

Title 10

MARYLAND DEPARTMENT OF HEALTH

Subtitle 07 HOSPITALS

10.07.14 Assisted Living Programs

Authority: Health-General Article, Title 19, Subtitle 18, Annotated Code of Maryland

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(18) (text unchanged)

(19) “Consultant” means an individual or organization, under contract with [a licensee] *an assisted living program*, that may:

(a)—(b) (text unchanged)

(20)—(23) (text unchanged)

(24) “Delegation of nursing tasks” means the formal process approved by the Maryland Board of Nursing which permits a professional nurse to assign nursing tasks to an unlicensed individual, a certified nursing assistant, or a medication technician, in accordance with COMAR 10.27.11.03, through:

(a) A nursing assessment of the [patient’s] *resident’s* nursing care needs prior to delegation of tasks;

(b)—(f) (text unchanged)

(25)—(38) (text unchanged)

(39) “Incident” means[:

(a) The death of a resident from other than natural causes;

(b) The disappearance or elopement of a resident;

(c) An assault on a resident resulting in injury;

(d) An injury to a resident which may require treatment by a health care practitioner, or an event such as a fall which could subsequently require treatment;

(e) Abuse, neglect, or financial exploitation of a resident;

(f) An error or omission in medication or treatment which may result in harm to the resident;

(g) An emergency situation or natural disaster; or

(h) Any other event that results in death, permanent harm, or severe temporary harm.] *an event that has occurred that has the potential to threaten the health and safety of a resident, including but not limited to, regulation .33 D. of this chapter.*

(40)—(50) (text unchanged)

(51) “Management firm” means an organization, under contract with an applicant for a license or a current [licensee] *licensed assisted living program*, that is intended to have or has full responsibility and control over the day-to-day operations of the assisted living program.

(52)—(89) (text unchanged)

.06 Restrictions.

A.—B. (text unchanged)

C. Drop-In or Day Services.

(1)—(3) (text unchanged)

(4) An individual who has applied for admission or who has been admitted to the [licensee] *assisted living program* who is transitioning to the assisted living program is counted as a resident.

D.—F. (text unchanged)

.08 Changes in an Assisted Living Program that Affect the Operating License.

A. General Information Related to Licensure.

(1) [A licensee] *An assisted living program* shall immediately notify the Department of any change in the information the [licensee] *licensed assisted living program* had submitted with the most recent application.

(2) A license is valid only in the name of the [licensee] *assisted living program* to [whom] *which* it is issued, and is not subject to sale, assignment, or other transfer.

(3) (text unchanged)

(4) A licensee] *licensed assisted living program* shall forward to the Department a copy of any report or citation of a violation of any applicable building codes, sanitary codes, fire safety codes, or other regulations affecting the health, safety, or welfare of residents within 7 calendar days of receipt of the report or citation. An assisted living program's failure to notify the Department may result in the imposition of a sanction.

B.—C. (text unchanged)

D. Name Change.

(1)—(2) (text unchanged)

(3) Upon processing, the Department shall issue a new license to the assisted living program that includes the new name of the [licensee] *assisted living program*.

E. (text unchanged)

F. Change of Ownership — Sale, Transfer, or Lease of a Facility.

(1)—(7) (text unchanged)

(8) Upon receipt of a new license, all use of the previously issued assisted living [licensee] *program's license* shall immediately cease.

(9) *Until a new license is issued to the new owner:*

(a) [A licensee] *An assisted living program* named in the original license shall remain responsible for the operation of the assisted living program [until a new license is issued to the new owner,]; and

(b) [the] *The current [licensee] assisted living program* shall remain responsible for correction of all outstanding deficiencies or impending sanctions [until a new license is issued to the new owner].

G.—H. (text unchanged)

I. Surrender of License.

(1) Unless the Department agrees to accept the surrender of a license, an assisted living program may not surrender a license to operate an assisted living program nor may the license lapse by operation of law while the [licensee] *assisted living program* is under investigation or while charges are pending against the [licensee] *assisted living program*.

(2) The Department may set conditions on its agreement with the [licensee] *licensed assisted living program* under investigation or against which charges are pending to accept surrender of the license.

.11 Investigation by Department.

A. (text unchanged)

B. Records and Reports.

(1) (text unchanged)

(2) Maintenance.

(a) The assisted living program shall maintain files on-site pertaining to:

(i)—(ii) (text unchanged)

(iii) Staff; [and]

(iv) Quality assurance activities[.]; *and*

(v) *The emergency and disaster plan developed in accordance with Regulation .47C of this chapter.*

(b)—(c) (text unchanged)

.14 Staffing Plan.

