpidem	(Ambien)	5mg

NOTES

1. Diminished sleep in the elderly is not necessarily pathological.
2. The doses listed are doses for “geriatric” or “elderly” residents. The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see survey procedures and probes) to show why it was necessary for the maintenance or improvement in the resident’s functional status.
3. Diphenhydramine, hydroxyzine, and chloral hydrate are not necessarily drugs of choice for sleep disorders. They are listed here only in the event of their potential use.
4. For drugs in this category, a gradual dose reduction should be attempted at least three times within six months before one can conclude that a gradual dose reduction is clinically contraindicated.

D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs

The **initiation** of the following hypnotic/sedative/anxiolytic drugs should not occur in any dose for any resident. (See Notes for exceptions.) Residents currently using these drugs or residents admitted to the facility while using these drugs should receive **gradual** dose reductions as part of a plan to eliminate or modify the symptoms for which they are prescribed. A gradual dose reduction should be attempted at least twice within one year before one can conclude that the gradual dose reduction is clinically contraindicated. Newly admitted residents using these drugs may have a period of adjustment before a **gradual** dose reduction is attempted.

CAUTION: Do not encourage rapid withdrawal of these drugs. This might result in severe psychological withdrawal symptoms.

Barbiturates (Examples)

Generic	Brand
Amobarbital	(Amytal)
Butabarbital	(Butisol, others)
Pentobarbital	(Nembutal)
Secobarbital	(Seconal)
Phenobarbital	(Many Brands)
Amobarbital-Secobarbital	(Tuinal)
Barbiturates with other drugs	(e.g., Fiorinal)

Miscellaneous Hypnotic/Sedative/Anxiolytics

Generic	Brand
Glutethimide	(Doriden)
Methprylon	(Noludar)
Ethchlorvynol	(Placidyl)
Meprobamate	(Equinal, Miltown)
Paraldehyde brands	(Many brands)

1. Any sedative drug is excepted from this Guideline when used as a single dose sedative for dental or medical procedures.
2. Phenobarbital is excepted from this Guideline when used in the treatment of seizure disorders.
3. When Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs are used outside these Guidelines they may be unnecessary drugs as a result of inadequate indications for use. (see Survey Procedures and Probes.)

E. Antipsychotic Drug Dosage Levels

The following examples of antipsychotic drugs should not be used in excess of the listed doses for residents with organic mental syndromes (now called “delirium, dementia, and amnestic and other cognitive disorders” by DSM-IV) unless higher doses (as evidenced by the resident’s response or the resident’s clinical record) are necessary to maintain or improve the resident’s functional status. To evaluate functional status, (see §§483.25(a) through (k)) and MDS 2.0 sections B through P.

SCREEN FOR HIGHER DOSES OF ANTIPSYCHOTIC DRUGS

These dose levels are **NOT MAXIMUM DOSES**. These daily dose levels are given to establish a point at which higher doses should be explained. If a resident is prescribed a higher dose than shown, the facility should explain the specific clinical circumstance requiring the higher dose.

ANTIPSYCHOTIC DRUGS		DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Generic	Brand	Dose
Chlorpromazine	(Thorazine)	75
Promazine	(Sparine)	150
Trifluoperazine	(Vesprin)	20
Thioridazine	(Mellaril)	75
Mesoridazine	(Serentil)	25
Acetophenazine	(Tindal)	20
Perphenazine	(Trilafon)	8
Fluphenazine	(Prolixin, Permitil)	
Trifluoperazine	(Stelazine)	8
Chlorprothixene	(Taractan)	75
Thiothixene	(Navane)	7
Haloperidol	(Haldol)	4
Molindone	(Moban)	10
Loxapine	(Loxitane)	10
Clozapine	(Clozaril)	50
Prochlorperazine	(Compazine)	10
Risperidone	(Risperdal)	2

ANTIPSYCHOTIC DRUGS		DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Generic	Brand	Dose
Olanzapine	(Zyprexa)	10
Quetiapine	(Seroquel)	200

1. The doses listed are **daily** doses (usually administered in divided doses) for residents with organic mental syndromes (now called “Delirium, Dementia, and Amnestic and other cognitive disorders by DSM-IV). The facility is encouraged to initiate therapy with lower doses and when necessary only **gradually** increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it is necessary for the maintenance or improvement in the resident’s functional status.
2. The “specific conditions” for use of antipsychotic drugs are listed under the Guideline for §§483.25(1)(1) and (2).
3. The dose of prochlorperazine may be exceeded for short term (seven days) treatment of nausea and vomiting. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can also be treated with higher doses for longer periods of time.
4. When antipsychotic drugs are used outside these Guidelines without valid reasons for the higher dose, they may be deemed unnecessary drugs as a result of excessive dose.

F. Monitoring for Antipsychotic Drug Side Effects

The facility assures that residents who are undergoing antipsychotic drug therapy receive adequate monitoring for significant side effects of such therapy with emphasis on the following:

- Tardive dyskinesia;
- Postural (orthostatic) hypotension;
- Cognitive/behavior impairment;
- Akathisia; and
- Parkinsonism.

NOTES: For a more detailed description of these side effects, see the RAP: Psychotropic Drug Use, pg. C-91, “Revised Long Term Care Resident Assessment Instrument User’s Manual,” Version 2.0, December 2002.

When antipsychotic drugs are used without monitoring for these side effects, they may be unnecessary drugs because of inadequate monitoring.

