

APA-1
6/93

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control 420 Department or Agency Alabama Department of Public Health

Rule Number 420-5-4-.06
Rule Title Care of Residents

 New XXX Amend Repeal Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? NA

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of Certifying Officer R. B. [Signature] Date 5/20/15

FORM APA2
11/96

STATE BOARD OF HEALTH
NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-5-4-.06 Care of Residents

INTENDED ACTION: To Amend

SUBSTANCE OF PROPOSED ACTION: To eliminate redundant word usage; to replace the word "will" with the stronger word "shall" in the requirement that first aid supplies be inspected annually.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held at 9:00 a.m. on June 16, 2015, at the Alabama Department of Public Health, RSA Tower, Suite 1540, 201 Monroe St., Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on July 3, 2015. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Ray Sherer, Division of Provider Services, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017.
Telephone number: (334) 206-5175.



P. Brian Hale, Agency Secretary

Care Of Residents.

(1) Medical Direction and Supervision. The medical care of residents shall be under the direction and supervision of a physician.

(a) Designation of Attending Physician. Upon admission, each resident shall be asked to designate an attending physician of his or her choice. If the resident is unable to designate an attending physician, or does not wish to designate an attending physician, the facility shall assist the resident in identifying an attending physician who will serve the resident. A resident shall be permitted to change the designation of his or her attending physician at any time. Whenever a resident requires medical attention, an attempt shall first be made to contact the resident's attending physician, except in medical emergencies requiring activation of the local Emergency Medical Services system (911 or another emergency call).

(b) Back-up Physician Support. Each assisted living facility shall have an agreement with one or more duly licensed physicians to serve in those instances when a resident's own attending physician cannot be reached, and to provide temporary medical attention to any resident whose attending physician is temporarily not available.

(c) The use of the word "physician" in these rules shall not be deemed to preclude a properly licensed nurse practitioner or a physician assistant from performing any function in an assisted living facility that otherwise would be required to be performed by a physician so long as that function is within the nurse practitioner's or physician assistant's scope of practice.

(2) Health Supervision.

(a) Observation. Each assisted living facility shall provide general observation and health supervision of the residents sufficient to develop awareness of changes in all residents' health conditions and physical abilities, and awareness of the need for medical attention or nursing services. Whenever a resident requires medical attention, nursing services, or changes in personal care and assistance with activities of daily living provided by the facility, the facility shall arrange for or assist the residents in obtaining necessary services.

(b) Services Beyond Capability of Assisted Living Facility. Whenever a resident requires hospitalization, medical, nursing, or other care beyond the capabilities and facilities of the assisted living facility, arrangements shall be made to

discharge the resident to an appropriate setting, or to transfer the resident promptly to a hospital or other health care facility able to provide the appropriate level of care.

(c) Mechanical Restraint and Seclusion. No form of restraint or seclusion shall be applied to residents of an assisted living facility except in extreme emergency situations when the resident presents a danger of harm to himself or herself or to other residents. In such an event, the facility shall immediately notify the resident's physician and sponsor, and appropriate treatment, transfer to an appropriate health care facility, or both shall be provided without any avoidable delay. In no event shall emergency behavioral symptoms of residents be treated with sedative medications, anti-psychotic medications, anti-anxiety medications, or other psychoactive medications in an assisted living facility.

(d) Care During Emergency or Illness. The resident's attending physician, or a backup physician, if the attending physician is unavailable, shall be promptly called at the onset of an illness or in case of an accident or injury to a resident. In case of a medical emergency that could result in death, serious medical impairment or disability to a resident, the local Emergency Medical Services ("EMS") system shall be activated by calling 911 or other emergency local telephone number.

(e) All assisted living facilities shall maintain the following telephone numbers, properly identified, and posted in a prominent location readily accessible and known to all staff members.

1. Each resident's attending physician, and the facility's backup physician or physicians.

2. 911, or the local emergency telephone number if the community is not served by a 911 telephone service.