A.—E. (text unchanged)

F. Electronic Monitoring Systems.

(1) (text unchanged)

(2) If an electronic monitoring system is approved by the Department for the assisted living program to use, the [licensee] *assisted living program* shall document the approval of the electronic monitoring system in the area provided on the Resident Assessment Tool.

(3)—(5) (text unchanged)

.15 Assisted Living Manager.

A. Qualifications.

(1) (text unchanged)

(2) The assisted living manager shall at a minimum:

(a)—(d) (text unchanged)

(e) Be immune to measles, mumps, rubella, and varicella [as evidenced by history of disease or vaccination;] *in accordance with Regulation .19K of this chapter;*

(f)—(j) (text unchanged)

(3) (text unchanged)

B.—C. (text unchanged)

.16 80-Hour Assisted Living Manager Training Course.

A. (text unchanged)

B. The completed manager's training course shall:

- (1) Consist of 80 hours of course work and include an examination; [and]
- (2) Provide the training through in-person courses, virtual training methods, or a combination of both[.];
- (3) *Teach, at minimum, the course content specified in Regulation .17 of this chapter; and*
- (4) *Contain subject matter relating to the management of licensed assisted living programs set forth in this chapter.*

C.—F. (text unchanged)

G. *Audit of Course Vendors. The Department may periodically, and for cause, perform an audit of approved vendors to determine compliance with this regulation and Regulation .17 of this chapter.*

.17 80-Hour Assisted Living Manager Basic Training Course.

A. The 80-hour assisted living manager basic training course shall include the following content:

- (1)—(4) (text unchanged)
- (5) Clinical management, 20 hours, including:
 - (a)—(i) (text unchanged)
 - (j) [Patient] *Resident* safety;
 - (k)—(t) (text unchanged)
 - (u) Trauma-informed care; [and]
 - (v) A trauma-informed approach to care delivery; *and*
 - (w) *An overview of the Clinical Laboratory Improvement Amendments (CLIA) Waiver process as it pertains to assisted living programs conducting or monitoring test results of residents, including but not limited to blood sugar testing, as described in:*

- (i) *42 CFR §493.5;*
- (ii) *42 CFR §493.15; and*
- (iii) *42 CFR §493.35—493.41;*

(6)—(13) (text unchanged)

B. (text unchanged)

.19 Other Staff—Qualifications.

A. (text unchanged)

B. Qualifications of Other Staff. The qualifications of other staff include:

- (1) Evidence that the staff [is] *are*:
 - (a) Free from tuberculosis in a communicable form in accordance with Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities; *and*
 - [(b) Immune to measles, mumps, rubella, and varicella as evidenced by history of disease or vaccination; and
 - (c)] (b) Free from any impairment which would hinder the performance of assigned responsibilities; *and*
 - (c) In compliance with §K of this regulation;

(2)—(8) text unchanged)

C.—J. (text unchanged)

K. *Measles, Mumps, Rubella, and Varicella Immunity.*

(1) *The assisted living program shall screen and maintain written documentation of each staff member's proof of immunity to common childhood infections including measles, mumps, rubella, and varicella.*

(2) *Proof of immunity to these diseases shall be verified by:*

- (a) *Documented evidence of administration of vaccine;*
- (b) *Laboratory evidence of immunity; or*
- (c) *For proof of varicella immunity, documented provider verification of a history of varicella or herpes zoster.*

(3) *The assisted living program shall require that staff who are not immune to measles, mumps, rubella, and varicella receive immunization for measles, mumps, rubella, and varicella, unless medically contraindicated or against the employee's religious beliefs.*

(4) *If a staff member refuses to be immunized for medical or religious reasons, the assisted living program shall document the refusal and the reason for the refusal.*

(5) *The assisted living program shall screen and maintain written documentation of proof of immunity for measles, mumps, rubella, and varicella or exemption, for each staff member within 120 calendar days following the staff member's start date of employment.*

.20 Personnel Records.

The assisted living program shall maintain the following information for each staff member:

A.—I. (text unchanged)

J. Documentation that the staff is:

- (1) (text unchanged)
- (2) Immune to measles, mumps, rubella, and varicella [as evidenced by history of disease or vaccination] *in accordance with Regulation .19K of this chapter.*

K.—O. (text unchanged)

.21 Delegating Nurse.