G. Antidepressant Drugs

The under diagnosis and under treatment of depression in nursing homes has been documented in a Journal of the American Medical Association paper entitled “Depression and Mortality in the Nursing Home” (JAMA, February 27, 1991-vol. 265, No. 8). CMS continues to support the accurate identification and treatment of depression in nursing homes.

The following is a list of commonly used antidepressant drugs:

Antidepressant Drugs	
Generic Name	Brand Name
Amitriptyline*	(Elavil)
Amoxapine	(Asendin)
Desipramine	(Norpramin, Pertofrane)
Doxepin*	(Sinequan)
Imipramine*	(Tofranil)
Maprotiline	(Ludiomil)
Nortriptyline	(Aventyl, Pamelor)
Protriptyline	(Vivactil)
Trimipramine*	(Surmontil)
Fluoxetine	(Prozac)
Sertraline	(Zoloft)
Trazodone	(Desyrel)
Clomipramine*	(Anafranil)
Paroxetine	(Paxil)
Bupropion	(Wellbutrin)
Isocarboxazid*	(Marplan)
Phenelzine*	(Nardil)
Tranlycypromine*	(Parnate)
Venlafaxine	(Effexor)
Nefazodone	(Serzone)
Fluvoxamine	(Luvox)

- These are not necessarily drugs of choice for depression in the elderly. They are listed here only in the event of their potential use.

F330 – §483.25(1)(2)(i)

Residents who have not used antipsychotic drugs are not given these drugs unless antipsychotic drug therapy is necessary to treat a specific condition as diagnosed and documented in the clinical record; and

Antipsychotic drugs should not be used unless the clinical record documents that the resident has one or more of the following “specific conditions”:

1. Schizophrenia;
2. Schizo-affective disorder;
3. Delusional disorder;
4. Psychotic mood disorders (including mania and depression with psychotic features);
5. Acute psychotic episodes;
6. Brief reactive psychosis;
7. Schizophreniform disorder;
8. Atypical psychosis;
9. Tourette’s disorder;
10. Huntington’s disease;
11. Organic mental syndromes (now called delirium, dementia, and amnestic and other cognitive disorders by DSM-IV) **with associated psychotic and/or agitated behaviors:**
 - a. Which have been quantitatively and objectively documented. This documentation is necessary to assist in:
 - (1) Assess whether the resident’s behavioral symptom is in need of some form of intervention,
 - (2) Determining whether the behavioral symptom is transitory or permanent,
 - (3) Relating the behavioral symptom to other events in the resident’s life in order to learn about potential causes (e.g., death in the family, not adhering to the resident’s customary daily routine),
 - (4) Ruling out environmental causes such as excessive heat, noise, overcrowding,
 - (5) Ruling out medical causes such as pain, constipation, fever, infection. For a more complete description of behavioral monitoring charts and how they can assist in the differential diagnosis of behavioral symptoms see the RAP on behavior problems (soon to be known as behavioral symptoms); and
 - b. Which are persistent, and
 - c. Which are not caused by preventable reasons; and
 - d. Which are causing the resident to:
 - (1) Present a danger to himself/herself or to others, or
 - (2) **Continuously** scream, yell, or pace if these specific behaviors cause an impairment in functional capacity (to evaluate functional capacity, see §483.25 (a) through (k) and MDS 2.0 sections B through P), or
 - (3) Experience psychotic symptoms (hallucinations, paranoia, delusions) not exhibited as dangerous behaviors or as screaming,

yelling, or pacing but which cause the resident distress or impairment in functional capacity; or

12. Short-term (7 days) symptomatic treatment of hiccups, nausea, vomiting or pruritus. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can be treated for longer periods of time.

Antipsychotics should not be used if one or more of the following is/are the **only** indication:

- Wandering;
- Poor self care;
- Restlessness;
- Impaired memory;
- Anxiety;
- Depression (without psychotic features);
- Insomnia;
- Unsociability;
- Indifference to surroundings;
- Fidgeting;
- Nervousness;
- Uncooperativeness; or
- Agitated behaviors which **do not** represent danger to the resident or others.

F331 – §483.25(l)(2)(ii)

Residents who use antipsychotic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs.

Interpretive Guidelines §483.25(l)(2)(ii)

Residents must, unless clinically contraindicated, have gradual dose reductions of the antipsychotic drug. The gradual dose reduction should be under close supervision. If the gradual dose reduction is causing an adverse effect on the resident and the gradual dose reduction is discontinued, documentation of this decision and the reasons for it should be included in the clinical record. Gradual dose reductions consist of tapering the resident's daily dose to determine if the resident's symptoms can be controlled by a lower dose or to determine if the dose can be eliminated altogether.

“Behavioral interventions” means modification of the resident's behavior or the resident's environment, including staff approaches to care, to the largest degree possible to accommodate the resident's behavioral symptoms.