(f) Each facility shall develop and implement a policy and procedure to ensure that each resident of the facility is free from abuse, neglect and exploitation. The facility shall ensure that all staff can demonstrate an understanding of what constitutes abuse, neglect, and exploitation and shall ensure that all staff understands his or her responsibility to immediately report suspected incidents of abuse, neglect or exploitation of a resident to the administrator. When abuse, neglect, or exploitation is alleged or suspected, the facility shall conduct and document a thorough investigation and take appropriate action to prevent further abuse. All allegations and suspicions shall be reported to the Assisted Living Unit of the ~~Alabama Department of Public Health~~ and to the victim's sponsor or responsible family member within 24 hours. Suspected abuse,

neglect, or exploitation of a resident shall be reported to the Department of Human Resources or law enforcement in accordance with Code of Ala. 1975, Section 38-9-8. At any time that a resident has been the victim of sexual assault or sexual abuse perpetrated by a staff member or visitor, local law enforcement authorities shall be immediately notified.

(g) Annual Physical Examination. In addition to the admission physical examination, each resident shall be given an annual physical examination, and findings from the annual physical examination shall be documented with a copy placed in the resident's medical examination record. In addition to any other items specified in the facility's policies and procedures, and in addition to any items deemed necessary or desirable by the resident's attending physician, the resident's weight shall be documented on the annual physical examination findings.

(h) Prior to admission, residents shall be evaluated for tuberculosis.

(i) Vaccines. Assisted living facilities shall immunize residents in accordance with current recommended CDC guidelines. Any particular vaccination requirement may be waived or delayed by the State Health Officer in the event of a vaccine shortage.

(j) Oxygen Therapy. If a resident receives oxygen therapy in a facility:

1. All oxygen equipment, such as tubing, masks, and nasal cannulae shall be maintained in a safe and sanitary condition.

2. All oxygen tanks shall be safely maintained and stored.

3. The facility shall require safe use of oxygen therapy. No smoking and appropriate precautionary signs shall be posted.

4. The facility shall ensure that each resident using oxygen therapy maintains an adequate supply of oxygen.

5. The facility shall have written policies and procedures governing oxygen administration and storage.

6. The facility shall ensure that all staff members are trained in safe handling of oxygen, in safety practices to be observed during oxygen administration, and in the facility's policies and procedures.

(k) Laboratory Tests. Any facility conducting or offering laboratory tests for its residents, including routine blood glucose monitoring, shall comply with federal law, and specifically with the applicable requirements of the federal Clinical Laboratory Improvement Act ("CLIA") as well as with applicable federal regulations. This requirement in some cases would require the facility to obtain a CLIA certificate, and in other cases would require the facility to obtain a CLIA waiver. For more information about CLIA requirements, a facility may contact the ~~Alabama Department of Public Health~~, Bureau of Health Provider Standards. For testing or monitoring requiring blood, either the resident must draw his or her own blood or the blood must be drawn by a physician ("MD" or "DO"), a physician's assistant ("PA"), a registered professional nurse ("RN"), or a licensed practical nurse ("LPN"). Blood and blood products, needles, sharps and other paraphernalia involved in collecting blood must be handled in a manner consistent with requirements of the federal occupational safety and health administration ("OSHA"). Personnel handling such materials must be vaccinated against blood borne diseases if such vaccinations are required by OSHA. Blood, blood products, needles, sharps and other paraphernalia involved in collecting blood shall be treated as medical waste and shall be disposed of in a manner compliant with the requirements of the State of Alabama Department of Environmental Management.

(3) Personal Care and Services.

(a) The facility shall offer appropriate activity programs to each resident, maintaining supplies and equipment as necessary to implement the activity programs.

(b) Pets residing at the facility or used in activity programs shall be in good health and shall have current vaccinations as required by law. Vaccination certificates, or copies of vaccination certificates, shall be kept on file at the facility to demonstrate compliance with this requirement.

(c) Mail, Telegrams, and Other Communications.

1. Incoming mail, telegrams, and other written communications addressed to the resident shall be delivered to the resident unopened. Outgoing mail shall be promptly delivered to regular postal channels upon receipt from the resident. Residents shall be permitted to receive telephone calls at the facility in complete privacy.