- A.—B. (text unchanged)
- C. Duties. The delegating nurse shall:
 - (1) (text unchanged)
 - (2) Be available on call at all times as required under this chapter or have a qualified alternate delegating nurse available on call; [and]
 - (3) *Maintain compliance with the Maryland Nurse Practice Act including, but not limited to, its implementing regulations in COMAR 10.27.09 and COMAR 10.27.11; and*
- [(3)] (4) (text unchanged)
- D.—E. (text unchanged)

.24 Resident-Specific Level of Care Waiver.

- A. (text unchanged)
- B. An assisted living program may not continue providing services to a resident whose needs exceed the level of care for which the [licensee] *licensed assisted living program* has authority to provide, without approval of the Department.
- C.—H. (text unchanged)

.26 Resident Agreement — General Requirements and Nonfinancial Content.

- A. (text unchanged)
- B. For a person admitted for short-term residential care, the resident or the resident agent and the assisted living manager or their designee shall sign, before or at the time of admission, a resident agreement as set forth in this regulation excluding the provisions of [§D(9)(c) and 8(d) and (e)] §D(10)(d) and (e) of this regulation.
- C. (text unchanged)
- D. The resident agreement shall include, at a minimum, the following provisions:
 - (1)—(10) (text unchanged)
 - (11) Obligations of the [licensee] *assisted living program*, the resident, or the resident representative as to:
 - (a)—(b) (text unchanged)
- E.—F. (text unchanged)

.27 Resident Agreement — Financial Content and Professional Liability Insurance Coverage Requirements.

- A. (text unchanged)
- B. *Professional Liability Coverage Notice in Resident Agreement. The resident agreement shall include the licensed assisted living program's status of professional liability insurance coverage, which includes, at minimum, if applicable:*
 - (1) *A statement that the assisted living program maintains professional liability insurance coverage;*
 - (2) *A statement that the assisted living program does not maintain professional liability insurance coverage; or*
 - (3) *A statement that the assisted living program's professional liability insurance coverage has lapsed for any period of time and has not been renewed.*
- C. *Professional Liability Insurance Coverage Notice to Residents.*
 - (1) *Notification of professional liability insurance coverage to current residents of a licensed assisted living program whose resident agreement was signed prior to November 1, 2026 may receive notification by separate provider communication in writing or by written electronic communication.*
 - (2) *Notification of professional liability insurance lapses in coverage shall be:*
 - (a) *Provided to current licensed assisted living program residents within 30 calendar days after the date the coverage lapsed, in writing or by written electronic communication; and*
 - (b) *Signed by the resident.*
 - (3) *Notification of professional liability insurance coverage status shall be provided to prospective residents in writing or by written electronic communication:*
 - (a) *At the first visit by the prospective resident during any period in which an assisted living program does not maintain professional liability insurance; and*
 - (b) *If the assisted living program does not maintain professional liability insurance at the time the prospective resident applies for admission, at the time of the application.*
 - (4) *At the time of application for admission, acknowledgement of receipt of notification of professional liability insurance coverage status shall be signed by the prospective resident.*
 - (5) *Notifications under this section shall be retained by the licensed assisted living program as part of the assisted living program's records.*
 - (6) *Each licensed facility-based assisted living program in the State that does not maintain professional liability insurance coverage shall post a notification in a conspicuous place visible to residents and guests that the assisted living program does not maintain professional liability insurance.*
- [B.] D.—[C.] E. (text unchanged)

.28 Service Plan.

- A. (text unchanged)
- B. Assessment of Condition.
 - (1) (text unchanged)

- (2) A full assessment of the resident shall be completed:
 - (a) Within 48 hours but not later than required by nursing practice and the [patient's] *resident's* condition after:
 - (i)—(ii) (text unchanged)
 - (b) (text unchanged)
 - (3)—(5) (text unchanged)
- C.—D. (text unchanged)

.29 Resident Record.

A.—C. (text unchanged)

D. Resident Care Notes.

(1) Appropriate staff shall write care notes for each resident:

- (a) (text unchanged)
- (b) At least [weekly;] *every two weeks*;
- (c) With any significant changes in the resident's condition[, including when incidents occur and any follow-up action is taken];
- (d) —(h) (text unchanged)

.31 Medication Management and Administration.

A.—F. (text unchanged)

G. The purpose of the medication regimen review required by §F of this regulation is to review with the assisted living manager [or designee]:

(1)—(5) (text unchanged)

H.—P. (text unchanged)

.33 Incident Reports.