“Clinically contraindicated” means that a resident **NEED NOT UNDERGO** a “gradual dose reduction” or “behavioral interventions” IF:

1. The resident has a “specific condition” (as listed under 1 through 10 on page P-185) and has a history of recurrence of psychotic symptoms (e.g., delusions, hallucinations), which have been stabilized with a maintenance dose of an antipsychotic drug without incurring significant side effects;
2. The resident has organic mental syndrome (now called “Delirium, Dementia, and Amnesic and other Cognitive Disorders” by DSM IV) and has had a gradual dose

reduction attempted TWICE in one year and that attempt resulted in the return of symptoms for which the drug was prescribed to a degree that a cessation in the gradual dose reduction, or a return to previous dose reduction was necessary; or

3. The resident's physician provides a justification why the continued use of the drug and the dose of the drug is clinically appropriate. This justification should include: (s) a diagnosis, but not simply a diagnostic label or code, but the description of symptoms, (b) a discussion of the differential psychiatric and medical diagnosis (e.g., why the resident's behavioral symptom is thought to be a result of a dementia with associated psychosis and/or agitated behaviors, and not the result of an unrecognized painful medical condition of a psychosocial or environmental stressor), (c) a description of the justification for the choice of a particular treatment, or treatments, and (d) a discussion of why the present dose is necessary to manage the symptoms of the resident. This information need not necessarily be in the physician's progress notes, but must be a part of the resident's clinical record.

F332 and F333 – §483.25(m) Medication Errors

The facility must ensure that - [F332] §483.25(m)(1); it is free of medication error rates of 5 percent or greater; and [F333] §483.25(m)(2); residents are free of any significant medication errors.

Interpretive Guidelines §483.25(m)

Medication Error - the observed preparation or administration of drugs or biologicals which is not in accordance with:

1. Physician's orders;
2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological;
3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils.

Significant medication error – one which causes the resident discomfort or jeopardizes his or her health and safety. Criteria for judging significant medication errors as well as examples are provided under significant and non-significant medication errors. Discomfort may be a subjective or related term used in different ways depending on the individual situation. (Constipation that is unrelieved by an ordered laxative that results in a drug error that is omitted for one day may be slightly uncomfortable or perhaps not uncomfortable at all. When the constipation persists for greater than three days, the constipation may be more significant. Constipation causing obstruction or fecal impaction can jeopardize the resident's health and safety.)

Medication error rate - is determined by calculating the percentage of errors. The numerator in the ratio is the total number of errors that the survey team observes, both significant and non-significant. The denominator is called "opportunities for errors" and includes all the doses the survey team observed being administered plus the doses

ordered but not administered. The equation for calculating a medication error rate is as follows:

Medication Error Rate = Number of Errors Observed divided by the Opportunities for Errors (doses given plus doses ordered but not given) X 100.

Medication error rate - a medication error rate of 5% or greater includes both significant and non-significant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written.

The error rate must be 5% or greater. Rounding of a lower rate (e.g., 4.6%) to a 5% rate is not permitted.

Significant and Non-significant Medication Errors

Determining Significance – the relative significance of medication errors is a matter of professional judgment. Follow three general guidelines in determining whether a medication error is significant or not:

Resident Condition - the resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated resident may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.

Drug Category – if the drug is from a category that usually requires the resident to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI) (i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs with NTI are as follows:

- A. Anticonvulsant: phenytoin (Dilantin), carbamazepine (Tegretol).
- B. Anticoagulants: warfarin (Coumadin).
- C. Antiarrhythmic: digoxin (Lanoxin).
- D. Antiasthmatics: theophylline (TheoDur).
- E. Antimanic Drugs: lithium salts (Eskalith, Lithobid).

Frequency of Error – if an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's drug was omitted several times, as verified by reconciling the number of tablets delivered with the number administered, classifying that error as significant would be more in order. This conclusion should be considered in concert with the resident's condition and the drug category.

Examples of Significant and Non-Significant Medication Errors – some of these errors are identified as significant. This designation is based on expert opinion without regard to the status of the resident. Most experts concluded that the significance of these errors, in and of themselves, have a high potential for creating problems for the typical long term care facility resident. Those errors identified as non-significant have also been

designated primarily on the basis of the nature of the drug. Resident status and frequency of error could classify these errors as significant.

Examples of Medication Errors Detected

Omissions Examples (Drug ordered but not administered at least once):

Drug Order	Significance
Haldol 1mg BID	NS
Motrin 400mg TID	NS
Quinidine 200mg TID	S**
Tearisol Drops 2 both eyes TID	NS
Metamucil one packet BID	NS
Multivitamin one daily	NS
Mylanta Susp. one oz., TID AC	NS
Nitrol Oint. one inch	S
* Not Significant	
**Significant	

Unauthorized Drug Examples (Drugs administered without a physician's order):

Drug Order	Significance
Feosol	NS
Coumadin 4mg	S
Zyloprim 100mg	NS
Tylenol 5 gr	NS
Motrin 400mg	NS

Wrong Dose Examples:

Drug Order	Administered	Significance
Timoptic 0.25% one drop in the left eye TID	Three drops in each eye	NS
Digoxin 0.125mg everyday	0.25mg	S
Amphojel 30ml QID	15ml	NS
Dilantin 125 SUSP 12ml	2ml	S

Wrong Route of Administration Examples:

Drug Order	Administered	Significance
Cortisporin Ear Drops 4 to 5 left ear QID	Left Eye	S

Wrong Dosage Form Examples:

Drug Order	Administered	Significance
Colace Liquid 100mg BID	Capsule	NS
Mellaril Tab 10mg	Liquid Concentrate	NS*

Drug Order	Administered	Significance
Dilantin Kapseals 100 mg three Kapseals p.o. HS	Prompt Phenytoin 100 mg three capsules p.o. HS	S
* If correct dose was given.		
** Parke Davis Kapseals have an extended rate of absorption. Prompt phenytoin capsules do not.		