2. Personnel of the facility shall assist residents with communications, such as writing letters or assisting with writing letters, or reading mail out loud if requested to do so.

(d) Activities of Daily Living. Residents of assisted living facilities shall be assisted and encouraged to maintain a clean, well-kept personal appearance. Each facility shall provide all needed assistance with activities of daily living to each resident.

1. Bathing. Residents shall be offered a bath or partial bath or shall be assisted with a bath or partial bath daily, and more often when necessary.

2. Oral Hygiene. Residents shall be assisted with oral hygiene to keep mouth, teeth, or dentures clean. Measures shall be used to prevent dry, cracked lips.

3. Hair. Resident's hair shall be kept clean, neat, and well groomed.

4. Manicure. Fingernails and toenails shall be kept clean and trimmed.

5. Shaving. Men shall be assisted with shaving or to be shaved as necessary to keep them clean and well groomed.

6. Food service. Food service shall be provided in a resident's room during temporary illness if necessary.

7. Personal Safety. Residents shall be provided assistance with personal safety.

8. Appointments. Residents shall be assisted in making and keeping appointments.

(4) Medications.

(a) An assisted living facility resident who is aware of his or her medications may self-administer his or her own medications. For the purposes of these rules, the term medication shall mean substances regulated by the Food and Drug Administration whose purpose is to treat, promote, maintain or improve a resident's health status. Nothing in these rules shall preclude a facility from using a licensed nurse to administer medication to a resident who is capable of self-administration as defined herein.

(b) For purposes of this section, "aware of his or her medications" shall mean either of the following:

1. The resident can maintain possession and control of his or her medications, and self-administer medications, without creating an unreasonable risk to health and safety; or

2. The resident has a reasonable lay person's understanding of the unit dose packaging system in use by the facility such that the resident could likely protect himself or herself from medication errors if unit dose packages are brought to the resident by facility staff. The resident shall have the opportunity to demonstrate his or her ability to correctly utilize the unit dose package system at every opportunity for medication use.

(c) A resident who is not aware of his or her medications is deemed to be severely cognitively impaired. Severely cognitively impaired is defined as a resident being incapable of recognizing his or her name, or if he or she does not understand and cannot be trained to understand the unit dose medication system in use by the facility, or if the resident likely cannot protect himself or herself from medication errors by facility staff.

(d) An assisted living facility resident who is aware of his or her medications as defined above may be assisted with the self-administration of medication by any assisted living facility staff, including staff members who hold no professional licensure. Assistance with self-administration of medication includes the following practices:

1. Reminding a resident who is aware of his or her medications as defined above that it is time to take a medication or medications, where such medications have been prescribed for a specific time of day, a specific number of times per day, specific intervals of time, or for a specific time in relation to mealtimes or other activities such as arising from bed or retiring to bed.

2. Physically assisting a resident who is aware of his or her medications as defined above by opening or helping to open a container holding oral medications.

3. Offering liquids to a resident who is aware of his or her medications as defined above to assist that resident in ingesting oral medications.

4. Physically bringing a container of oral medications to a resident who is aware of his or her medications as defined above.

(e) Assistance with self-administration of medications shall under no circumstances include any of the following practices:

1. Giving a resident injections of any kind.

2. Administering eye drops, eardrops, nose drops, inhalers, suppositories, or enemas.
3. Telling or reminding a resident that it is time to take a PRN, or as needed medication.
4. Crushing or splitting medications.
5. Placing medications in a feeding tube.
6. Mixing medications with food or liquids.

Provided, that a resident who is capable of maintaining possession and control of his or her own medications, who does maintain possession and control of his or her medications, and who would be capable of self-administration of his or her own medications but for limitations of mobility or dexterity, may be assisted with eye drops, ear drops, or nose drops by unlicensed facility staff so long as the assistance provided is under the total control and direction of the resident.

(f) A resident of an assisted living facility who is severely cognitively impaired shall have medications administered only by an individual who is currently licensed to practice medicine or osteopathy by the Medical Licensure Commission of Alabama, or by an individual who is currently licensed by the Alabama State Board of Nursing as a Registered Professional Nurse ("RN") or Licensed Practical Nurse ("LPN"). Residents with a chronic condition that cause him or her to be severely cognitively impaired shall be appropriately discharged.