A.—C. (text unchanged)

D. The assisted living program shall notify the OHCQ within 24 hours of [a resident death resulting from: (1) Abuse; (2) Neglect; (3) Wandering; (4) Elopement; (5) A medication error; (6) Burns; or (7) Any injury incurred at the assisted living program.]:

(1) *A death of a resident from other than natural causes, including but not limited to:*

- (a) *Abuse;*
- (b) *Neglect;*
- (c) *Wandering;*
- (d) *Elopement;*
- (e) *A medication error;*
- (f) *Burns; or*
- (g) *Any injury incurred at the assisted living program.*

(2) *A serious event including, but not limited to:*

- (a) *The disappearance or elopement of a resident;*
- (b) *An assault on a resident resulting in injury;*
- (c) *An injury to a resident which requires treatment by a health care practitioner;*
- (d) *Falls which require treatment;*
- (e) *Abuse, neglect, or financial exploitation of a resident;*
- (f) *An error or omission in medication or treatment which results in harm to the resident;*

- (g) *An emergency situation involving a resident that requires transfer to an emergency department or urgent care facility due to an injury, sudden change in condition, or other significant threat to the resident's health or safety;*
- (h) *Natural disaster; or*
- (3) *Any other event that results in death, permanent harm, or severe temporary harm.*

.36 Resident's Rights.

A. Resident Bill of Rights.

- (1) An assisted living program shall develop a Resident Bill of Rights that, at a minimum, includes the following rights:
 - (a)—(d) (text unchanged)
 - (e) Choose a pharmacy provider, if the provider can comply with the assisted living programs' reasonable policies and procedures for [patient] *resident* safety in medication supply and administration;
 - (f)—(aa) (text unchanged)
 - (2) (text unchanged)
- B.—D. (text unchanged)

.47 Emergency Preparedness.

A.—B. (text unchanged)

C. Emergency and Disaster Plan.

- (1)—(6) (text unchanged)
 - (7) The assisted living program shall:
 - (a) Identify a facility, facilities, or an alternate location or locations that have agreed to house the [licensee's] *assisted living program's* residents during an emergency evacuation; and
 - (b) (text unchanged)
 - (8)—(11) (text unchanged)
- D.—F. (text unchanged)

.49 Common Use Areas.

A.—E. (text unchanged)

F. Kitchen.

- (1)—(3) (text unchanged)
- (4) An assisted living program with fewer than 17 residents:
 - (a)—(d) (text unchanged)
 - (e) Shall maintain potentially hazardous food as defined in COMAR 10.15.03.02B at [45°F] *41°F* or below, or [140°F] *135°F* or above, until served to residents;
 - (f)—(h) (text unchanged)
 - (i) Shall provide refrigeration operated at or below [45°F] *41°F* and equipped with an indicating thermometer graduated at 2°F intervals; and
 - (j) (text unchanged)

.50 Resident's Room and Furnishings.

A. Resident Room.

- (1)—(5) (text unchanged)
 - (6) Resident rooms shall be for the private use of the assigned resident or residents. A resident's room shall have a latching door and may have a lock on the resident room side of the door at the [licensee's] *assisted living program's* option.
 - (7)—(10) (text unchanged)
- B.—D. (text unchanged)

Subtitle 10 LABORATORIES

10.10.03 Medical Laboratories – Licenses

Authority: Environment Article, §6-303; Health-General Article, §§2-104(b), 17-202, 17-205—17-210, 17-212, 17-502, 17-503, 17-505, and 17-510; Annotated Code of Maryland

.02 Letters of Exception.

A. Eligibility.

- (1) (text unchanged)
 - (2) An individual eligible for a letter of exception shall:
 - (a) (text unchanged)
 - (i) Being a doctor of medicine or doctor of osteopathy licensed in the State and having laboratory training or experience appropriate for the testing performed; [or]
(ii) Being a registered nurse or delegating nurse licensed in the State performing services under COMAR 10.07.14 or COMAR 10.12.04; or
[(ii)] *(iii)* (text unchanged)
 - (b) Provide evidence of training in the performance and interpretation of excepted tests and be licensed in the State as a:
 - (i)—(v) (text unchanged)
 - (vi) Dentist; [or]
 - (vii) Pharmacist; [or]
 - (viii) Registered nurse; or*
 - (ix) Delegating nurse; or*
 - (c) (text unchanged)
 - (3) (text unchanged)
- B.—D. (text unchanged)

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