Wrong Drug Examples:

Drug Order	Administered	Significance
Tums	Oscal	NS
Vibramycin	Vancomycin	S

Wrong Time Examples:

Drug Order	Administered	Significance
Digoxin 0.25mg daily at 8 a.m.	At 9:30 am	NS
Percocet 2 Tabs 20 min. before painful treatment	2 Tabs given 3 after treatment	S

Medication Errors Due to Failure to Follow Manufacturers Specifications or Accepted Professional Standards

The following situations in drug administration may be considered medication errors:

- Failure to “Shake Well”: The failure to “shake” a drug product that is labeled “shake well.” This may lead to an under dose or over dose depending on the drug product and the elapsed time since the last “shake.” The surveyor should use common sense in determining the adequacy of the shaking of the medication. Some drugs, for example dilantin, are more critical to achieve correct dosage delivery than others.
- Insulin Suspensions: Also included under this category is the failure to “mix” the suspension without creating air bubbles. Some individuals “roll” the insulin suspension to mix it without creating air bubbles. Any motion used is acceptable so long as the suspension is mixed and does not have air bubbles in it prior to the administration.
- Crushing Medications that should not be Crushed: Crushing tablets or capsules that the manufacturer states “do not crush.”

Exceptions to the “Do Not Crush” rule:

- If the prescriber orders a drug to be crushed which the manufacturer states should not be crushed, the prescriber or the pharmacist must explain, in the clinical record, why crushing the medication will not adversely affect the resident. Additionally, the pharmacist should inform the facility staff to observe for pertinent adverse effects.

- If the facility can provide literature from the drug manufacturer or from a reviewed health journal to justify why modification of the dosage form will not compromise resident care.
- Adequate Fluids with Medications: The administration of medications without adequate fluid when the manufacturer specifies that adequate fluids be taken with the medication. For example:
 - Bulk laxatives (e.g., Metamucil, Fiberall, Serutan, Konsyl, Citrucel);
 - Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) should be administered with adequate fluid. Adequate fluid is not defined by the manufacturer but is usually four to eight ounces. The surveyor should count fluids consumed during meals or snacks (such as coffee, juice, milk, soft drinks, etc.) as fluids taken with the medication, as long as they have consumed within a reasonable time of taking the medication (e.g., within approximately 30 minutes). If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted; and
 - Potassium supplements (solid or liquid dosage forms) such as: Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K, or Ten K should be administered with or after meals with a full glass (e.g., approximately 4 - 8 ounces of water or fruit juice). This will minimize the possibility of gastrointestinal irritation and saline cathartic effect. If the resident refuses to take adequate fluid, the facility should not be at fault so long as they made a good faith effort to offer fluid, and provided any assistance that may be necessary to drink the fluid. It is important that the surveyor not apply this rule to residents who are fluid restricted.
- Medications that Must be Taken with Food or Antacids: The administration of medications without food or antacids when the manufacturer specifies that food or antacids be taken with or before the medication is considered a medication error. The most commonly used drugs that should be taken with food or antacids are the Nonsteroidal Anti-Inflammatory Drugs (NSAIDs). There is evidence that elderly, debilitated persons are at greater risk of gastritis and GI bleeds, including silent GI bleeds. Determine if the time of administration was selected to take into account the need to give the medication with food.

Examples of commonly used NSAIDs are as follows:

Generic Name	Brand Name
Diclofenac	Voltaren, Cataflam
Diflunisal	Dolobid
Etodolac	Lodine
Fenoprofen	Nalfon
Ibuprofen	Motrin, Advil
Indomethacin	Indocin
Ketoprofen	Orudis, Oruvail
Mefenamic Acid	Ponstel
Nabumetone	Relafen
Naproxen	Naprosyn, Aleve
Piroxicam	Feldene
Sulindac	Clinoril
Tolmetin	Tolectin

- Medications Administered with Enteral Nutritional Formulas: Administering medications immediately before, immediately after, or during the administration of enteral nutritional formulas (ENFs) without achieving the following minimum objectives:
 - Check the placement of the naso-gastric or gastrostomy tube in accordance with the facility's policy on this subject. **NOTE:** If the placement of the tube is not checked, this is not a medication error; it is a failure to follow accepted professional practice and should be evaluated under Tag F281 requiring the facility to meet professional standards of quality.
 - Flush the enteral feeding tube with at least 30 ml of preferably warm water before and after medications are administered. While it is noted that some facility policies ideally adopt flushing the tube after each individual medication is given, as opposed to after the group of multiple medications is given, unless there are known compatibility problems between medicines being mixed together, a minimum of one flushing before and after giving the medications is all the surveyor need review. There may be cases where flushing with 30 ml after each single medication is given may overload an individual with fluid, raising the risk of discomfort or stress on body functions. Failure to flush, before and after, would be counted as one medication error and would be included in the calculation for medication errors exceeding 5 percent.