(g) Medications of any kind, including over the counter medications, legend drugs and controlled substances, may be administered to a resident of an assisted living facility only after the drugs have been prescribed specifically for the resident by an individual currently licensed to prescribe medications in Alabama.

(h) All medications administered to residents in an assisted living facility, including over the counter medications, shall be contemporaneously recorded on a standard medication administration record. "Contemporaneously recorded" means recorded at the same time or immediately after medications are administered.

(i) The medication administration record shall include at least the following:

1. The name of the resident to whom the medication was administered.

2. The name of the medication administered.
3. The dosage of the medication administered.
4. The method of administration.
5. The site of injection or application, if the medication was injected or applied.
6. The date and time of the medication administration.
7. Any adverse reaction to the medication.
8. The printed name and written signature of the individual administering the medication.

(j) Medications kept under the control or custody of an assisted living facility shall be packaged by the pharmacy and shall be maintained by the facility in unit dose packaging. Unless a resident can and does self-manage his or her own medications, an assisted living facility shall require each resident to use a single pharmacy. This does not apply to emergency pharmacy services. All residents not self-managing medications must use a single pharmacy, but all residents need not use the same pharmacy that is used by other residents, unless express policy of the assisted living facility provides otherwise and all residents are informed of such policy and provided a copy of such policy prior to or at the time of admission or 30 days prior to the policy taking effect. The assisted living facility shall require pharmacies used for medication supply for residents not self-managing their medications to review all ordered medication regimens for possible adverse drug interactions and to advise the facility and the prescribing health care provider when these are detected.

(k) If controlled substances prescribed for residents of any assisted living facility are kept in the custody of the assisted living facility, they shall be stored in a manner that is compliant with state law, federal law, the requirements of the Alabama State Board of Pharmacy and any requirements prescribed by the Alabama State Board of Health. At a minimum, controlled substances in the custody of the facility shall be stored using a double lock system, and the facility shall maintain a system to account for all controlled substances in its possession. All other medications in the custody of the facility shall be stored using at least a single lock. This shall include medications stored in a resident's room when the staff and not the resident have access to the medications. Medications may be kept in the custody of an individual resident who is aware of his or her medications and who can safely manage his or her medications.

Such medications may be stored in a locked container accessible only to the resident and staff, or may be stored in the resident's living quarters, if the room is single occupancy and has a locking entrance.

(l) Medication administration records and written physician orders for all over-the-counter drugs, legend drugs, and controlled substances shall be retained for a period of not less than three years. They shall be available for inspection and copying on demand by agents of the State Board of Health. They shall further be made available for inspection at reasonable times by residents who are not cognitively impaired and by the sponsors of residents who are cognitively impaired.

(m) Labeling of Drugs and Medicines. All containers of medicines and drugs shall be labeled in accordance with the rules of the Alabama State Board of Pharmacy and shall include appropriate cautionary labels, such as, "Shake Well," or "For External Use Only." Medications maintained as stock must contain the manufacturer's label and shall be properly labeled in accordance with accepted professional standards.

(n) Disposal of Medications.

1. Controlled substances and legend drugs dispensed to residents, that are unused because the medication is discontinued or because the resident dies, shall be destroyed within 30 days, except unused legend drugs may be donated to a charitable clinic pursuant to Alabama Administrative Code, Chapter 420-11-11 et. Seq.

2. Medications of residents who are discharged or transferred to another facility shall be returned to the residents. The responsible party will sign a statement that these medications have been received. The statement shall list the pharmacy, prescription number, date, resident's name and strength of the medication and the amount. This statement shall be maintained in a file for at least two years. Discontinued medications shall not be stored or housed in the facility.

3. When medication is destroyed on the premises of the assisted living facility, a record shall be made and filed for at least two years. This record shall include: the name of the assisted living facility, the method of disposal, the pharmacy, the prescription number, the name of the resident, the name, strength, and dosage of the medication, and the amount and the reason for the disposal. This record shall be signed and dated by the individual performing the destruction and by at least one witness.