- o The administration of enteral nutrition formula and administration of dilantin should be separated to minimize interaction. The surveyor should look for appropriate documentation and monitoring if the two are administered simultaneously. If the facility is not aware that there is a potential for an interaction between the two when given together, and is not monitoring for outcome of seizures or unwanted side effects of dilantin, then the surveyor should consider simultaneous administration a medication error.
- Medications Instilled into the Eye: The administration of eye drops without achieving the following critical objectives:
 - o **Eye Contact:** The eye drop, but not the dropper, must make full contact with the conjunctival sac and then be washed over the eye when the resident closes the eyelid; and
 - o **Sufficient Contact Time:** The eye drop must contact the eye for a sufficient period of time before the next eye drop is instilled. The time for optimal eye drop absorption is approximately 3 to 5 minutes. (It should be encouraged that when the procedures are possible, systemic effects of eye medications can be reduced by pressing the tear duct for one minute after eye drop administration or by gentle eye closing for approximately three minutes after the administration.)
- Allowing Resident to Swallow Sublingual Tablets: If the resident persists in swallowing a sublingual tablet (e.g., nitroglycerin) despite efforts to train otherwise, the facility should endeavor to seek an alternative dosage form for this drug.
- Medication Administered Via Metered Dose Inhalers (MDI): The use of MDI in other than the following ways (this includes use of MDI by the resident). This is an error if the person administering the drug did not do all the following:
 - o Shake the container well;
 - o Position the inhaler in front of or in the resident's mouth. Alternatively a spacer may be used;
 - o For cognitively impaired residents, many clinicians believe that the closed mouth technique is easier for the resident and more likely to be successful. However, the open mouth technique often results in better and deeper penetration of the medication into the lungs, when this method can be used; and
 - o If more than one puff is required, (whether the same medication or a different medication) wait approximately a minute between puffs.

NOTE: If the person administering the drug follows all the procedures outlined above, and there is a failure to administer the medication because the resident can't cooperate (for example, a resident with dementia may not understand the procedure), this should not be called a medication error. The surveyor should evaluate the facility's responsibility to assess the resident's circumstance, and possibly attempt other dosage forms such as oral dosage forms or nebulizers.

Determining Medication Errors

Timing Errors – If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, **BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY.** Counting a drug with a long half - life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug has a long half - life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).

To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

Prescriber's Orders -- the latest recapitulation of drug orders is sufficient for determining whether a valid order exists provided the prescriber has signed the "recap." The signed "recap," if the facility uses the "recap" system and subsequent orders constitute a legal authorization to administer the drug.

F385

§483.40 Physician Services

A physician must personally approve in writing a recommendation that an individual be admitted to a facility. Each resident must remain under the care of a physician.

§483.40(a) Physician Supervision

The facility must ensure that:

- (1) The medical care of each resident is supervised by a physician; and
- (2) Another physician supervises the medical care of residents when their attending physician is unavailable.

F386

§483.40(b) Physician Visits

The physician must--

- (1) Review the resident's total program of care, including medications and treatments, at each visit required by paragraph (c) of this section;
- (2) Write, sign, and date progress notes at each visit; and
- (3) Sign and date all orders with the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved facility policy after an assessment for contraindications.

Intent §483.40(b)

The intent of this regulation is to have the physician take an active role in supervising the care of residents. This should not be a superficial visit, but should include an evaluation of the resident's condition and a review of and decision about the continued appropriateness of the resident's current medical regime.

F389**§483.40(d) Availability of Physicians for Emergency Care**

The facility must provide or arrange for the provision of physician services 24 hours a day, in case of emergency.

Interpretive Guidelines §483.40(d)

If a resident's own physician is unavailable, the facility should attempt to contact that physician's designated referral physician before assuming the responsibility of assigning a physician. Arranging for physician services may include assuring resident transportation to a hospital emergency room/ward or other medical facility if the facility is unable to provide emergency medical care at the facility.

F425**§483.60 Pharmacy Services**

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in §483.75(h) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

Interpretive Guidelines §483.60

The facility is responsible under §483.75(h) for the "timeliness of the services."

A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met.

F426**§483.60(a) Procedures**

A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

F427**§483.60(b) Service Consultation**

The facility must employ or obtain the services of a licensed pharmacist who--

- (1) Provides consultation on all aspects of the provision of pharmacy services in the facility;
- (2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and
- (3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

Interpretive Guidelines §483.60(b)(2) and (3)

A record of receipt and disposition of controlled drugs does not need to be proof of use sheets. The facility can use existing documentation such as the Medication Administration Record (MAR) to accomplish this record.

Periodic reconciliations should be monthly. If they reveal shortages, the pharmacist and the director of nursing may need to initiate more frequent reconciliations. In situations in which loss of controlled drugs is evident, the facility may have to utilize proof of use sheets on all controlled drugs for all shifts. However, when the source of shortage is located and remedied, the facility may go back to periodic reconciliation by the pharmacist.

Please note that the regulation does not prohibit shortages of controlled drugs - only that a record be kept and that it be periodically reconciled. If the survey reveals that all controlled drugs are not accounted for, refer the case to the State nursing home licensure authority, or to the State Board of Pharmacy.

F428

§483.60(c) Drug Regimen Review

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

Interpretive Guidelines §483.60(c)(1)

It may be necessary to review more frequently (e.g., every week) depending on the residents' condition and the drugs they are taking.

F429

§483.60(c)(2) The pharmacist must report any irregularities to the attending physician, and the director of nursing, and

Miscellaneous Drugs That Are Potentially Inappropriate in the Elderly

The following list of drugs and diagnoses/drug combinations have been partially adapted from a paper entitled "Explicit Criteria for Determining Inappropriate Medication Use by the Elderly" by Mark H. Beers, MD. This paper was published in the "Archives of Internal Medicine," Volume 157, July 28, 1997. The paper lists numerous drugs and diagnosis/drug combinations that are judged to place a person over the age of 65 at greater risk of adverse drug outcomes (ADR). The judgments in this paper were arrived at through an extensive review of the literature by a panel of experts. There are two important quotations from the paper that the surveyor should keep in mind at all times:

1. "These criteria were developed to predict when the potential for adverse outcomes is greater than the potential for benefit."
2. "Without measuring outcomes, criteria cannot determine whether adverse outcomes have occurred; they can only determine that they are more likely to occur."

These criteria are divided into two broad categories. Drug therapy that is classified as having “high severity” and therapy that is considered as not having “high severity.” Severity is defined as: “a combination of both the likelihood that an adverse outcome would occur and the clinical significance of that outcome should it occur.” The survey guidelines are located in two parts, F329 and F429. The surveyor has the option to cite at either or both tags depending on the situation.

1. Drug Therapy With High Potential for Severe Adverse Outcomes in Persons Over 65 that are to be used to determine compliance with §483.25(l)(1), Unnecessary Drug (F329), and
2. Drug Therapy With High Potential for Less Severe Adverse Outcomes In Persons Over 65 that are to be used to determine compliance with §483.60(c)(1), Drug Regimen Review Report (F429) which are located under guidance to surveyors for drug regimen review.

It should be noted that medication alterations may not be appropriate for some short-term residents. Many residents arrive in the long term care setting already on medications that they have managed to tolerate for years or that have been prescribed in the hospital. For some short-stay residents, it is difficult to change these medications without a period of observation and information gathering. Therefore, review by the surveyor is not necessary for drug therapy given the first seven consecutive days upon admission/readmission, unless there is an immediate threat to health and safety.

List of Drug Combinations With High Potential for Less Severe Adverse Outcomes

1. Phenylbutazone (Butazolidin)

Risk: “May produce serious hematological side effects (blood disorders) and should not be used in elderly patients.”

Blood disorders include bone marrow depression, aplastic anemia, agranulocytosis, leukopenia, pancytopenia, thrombocytopenia, macrocytic or megoblastic anemia.

2. Trimethobenzamide (Tigan)

Risk: “Trimethobenzamide is one of the least effective antiemetics, yet it can cause extrapyramidal side effects.”

Extrapyramidal side effects may involve various combinations of tremors, postural unsteadiness, lack of or slowness of movement, cogwheel rigidity, expressionless face, drooling, infrequent blinking, shuffling gate, decreased arm swing, and rigidity of muscles in the limbs, neck, and trunk.

3. Indomethacin (Indocin, Indocin SR)

Risk: “Of all the nonsteroidal anti-inflammatory drugs, indomethacin produces the most central nervous system side effects and should therefore be avoided in the elderly.” The most common side effects (in order of frequency of occurrence) are

headache (10%), dizziness (3-9%), and vertigo, somnolence, depression, and fatigue (1-3%).

Exception: It is considered acceptable to use indomethacin for short term (e.g., 1 week) treatment of an acute episode of gouty arthritis.

4. Dipyridamole (Persantine)

Risk: “Dipyridamole frequently cause orthostatic hypotension in the elderly. It has been proven beneficial only in patients with artificial heart valves. Whenever possible, its use in the elderly should be avoided.

5. Reserpine (Serpasil)

Combination products such as Ser-Ap-Es, Serathide, Hydropres, Unipres, Uni-serp, Diutensen-R, Metatensin #2 & #4, Diupres, Hydroserpine, Hydromox-R, Regroton, Renese-R, Salutensin.

Risk: “Reserpine imposes unnecessary Risks in the elderly, inducing depression, impotence, sedation, and orthostatic hypotension. Safer alternatives exist.”

6. Diphenhydramine (Benadryl)

Note: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329)) already has guidelines for these drugs under: D. Drugs for Sleep Induction. The surveyor should use that guideline if diphenhydramine is being used as a hypnotic. If diphenhydramine is being used as an antihistamine, this guideline should be used.

Risk: “Diphenhydramine is potently anticholinergic and usually should not be used as a hypnotic in the elderly. When used to treat or prevent allergic reactions, it should be used in the smallest dose and with great caution.” Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations.

Exception: For treatment of allergies, review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

7. Ergot Mesyls (Hydergine), Cyclospasmol

Risk: “Hydergine and the central vasodilators have not been shown to be effective, in the doses studied for treatment of dementia or any other condition.”

8. Muscle Relaxants

Muscle Relaxants such as Methocarbamol (Robaxin), Carisoprodol (Soma), Chlorzoxazone (Paraflex) Metaxalone (Skelaxin), Cyclobenzaprine (Flexeril), Dantrolene (Dantrium), Orphenadrine (Norflex, Banflex, Myotrol).

Risk: “Most muscle relaxants are poorly tolerated by the elderly, leading to anticholinergic side effects, sedation, and weakness.” Anticholinergic side effects include symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

9. Antihistamines

Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril, Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripeleennamine (PBZ), Dexchlorpheniramine (Polaramine).

Risk: “All nonprescription and many prescription antihistamines have a potent anticholinergic properties.” Anticholinergic side effects can include such symptoms as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. When used to treat or prevent allergic reactions, antihistamines should be used in the smallest possible dose, and for the shortest period of time, and with great caution.

Diagnosis/Drug Combinations with High Potential for Less Severe Outcomes

1. Diabetes

Drugs: Corticosteroids such as Beclomethasone (Beclovent, Vanceril), Betamethasone (Celestone), Cortisone Acetate (Cortone Acetate), Dexamethasone (Decadron, Dexone), Hydrocortisone (Cortef), Methylprednisolone (Medrol), Prednisolone (many brands), Prednisone (many brands).

Risk: “May worsen diabetic control, if recently started.”