(5) Storage of Medical Supplies and Poisons.

(a) First Aid Supplies. First aid supplies shall be maintained in a place readily accessible to persons providing personal care and services in the assisted living facility. These supplies shall ~~will~~ be inspected at least annually to ensure their usability.

(b) Poisonous or External Use Substances. Cleaning supplies and poisons shall be attended at all times or shall be kept in a secure area.

(6) Admission and Retention of Residents.

(a) An assisted living facility shall not admit or retain a resident who is severely cognitively impaired as defined in section (4)(c).

(b) An assisted living facility shall not admit nor once admitted shall it retain a resident who requires medical or skilled nursing care for an acute condition or exacerbation of a chronic condition which is expected to exceed 90 days unless:

1. The individual is capable of performing and does perform all tasks related to his or her own care; OR

2. The individual is incapable of performing some or all tasks related to his or her own care due to limitations of mobility or dexterity BUT the individual has sufficient cognitive ability to direct his or her own care AND the individual is able to direct others and does direct others to provide the physical assistance needed to complete such tasks, AND the facility staff is capable of providing such assistance and does provide such assistance.

(c) An assisted living facility shall not admit a resident who is receiving or in need of hospice care at the time of admission. If a resident of an assisted living facility is diagnosed with a terminal illness other than dementia and requires hospice care, the resident may be admitted to a properly licensed and certified hospice program. The facility may permit the resident to remain in the facility by arranging for such care to be delivered by properly licensed individuals. A resident receiving hospice care may remain in the facility beyond 90 days. The facility would in all cases remain responsible for the appropriate delivery of such care and must take necessary steps to ensure that appropriate care needed by a resident is delivered to the resident. If the facility is unable or becomes unable to meet an admitted resident's needs, or if an admitted resident requires care beyond what the facility may lawfully provide pursuant to this section, then the facility shall promptly make arrangements to discharge or transfer the resident to a safe and

appropriate placement in accordance with the discharge procedures and prearranged plan required by these rules for assisted living facilities.

(c) Individuals with acute infectious pulmonary disease, such as influenza or active tuberculosis, or with other diseases capable of transmission to other residents through normal resident-to-resident contact shall be temporarily denied admission until certified by a physician to be free of a contagious condition.

(d) Individuals with infected draining wounds shall be temporarily denied admission until the wound is sufficiently healed to have stopped draining.

(e) No assisted living facility shall hold itself out to the public as a "specialty care assisted living facility," as a "Dementia Care Facility," as an "Alzheimer's Care Facility," or otherwise as specializing in or as being competent to care for individuals suffering from dementia or Alzheimer's disease. No facility shall hold itself out to the public as an assisted living facility unless the facility has a current, valid license as an assisted living facility.

(f) No assisted living facility shall be operated in whole or in part in a manner that prevents free and unhindered egress from the facility by any of its residents.

(g) An assisted living facility shall not admit a resident, nor shall it retain any resident, if such resident, because of dementia, cannot safely reside in the facility unless his or her egress from the facility is restricted.

(7) Resident transport. If a resident is unable to ride in an upright position or if such resident's condition is such that he or she needs observation or treatment by Emergency Medical Services personnel, or if the resident requires transportation on a stretcher, gurney or cot, the facility shall arrange or request transportation services only from providers who are ambulance service operators licensed by the ~~Alabama~~ State Board of Health. If such resident is being transported to or from a health care facility in another state, transportation services may be arranged with a transport provider licensed as an ambulance service operator in that state. For the purposes of this rule, an upright position means no more than 20 degrees from vertical.

Author: Rick Harris

Statutory Authority: Code of Ala. 1975, §§22-21-20, et seq.

History: Filed November 20, 1991. **Amended:** Filed

September 20, 2000; effective October 25, 2000. **Repealed and New**

Rule: Filed October 18, 2001; effective November 22, 2001.

Amended: Filed June 23, 2004; effective July 28, 2004. **Amended:**
Filed March 21, 2007; effective April 25, 2007.