If Recently Started: The panelists for the Beers’ study believed that the severity of adverse reaction would be substantially greater when these drugs were recently started. **In general**, the greatest risk would be within **about** a 1-month period. If the surveyor encounters the use of this drug within the first month, they should pay close attention to obtaining a rationale for its use during that time. The surveyor should be responsible for indepth investigation to determine when the drug was actually started. It should be noted that rapid withdrawal of these medicines in a steroid-dependent person can cause serious side effects.

2. Active or recurrent gastritis, peptic ulcer disease or gastroesophageal reflux disease.

Drugs: Aspirin in excess of 325 mg. per day.

Risk: “May exacerbate ulcer disease, gastritis, and gastroesophageal reflux disease (GERD).”

Note: The panelists did not believe that enteric coated aspirin would be beneficial since aspirin exacerbates these conditions primarily through its systemic effects rather than its local effects.

Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence.

Drugs: Potassium supplements such as Kaochlor, Klorvess, Kaon, K-Lor, K-Tab, K-Dur, K-Lyte, Slow K, Klotrix, Micro K or Ten K. This includes liquid oral dosage forms which, if used, should be administered after meals with an optimal amount of water or fruit juice (depending on the resident's fluid restrictions) to decrease the potential of gastric distress or bad taste as much as possible.

Risk: "May cause gastric irritation with symptoms similar to ulcer disease."

Potential Side Effects: Nausea, dyspepsia, vomiting, abdominal pain, heartburn, epigastric pain, diarrhea, flatulence.

Exception: Use of these medications to treat low potassium levels until they return to normal range if determined by the prescriber that use of fresh fruits and vegetables or other dietary supplementation is not adequate or possible.

3. Seizures or Epilepsy

Drugs: Clozapine (Clozaril), Chlorpromazine (Thorazine), Thioridazine (Mellaril), Chlorprothixene (Taractan), Metoclopramide (Reglan), Fluphenazine (Prolixin, Permitil), Perphenazine (Trilafon), Mesoridazine (Serentil), Prochlorperazine (Compazine), Promazine (Sparine), Trifluoperazine (Stelazine), Triflupromazine (Vesprin), Haloperidol (Haldol), Loxapine (Loxitane), Molindone (Moban), Olanzapine (Zyprexa), Pimozide (Orap), Risperidone (Risperdal), Thiothixene (Navane), Quetiapine (Seroquel).

Risk: "May lower seizure threshold."

Potential Side Effect: Increased risk of seizure activity.

Exception: Use of these drugs within the already established CMS guidelines (483.25(1)) for a 72 hour period or less, when treating acute psychosis, such that the individual is a danger to self or others.

4. Benign Prostatic Hypertrophy (BPH)

Drugs: Narcotic drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphene (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.).

Risk: "Anticholinergic drugs may impair micturition and cause obstruction in men with BPH."

Potential Side Effects: Urinary retention, urinary incontinence, reflux, pyelonephritis, nephritis, low grade temperature, low back pain.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Drugs: Flavoxate (Urispas), Oxybutynin (Ditropan), Bethanechol (Urecholine, Duvoid).

Risk: “Bladder relaxants may cause obstruction in persons with BPH.”

Potential Side Effects: Urinary retention, incontinence, hesitancy, reflux, hydronephrosis.

5. Constipation

Drugs: Anticholinergic antihistamines such as Chlorpheniramine (Chlor-Trimeton), Diphenhydramine (Benadryl), Hydroxyzine (Vistaril & Atarax), Cyproheptadine (Periactin), Promethazine (Phenergan), Tripeleminamine (PBZ), Dexchlorpheniramine (Polaramine).

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anti-Parkinson medications such as Benztropine (Cogentin), Trihexyphenidyl (Artane), Procyclidine (Kemadren), Biperiden (Akineton).

GI Antispasmodics such as Dicyclomine (Bentyl), Hyoscyamine (Levsin & Levsinex), Propantheline (Pro-Banthine), Belladonna Alkaloids (Donnatal), Clidinium containing products such as Librax.

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

Anticholinergic antidepressant drugs such as Amitriptyline (Elavil), Amoxapine (Asendin), Clomipramine (Anafranil), Desipramine (Pertofrane), Doxepin (Adapin, Sinequan), Imipramine (Tofranil), Maprotiline (Ludiomil), Nortriptyline (Aventyl, Pamelor), Protriptyline (Vivactil).

Narcotic Drugs such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphene (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.).

Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness.

6. Insomnia

Drugs:

- Decongestants such as Phenylephrine (Duo-Medihaler), Phenylpropanolamine (Genex), Pseudoephedrine (Novafed, Sudafed, Triaminic AM, Efidac/24);
- Theophylline (Elixophyllin, Bronkodyl, Theo-Dur, Slo-Bid);
- Desipramine (Pertofrane, Norpramin);
- Selective Serotonin Reuptake Inhibitors such as Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft);
- Methylphenidate (Ritalin);
- Monamine Oxidase Inhibitors (MAOIs) such as Phenelzine (Nardil), Tranylcypromine (Parnate); and
- Beta Agonists such as Isoproterenol (Isuprel), Albuterol (Proventil), Bitolterol (Tornalate), Terbutaline (Brethine).

Risk: “May cause or worsen insomnia.”

(The surveyor should consider that insomnia is often a symptom of untreated depression and Chronic Obstructive Pulmonary Disease (COPD.))

F430

§483.60(c)(2)

these reports must be acted upon.

Interpretive Guidelines §483.60(c)(2)

The director of nursing and the attending physicians are not required to agree with the pharmacist’s report, nor are they required to provide a rationale for their “acceptance” or “rejection” of the report. They must, however, act upon the report. This may be accomplished by indicating acceptance or rejection of the report and signing their names. The facility is encouraged to provide the medical director with a copy of drug regimen review reports and to involve the medical director in reports that have not been acted upon.

F431

§483.60(d) Labeling of Drugs and Biologicals

Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

Interpretive Guidelines §483.60(d)

This section imposes currently accepted labeling requirements on **facilities**, even though the pharmacies will be immediately responsible for accomplishing the task.

The critical elements of the drug label in a long-term care facility are the name of the drug and its strength.

The names of the resident and the physician do not have to be on the label of the package, but they must be identified with the package in such a manner as to assure that the drug is administered to the right patient.

All drugs approved by the Food and Drug Administration must have expiration dates on the manufacturer's container. "When applicable" means that expiration dates must be on the labels of drugs used in long term care facilities unless State law stipulates otherwise.

F432

§483.60(e) Storage of Drugs and Biologicals

- (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.
- (2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

Interpretive Guidelines §483.60(e)

Compartments in the context of these regulations include but are not limited to drawers, cabinets, rooms, refrigerators, carts, and boxes. The provisions for authorized personnel to have access to keys must be determined by the facility management in accordance with Federal, State, and local laws and facility practices. "Separately locked" means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs.

F441

§483.65 Infection Control

The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.

§483.65(a) Infection Control Program

The facility must establish an infection control program under which it--

- (1) Investigates, controls, and prevents infections in the facility;
- (2) Decides what procedures, such as isolation should be applied to an individual resident; and
- (3) Maintains a record of incidents and corrective actions related to infections.

Intent §483.65(a)

The intent of this regulation is to assure that the facility has an infection control program which is effective for investigating, controlling, and preventing infections. If infection control has been identified as an area of concern during Phase 1 of the survey, investigate aspects of the program, as appropriate, during Phase 2.

Interpretive Guidelines §483.65(a)

The facility's infection control program must have a system to monitor and investigate causes of infection (nosocomial and community acquired) and manner of spread. A facility should, for example, maintain a separate record on infection that identifies each resident with an infection, states the date of infection, the causative agent, the origin or site of infection, and describes what cautionary measures were taken to prevent the spread of the infection within the facility. The system must enable the facility to analyze clusters, changes in prevalent organisms, or increases in the rate of infection in a timely manner.

F442**§483.65(b) Preventing Spread of Infection**

(1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.

F443

§483.65(b)(2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.

F444

§483.65(b)(3) The facility must require staff to wash their hands after each direct resident contact for which handwashing is indicated by accepted professional practice.

Intent §483.65(b)(3)

The intent of this regulation is to assure that staff use appropriate handwashing techniques to prevent the spread of infection from one resident to another.

Interpretive Guidelines §483.65(b)(3)

Procedures must be followed to prevent cross-contamination, including handwashing or changing gloves after providing personal care, or when performing tasks among individuals which provide the opportunity for cross-contamination to occur. Facilities for handwashing must exist and be readily available to staff. The facility should follow the CDC's "Guideline for Handwashing and Hospital Environmental Control, 1985," for handwashing.

F514**§483.75(l) Clinical Records**

(1) The facility must maintain clinical records on each resident in accordance with accepted professional standards and practices that are--

- (i) Complete;
- (ii) Accurately documented;

- (iii) Readily accessible; and
- (iv) Systematically organized.

Intent §483.75(l)(1)

To assure that the facility maintains accurate, complete, and organized clinical information about each resident that is readily accessible for resident care.

Interpretive Guidelines §483.75(l)(1)

A complete clinical record contains an accurate and functional representation of the actual experience of the individual in the facility. It must contain enough information to show that the facility knows the status of the individual, has adequate plans of care, and provides sufficient evidence of the effects of the care provided. Documentation should provide a picture of the resident's progress, including response to treatment, change in condition, and changes in treatment.

The facility determines how frequently documentation of an individual's progress takes place apart from the annual comprehensive assessment, periodic reassessments when a significant change in status occurs, and quarterly monitoring assessments. Good practice indicates that for functional and behavioral objectives, the clinical record should document change toward achieving care plan goals. Thus, while there is no "right" frequency or format for "reporting" progress, there is a unique reporting schedule to chart each resident's progress in maintaining or improving functional abilities and mental and psychosocial status. Be more concerned with whether the staff has sufficient progress information to work with the resident and less with how often that information is gathered.

In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures are acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access, and reconstruction of information must be in place. The following guideline is an example of how such a system may be set up:

- There is a written policy, at the health care facility, describing the attestation policy(ies) in force at the facility.
- The computer has built-in safeguards to minimize the possibility of fraud.
- Each person responsible for an attestation has an individualized identifier.
- The date and time is recorded from the computer's internal clock at the time of entry
- An entry is not to be changed after it has been recorded.
- The computer program controls what sections/areas any individual can access or enter data, based on the individual's personal identifier (and, therefore his/her level of professional qualifications).

F520

§483.75(o) Quality Assessment and Assurance

- (1) A facility must maintain a quality assessment and assurance committee consisting of--
- (i) The director of nursing services;

- (ii) A physician designated by the facility; and
- (iii) At least 3 other members of the facility's staff.

F521

(2) The quality assessment and assurance committee -

- (i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and
- (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.